UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)
☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2024

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-36747

Vivani Medical, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**02-0692322**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

1350 S. Loop Road, Alameda, CA 94502
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(415) 506-8462**

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock	VANI	NASDAQ Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes☐ No ☒

As of August 12, 2024, the registrant had 55,255,856 shares of common stock, par value $0.0001 per share outstanding.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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PART I. FINANCIAL STATEMENTS

Item 1. Financial Statements

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Balance Sheets (unaudited)
(In thousands, except per share data)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,919	$ 20,654
Prepaid expenses and other current assets	1,418	2,408
Total current assets	26,337	23,062
Property and equipment, net	1,710	1,729
Right-of-use assets	18,801	19,616
Restricted cash	1,338	1,338
Other assets	38	52
Total assets	$ 48,224	$ 45,797
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 645	$ 542
Accrued expenses	1,660	1,727
Litigation accrual	1,675	1,675
Accrued compensation expense	384	396
Current operating lease liabilities	1,420	1,383
Total current liabilities	5,784	5,723
Long-term operating lease liabilities	18,616	19,313
Total liabilities	24,400	25,036
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, par value $0.0001 per share; 10,000 shares authorized; none outstanding	-	-
Common stock, par value $0.0001 per share; 300,000 shares authorized; shares issued and outstanding:55,197 and 51,031 at June 30, 2024 and December 31, 2023, respectively	6	5
Additional paid-in capital	133,588	119,054
Accumulated other comprehensive income	63	140
Accumulated deficit	(109,833)	(98,438)
Total stockholders' equity	23,824	20,761
Total liabilities and stockholders' equity	$ 48,224	$ 45,797

The accompanying notes are an integral part of these condensed consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development, net of grants	$ 3,513	$ 3,864	$ 7,239	$ 7,819
General and administrative, net of grants	2,168	3,139	4,669	5,785
Total operating expenses	5,681	7,003	11,908	13,604
Loss from operations	(5,681)	(7,003)	(11,908)	(13,604)
Other income, net	325	477	513	760
Net loss	$ (5,356)	$ (6,526)	$ (11,395)	$ (12,844)
Net loss per common share - basic and diluted	$ (0.10)	$ (0.13)	$ (0.21)	$ (0.25)
Weighted average common shares outstanding - basic and diluted	55,021	50,795	53,612	50,748

The accompanying notes are an integral part of these condensed consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Statements of Comprehensive Loss (unaudited)
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Net loss	$ (5,356)	$ (6,526)	$ (11,395)	$ (12,844)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(25)	21	(77)	30
Comprehensive loss	$ (5,381)	$ (6,505)	$ (11,472)	$ (12,814)

The accompanying notes are an integral part of these condensed consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Statements of Stockholders' Equity (unaudited)
(In thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balance, January 1, 2024	51,031	$ 5	$ 119,054	$ 140	$ (98,438)	$ 20,761
Issuance of common stock and warrants in connection with securities purchase agreement, net of issuance costs $1.3 million	3,947	-	13,687	-	-	13,687
Stock-based compensation expense	-	-	353	-	-	353
Foreign currency translation adjustments	-	-	-	(52)	-	(52)
Net loss	-	-	-	-	(6,039)	(6,039)
Balance, March 31, 2024	54,978	5	133,094	88	(104,477)	28,710
Issuance of common stock in connection with At-the-Market offering, net of issuance costs $240K	219	1	111	-	-	112
Stock-based compensation expense	-	-	383	-	-	383
Foreign currency translation adjustments	-	-	-	(25)	-	(25)
Net loss	-	-	-	-	(5,356)	(5,356)
Balance, June 30, 2024	55,197	$ 6	$ 133,588	$ 63	$ (109,833)	$ 23,824

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balance, January 1, 2023	50,736	$ 5	$ 117,054	$ 35	$ (72,786)	$ 44,308
Option exercises	53	-	-	-	-	-
Stock-based compensation expense	-	-	369	-	-	369
Foreign currency translation adjustments	-	-	-	9	-	9
Net loss	-	-	-	-	(6,318)	(6,318)
Balance, March 31, 2023	50,789	5	117,423	44	(79,104)	38,368
Option exercises	10	-	7	-	-	7
Stock-based compensation expense	-	-	524	-	-	524
Foreign currency translation adjustments	-	-	-	21	-	21
Net loss	-	-	-	-	(6,526)	(6,526)
Balance, June 30, 2023	50,799	$ 5	$ 117,954	$ 65	$ (85,630)	$ 32,394

The accompanying notes are an integral part of these condensed consolidated financial statements.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows (unaudited)
(In thousands)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (11,395)	$ (12,844)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	199	188
Stock-based compensation	736	893
Non-cash lease expense	155	128
Fixed assets write-off	34	-
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,004	(1,270)
Accounts payable	107	822
Accrued compensation expenses	(12)	(90)
Accrued expenses	(141)	(343)
Net cash used in operating activities	(9,313)	(12,516)
Cash flows from investing activities:		
Purchases of property and equipment	(219)	(81)
Net cash used in investing activities	(219)	(81)
Cash flows from financing activities:		
Net proceeds from exercise of options	-	7
Issuance of common stock and warrants in connection with securities purchase agreement, net of issuance costs	13,687	-
Issuance of common stock and warrants in connection with the At-the-Market offering, net of issuance costs	112	-
Net cash provided by financing activities	13,799	7
Effect of exchange rate changes on cash and cash equivalents	(2)	0
Cash, cash equivalents and restricted cash:		
Net increase (decrease)	4,265	(12,590)
Balance at beginning of period	21,992	46,442
Balance at end of period	$ 26,257	$ 33,852
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Income taxes	$ 2	$ 1
Non-cash investing and financing activities:		
Establishment of operating right-of-use assets through operating lease obligations	$ -	$ 20,755
Purchases of property and equipment in accounts payable and accrued expenses	$ (5)	$ -

The accompanying notes are an integral part of these condensed consolidated financial statements.

Notes to Condensed Consolidated Financial Statements (unaudited)

Note 1. Organization and Business Operations

Vivani Medical, Inc. ("Vivani," the "Company," "we," "us," "our" or similar terms) is a preclinical stage biopharmaceutical company which develops miniaturized, subdermal implants utilizing its proprietary NanoPortal™ technology, which is designed to enable long-term, near constant-rate delivery of a broad range of medicines to treat chronic diseases. Vivani uses this platform technology to develop and potentially commercialize drug implant candidates, alone or in collaboration with pharmaceutical company partners to address a leading cause of poor clinical outcomes in the treatment of chronic disease, medication non-adherence. According to the U.S. Centers for Disease Control and Prevention, adherence is defined as the extent to which an individual's behavior, including taking medications, corresponds to recommendations from a health care provider. An alarmingly high proportion of patients, approximately 50%, do not take their medicine as prescribed in the real world, a statistic that applies to both daily oral as well as weekly injectable medicines. For example, a recent study has shown that 64% of patients taking Wegovy® (semaglutide injectable) discontinue therapy within the first year of treatment, a number that increases to 76% by the second year. Unfortunately, GLP-1 discontinuation may result in a quick reversal of the health benefits in the majority of patients.

At Vivani, we are developing a portfolio of miniature, subdermal drug implant candidates that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing medication adherence by delivering therapeutic drug levels for up to six months or longer. In addition, our aim is to minimize fluctuations in patients' drug levels through the use of our NanoPortal™ technology, which may improve the tolerability profiles for medicines, including GLP-1 receptor agonists, that produce side effects associated with fluctuating drug levels in the blood.

Vivani resulted from the business combination of Second Sight Medical Products, Inc. ("Second Sight") and Nano Precision Medical, Inc. ("NPM"). On August 30, 2022, Second Sight and NPM completed their merger pursuant to which NPM became a wholly owned subsidiary of Second Sight and the combined company of NPM and Second Sight was renamed Vivani Medical, Inc. Vivani's main priority is the further development of the company's lead program NPM-115, a miniature, 6-month, GLP-1 implant candidate for chronic weight management in obese or overweight patients with one or more risk factors and further development of the balance of company's miniature, long-acting drug implant portfolio. In parallel, Vivani's management team remains committed to identifying and exploring strategic options that will enable further development of its pioneering neurostimulation systems from legacy company Second Sight aimed at helping patients recover critical body functions.

In December 2022, we contributed our neurostimulation assets and certain liabilities to Cortigent, Inc. ("Cortigent"), a wholly owned subsidiary of Vivani. Cortigent has 5,000,000 shares of common stock outstanding, all owned by Vivani. Cortigent is advancing the Company's pioneering neurostimulation technology. 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. The Registration Statement on Form S-1 was recently amended and filed with the SEC on June 7, 2024 to refresh the financial information and provide minor updates to the business.

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. As part of this change of incorporation the Company established a par value of $0.0001 per share and all periods have been retroactively adjusted to reflect this change.

An Investigational New Drug Application ("IND") for NPM-119 (GLP-1 implant) was filed with the U.S. Food and Drug Administration ("FDA") on July 14, 2023, to support the initiation of a first-in-human study of an exenatide implant in patients with type 2 diabetes. On August 18, 2023, FDA provided written notification that the study was on full clinical hold, primarily due to insufficient Chemistry, Manufacturing, and Controls ("CMC") information to assess the risk to human subjects. After providing additional information to sufficiently address the FDA's concerns, the FDA lifted the clinical hold on NPM-119 on June 13, 2024 allowing for the proposed study to proceed. The primary objective of this first-in-human clinical study was to evaluate the safety, tolerability and pharmacokinetics of NPM-119 in type 2 diabetes patients. The initial study design also incorporated Bydureon BCise® (exenatide injection) for comparison purposes.

