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 September 30, 2023

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)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	VANI	NASDAQ

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 November 10, 2023, the registrant had 51,025,060 shares of common stock, par value $0.0001 per share and 7,680,938 warrants, outstanding.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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Item 1. Financial Statements

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,821	$ 45,076
Prepaid expenses and other current assets	5,861	2,452
Total current assets	30,682	47,528
Property and equipment, net	1,134	1,182
Right-of-use assets	20,050	779
Restricted cash	1,366	1,366
Deposits and other assets	87	275
Total assets	$ 53,319	$ 51,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,891	$ 1,177
Accrued expenses	1,815	2,358
Litigation accrual	1,675	1,675
Accrued compensation expense	676	657
Current operating lease liabilities	1,376	955
Total current liabilities	7,433	6,822
Long term operating lease liabilities	19,679	—
Total liabilities	27,112	6,822
Commitments and contingencies (Note 10)		
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: 51,025 as of September 30, 2023 and 50,736 as of December 31, 2022, respectively	5	5
Additional paid-in capital	118,568	117,054
Accumulated other comprehensive loss	46	35
Accumulated deficit	(92,412)	(72,786)
Total stockholders' equity	26,207	44,308
Total liabilities and stockholders' equity	$ 53,319	$ 51,130

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)

	For the Three Months ended September 30,		For the Nine Months ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development, net of grants	$ 4,441	$ 3,859	$ 12,260	$ 9,742
General and administrative	2,703	1,585	8,488	3,709
Total operating expenses	7,144	5,444	20,748	13,451
Loss from operations	(7,144)	(5,444)	(20,748)	(13,451)
Other income (expense), net	362	6,867	1,122	6,846
Net income/(loss)	$ (6,782)	$ 1,423	$ (19,626)	$ (6,605)
Net income/(loss) per common share – basic	$ (0.13)	$ 0.04	$ (0.39)	$ (0.18)
Net income/(loss) per common share – diluted	$ (0.13)	$ 0.04	$ (0.39)	$ (0.18)
Weighted average common shares outstanding – basic	50,837	37,965	50,757	37,712
Weighted average common shares outstanding – diluted	50,837	38,477	50,757	37,712

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

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Statements of Comprehensive Income (Loss) (unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net income (loss)	$ (6,782)	$ 1,423	$ (19,626)	$ (6,605)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(19)	(26)	11	(26)
Comprehensive income (loss)	$ (6,801)	$ 1,397	$ (19,615)	$ (6,631)

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

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Condensed Consolidated Statements of Stockholders' Equity (Deficit) (unaudited)
(in thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
Balance, January 1, 2022	36,803	$ 4	$ 61,358	$ —	$ (58,897)	$ 2,465
Repurchase of common stock	4	—	—	—	—	—
Options exercised	24	—	1	—	—	1
Stock-based compensation expense	—	—	340	—	—	340
Net loss	—	—	—	—	(3,924)	(3,924)
Balance, March 31, 2022	36,831	$ 4	$ 61,699	$ —	$ (62,821)	$ (1,118)
Options exercised	6	—	12	—	—	12
Stock-based compensation expense	—	—	394	—	—	394
Net loss	—	—	—	—	(4,104)	(4,104)
Balance, June 30, 2022	36,837	$ 4	$ 62,105	$ —	$ (66,925)	$ (4,816)
Options exercised	763	—	3	—	—	3
Shares issued for SSMP assets	13,136	1	54,384	—	—	54,385
Stock-based compensation expense	—	—	391	—	—	391
Foreign currency translation adjustment	—	—	—	(26)		(26)
Net income	—	—	—	—	1,423	1,423
Balance, September 30, 2022	50,736	$ 5	$ 116,883	$ (26)	$ (65,502)	$ 51,360

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance, January 1, 2023	50,736	$ 5	$ 117,054	$ 35	$ (72,786)	$ 44,308
Options exercised	53	—	—	—	—	—
Stock-based compensation expense	—	—	369	—	—	369
Foreign currency adjustment	—	—	—	9	—	9
Net loss	—	—	—	—	(6,318)	(6,318)
Balance, March 31, 2023	50,789	$ 5	$ 117,423	$ 44	$ (79,104)	$ 38,368
Options exercised	10	—	7	—	—	7
Stock-based compensation expense	—	—	524	—	—	524
Foreign currency adjustment	—	—	—	21	—	21
Net loss	—	—	—	—	(6,526)	(6,526)
Balance, June 30, 2023	50,799	$ 5	$ 117,954	$ 65	$ (85,630)	$ 32,394
Options exercised	226	—	103	—	—	103
Stock-based compensation expense	—	—	511	—	—	511
Foreign currency adjustment	—	—	—	(19)	—	(19)
Net loss	—	—	—	—	(6,782)	(6,782)
Balance, September 30, 2023	51,025	$ 5	$ 118,568	$ 46	$ (92,412)	$ 26,207