On August 25, 2023, the Company and Cortigent entered into an Amendment 1 (the "Amendment") to the Transition Funding, Support and Services Agreement dated March 19, 2023 (the "TFSSA"). Pursuant to the TFSSA, Vivani has agreed to advance funds and provide or cause to be provided to Cortigent the services and funding intended to cover salaries and related costs, rent and other overhead in order to permit Cortigent to operate in substantially the same manner in which business operations of Cortigent were previously operated by Second Sight, prior to the formation of Cortigent, which obligations will continue, in the case of the funding obligations, until the earlier of December 31, 2024 or the closing of an initial public offering of Cortigent (the "Funding Support Term"). Under the Amendment, Cortigent has agreed to repay $1,500,000 to Vivani at the conclusion of the Funding Support Term. In addition, at the conclusion of the Funding Support Term, Cortigent will enter into a five-year promissory note at 5% interest for $2,000,000 in favor of Vivani. Consequently, Vivani will forgive any remaining amounts due by Cortigent to the Company under the TFSSA. In October 2023, Vivani implemented a reduction-in-force to conserve cash that decreased Cortigent's employees from 14 to 7 while continuing the ongoing Orion® clinical study and basic operations.

In the fourth quarter of 2023, Vivani Medical Australia Pty Ltd., a wholly owned subsidiary in Australia was established to support studies of our product candidates.

In February 2024, Vivani announced positive preclinical weight loss data with its exenatide implant that was comparable to semaglutide, the active ingredient in Ozempic®/Wegovy®, and a strategic shift to prioritize the Company's obesity portfolio. In a study of high-fat diet-induced obese mice, the exenatide implant generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to the extent of weight loss observed in mice treated with semaglutide injections (Ozempic®) in the same study.

In February, the Company also disclosed that semaglutide is the active pharmaceutical ingredient in NPM-139, another miniature, long term subdermal GLP-1 implant in development for chronic weight management further demonstrating our prioritization on obesity. NPM-139 also has the added potential benefit of once-yearly administration.

On March 1, 2024, the Company entered into a securities purchase agreement ("Securities Purchase Agreement") with an institutional investor to purchase 3,947,368 shares of common stock, par value $0.0001 per share (the "Common Stock") and warrants to purchase up to an aggregate of 3,947,368 shares of common stock at a purchase price of $3.80 per share and accompanying warrant in a registered direct offering (the "Offering"). The warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance, and will expire three years following the date of issuance.

On April 22, 2024, the Company entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC ("Jefferies"), under which the Company may offer and sell, from time to time at its sole discretion, shares of the Common Stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its Common Stock in accordance with the Sales Agreement.

On May 28, 2024, Vivani announced the publication of positive weight loss data supporting the potential veterinary use of OKV-119, the company's miniature, long-acting GLP-1 implant under development with partner Okava Pharmaceuticals, Inc. ("Okava") for the treatment of pre-diabetes, diabetes and obesity in companion felines. The device is intended to be conveniently inserted under the skin during routine veterinary visits and is being designed to deliver six months of GLP-1 therapy with a single administration.

As stated previously, on June 13, 2024, Vivani announced that the FDA cleared the IND and lifted the clinical hold for NPM-119, the Company's miniature, six-month GLP-1 implant under development for the treatment of patients with type 2 diabetes.

On July 11, 2024, the Company provided an update of the clinical development plans for NPM-115, the clinical program associated with the miniature, long-acting GLP-1 (high-dose exenatide) implant for chronic weight management in obese and overweight individuals. The Company has redesigned the First-in-Human study, LIBERATE-1, initially intended to explore the safety, tolerability and pharmacokinetics of its exenatide implant in patients with type 2 diabetes, to evaluate the implant in obese and overweight patients. The study will enroll patients who will be titrated on weekly semaglutide injections for eight weeks before being randomized to receive a single exenatide implant, weekly exenatide injections (Bydureon BCise®) or weekly semaglutide injections (Wegovy®) for a nine-week treatment duration. The LIBERATE-1 study will be conducted in Australia and is anticipated to be initiated in the fourth quarter of 2024, subject to regulatory clearance, with data from the study expected in 2025.

Liquidity and Capital Resources

From inception, our operations have been funded primarily through the sales of our common stock and warrants.

Our financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We are subject to the risks and uncertainties associated with a business with no revenue that is developing novel medical devices, including limitations on our operating capital resources. We have incurred recurring operating losses and negative operating cash flows since inception, and we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future.

On March 1, 2024, the Company entered into the Securities Purchase Agreement relating to the issuance of 3,947,368 shares of the Common Stock and warrants to purchase up to an aggregate of 3,947,368 shares of Common Stock (the "Warrants"), to such investor at a purchase price of $3.80 per share and accompanying warrants in the Offering. The Warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance and will expire three years following the date of issuance. Simultaneously, the Company also entered into a placement agency agreement with Maxim Group LLC ("Maxim" and such agreement, the "Placement Agency Agreement," and together with the Securities Purchase Agreement, the "Agreements"), who acted as the sole placement agent for the Offering. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million, during the six months ended June 30, 2024. For additional information, refer to Note 6. Equity Securities of the Notes to Condensed Consolidated Financial Statements.

On April 22, 2024, the Company entered into the Sales Agreement with Jefferies, under which the Company may offer and sell, from time to time at its sole discretion, shares of the Common Stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its Common Stock in accordance with the Sales Agreement. For additional information, refer to Note 6. Equity Securities of the Notes to Condensed Consolidated Financial Statements.

We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations into the second half of 2025. Our ability to continue as a going concern is dependent on our ability to develop profitable operations through implementation of our business initiatives and/or raise additional capital, however, there can be no assurances that we will be able to do so.

Note 2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

These unaudited interim financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and following the requirements of the SEC for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. In our opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of our financial position and our results of operations and cash flows for periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with our financial statements and accompanying notes for the fiscal year ended December 31, 2023, included within our Annual Report on Form 10-K filed with the SEC on March 26, 2024. The results of the interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. On an ongoing basis, management evaluates its estimates, including, but not limited to, those related to useful lives of long-lived assets, stock-based compensation and evaluation of going concern. Management bases its estimates on historical experience and on various assumptions that management believes to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Operating Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. Our chief operating decision-maker, our Chief Executive Officer, reviews financial information presented for each of our segments. We have two reporting segments, specifically the Biopharm Division and Neurostimulation Division. Neither division is revenue producing. The Biopharm Division includes activities from NPM and Vivani Medical Australia Pty Ltd. The Neurostimulation Division includes activities from Cortigent and our subsidiary in Switzerland.

During the three months ended June 30, 2024, the Biopharm Division and Neurostimulation Division incurred operating expenses of $5.2 million and $0.5 million, respectively. During the three months ended June 30, 2024, consolidated net loss for the Biopharm Division was $4.8 million and for the Neurostimulation Division was $0.5 million.

During the six months ended June 30, 2024, the Biopharm Division and Neurostimulation Division incurred operating expenses of $10.9 million and $1.0 million, respectively. During the six months ended June 30, 2024, consolidated net loss for the Biopharm Division was $10.3 million and for the Neurostimulation Division was $1.1 million.

As of June 30, 2024, total assets for the Biopharm Division and the Neurostimulation Division was $47.0 million and $1.2 million, respectively.

The Company's long-term assets are located in the United States.

Significant Accounting Policies

Our significant accounting policies are set forth in our financial statements for the year ended December 31, 2023, included within our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on March 26, 2024.

Recently Issued Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No.2023-07, *Improvements to Reportable Segment Disclosures (Topic 280)*. This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. The ASU is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Adoption of the ASU should be applied retrospectively to all prior periods presented in the financial statements. Early adoption is also permitted. This ASU will likely result in us including the additional required disclosures when adopted. We are currently evaluating the provisions of this ASU and expect to adopt them for the year ending December 31, 2024.

In December 2023, the FASB issued ASU No.2023-09, *Improvements to Income Tax Disclosures (Topic 740)*. The ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is also permitted for annual financial statements that have not yet been issued or made available for issuance. This ASU will result in the required additional disclosures being included in our consolidated financial statements, once adopted.

Note 3. Concentration of Risk

Credit Risk

Financial instruments that subject us to concentrations of credit risk consist primarily of cash, certificates of deposit and money market funds. We maintain cash, certificates of deposit and money market funds with financial institutions that we deem reputable.

Foreign Operations

The accompanying condensed consolidated financial statements as of June 30, 2024 and 2023 include assets amounting to approximately $26,000 and $0.1 million, respectively, relating to our operations in Switzerland. In the fourth quarter of 2023, Vivani Medical Australia Pty Ltd., a wholly owned subsidiary in Australia was established to support studies of our product candidates. Unanticipated events in foreign countries could disrupt our operations and impair the value of these assets.

Note 4. Fair Value Measurements

The authoritative guidance with respect to fair value establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below. Disclosure as to transfers in and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that we have the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange-based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently traded non-exchange-based derivatives and commingled investment funds, and are measured using present value pricing models.

We determine the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, we perform an analysis of the assets and liabilities at each reporting period end.

Cash equivalents, which includes certificates of deposit and money market funds, are the only financial instruments measured and recorded at fair value on our condensed consolidated balance sheet, and are valued using Level 1 inputs. As of June 30, 2024 and 2023, we did not have any Level 1 and Level 2 financial liabilities or Level 3 financial assets or liabilities measured at fair value on a recurring basis. We did not have any transfers between Level 1 and Level 2 or transfers in or out of Level 3 during the three and six months ended June 30, 2024 and 2023.