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)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (19,626)	$ (6,605)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	259	271
Stock-based compensation	1,404	1,125
Non-cash lease expense	829	23
Gain on bargain purchase	—	(6,877)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(3,286)	(792)
Accounts payable	718	(1,163)
Accrued compensation expenses	18	102
Accrued expenses	(534)	332
Net cash used in operating activities	(20,218)	(13,584)
Cash flows from investing activities:		
Purchase of intangibles	—	(48)
Purchases of property and equipment	(144)	(249)
Net cash used in investing activities	(144)	(297)
Cash flows from financing activities:		
Cash acquired in merger for stock consideration	—	55,374
Proceeds from SAFE note	—	8,000
Net proceeds from exercise of options	110	16
Net cash provided by financing activities	110	63,390
Effect of exchange rate changes on cash and cash equivalents	(3)	(3)
Cash, cash equivalents and restricted cash:		
Net increase (decrease)	(20,255)	49,506
Balance at beginning of period	46,442	2,178
Balance at end of period	$ 26,187	$ 51,684
Non-cash investing and financing activities:		
Establishment of operating right-of-use assets through operating lease obligations	$ 20,755	$ —
Cancellation of SAFE indebtedness in merger	$ —	$ 8,000
Net liabilities acquired in merger for stock consideration	$ —	$ 2,112

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

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 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 implants, 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. For example, approximately 50% of patients treated for type 2 diabetes are non-adherent to their medicines which can lead to poor clinical outcomes. We are developing a portfolio of miniature, subdermal drug implants that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing adherence by delivering therapeutic drug levels for up to 6 months or longer. In addition, by leveraging our proprietary NanoPortal implant technology we can design implants that deliver minimally fluctuating drug levels that may improve the tolerability profiles for certain medicines for which side effects are associated with fluctuating drug levels such as GLP-1 receptor agonists (GLP-1s).

In February 2022, we announced the signing of a definitive merger agreement between Nano Precision Medical, Inc. ("NPM") and Second Sight Medical Products, Inc. ("Second Sight"), pursuant to which NPM became a wholly owned subsidiary of Second Sight. On August 30, 2022, the merger closed and the combined company of NPM and Second Sight was renamed Vivani Medical, Inc.

In December 2022, we contributed our neuromodulation assets and certain liabilities to Cortigent, Inc. ("Cortigent") a newly formed corporation in Delaware, and wholly owned subsidiary of Vivani, in exchange for 20 million shares of common stock of Cortigent. While the primary focus of Vivani is to develop and ultimately commercialize our drug implant business from legacy company NPM, Vivani's new management team remains committed to identifying and exploring strategic options for the further advancement of the neuromodulation business of Cortigent which includes the development of its pioneering neurostimulation systems to help patients recover critical body functions. 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. Cortigent will likely continue to be majority-owned by Vivani immediately following its initial public offering.

Subject to completion of Cortigent's initial public offering, Vivani intends to focus exclusively on further development of the drug implant 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.

Vivani has added NPM-115 (high-dose exenatide implant) to its emerging portfolio under development for chronic weight management in obese or overweight patients. Although Vivani's exenatide implant was initially being developed for the treatment of type 2 diabetes, we have observed in preclinical studies that the exenatide implant was associated with ~16.6% lower weight than a vehicle control implant after 3 weeks of implantation in non-obese Sprague-Dawley rats, and that this weight difference was substantially maintained for the full 16-week treatment duration. This result is consistent with the magnitude of weight loss reported in the literature from a separate study that administered semaglutide, the drug substance in the blockbuster products Ozempic®, Wegovy®, and Rybelsus®, in the same animal model. Vivani seeks to investigate the potential of exenatide, when delivered at the appropriate dose and with a delivery mechanism that mitigates issues of medication adherence, to achieve weight loss effects in humans, subject to regulatory clearance. Given the extraordinary adoption of GLP-1 products for the treatment of obesity, Vivani intends to emphasize NPM-115 and advance the program towards human testing.

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 the first-in-human study of NPM-119 in patients with type 2 diabetes, also named LIBERATE-1™. On August 18, 2023, FDA provided written notification that the LIBERATE-1 study was on full clinical hold, exclusively due to insufficient Chemistry, Manufacturing, and Controls ("CMC") information to assess the risk to human subjects. Vivani remains actively engaged in discussions with FDA as part of its efforts to lift the clinical hold and enable the expeditious initiation of LIBERATE-1. In parallel, Vivani plans to submit an application to a Human Research Ethics Committee in Australia to support the initiation of an alternative first-in-human trial in that country while continuing our efforts to lift the clinical hold with the FDA. If available, we intend to utilize research and development incentives and rebates from the Australian government in order to defray a portion of the costs from the trial. Since clinical studies conducted in Australia comply with the International Conference on Harmonization (ICH) guidelines, we plan to use relevant clinical data generated in Australia to support regulatory activities in other geographies including the US.

NPM-139 (undisclosed compound and partner) continues to demonstrate the potential as a once-yearly implant under development for chronic weight management obese or overweight patients. Because of the discontinuation of the parent compound by the undisclosed third-party partner, Vivani is removing NPM-159 from its portfolio.

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, the Company 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 Medical Products, Inc., 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 the Company 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 the Company. The Company will forgive any remaining amounts due by Cortigent to the Company under the TFSSA.

Agreement and Plan of Merger with Nano Precision Medical, Inc.

On February 4, 2022, Second Sight entered into an agreement and plan of merger (the "Merger Agreement") with NPM. The Merger was approved by the shareholders of Second Sight on July 27, 2022, and closed on August 30, 2022. Upon consummation of the Merger, NPM became a wholly owned subsidiary of Second Sight. Concurrent with the Merger, Second Sight changed its name to Vivani Medical, Inc., and changed its trading symbol from EYES to VANI, and trades under the ticker VANI on the NASDAQ market. Certain investors and members of the NPM board of directors are also investors and members of the board of directors of Second Sight.

Under the terms and conditions of the Merger Agreement, the securities of NPM converted into the right to receive shares of Second Sight's common stock representing 77.32% of the total issued and outstanding shares of common stock of Second Sight on a fully converted basis, including, without limitation, giving effect to the conversion of all options, warrants, and any and all other convertible securities assuming net settlement. Second Sight filed a Registration Statement on Form S-4 on May 13, 2022, in connection with the Merger to register the merger shares effective June 24, 2022.

On February 4, 2022, in connection with the Merger, Second Sight and NPM also entered into a Simple Agreement for Future Equity ("SAFE") whereby Second Sight provided to NPM an investment advance of $8 million. The Merger Agreement provided that the SAFE would terminate if the Merger were to be successfully completed. Under the terms of the SAFE, upon successfully completion of the Merger on August 30, 2022, the investment advance was eliminated. Under the accounting for a business combination, the $8 million adjusted the purchase consideration.

The Merger involved a change of control and was accounted for as a reverse merger in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Under this method of accounting, Second Sight was treated as the "acquired" company for financial reporting purposes with NPM as the acquirer. The assets acquired and liabilities assumed by NPM were recorded at fair value under Accounting Codification Standard ("ASC"), *Business Combinations.* Accordingly, on August 30, 2022 (the "Acquisition Date"), NPM (a calendar year-end entity) was deemed to have acquired 100% of the outstanding common shares and voting interest of Second Sight. The results of Second Sight's operations have been included in the consolidated financial statements since that date.

The acquisition-date fair value of consideration transferred totaled $54.4 million, which consisted of the fair value of the 13,136 common shares deemed issued to Second Sight shareholders, was determined based on the per share closing price of the Company's common shares on the acquisition date of $4.14.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the acquisition date (in thousands):

At August 30, 2022

Cash	$	55,374
Property and equipment		99
Prepaid expenses		1,657
Right of use assets		140
Other assets		56
Total identifiable assets acquired		57,326
Current liabilities		(3,913)
Right of use liabilities		(151)
Total liabilities assumed		4,064
Net identifiable assets acquired	$	53,262

The SAFE loan of $8.0 million was cancelled in the Merger which adjusted the fair value of net assets acquired.

The following table summarizes the calculation of the gain on bargain purchase (in thousands):

Total consideration	$	54,385
SAFE loan forgiven		(8,000)
Less net identifiable assets acquired		(53,262)
Gain on bargain purchase	$	6,877

Because NPM purchased 100% of Second Sight and the fair value of identifiable assets acquired and liabilities assumed exceeded the fair value of the consideration, we reassessed the recognition and measurement of identifiable assets acquired and liabilities assumed and concluded that all acquired assets and assumed liabilities were properly recognized and that the valuation procedures and resulting measures were appropriate. As a result, we recognized a gain of $6.9 million.