The following table summarizes assets measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	As of June 30, 2024			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents:				
Certificates of deposit	$ 7,057	$ 7,057	$ -	$ -
Money market funds	16,849	16,849	-	-
Total	$ 23,906	$ 23,906	$ -	$ -

	As of December 31, 2023			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents:				
Money market funds	$ 18,629	$ 18,629	$ -	$ -
Total	$ 18,629	$ 18,629	$ -	$ -

Note 5. Selected Balance Sheet Detail

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Property and equipment at cost:		
Equipment	$ 3,748	$ 3,511
Furniture and fixtures	367	354
Computer software	30	7
Construction in progress	-	299
Total property and equipment	4,145	4,171
Accumulated depreciation and amortization	(2,435)	(2,442)
Property and equipment, net	$ 1,710	$ 1,729

Note 6. Equity Securities

We are authorized to issue 300,000,000 shares of common stock with 55,196,703 issued and outstanding as of June 30, 2024. In addition, we are authorized to issue 10,000,000 shares of preferred stock with none issued as of June 30, 2024.

Securities Purchase Agreement

On March 1, 2024, the Company entered into the Securities Purchase Agreement relating to the issuance of 3,947,368 shares of the Common Stock and Warrants to purchase up to an aggregate of 3,947,368 shares of common stock, at a purchase price of $3.80 per share and accompanying warrants in the Offering. The Warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance and will expire three years following the date of issuance. The Company also entered into a Placement Agency Agreement with Maxim, who acted as the sole placement agent for the Offering. In connection with the Placement Agency Agreement, the Company agreed to pay Maxim an aggregate cash fee of 7.0% of the aggregate proceeds raised from the sale and issuance of the shares of common stock and accompanying warrants. Pursuant to the Placement Agency Agreement, the Company also agreed to reimburse Maxim up to $65,000 for its legal expenses. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other estimated offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million, during the six months ended June 30, 2024.

Pursuant to the terms of the Securities Purchase Agreement, until 45 days following the closing of the Offering, the Company agreed not to issue (or enter into any agreement to issue) any shares of common stock or common stock equivalents, subject to certain exceptions. The Company has further agreed not to enter into an agreement involving a variable rate transaction until one year following the closing of the Offering. In addition, the Company's directors and officers have entered into lock-up agreements with the Company pursuant to which each of them has agreed not to, for a period of 90 days from the closing of the Offering, offer, sell, transfer or otherwise dispose of the Company's securities, subject to certain exceptions.

At-the-Market Sales Agreement

On April 22, 2024, the Company entered into the Sales Agreement with Jefferies, under which the Company may offer and sell, from time to time at its sole discretion, shares of the Common Stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its Common Stock in accordance with the Sales Agreement.

The Company may sell the Common Stock under the Sales Agreement (A) in privately negotiated transactions; (B) as block transactions; or (C) by any other method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Capital Market or sales made into any other existing trading market for the shares of Common Stock. Jefferies will use commercially reasonable efforts to place the shares of Common Stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions we may impose). The Company will pay Jefferies a commission of up to three percent (3.0%) of the gross sales proceeds of any Common Stock sold through Jefferies under the Sales Agreement, and also has provided Jefferies with customary indemnification rights. In addition, the Company has agreed to reimburse certain legal expenses and fees incurred by Jefferies in connection with the offering.

The Company is not obligated to make any sales of Common Stock under the Sales Agreement. The offering of shares of Common Stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all Common Stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms.

During the six months ended June 30, 2024, the Company issued 218,238 shares of common stock for gross proceeds of $412,000 as part of the Sales Agreement with Jefferies. The Company paid expenses of $300,500, resulting in net proceeds of $112,000.

Note 7. Warrants

A summary of warrant activity for the six months ended June 30, 2024 is presented below (in thousands, except per share and contractual life data).

	Number of Shares		Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding as of December 31, 2023	9,733	$	11.60	1.4
Issued	3,947	$	3.80	
Exercised	-	$	-	
Forfeited or expired	(3,196)	$	28.89	
Warrants outstanding as of June 30, 2024	10,484	$	3.39	2.18
Warrants exercisable as of June 30, 2024	10,484	$	3.39	2.18

NPM, prior to the merger with Second Sight, issued common stock and warrants (collectively, the "unit" or "units") in 2019, 2020 and 2021 for $3.15 per unit. Outstanding warrants to purchase common stock are shown in the table above and generally expire five years from the date of issuance at $3.15 per share exercise price are transferable into one share of common stock and may be exercised on a cashless basis.

Second Sight underwriter warrants of 10,125 were outstanding and are convertible into 3,375 shares, included in the table above, and converted as part of the merger for Vivani warrants on a like-for-like basis. The weighted average exercise price of these warrants is $3.75.

In connection with the Securities Purchase Agreement entered on March 1, 2024, relating to the issuance of 3,947,368 shares of the Common Stock, par value of $0.0001 per share, the Company issued Warrants to purchase 3,947,368 shares of common stock at an exercise price of $3.80 per share. These Warrants are exercisable immediately upon issuance and will expire three years following the date of issuance. The Warrants may be exercised on a cashless basis.

The warrants outstanding as of June 30, 2024 had no intrinsic value.

Note 8. Stock-Based Compensation

Equity Incentive Plan

The Vivani Medical, Inc. 2022 Omnibus Incentive Plan (the "2022 Plan") became effective on August 30, 2022. Under the 2022 Plan, 10,033,333 shares were authorized for issuance at its effective date. The maximum number of shares with respect to which stock awards could be granted is offset and reduced by stock awards previously granted under the 2022 Plan. As of June 30, 2024, 2,359,532 shares of common stock were available for future issuance under the 2022 Plan pursuant to stock awards that had not previously been granted.

For stock option grants, the option price is determined by the Board of Directors but cannot be less than the fair value of the shares at the grant date. Generally, the options vest ratably over four years and expire ten years from the grant date. The plan provides for accelerated vesting if there is a change of control, as defined in the Plan.

Stock Options

A summary of stock option activity is presented below (in thousands, except per share and contractual life data).

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)
Options outstanding as of December 31, 2023	6,091	$ 2.60	
Granted	818	$ 1.70	
Exercised	-	$ -	
Forfeited or expired	(293)	$ 1.24	
Options outstanding, vested and expected to vest as of June 30, 2024	6,616	$ 2.55	6.90
Options exercisable as of June 30, 2024	4,456	$ 3.00	6.00

The estimated aggregate intrinsic value of stock options exercisable as of June 30, 2024 was $0.01 million.

Restricted Stock Units (RSUs)

A summary of restricted stock activity and related information (in thousands, except per share data):

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2023	403	$ 0.93
Granted	292	$ 1.69
Vested and released	-	$ -
Forfeited and canceled	-	$ -
Outstanding as of June 30, 2024	695	$ 1.25

During the six months ended June 30, 2024, the Company granted 292,500 RSUs, subject to market conditions which required our stock price to exceed $3.15 per share for three consecutive days in the four years from grant date for the RSUs to vest. Upon achievement of the market condition, one-third of the award will vest, and thereafter, one-third of the award will vest on the first and second anniversary of the achievement date, subject to the recipient's continued service through each applicable vesting date.

During the six months ended June 30, 2023, the Company granted 402,500 RSUs, subject to market conditions which required our stock price to exceed $3.15 per share for three consecutive days in the four years from grant date for the RSUs to vest. Upon achievement of the market condition, one-third of the award will vest, and thereafter, one-third of the award will vest on the first and second anniversary of the achievement date, subject to the recipient's continued service through each applicable vesting date.

Stock-Based Compensation Expense

The following table summarizes total stock-based compensation expense for stock options and RSUs, which is included in the statements of operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 248	$ 284	$ 483	$ 532
General and administrative	135	240	253	361
Total stock-based compensation expense	$ 383	$ 524	$ 736	$ 893

As of June 30, 2024, there was $2.3 million of total unrecognized stock-based compensation expense related to outstanding stock options that will be recognized over a weighted average period of 1.4 years. As of June 30, 2024, there was $0.4 million of total unrecognized compensation expense related to outstanding RSUs that will be recognized over a weighted average period of 0.8 years

Stock Options

During the six months ended June 30, 2024, we granted stock options to purchase818,209 shares of common stock to certain employees and board members. The options are exercisable for a period of ten years from the date of grant at a weighted average price of $1.70 per share, which was calculated at the fair value of our common stock on the respective grant date. The options generally vest over a period of four years.

Stock Options (Service Vesting)

During the six months ended June 30, 2024, 818,209 stock options subject to service vesting, were issued and valued at $1.1 million using the Black-Scholes option-pricing model. During the six months ended June 30, 2023, 921,817 stock options subject to service vesting, were issued and valued at $0.9 million using the Black-Scholes option-pricing model. The calculated value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions.