We recognized $0.7 million of acquisition related costs that were expensed in the twelve months ended December 31, 2022. These costs are included in the consolidated income statement in the line item entitled "General and administrative."

Pro forma consolidated net loss as if Second Sight had been included in the consolidated results was $20.6 million for the nine months ended September 30, 2022.

Liquidity

From inception, our operations have been funded primarily through the sales of our common stock and warrants. The completion of our reverse merger with Second Sight provided $53.3 million in net assets including approximately $55.4 million in cash.

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. 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. We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations into early 2025.

2. Basis of Presentation, Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

These unaudited interim financial statements have been prepared in accordance with United States 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, 2022, included within our Annual Report on Form 10-K filed with the SEC on March 31, 2023. 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.

Income taxes - interim periods

In calculating the provision for interim income taxes, in accordance with ASC 740, *Income Taxes*, an estimated annual effective tax rate is applied to year-to-date ordinary income. At the end of each interim period, we estimate the effective tax rate expected to be applicable for the full fiscal year. This differs from the method utilized at the end of an annual period.

Use of estimates

The preparation of financial statements requires management to make a number of estimates and assumptions related to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the period. Estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Some of the more significant estimates include the purchase price of net assets acquired in the Merger, useful lives of long-lived assets, the fair value of equity-based compensation, and the estimated incremental borrowing rate used in calculating lease assets and liabilities and evaluation of going concern. Actual results could differ materially from those estimates.

Net income/loss per share

Basic net income/loss per share is computed using net income/loss from operations divided by the weighted-average number of shares of common stock outstanding during the period.

Diluted net income/loss per share represents net income/loss from operations divided by the weighted- average number of common shares outstanding during the period, including all potentially dilutive common stock equivalents. Common stock equivalents consist of shares subject to warrants and share-based awards with exercise prices less than the average market price of common stock for the period, to the extent their inclusion would be dilutive.

The computation of the weighted-average shares of common stock outstanding for diluted EPS excludes the following potential common shares as of September 30, 2023, and 2022 (in thousands):

	September 30, 2023	September 30, 2022
Shares underlying warrants outstanding	10,311	10,311
Shares underlying stock options outstanding	6,043	4,515
Shares underlying RSU's	403	—

The shares underlying the SAFE obligation were issuable only if the Merger were to be terminated. These contingently issuable shares were excluded from the dilutive computation because conversion was not "probable" as defined in the accounting literature. However, if the evaluation met the probability threshold, the shares would be excluded from diluted EPS since their inclusion would have an anti-dilutive effect.

Significant Accounting Policies

Our significant accounting policies are set forth in our financial statements for the year ended December 31, 2022, included within our Annual Report on Form 10-K filed with the SEC on March 31, 2023.

Recently Issued Accounting Pronouncements

We do not believe that any recently issued, but not yet effective, accounting standards, if adopted, will have a material effect on the financial statements.

3. Concentration of Risk

Credit Risk

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

Foreign Operations

The accompanying condensed consolidated financial statements as of September 30, 2023, include gross assets amounting to $0.1 million relating to operations of our subsidiary based in Switzerland.

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.

Cash equivalents, which includes money market funds, are the only financial instrument measured and recorded at fair value on our consolidated balance sheet, and they are valued using Level 1 inputs.

Assets measured at fair value on a recurring basis are as follows (in thousands):

	Total	Level 1	Level 2	Level 3
September 30, 2023 (unaudited):				
Money market funds	$ 23,250	$ 23,250	$ —	$ —
December 31, 2022:				
Money market funds	$ 44,417	$ 44,417	$ —	$ —

5. Selected Balance Sheet Detail

Property and equipment

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

	September 30, 2023	December 31, 2022
Equipment	$ 3,728	$ 3,520
Furniture and fixtures	10	10
Software	54	51
Leasehold improvements	12	12
	3,804	3,593
Accumulated depreciation and amortization	(2,670)	(2,411)
Property and equipment, net	$ 1,134	$ 1,182

Right-of-use assets and operating lease liabilities

We lease certain office space and equipment 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.