	Six Months Ended June 30,	
	2024	**2023**
Risk-free interest rate	4.18% to 5.10%	3.99% to 4.45%
Expected dividend yield	0%	0%
Expected volatility	100%	100%
Expected term	5.27 to 6.02 years	4.00 to 6.2 years

Stock Options (Market Conditions Vesting)

During the six months ended June 30, 2023, 200,000 stock options were granted and subject to market conditions which required our stock price to exceed $3.30 per share for three consecutive days in the four years from grant date for the stock option to vest.These stock options with market conditions vesting were valued at $0.1 million. The fair value of these options subject to market conditions were valued using the Monte-Carlo Simulation model with the following assumptions:

- **Beginning Stock Price.** We utilized the Company's publicly traded share price as of the Valuation Date as the beginning stock value. At the Valuation Date, the publicly traded common share price was $1.09 per share.
- **Drift Rate.** In determining the value of the instrument in the risk-neutral framework, risk-free rates were estimated based on the applicable treasury rate for the projection period. For each simulation, the term of the risk-free rate was based on the term from the Valuation Date through the latest date on which the award could vest (i.e., two years following the Performance Period End Date). Please note that, for the purposes of calculating the service period associated with the Subject Interest, the Company's cost of equity was utilized as the drift rate.
- **Volatility.** The total equity volatility (standard deviation) was based on a total equity volatility analysis.
- **Period.** The period was measured as the number of years from the Valuation Date through the PSO expiration date (10 years following the date of grant).
- **Dividends.** The Company has not historically paid dividends. In addition, the Company does not expect to pay dividends going forward. As such,no dividends were considered in our analysis.

Restricted Stock Units (RSUs)

During the six months ended June 30, 2024, the Company granted 292,500 RSUs. These RSUs are subject to performance vesting criteria, based on market conditions which required our stock price to exceed $3.15 per share for three consecutive days in the four years from grant date for the RSUs to vest.The assumptions used to estimate the fair value of the performance-based restricted stock units granted during the six months ended June 30, 2024 and June 30, 2023 and valued using a Monte Carlo simulation were as follows:

	Six Months Ended June 30,	**Six Months Ended June 30,**
	2024	**2023**
RSUs Granted	292,500	402,500
Valuation date stock price	$1.81	$1.09
Risk-free interest rate	4.53%	4.13%
Expected dividend yield	0%	0%
Expected volatility	100%	100%
Simulation term	4 Years	4 Years

The steps involved in utilizing the Monte Carlo simulation in order to value the performance-based RSUs included the following:

1. Projection of the Company's Common Stock Value. The performance-based RSUs were measured based on the Company's underlying common stock value over the performance period (four years following the Valuation Date).

Additionally, we considered the two-year vesting period following achievement of the performance condition. Accordingly, our common stock value was simulated over a six-year period to capture iterations through which the performance condition was satisfied on the Performance Period End Date. The analysis involved projecting our common stock value starting with our current common stock value. The forecasted stock price was based on the Geometric Brownian motion ("GBM"), and the Monte Carlo simulation generated random variables using the GBM to forecast our stock price on a daily basis over the specified period assuming 252 trading days per year. The Monte Carlo simulation for the PSO utilized the following assumptions:

- **Beginning Stock Price.** As of the Valuation Date, we were a publicly traded company with an observable share price. Therefore, we utilized our publicly traded share price as of the Valuation Date as the beginning stock value.
- **Drift Rate.** In determining the value of the instrument in the risk-neutral framework, risk free rates were estimated based on the applicable treasury rate for the projection period. For each simulation, the term of the risk-free rate was based on the term from the Valuation Date through the latest date on which the award could vest (i.e., two years following the Performance Period End Date). Please note that, for the purposes of calculating the service period associated with the Subject Interest, our cost of equity was utilized as the drift rate.
- **Volatility.** The total equity volatility (standard deviation) was based on a total equity volatility analysis.
- **Period.** The period was measured as the number of years from the Valuation Date through the latest date on which the award could vest.
- **Dividends.** We have not historically paid dividends nor do we expect to pay dividends going forward. As such,no dividends were considered in our analysis.

2. Consideration of the Performance-Vesting Schedule. As previously discussed, our publicly traded common share price must equal or exceed the Stock Price Hurdle amount of $3.15 over a 3-consecutive-trading-day rolling period on or before the Performance Period End Date. If such performance condition is achieved,1/3 of the award shall vest on the Hurdle Achievement Date, 1/3 of the award shall vest one year following the Hurdle Achievement Date, and 1/3 of the award shall vest two years following the Hurdle Achievement Date.

3. Performance-Based RSU Value Conclusion The proceeds from the vesting of common shares were then discounted to the Valuation Date using the applicable risk-free rate, which is consistent with the assumption utilized to project stock prices in our Monte Carlo simulation. For the purpose of calculating the weighted service period associated with the Subject Interest, a separate simulation was performed using our cost of equity as the drift rate. The service period was then determined based on the median Hurdle Achievement Date.

Note 9. Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted average number of shares of common stock outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include common stock options, RSUs and warrants issued and outstanding.

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	$ (5,356)	$ (6,526)	$ (11,395)	$ (12,844)
Denominator:				
Weighted average common shares outstanding - basic and diluted	55,021	50,795	53,612	50,748
Net loss per common share, basic and diluted	$ (0.10)	$ (0.13)	$ (0.21)	$ (0.25)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods presented, as the inclusion of all potential common stock equivalents outstanding would have been antidilutive.

During the six months ended June 30, 2024 and 2023, the following common stock equivalents were excluded from the computation of diluted net loss per share because including them would have been antidilutive (in thousands).

	June 30,	
	2024	2023
Stock options issued and outstanding	6,616	6,139
Restricted stock units issued and outstanding	695	403
Warrants to purchase common stock	10,484	10,311
Total	17,795	16,853

Note 10. Right-of-use Assets and Operating Lease Liabilities

We lease certain office, laboratory, research and development space for our use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Lease costs are recognized in the income statement over the lease term on a straight-line basis. Depreciation is computed using the straight-line method over the estimated useful life of the respective assets. The depreciable life of assets and leasehold improvements are limited by the expected lease term. Our lease agreements do not contain any material residual value guarantees or restrictive covenants. As most of our leases do not provide an implicit rate, we used our estimated incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

On November 21, 2022, Vivani entered into a triple net lease agreement for a single building with 43,645 square feet of space in Alameda, California. The stated term of the lease commenced on June 1, 2023 and terminates on September 30, 2033, ten years and four months. The lease term is based on the non-cancellable period in the lease agreement. There are two options to extend the lease, each for a term of five years; however, the extension options were not included in the measurement of the ROU asset and lease liability since it is not reasonably certain that the Company will exercise such extension options. Payments increase annually from $2,676,311 to $3,596,784, or 124 monthly payments less the first four which are abated, totaling approximately $31.0 million. Vivani is responsible for insurance, property taxes and common area maintenance charges. Vivani deposited $1.3 million to guarantee a letter of credit to secure the lease and this amount is recorded as restricted cash, long-term on the balance sheets as of June 30, 2024 and December 31, 2023. The lease in Emeryville, California expired on September 30, 2023.

On February 1, 2023, we entered into a lease agreement, effective March 1, 2023, to sublease office space to replace Cortigent's headquarters. Our rental payments amount to $22,158 per month plus operating expenses, to lease 14,823 square feet of office space at 27200 Tourney Road, Valencia, California 91355. The sublease has a term of two years and two months. We also entered into a lease for storage space on January 25, 2023, in the same building at a cost of $6,775 per month for a term of two years and one month.

The following table summarizes supplemental balance sheet information related to the Company's operating leases (in thousands):

	Balance Sheet Classification	June 30, 2024	December 31, 2023
Assets			
Non-current assets	Right-of-use assets	$ 18,801	$ 19,616
Liabilities			
Current	Current operating lease liabilities	$ 1,420	$ 1,383
Long-term	Long-term operating lease liabilities	$ 18,616	$ 19,313

Operating lease cost was $0.8 million and $0.6 million during the three months ended June 30, 2024 and 2023, respectively, and $1.7 million and $0.9 million during the six months ended June 30, 2024 and 2023, respectively.

Variable lease cost, comprising primarily of common area maintenance charges and taxes, for the operating lease was $0.1 million and $0.1 million during the three months ended June 30, 2024 and 2023, respectively, and $0.2 million and $0.2 million during the six months ended June 30, 2024 and 2023, respectively.

The following table summarizes a maturity analysis of our lease liabilities showing the aggregate lease payments as of June 30, 2024 (in thousands except weighted average data):

Year Ending December 31,	Amount
2024	$ 1,551
2025	2,914
2026	2,889
2027	2,976
2028	3,065
Thereafter	15,862
Total lease payments	$ 29,257
Less imputed interest	(9,082)
Total lease liabilities	$ 20,175
Weighted average discount rate	8.40%
Weighted average remaining lease term	9.05 years

Other information related to leases are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cash paid for operating lease liabilities	$ 763	$ 382	1,518	759

Note 11. Commitments and Contingencies

Indemnification Agreements

We maintain indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law.

Clinical Trial Agreements

Based upon FDA approval of Argus II, which was obtained in February 2013, we were required to collect follow-up data from subjects enrolled in our pre-approval trial for a period of up to ten years post-implant, which was extended through the year 2019. This requirement to collect follow-up data was halted in 2020 with FDA approval. In addition, we conducted three post-market studies to comply with U.S. FDA, French, and European post-market surveillance regulations and requirements and are conducting an early feasibility clinical study of Orion. We have contracted with various universities, hospitals, and medical practices to provide these services. Payments are based on procedures performed for each subject and are charged to clinical and regulatory expense as incurred. Total amounts expensed during the three months ended June 30, 2024 and 2023 were $4,000 and $90,000, respectively, and during the six months ended June 30, 2024 and 2023 were $10,000 and $116,000, respectively.