Assets	**Classification**	**September 30, 2023 (in thousands)**	**December 31, 2022 (in thousands)**
Non-current assets	Right-of-use assets	$ 20,050	$ 779
Liabilities			
Current	Current operating lease liabilities	$ 1,376	$ 955
Long term	Long term operating lease liabilities	$ 19,679	$ —

	For the three months ended September 30, 2023	**For the three months ended September 30, 2022**	**For the nine months ended September 30, 2023**	**For the nine months ended September 30, 2022**
Cash paid for operating lease liabilities (in thousands)	$ 375	$ 265	1,134	687

Operating lease cost, was $1.1 million and $0.2 million and was $2.0 million and $0.7 million during the three-month and nine-month periods ended September 30, 2023 and 2022, respectively. Variable lease cost comprising primarily of common area maintenance charges and taxes for the operating lease was $0.4 million and $0.1 million and was $0.6 million and $0.2 million during the three-month and nine-month periods ended September 30, 2023 and 2022, respectively.

On February 1, 2023, we entered into a lease agreement, effective March 1, 2023, to sublease office space to replace Cortigent's existing 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 sub-lease 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.

Vivani entered into a triple net lease agreement for a single building with 43,645 square feet of space in Alameda, California on November 21, 2022. The stated term of the lease commences on June 1, 2023 and terminates on September 30, 2033, ten years and 4 months. Payments increase annually from $2,676,311 to $3,596,784, or 124 payments less the first four which are abated, totaling approximately $31 million. Vivani will be responsible for insurance, property taxes and CAM charges. Vivani was required to deposit $1.4 million to guarantee a letter of credit to secure the lease and this amount is included in long-term assets on the balance sheet at September 30, 2023. The lease in Emeryville, California expired on September 30, 2023.

The Company evaluated the lease under the provisions of ASC 842*, Leases*. The following table summarizes a maturity analysis of our lease liabilities showing the aggregate lease payments as of September 30, 2023 (in thousands):

Year Ending December 31,	
2023	$ 798
2024	3,070
2025	2,914
2026	2,889
2027	2,976
Thereafter	18,927
Total lease payments	$ 31,574
Less imputed interest	(10,519)
Total lease liabilities	$ 21,055
Weighted-average discount rate	8.41%
Weighted-average remaining lease term	9.70 years

6. Equity Securities

We are authorized to issue 300,000,000 shares of common stock with 51,025,060 issued as of September 30, 2023. In addition, we are authorized to issue 10,000,000 shares of preferred stock with none issued. On August 19, 2022, the Company initiated a reverse stock split of one share for every three shares. All share numbers have been retroactively adjusted for the split. On August 30, 2022, 13,136,362 shares were deemed issued for the merger acquisition.

7. Warrants

NPM, prior to the Merger, issued common stock and warrants (collectively, the "unit" or "units") in 2019, 2020 and 2021 for $3.15 per unit. Outstanding warrants of 7,746,855 to purchase common stock are shown in the table below and generally expire 5 years from the date of issuance at $3.15 per share, are transferable into one share of common stock and may be exercised on a cashless basis. The warrants qualified for an exception to derivative accounting and, accordingly, their value was not bifurcated from the total purchase price.

Second Sight warrants of 7,691,063 were outstanding and are convertible into 2,563,688 shares in the table below 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 $35.24. Of this total 7,680,938 warrants are convertible into 2,560,313 shares and are tradeable on the open market. Under accounting standards in a business combination, these warrants were measured at fair value as of the Merger date; however, the warrants were substantially out-of-the-money and were assigned no value.

A summary of warrant activity for the nine months ended September 30, 2023 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, 2022	10,311	$ 11.13	2.31
Issued	—		
Exercised	—		
Forfeited or expired	—		
Warrants outstanding as of September 30, 2023	10,311	$ 11.13	1.56
Warrants exercisable as of September 30, 2023	10,311	$ 11.13	1.56

The warrants outstanding as of September 30, 2023, had no intrinsic value.

8. Stock-Based Compensation

A summary of stock option activity for the nine months ended September 30, 2023, 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, 2022	5,272	$ 3.07	7.15
Granted	1,294	$ 1.24	
Exercised	(327)	$ 0.53	
Forfeited or expired	(196)	$ 2.84	
Options outstanding, vested and expected to vest as of September 30, 2023	6,043	$ 2.82	7.17
Options exercisable as of September 30, 2023	3,854	$ 3.41	6.19

The estimated aggregate intrinsic value of stock options exercisable as of September 30, 2023, was $0.1 million. As of September 30, 2023, there was $2.1 million of total unrecognized compensation cost related to outstanding stock options that will be recognized over a weighted average period of 1.2 years.