Litigation, Claims and Assessments

One opposition filed by Pixium Vision SA ("Pixium") is pending in the European Patent Office challenging the validity of a European patent owned by Cortigent. The outcome of the challenge is not certain, however, if successful, it may affect our ability to block competitors from utilizing Cortigent's neurostimulation patented technology. We believe a successful challenge will not have a material effect on our ability to manufacture and sell our products, or otherwise have a material effect on Cortigent's operations.

As described in the Company's 10-K for the year ended December 31, 2020, the Company had entered into a Memorandum of Understanding ("MOU") for a proposed business combination with Pixium. In response to a press release by Pixium dated March 24, 2021, and subsequent communications between us and Pixium, our Board of Directors determined that the business combination with Pixium was not in the best interest of our shareholders. On April 1, 2021, we gave notice to Pixium that we were terminating the MOU between the parties and seeking an amicable resolution of termination amounts that may be due, however no assurance can be given that an amicable resolution will be reached. We accrued $1,000,000 of liquidated damages as contemplated by the MOU in accounts payable as of March 31, 2021 and remitted that amount to Pixium in April 2021. Pixium indicated that it considered this termination wrongful, rejected the Company's offers, but retained the $1,000,000 payment. On May 19, 2021, Pixium filed suit in the Paris Commercial Court, and currently claim damages of approximately €5.1 million or about $5.6 million. We believe we have fulfilled our obligations to Pixium with the liquidated damages payment of $1,000,000. On December 8, 2022, the Company received notice that the Paris Commercial Court has rendered its judgment, including finding that the Company's termination of the MOU was not valid. In the judgment, the Company was ordered to pay to Pixium the amount of €2,500,000 minus a €947,780 credit for the $1,000,000 already paid for, a net amount payable of approximately €1,552,220. On May 24, 2023, the Company filed an appeal against the judgment from the Paris Commercial Court except in so far as such prior judgment dismissed (i) Pixium's claim for the Company to pay it a sum of €480,693 relating to the alleged time spent by its teams, (ii) Pixium's application to order the Company to pay it a sum of €1,500,000 in respect to alleged loss of opportunity and (iii) deducted the sum of $1,000,000 that we already paid Pixium and which Pixium retained converted into euros at the date of the judgment. Thereafter Pixium filed its brief with Paris Court of Appeal and filed a cross-appeal on January 18, 2024. Meanwhile, the Company received notice that the Paris Commercial Court had opened safeguard proceedings against Pixium by judgment dated October 9, 2023, then in its judgment dated November 13, 2023, converted safeguard proceedings into receivership, and in its judgment dated January 31, 2024, converted Pixium's receivership proceedings to liquidation proceedings, the transfer plan being rejected. As a result, Pixium's liquidator intervened on behalf of Pixium in the pending proceedings before the Paris Court of Appeal and filed its brief on March 21, 2024. The Company filed its brief in reply with the Paris Court of Appeal on April 17, 2024. Proceedings before the Paris Court of Appeal are pending. In parallel, since the Company has failed to enforce the judgment, Pixium has requested the pre-trial judge to strike out the Company's appeal for failure to enforce the judgment. The hearing took place on June 4, 2024 and the decision is expected to be handed down on September 10, 2024, which is an approximate date that is subject to change. The Company recorded a charge of $1,675,000 for the year ended December 31, 2022, related to this matter but plans to continue its appeal against the preliminary judgment.

We are party to litigation arising in the ordinary course of business. It is our opinion that the outcome of such matters will not have a material effect on our results of operations, however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our products, plans and strategy for our business and related financing, contains forward-looking statements that involve risks and uncertainties, including statements regarding our expected financial results in future periods. The words "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "might," "plans," "projects," "will," "would," "strategy" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Examples of forward-looking statements include, among others, statements we make regarding expectations for revenues, liquidity, cash flows and financial performance, the anticipated results of our development efforts and the timing for receipt of required regulatory approvals, including those required to commence clinical development of our product candidates, insurance reimbursements and product launches, our financing plans and future capital requirements, and statements regarding the anticipated or projected impact of our merger on our business, results of operations, financial condition or prospects, the materially adverse impact of the COVID-19 coronavirus pandemic and related public health measures on our business. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. We assume no obligations to update these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report or to reflect actual outcomes.

Business Overview

Vivani Medical, Inc. ("Vivani," the "Company," "we," "us," "our" or similar terms) is a preclinical stage biopharmaceutical company which develops miniaturized, subdermal implants utilizing its proprietary NanoPortal™ technology to enable long-term, near constant-rate delivery of a broad range of medicines to treat chronic diseases. Vivani uses this platform technology to develop and potentially commercialize drug implant candidates, alone or in collaboration with pharmaceutical company partners to address a leading cause of poor clinical outcomes in the treatment of chronic disease, medication non-adherence. According to the U.S. Centers for Disease Control and Prevention, adherence is defined as the extent to which an individual's behavior, including taking medications, corresponds to recommendations from a health care provider. An alarmingly high proportion of patients, approximately 50%, do not take their medicine as prescribed by their physician in the real world, a statistic which holds for both weekly injectable and daily oral medications. In addition, a recent study has shown that 64% of patients taking Wegovy® (semaglutide for weight management) discontinue therapy within the first year, a number which increases to 76% by year two. The Company is developing a portfolio of miniature, subdermal drug implant candidates that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing medication adherence by delivering therapeutic drug levels for up to six months or longer. In addition, our aim is to minimize fluctuations in patients' drug levels through the use of our proprietary NanoPortal™ implant technology, which may improve the tolerability profiles for medicines, including GLP-1 receptor agonists, that produce side effects associated with fluctuating drug levels in the blood.

Vivani resulted from the business combination of Second Sight Medical Products, Inc. ("Second Sight") and Nano Precision Medical, Inc. ("NPM"). On August 30, 2022, Second Sight and NPM closed their merger pursuant to which NPM became a wholly owned subsidiary of Second Sight and the combined company of NPM and Second Sight was renamed Vivani Medical, Inc. Vivani's main priority is the further development of the company's lead program NPM-115, a miniature, six-month, GLP-1 implant candidate for chronic weight management in obese or overweight patients with one or more risk factors and further development of the balance of company's miniature, long-term drug implant portfolio. In parallel, Vivani's management team remained committed to identifying and exploring strategic options that will enable further development of its pioneering neurostimulation systems from legacy company Second Sight aimed at helping patients recover critical body functions.

Moving forward, Vivani's focus will be on the further development of NPM115 and its emerging pipeline of innovative miniature, long-term drug implants to treat patients with chronic diseases and high unmet medical need. The origins of this business started while its current Vivani CEO and NPM co-founder Adam Mendelsohn and two of his graduate school colleagues, Kathleen Fischer and Lily Peng, at the University of California, San Francisco ("UCSF") and the University of California, Berkeley ("UCB"), entered business school competitions leveraging their growing knowledge of chemistry, drug delivery, and nanoscale technology to propose the development of new miniature, biocompatible, drug implant prototypes capable of releasing therapeutic drug levels over an extended period of time. Based on their success and encouragement from professors and others, including medical device/pharmaceutical icon Alfred E. Mann, Dr. Mendelsohn and colleagues started NPM in 2009 and operations began in 2011 in an incubator on the UCB campus. Today, the Company has grown to36 full-time employees and its current headquarters and operations are located at 1350 South Loop Road, Alameda, California.

Vivani's implant technology, which we refer to as NanoPortal™, utilizes a space-efficient design that allows a miniaturized implant to provide many months of therapeutic delivery of potent molecules. The technology has no moving parts, which is intended to minimize fluctuating drug delivery over the duration of the implant and is also tunable. Vivani has primarily been developing implant candidates around peptide therapeutics, but the technology has potential application across a wide range of molecular types. The key innovative component of the technology is a biocompatible titanium-oxide nano-porous membrane which consists of millions of precisely sized nanotubes whose inner diameters represent the only path for drug molecules to exit the reservoir once the implant is fully assembled.

In December 2022, we contributed our neurostimulation assets and certain liabilities to Cortigent, Inc. ("Cortigent"), a wholly owned subsidiary of Vivani. Cortigent has 5,000,000 shares of common stock outstanding, all owned by Vivani. Cortigent is advancing the Company's pioneering neurostimulation technology. 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. The Registration Statement on Form S-1 was recently amended and filed with the SEC on June 7, 2024 to refresh the financial information and provide minor updates to the business.

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. As part of this change of incorporation the Company established a par value of $0.0001 per share and all periods have been retroactively adjusted to reflect this change.

An Investigational New Drug Application ("IND") for NPM-119 (GLP-1 implant for the treatment of type 2 diabetes) was filed with the U.S. Food and Drug Administration ("FDA") on July 14, 2023, to support the initiation of the first-in-human study of NPM-119 in patients with type 2 diabetes. On August 18, 2023, FDA provided written notification that the proposed NPM-119 study was on full clinical hold, primarily due to insufficient Chemistry, Manufacturing, and Controls ("CMC") information to assess the risk to human subjects. Vivani provided the FDA with the requested CMC information and the FDA subsequently cleared the IND and lifted the full clinical hold on June 13, 2024.