During the nine months ended September 30, 2023, we granted stock options to purchase 1,293,817 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 $1.24 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. The fair value of options subject to only service conditions are valued using the Black-Scholes option pricing model, while those subject to performance or market conditions are valued using the Monte-Carlo Simulation model. During the nine-months ended September 30, 2023, 200,000 options were issued and valued at $0.1 million using the Monte-Carlo model using 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.

During the nine-months ended September 30, 2023, 1,093,817 options were issued and valued at $1.1 million using the Black-Scholes option-pricing model using the following assumptions: expected term of 4.00 to 6.20 years, volatility of 100%, risk-free interest rate of 3.99% to 4.45%, and expected dividend rate of 0.0%.

We also granted 402,500 RSU's (as defined below) during the nine months ended September 30, 2023. These RSUs had 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 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. At the Valuation Date, the Company's 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, 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 in a separate 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. The Monte Carlo simulation was then iterated 100,000 times and the concluded fair value of the performance-based RSUs was based on the average result from the simulation. For the purposes 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.

The following table summarizes restricted stock unit ("RSU") activity for the nine months ended September 30, 2023 (in thousands, except per share data):

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2022	—	$ —
Awarded	403	0.93
Vested and released	—	—
Forfeited/canceled	—	—
Outstanding as of September 30, 2023	403	$ 0.93

As of September 30, 2023, there was $0.2 million of total unrecognized compensation cost related to the outstanding RSUs that will be recognized over a weighted average period of 0.4 years.

Stock-based compensation expense recognized for stock-based awards in the condensed consolidated statements of operations for the three and nine months ended September 30, 2023, and 2022 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 277	$ 274	$ 809	$ 788
General and administrative	234	117	595	337
Total	$ 511	$ 391	$ 1,404	$ 1,125

9. Risk and Uncertainties

We continue to monitor the ongoing COVID-19 global pandemic which has resulted in travel and other restrictions to reduce the spread of the disease. We presently are not experiencing any significant disruptions from the ongoing COVID-19 pandemic. All clinical and chemistry, manufacturing and control activities are currently active.

The safety, health and well-being of all patients, medical staff and internal and external teams is the paramount and primary focus. As the pandemic and its resulting restrictions evolve in jurisdictions across the country, the potential exists for further disruptions to projected timelines. We are in close communication with clinical teams and key vendors and are prepared to take action should the pandemic worsen and impact the business in the future.

10. Commitments and Contingencies

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 for the three and nine months ended September 30, 2023 were $4,000 and $119,000, respectively. Total amounts charged for the three and nine months ended September 30, 2022 were $2,000 and $2,000, respectively.

Litigation, Claims and Assessments

Three oppositions filed by Pixium Vision SA ("Pixium") are pending in the European Patent Office, each challenging the validity of a European patent owned by us. The outcomes of the challenges are not certain, however, if successful, they may affect our ability to block competitors from utilizing our patented technology. We do not believe a successful challenge will have a material effect on our ability to manufacture and sell our products, or otherwise have a material effect on our 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. In April, 2021, we remitted $1,000,000 to Pixium for liquidated damages as contemplated by the MOU. 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 9, 2022, the Company received notice that the Paris Commercial Court has rendered its judgement, including finding that the Company's termination of the MOU was not valid. In the judgement, 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. The Company filed an appeal with the Appeals Court of Paris on May 24, 2023. The Company recorded a charge of $1,675,000 for the year ended December 31, 2022, related to this matter but plans to raise any and all legal challenges to this preliminary judgement.

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.

11. Subsequent Events

The Company evaluated subsequent events for recognition and disclosure through the date the financial statements were issued or filed. Nothing has occurred outside normal operations that required recognition or disclosure in these financial statements except as follows:

While Cortigent continues to pursue its efforts towards its initial public offering, in October 2023, certain of its employees have been furloughed as an expense reduction measure. This action, as well as other measures that may be taken in the future, may adversely affect the operations of Cortigent, including its ability to conduct its initial public offering, particularly if such furloughed employees determine to seek employment elsewhere. In addition, such employees have asserted and others in the future may assert their entitlement to payments or other benefits in connection with their furlough or, if applicable, termination, which may cause the Company or Cortigent to incur additional expenses if the Company determines to, or is required to, satisfy such asserted entitlements.

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.

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 implants, 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. For example, approximately 50% of patients treated for type 2 diabetes are non-adherent to their medicines which can lead to poor clinical outcomes. We are developing a portfolio of miniature, subdermal drug implants that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing adherence by delivering therapeutic drug levels for up to 6 months or longer. In addition, by leveraging our proprietary NanoPortal implant technology we can design implants that deliver minimally fluctuating drug levels that may improve the tolerability profiles for certain medicines for which side effects are associated with fluctuating drug levels such as GLP-1 receptor agonists (GLP-1s).