On August 25, 2023, Vivani and Cortigent entered into an Amendment No.1 (the "Amendment") to the Transition Funding, Support and Services Agreement dated March 19, 2023 (the "TFSSA"). Pursuant to the TFSSA, Vivani has agreed to advance funds and provide or cause to be provided to Cortigent the services and funding intended to cover salaries and related costs, rent and other overhead in order to permit Cortigent to operate in substantially the same manner in which business operations of Cortigent were previously operated by Second Sight, prior to the formation of Cortigent, which obligations will continue, in the case of the funding obligations, until the earlier of December 31, 2024 or the closing of an initial public offering of Cortigent (the "Funding Support Term"). Under the Amendment, Cortigent has agreed to repay $1,500,000 to Vivani at the conclusion of the Funding Support Term. In addition, at the conclusion of the Funding Support Term, Cortigent will enter into a five-year promissory note at 5% interest for $2,000,000 in favor of Vivani. Consequently, Vivani will forgive any remaining amounts due by Cortigent to the Company under the TFSSA. In October 2023, Vivani implemented a reduction-in-force to conserve cash that decreased Cortigent's employees while continuing the ongoing Orion® clinical study and basic operations.

In the fourth quarter of 2023, Vivani Medical Australia Pty Ltd., a wholly-owned subsidiary in Australia was established to support studies of our product candidates.

In February 2024, Vivani announced positive preclinical weight loss data with NPM-115 (GLP-1 implant) comparable to semaglutide, the active ingredient in Ozempic®/Wegovy®, and a strategic shift to prioritize our obesity portfolio. In a study of high-fat diet-induced obese mice, NPM-115 generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to weight loss observed in mice treated with semaglutide injections (Ozempic®/Wegovy®) in the same study. The Company also disclosed that semaglutide is the active pharmaceutical ingredient in NPM-139, a miniature, subdermal GLP-1 implant in development for chronic weight management, with the added potential benefit of once-yearly administration.

On March 1, 2024, the Company entered into a securities purchase agreement with an institutional investor to purchase 3,947,368 shares of common stock and warrants to purchase up to an aggregate of 3,947,368 shares of common stock at a purchase price of $3.80 per share and accompanying warrant in a registered direct offering. The warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance, and will expire three years following the date of issuance. For additional information, refer to Note 6. Equity Securities of the Notes to Condensed Consolidated Financial Statements in this quarterly report on Form 10-Q.

On March 6, 2024, the Company announced the appointment of Daniel Bradbury to its Board of Directors. Under Bradbury's leadership as CEO, Amylin Pharmaceuticals, with partner Alkermes, secured the 2012 approval of Bydureon® (exenatide injection), the world's first weekly GLP-1 receptor agonist, a class of drugs that now includes blockbusters Ozempic®, Trulicity® and Wegovy®.

On April 22, 2024, the Company entered into a sales agreement with an underwriter, under which the Company may offer and sell, from time to time at its sole discretion, shares of common stock, having an aggregate offering price of up to $75.0 million through such underwriter as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of common stock in accordance with the sales agreement. For additional information, refer to Note 6. Equity Securities of the Notes to Condensed Consolidated Financial Statements.

On May 28, 2024, Vivani announced the publication of positive weigh loss data supporting the potential veterinary use of OKV-119, the Company's miniature, long-term GLP-1 implant under development with partner Okava for the treatment of pre-diabetes, diabetes, and obesity in companion felines. The device is intended to be conveniently inserted under the skin during routine veterinary visits and is being designed to deliver six months of GLP-1 therapy with a single implant.

On June 13, 2024, the Company announced that the FDA cleared the IND for NPM-119, a miniature, long-term subdermal GLP-1 implant under investigation to address medication non-adherence and potentially improve tolerability in patients with type 2 diabetes. The proposed first-in-human clinical study was designed to evaluate the safety, tolerability and pharmacokinetic profile of the exenatide implant versus the marketed exenatide injectable, Bydureon BCise®.

On July 11, 2024, the Company provided an update of the clinical development plans for NPM-115, the miniature, long-acting GLP-1 (high-dose exenatide) implant for the treatment of chronic weight management in obese and overweight individuals. The Company has redesigned the first-in-human study, LIBERATE-1, to explore the safety, tolerability and pharmacokinetics of an exenatide implant (initially using the same test article proposed for NPM-119) in obese and overweight patients. The study will enroll patients who will be titrated on weekly semaglutide injections for eight weeks before being randomized to receive a single exenatide implant, weekly exenatide injections (Bydureon BCise®) or weekly semaglutide injections (Wegovy®) for a nine-week treatment duration. The LIBERATE-1 study will be conducted in Australia and is anticipated to be initiated in the fourth quarter of 2024, pending regulatory clearance, with data from the study expected in 2025.

Funding and Liquidity

Capital Funding

From inception, our operations have been funded primarily through the sales of our common stock and warrants. On March 1, 2024, the Company entered into the Securities Purchase Agreement relating to the issuance of 3,947,368 shares of the Company's common stock, par value of $0.0001 per share (the "Common Stock") and warrants to purchase up to an aggregate of 3,947,368 shares of common stock (the "Warrants"), to such investor at a purchase price of $3.80 per share and accompanying warrants in a registered direct offering (the "Offering"). The Warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance and will expire three years following the date of issuance. Simultaneously, the Company also entered into a placement agency agreement with Maxim Group LLC ("Maxim" and such agreement, the "Placement Agency Agreement," and together with the Securities Purchase Agreement, the "Agreements"), who acted as the sole placement agent for the Offering. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million, during the six months ended June 30, 2024. For additional information, refer to Note 6. Equity Securities of the Notes to Condensed Consolidated Financial Statements in this quarterly report on Form 10-Q.

On April 22, 2024, the Company entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC ("Jefferies"), under which the Company may offer and sell, from time to time at its sole discretion, shares of the Common Stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its Common Stock in accordance with the Sales Agreement. For additional information, refer to Note 6. Equity Securities of the Notes to Condensed Consolidated Financial Statements.

Non-Capital Funding

From time to time, we receive grants that help fund specific development programs. Any amounts received pursuant to grants are offset against the related operating expenses as the costs are incurred. Commencing in January 2018, we were awarded a $1.6 million grant (with the intent to fund $6.4 million over five years subject to annual review and approval) from the National Institutes of Health (the "NIH") to fund the "Early Feasibility Clinical Trial of a Visual Cortical Prosthesis". The final year of the grant ended in March 2024. During the six months ended June 30, 2024 and 2023 total grants offsetting against operating expenses were $0.1 million and $0.3 million, respectively.

Liquidity

We have experienced recurring operating losses and negative operating cash flows since inception and have financed our working capital requirements through the recurring sale of our equity securities. Our financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

To finance our operations, we will need to raise additional capital, which cannot be assured. Our operating plan may change as a result of many factors currently unknown to us, and we will need to seek additional funds through public or private equity offerings or debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, or we may be unable to expand or maintain our operations, maintain our current organization and employee base or otherwise capitalize on our business opportunities, as desired, which could materially and adversely affect our business, financial condition and results of operations.

We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations into the second half of 2025. Our ability to continue as a going concern is dependent on our ability to raise additional capital and/or develop profitable operations through implementation of our business initiatives, however, there can be no assurances that we will be able to do so.

Critical Accounting Policies and Estimates

The preparation of our condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States ("GAAP") and the requirements of the United States Securities and Exchange Commission require management to make estimates, assumptions and judgments that affect the amounts, liabilities, revenue and expenses reported in the financial statements and the notes to the financial statements. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies during the six months ended June 30, 2024.

Results of Operations

Operating Expenses. We recognize our operating expenses as incurred in two general operational categories: research and development and general and administrative. Our operating expenses also include a non-cash component related to the amortization of stock-based compensation for research and development and general and administrative personnel. From time-to-time we have received grants from institutions or agencies, such as the National Institutes of Health, to help fund some of the cost of our development efforts. We have recorded these grants as reductions to operating expenses.

- Research and development expense consist primarily of employee compensation and consulting costs related to the design, development, and enhancements of our current and potential future products, as well as internal and external costs associated with conducting clinical trials and maintaining relationships with regulatory agencies, as well as facilities costs, which include expenses for rent, maintenance of facilities and depreciation of equipment, offset by grant revenue received in support of specific research projects. We expense our research and development costs as they are incurred. We expect research and development expenses to increase in the future as we pursue further enhancements of our existing product and develop technology for our potential future products. We also expect to receive additional grants in the future that will primarily offset research and development costs.

- General and administrative expense consist primarily of salaries and related expenses for executive, legal, finance, human resources, information technology and administrative personnel, as well as recruiting and professional fees, patent filing and annuity costs, insurance costs and other general corporate expenses, including rent and other facility related costs. We expect general and administrative expenses to increase as we add personnel and incur additional costs related to the growth of our business and operate as a public company.

Comparison of the Three Months Ended June 30, 2024 and 2023

Research and development expense. Research and development expense during the three months ended June 30, 2024 was $3.5 million, compared to $3.9 million during the three months ended June 30, 2023. The decrease of $0.4 million, or 9%, was primarily attributable to staffing reduction and reduced use of outside services from our neurostimulation division.

General and administrative expense. General and administrative expense during the three months ended June 30, 2024 was $2.2 million, compared to $3.1 million during the three months ended June 30, 2023. The decrease of $1.0 million, or 31%, was primarily attributable to staffing reductions along with reduced outside legal services from our neurostimulation division, in addition to reduced professional services from our Biopharma division.

Other income, net. Other income, net during the three months ended June 30, 2024 was $0.3 million, compared to $0.5 million during the three months ended June 30, 2023. The change was not significant.

Comparison of the Six Months Ended June 30, 2024 and 2023

Research and development expense. Research and development expense decreased by $0.6 million, or 7%, to $7.2 million in the first six months of 2024 from $7.8 million in the same period of 2023. The costs decreased was primarily attributable to staffing reduction and reduced use of outside services from our neurostimulation division, partially offset by the increase in Alameda site facility expense allocation from our Biopharma division.

General and administrative expense. General and administrative expense decreased $1.1 million, or 19%, to $4.7 million in the first six months of 2024 from $5.8 million in the same period of 2023. This decrease was primarily attributable to staffing reductions along with reduced outside legal services from our neurostimulation division.

Other income, net. Other income, net during the six months ended June 30, 2024 was $0.5 million, compared to $0.8 million during the six months ended June 30, 2023. The decrease was due to lower interest associated with lower cash balances.

Liquidity and Capital Resources

We have experienced recurring operating losses and negative operating cash flows since inception and have financed our working capital requirements through the recurring sale of our equity securities. Our financial statements have been presented on the basis that our business is a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

On March 1, 2024, the Company entered into the Securities Purchase Agreement relating to the issuance of 3,947,368 shares of the Company's common stock, par value of $0.0001 per share and warrants to purchase up to an aggregate of 3,947,368 shares of common stock at a purchase price of $3.80 per share and accompanying warrants in a registered direct offering. The Warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance and will expire three years following the date of issuance. In connection with the Placement Agency Agreement, the Company agreed to pay Maxim an aggregate cash fee of 7.0% of the aggregate proceeds raised from the sale and issuance of the shares of common stock and accompanying warrants. Pursuant to the Placement Agency Agreement, the Company also agreed to reimburse Maxim up to $65,000 for its legal expenses. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other estimated offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million, during the six months ended June 30, 2024. For additional information, refer to Note 6. Equity Securities of the Notes to Condensed Consolidated Financial Statements in this quarterly report on Form 10-Q.

On April 22, 2024, the Company entered into the Sales Agreement with Jefferies, under which the Company may offer and sell, from time to time at its sole discretion, shares of the Common Stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its Common Stock in accordance with the Sales Agreement. For additional information, refer to Note 6. Equity Securities of the Notes to Condensed Consolidated Financial Statements.

We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations into the second half of 2025. Our ability to continue as a going concern is dependent on our ability to develop profitable operations through implementation of our business initiatives and/or raise additional capital, however, there can be no assurances that we will be able to do so.

We are subject to the risks and uncertainties associated with a business with no revenue that is developing a novel pharmaceutical product candidates and medical device candidates, including limitations on our operating capital resources and uncertain demand for our products. We have incurred recurring operating losses and negative operating cash flows since inception, and we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future. We expect our operating expenses to increase significantly as we continue our business operations, particularly as we prepare to and initiate our planned clinical trial and conduct our other research and development activities. Conducting clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete and we may never generate the necessary data or results required to obtain marketing approval. We do not expect revenues until we are successful in completing the development and obtaining marketing approval for our products. We expect expenses to increase in connection with our ongoing activities, particularly as we initiate clinical trials, initiate new research and development projects and seek marketing approval for any product candidates that we successfully develop. If we are required to conduct additional nonclinical or clinical activities preclinical or IND-enabling activities such as additional pre-clinical, our overall expenditures would increase. In addition, if we obtain marketing approval, we expect to incur significant additional expenses related to sales, marketing, distribution and other commercial infrastructure to commercialize such product. In addition, our product candidates, if approved, may not achieve commercial success. We incur significant costs associated with operating as a public company in a regulated industry.

Until such time, if ever, we can generate product revenues, we anticipate that we will seek to fund our operations through public or private equity or debt financings, grants, collaborations, strategic partnerships or other sources. However, we may be unable to raise additional capital or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity, convertible debt or other equity-linked securities, the ownership interests of some or all of our common stockholders will be diluted, the holders of new equity securities may have priority rights over our existing stockholders and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If adequate funds are not available, we may be required to curtail operations significantly or to obtain funds by entering into agreements on unattractive terms. If, for example, we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us. Our inability to raise capital could have a material adverse effect on our business, financial condition and results of operations.

Cash, cash equivalents and restricted cash increased by $4.3 million from $22.0 million as of December 31, 2023 to $26.3 million as of June 30, 2024. Working capital was $20.6 million as of June 30, 2024, as compared to $17.3 million as of December 31, 2023, an increase of $3.2 million. We use our cash and cash equivalents and working capital to fund our operating activities.

Cash Flows from Operating Activities

During the six months ended June 30, 2024, we used $9.3 million of cash in operating activities, consisting primarily of a net loss of $11.4 million, partially offset by $1.0 million provided by a net change in operating assets and liabilities and non-cash items totaling $1.1 million for depreciation and amortization of property and equipment, stock-based compensation and lease expense.

During the six months ended June 30, 2023, we used $12.5 million of cash in operating activities, consisting primarily of a net loss of $12.8 million and a net increase in net operating assets of $0.9 million, partially offset by non-cash charges of $1.2 million for depreciation and amortization of property and equipment, stock-based compensation and lease expense.

Cash Flows from Investing Activities

Cash used for investing activities during the six months ended June 30, 2024 and 2023 was $0.2 million and $81,000, respectively, primarily attributable to the purchase of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities was $13.8 million during the six months ended June 30, 2024, primarily attributable to a securities purchase agreement with an institutional investor. For additional information, refer to Note 6. Equity Securities of the Notes to Condensed Consolidated Financial Statements in this quarterly report on Form 10-Q.

There were no cash flows from financing activities during the six months ended June 30, 2023.

Off-Balance Sheet Arrangements

As of June 30, 2024, we did not have any transactions, obligations or relationships that constitute off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Sensitivity

The primary objective of our investment activities is to maintain the safety of principal and preserve liquidity without incurring significant risk. We invest cash in excess of our current needs in certificates of deposit and money market funds. In general, money market funds are not considered to be subject to interest rate risk because the interest paid on such funds fluctuates with the prevailing interest rate. As of June 30, 2024, our cash equivalents consisted of certificates of deposit, money market funds and restricted cash as collateral for our lease.

Exchange Rate Sensitivity

The majority of our operating expenses were denominated in U.S. dollars. We have not entered into foreign currency forward contracts to hedge our operating expense exposure to foreign currencies, but we may do so in the future.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, including our Chief Executive Officer ("CEO") and our Chief Financial Officer ("CFO"), evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. As of June 30, 2024, based on the evaluation of these disclosure controls and procedures, our CEO and CFO have concluded that our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter endedJune 30, 2024, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We are updating our internal control environment to address changes in our risks in financial reporting to accommodate our operating activities, staffing levels, and segregation of duties. Such changes may result in new or reduced controls.

Inherent Limitations on Effectiveness of Controls

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings

One opposition filed by Pixium Vision SA ("Pixium") is pending in the European Patent Office challenging the validity of a European patent owned by Cortigent. The outcome of the challenge is not certain, however, if successful, it may affect our ability to block competitors from utilizing Cortigent's neurostimulation patented technology. We believe a successful challenge will not have a material effect on our ability to manufacture and sell our products, or otherwise have a material effect on Cortigent's operations.

As described in the Company's 10-K for the year ended December 31, 2020, the Company had entered into a Memorandum of Understanding ("MOU") for a proposed business combination with Pixium. In response to a press release by Pixium dated March 24, 2021, and subsequent communications between us and Pixium, our Board of Directors determined that the business combination with Pixium was not in the best interest of our shareholders. On April 1, 2021, we gave notice to Pixium that we were terminating the MOU between the parties and seeking an amicable resolution of termination amounts that may be due, however no assurance can be given that an amicable resolution will be reached. We accrued $1,000,000 of liquidated damages as contemplated by the MOU in accounts payable as of March 31, 2021 and remitted that amount to Pixium in April 2021. Pixium indicated that it considered this termination wrongful, rejected the Company's offers, but retained the $1,000,000 payment. On May 19, 2021, Pixium filed suit in the Paris Commercial Court, and currently claim damages of approximately €5.1 million or about $5.6 million. We believe we have fulfilled our obligations to Pixium with the liquidated damages payment of $1,000,000. On December 8, 2022, the Company received notice that the Paris Commercial Court has rendered its judgment, including finding that the Company's termination of the MOU was not valid. In the judgment, the Company was ordered to pay to Pixium the amount of €2,500,000 minus a €947,780 credit for the $1,000,000 already paid for, a net amount payable of approximately €1,552,220. On May 24, 2023, the Company filed an appeal against the judgment from the Paris Commercial Court except in so far as such prior judgment dismissed (i) Pixium's claim for the Company to pay it a sum of €480,693 relating to the alleged time spent by its teams, (ii) Pixium's application to order the Company to pay it a sum of €1,500,000 in respect to alleged loss of opportunity and (iii) deducted the sum of $1,000,000 that we already paid Pixium and which Pixium retained converted into euros at the date of the judgment. Thereafter Pixium filed its brief with Paris Court of Appeal and filed a cross-appeal on January 18, 2024. Meanwhile, the Company received notice that the Paris Commercial Court had opened safeguard proceedings against Pixium by judgment dated October 9, 2023, then in its judgment dated November 13, 2023, converted safeguard proceedings into receivership, and in its judgment dated January 31, 2024, converted Pixium's receivership proceedings to liquidation proceedings, the transfer plan being rejected. As a result, Pixium's liquidator intervened on behalf of Pixium in the pending proceedings before the Paris Court of Appeal and filed its brief on March 21, 2024. The Company filed its brief in reply with the Paris Court of Appeal on April 17, 2024. Proceedings before the Paris Court of Appeal are pending. In parallel, since the Company has failed to enforce the judgment, Pixium has requested the pre-trial judge to strike out the Company's appeal for failure to enforce the judgment. The hearing took place on June 4, 2024, and the decision will be handed down on September 10, 2024, which is an approximate date that is subject to change. The Company recorded a charge of $1,675,000 for the year ended December 31, 2022, related to this matter but plans to continue its appeal against the preliminary judgment.