In February 2022, we announced the signing of a definitive merger agreement between Nano Precision Medical, Inc.("NPM") and Second Sight Medical Products, Inc. ("Second Sight") pursuant to which NPM became a wholly owned subsidiary of Second Sight. On August 30, 2022, the merger closed and the combined company of NPM and Second Sight was renamed Vivani Medical, Inc.

In December 2022, we contributed our neuromodulation assets and certain liabilities to Cortigent, Inc., a newly formed wholly owned subsidiary of Vivani, in exchange for 20 million shares of common stock of Cortigent. While the primary focus of Vivani is to develop and ultimately commercialize our drug implant business from legacy company NPM, Vivani's new management team remains committed to identifying and exploring strategic options for the further advancement of the neuromodulation business of Cortigent which includes the development of its pioneering neurostimulation systems to help patients recover critical body functions. 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. While Cortigent continues to pursue its efforts toward its initial public offering, it has furloughed some of its employees as an expense-reduction measure. There can be no assurance that Cortigent can complete its initial public offering on favorable terms, in a timely manner or at all.

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.

Subject to completion of Cortigent's initial public offering, Vivani intends to focus exclusively on further development of the drug implant business.

Vivani has added NPM-115 (high-dose exenatide implant) to its emerging portfolio under development for chronic weight management obese or overweight patients. Although Vivani's exenatide implant was initially being developed for the treatment of type 2 diabetes, we have observed in preclinical studies that the exenatide implant was associated with ~16.6% lower weight than a vehicle control implant after 3 weeks of implantation in non-obese Sprague-Dawley rats, and that this weight difference was substantially maintained 16-week treatment duration of the study. This result is consistent with the magnitude of weight loss reported in the literature from a separate study that administered semaglutide, the drug substance in the blockbuster products Ozempic®, Wegovy®, and Rybelsus®, in the same animal model. Vivani seeks to investigate the potential of exenatide, when delivered at the appropriate dose and with a delivery mechanism that mitigates issues of medication adherence, to achieve weight loss effects in humans, subject to regulatory clearance. Given the extraordinary adoption of GLP-1 products for the treatment of obesity, Vivani intends to emphasize NPM-115 and advance the program towards human testing.

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 the first-in-human study of NPM-119 in patients with type 2 diabetes, also named LIBERATE-1™. On August 18, 2023, FDA provided written notification that the LIBERATE-1 study was on full clinical hold, exclusively due to insufficient Chemistry, Manufacturing, and Controls ("CMC") information to assess the risk to human subjects. Vivani remains actively engaged in discussions with FDA as part of its efforts to lift the clinical hold and enable the expeditious initiation of LIBERATE-1. In parallel, Vivani plans to submit an application to a Human Research Ethics Committee in Australia to support the initiation of an alternative first-in-human trial in that country while continuing our efforts to lift the clinical hold with the FDA. If available, we intend to utilize research and development incentives and rebates from the Australian government in order to defray a portion of the costs from the trial. Since clinical studies conducted in Australia comply with the International Conference on Harmonization (ICH) guidelines and data generated here are accepted by the FDA, we plan to use relevant clinical data generated in Australia to support regulatory activities in other geographies including the US.

NPM-139 (undisclosed compound and partner) continues to demonstrate the potential as a once-yearly implant under development for chronic weight management in obese or overweight patients. Because of the discontinuation of the parent compound by the undisclosed third-party partner, Vivani is removing NPM-159 from its portfolio.

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, the Company 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 Medical Products, Inc., 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 the Company 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 the Company. The Company will forgive any remaining amounts due by Cortigent to the Company under the TFSSA.

Liquidity

From inception, our operations have been funded primarily through the sales of our common stock and warrants. The completion of our reverse merger with Second Sight Medical Products, Inc. provided $53.3 million in net assets including approximately $55.4 million in cash.

Second Sight was awarded a $6.4 million National Institutes of Health ("NIH") five-year grant (with annual reviews) from NIH to fund the "Early Feasibility Clinical Trial of a Visual Cortical Prosthesis." The fifth and final year grant of $1.0 million was approved in March 2023.

We are subject to the risks and uncertainties associated with a business with no revenue that is developing novel pharmaceutical product candidates and medical devices candidates. 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 of NPM-119 and conduct our other research and development activities.