We are party to litigation arising in the ordinary course of business. It is our opinion that the outcome of such matters will not have a material effect on our financial statements, however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

Our business is subject to numerous material and other risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Form 10-Q, including our consolidated financial statements and the related notes, and in our other filings with the SEC. If any of the stated risks actually occur, our business, prospects, operating results, and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment. The material risks associated with our business were most recently discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 that we filed on March 26, 2024. There have been no material changes from the risk factors previously disclosed in such filing, expect as noted below:

Risks Related to Our Financial Position and Need for Additional Capital

We will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we will incur significant costs associated with sales, marketing, manufacturing, and distribution activities. Our expenses could increase beyond expectations if required by the FDA, the EMA or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. For example, on June 13, 2024, the FDA lifted the full clinical hold that they had previously implemented on the LIBERTATE-1 study on August 18, 2023 and have cleared us to initiate the LIBERATE-1™ Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of NPM-119 (exenatide), our miniature, six-month GLP-1 implant in development for treatment of type 2 diabetes. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate. We are not permitted to market or promote any product candidate before it receives marketing approval from the regulatory authorities. Accordingly, we will need to obtain substantial additional funding in order to continue our operations and pursue our business objectives.

Risks Related to Product Development, Clinical Testing and Commercialization

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing our product candidates, and our clinical development efforts may not yield favorable results.

To receive regulatory approval for our product candidates, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, the EMA, and comparable foreign authorities. We have not yet conducted clinical trials for our current product candidates and clinical testing of such product candidates may not yield results to support continued development or seeking regulatory approval. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent development and approval of our product candidates, including the following:

- we may be unable to initiate or conduct planned clinical trials on our anticipated timelines, including as a result of failing to obtain any clearances necessary to conduct clinical trials or being subject to clinical holds that prevent continuation of such trials;
- clinical trials may produce negative or inconclusive results;
- preclinical studies conducted with product candidates during clinical development to, among other things, evaluate their safety, tolerability and pharmacokinetics and optimize their formulation may produce unfavorable results;
- patient recruitment and enrollment in clinical trials may be slower than anticipated;
- costs of development may be greater than anticipated;
- our product candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved;
- if one or more product candidates are developed in collaboration with third parties, such parties may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner;
- we may face delays or other challenges associated with the availability and sourcing key raw materials and/or key components; and
- we may encounter difficulties in developing product candidates related to our proprietary NanoPortal implant technology or difficulties associated with the long-term purity, potency, safety, or stability of our product candidates.

For example, on June 13, 2024, the FDA lifted the full clinical hold that they had previously implemented on the LIBERTATE-1 study on August 18, 2023 and have cleared us to initiate the LIBERATE-1™ Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of NPM-119 (exenatide), our miniature, six-month GLP-1 implant in development for treatment of type 2 diabetes. The LIBERATE-1 study will be conducted in Australia and is anticipated to be initiated in the fourth quarter of 2024 after the HREC approval.

We could experience delays in the commencement or completion of clinical trials, which could result in increased costs or otherwise impair our research and development efforts.

Delays in the commencement or completion of clinical trials could significantly impact our drug development costs and otherwise impair our research and development efforts. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

- obtaining regulatory approval to commence one or more clinical trials;
- reaching agreement on acceptable terms with prospective third-party contract research organizations and clinical trial sites;
- obtaining institutional review board approval to conduct one or more clinical trials at a prospective site;
- recruiting and enrolling patients to participate in one or more clinical trials; and
- the failure of our collaborators to adequately resource our product candidates.

For example, on June 13, 2024, the FDA lifted the full clinical hold that they had previously implemented on the LIBERTATE-1 study on August 18, 2023 and have cleared us to initiate the LIBERATE-1™ Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of NPM-119 (exenatide), our miniature, six-month GLP-1 implant in development for treatment of type 2 diabetes. The LIBERATE-1 study will be conducted in Australia and is anticipated to be initiated in the fourth quarter of 2024 after the HREC approval.

Our product candidates are subject to extensive regulation under the FDA, the EMA and comparable foreign authorities, and must undergo extensive clinical testing that can be costly and time consuming, with no assurance that regulatory approval will be obtained for any of our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing, and distribution of our product candidates are subject to extensive regulation by the FDA and other U.S. regulatory agencies, the EMA, or comparable authorities in foreign markets. In the U.S., neither we nor any collaborators are permitted to conduct clinical testing in humans with our product candidates unless and until clearance is received to conduct clinical investigations under an IND from the FDA or receive similar authorizations abroad. For example, on June 13, 2024, the FDA lifted the full clinical hold that they had previously implemented on the LIBERTATE-1 study on August 18, 2023 and have cleared us to initiate the LIBERATE-1™ Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of NPM-119 (exenatide), our miniature, six-month GLP-1 implant in development for treatment of type 2 diabetes. The LIBERATE-1 study will be conducted in Australia and is anticipated to be initiated in the fourth quarter of 2024 after the HREC approval. In addition, marketing of such product candidates may not occur unless and until approval of a new drug application ("NDA") from the FDA or similar approvals by comparable foreign regulatory authorities are secured.

With respect to one or more of our product candidates, we may seek regulatory approval in the U.S. by filing an NDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which is referred to as the 505(b)(2) pathway. The 505(b)(2) pathway allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. For our exenatide implants for example, we may intend to rely on certain information from Bydureon® and/or Bydureon BCise®, AstraZeneca's exenatide extended-release injectable products. If we are unable to reference data generated for Bydureon® and/or Bydureon BCise®, additional clinical studies, including a cardiovascular outcomes ("CVOT") study, may be required and would add significant additional costs and a significant delay in our efforts to seek and secure marketing approval. Further, if a CVOT study were conducted, there can be no assurance that the study would generate favorable results and support regulatory approval.

Risks Related to Ownership of Our Common Stock

Because we became a reporting company under the Exchange Act by means other than a traditional underwritten initial public offering, we may not be able to attract the attention of research analysts at major brokerage firms.

Vivani resulted from the August 2022 business combination of Second Sight and NPM. Vivani's main priority is the further development of the Company's lead program NPM-115, which is a miniature, six-month, GLP-1 implant candidate for the treatment of chronic weight management and the balance of the Company's emerging portfolio of miniature, long-acting, GLP-1 implant candidates. In parallel, Vivani's management team remained committed to identifying and exploring strategic options for the Neuromodulation Division (formerly Second Sight) that will enable further development of its pioneering neurostimulation systems to help patients recover critical body functions.

Because the NPM business did not become a reporting company by conducting an underwritten initial public offering of our common stock, security analysts of brokerage firms may not provide coverage of our company. In addition, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we became a public reporting company by means of an underwritten initial public offering, because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

No Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements were adopted, modified, or terminated by officers or directors of the Company, nor were there any material changes to the procedures by which security holders may recommend nominees to the Company's board of directors, during the quarter ended June 30, 2024.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Exhibit Description
2.1	Agreement and Plan of Merger by and among Second Sight Medical Products, Inc. and Nano Precision Medical, Inc., dated February 4, 2022 (incorporated by reference to Exhibit 2.1 in the Registrant's Current Report on Form 8-K filed with the SEC on February 8, 2022).
3.1	Certificate of Incorporation of Vivani Medical, Inc., filed with the Secretary of State of Delaware and effective, July 6, 2023 (incorporated by reference to Exhibit 3.1 in the Registrant's Current Report on Form 8-K filed with the SEC on July 10, 2023).
3.2	Bylaws of Vivani Medical, Inc. effective July 6, 2023 (incorporated by reference to Exhibit 3.2 in the Registrant's Current Report on Form 8-K filed with the SEC on July 10, 2023).
10.1	Open Market Sale Agreement[SM] by and between the Company and Jefferies LLC, dated April 22, 2024 (incorporated by reference to Exhibit 1.2 of the Company's Registration Statement on Form S-3 filed on April 22, 2024).
31.1*	Certification of Principal Executive Officer of Vivani Medical, Inc. pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial and Accounting Officer of Vivani Medical, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certifications of Principal Executive Officer and Principal Financial and Accounting Officer of Vivani Medical, Inc. pursuant to Rule 13a-14(b) under the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instant Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
*	Filed herewith.
**	This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

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 thereunto duly authorized.

Name	Title	Date
/s/ Adam Mendelsohn Adam Mendelsohn	Chief Executive Officer (Principal Executive Officer)	August 13, 2024
/s/ Brigid Makes Brigid Makes	Chief Financial Officer (Principal Financial and Accounting Officer)	August 13, 2024

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam Mendelsohn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vivani Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2024

/s/ Adam Mendelsohn
Adam Mendelsohn
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brigid Makes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vivani Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2024

/s/ Brigid Makes
Brigid Makes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certifications of Principal Executive Officer and Principal Financial Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted
Pursuant To Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), Adam Mendelsohn, Chief Executive Officer (Principal Executive Officer) and Brigid Makes, Chief Financial Officer (Principal Financial and Accounting Officer) of Vivani Medical, Inc. (the "Company"), each hereby certifies that, to the best of his or her knowledge:

1. The Quarterly Report of the Company on Form 10-Q (the "Report") for thesix months ended June 30, 2024, to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2024

/s/ Adam Mendelsohn
Adam Mendelsohn
Chief Executive Officer
(Principal Executive Officer)

/s/ Brigid Makes
Brigid Makes
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vivani Medical, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.