On August 18, 2023, FDA provided written notification that the LIBERATE-1 study was on Full Clinical Hold exclusively due to insufficient Chemistry, Manufacturing, and Controls ("CMC") information to assess the risk to human subjects. If we are required to conduct additional nonclinical and/or clinical activities, our overall expenditures relating to our NPM-119 program would increase. Our financial statements have been presented on the basis that our business is a going concern, which contemplates the realization of assets and 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 early 2025.

Merger Agreement

As discussed in the Notes to Condensed Consolidated Financial Statements of the Company, on February 4, 2022, the Company entered the Merger Agreement with Second Sight. On May 13, 2022, the Company filed a Registration Statement on Form S-4 (the "Registration Statement") with the SEC in connection with the contemplated Merger, which is currently effective. Shareholders of the Company approved the Merger on July 27, 2022, and the merger was completed in August 2022.

Safe Agreement

On February 4, 2022, in connection with the Merger, Second Sight and NPM also entered into a Simple Agreement for Future Equity ("SAFE") whereby Second Sight provided to NPM an investment advance of $8 million. If the Merger were to be terminated without completion, NPM would issue to Second Sight that number of shares of NPM common stock equal to not less than 2.133% of the issued and outstanding shares of NPM common stock assuming exercise or conversion of all outstanding vested and unvested options, warrants, and convertible securities. The agreement provided that the SAFE would terminate if the Merger were to be successfully completed.

Under the terms of the SAFE, upon successfully completion of the Merger on August 30, 2022, the investment advance was eliminated. Under the accounting for a business combination, the $8 million adjusted the purchase consideration.

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 nine months ended September 30, 2023.

Results of Operations

Operating Expenses. We generally 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. We have received grants from institutions or agencies, such as the National Institutes of Health, to help fund the some of the cost of our development efforts. We have recorded the amount of funding received from these grants as reductions to operating expenses.

- Research and development expenses consist primarily of employee compensation and consulting costs related to the design, development, and enhancements of our current and potential future products, and clinical as well as internal and external costs associated with conducting clinical trials and maintaining relationships with regulatory agencies offset by grant revenue received in support of specific research projects. We expense our research and development costs as they are incurred.

- General and administrative expenses 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.

Comparison of the Three Months Ended September 30, 2023 and 2022

Research and development expense. Research and development expense increased by $0.5 million, or 15%, to $4.4 million in the third quarter of 2023 from $3.9 million in the third quarter of 2022. The costs increased due to costs of our acquired company Second Sight being included from the merger acquisition date of August 30, 2022. This inclusion increased these costs for the quarter by $0.3 million. The remainder of the increase was primarily due to drug implants development costs.

General and administrative expense. General and administrative expense increased $1.1 million, or 71%, to $2.7 million in the third quarter of 2023 from $1.6 million in the same period of 2022. This increase was attributable to increased costs associated with the inclusion of our acquired company Second Sight which increased $0.6 million in the third quarter of 2023 versus the partial quarter of 2022 which only included one month from the merger date, higher costs associated with being a public company for D&O insurance and professional fees, and higher payroll related expenses.

Other income (expense). Other income was impacted by the merger acquisition of cash which increased our interest income to $0.4 million for the three months ended September 30, 2023. The quarter ended September 30, 2022 was impacted by the gain on bargain purchase of $6.9 million recorded on the purchase of Second Sight at the time of the merger.

Comparison of the Nine Months Ended September 30, 2023 and 2022

Research and development expense. Research and development expense increased by $2.6 million, or 26%, to $12.3 million in the first nine months of 2023 from $9.7 million in the same period of 2022. The costs increased due to costs of our acquired company Second Sight being included from the merger acquisition date of August 30, 2022. This inclusion increased these costs for the period by $1.4 million. The remainder of the increase was primarily due to drug implants development costs and increased payroll related costs.

General and administrative expense. General and administrative expense increased $4.8 million, or 129%, to $8.5 million in the first nine months of 2023 from $3.7 million in the same period of 2022. This increase was attributable to increased costs associated with the inclusion of our acquired company Second Sight which increased $2.7 million in the first nine months of 2023 versus the partial inclusion of one month in 2022 after the merger date, higher public company costs and higher payroll related expenses.

Other income (expense). Other income was impacted by the merger acquisition of cash which increased our interest income to $1.1 million for the nine months ended September 30, 2023. The income for the nine months ended September 30, 2022 included $6.9 million for the gain on bargain purchase from the acquisition of Second Sight.

Liquidity and Capital Resources

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. 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. Our cash balance as of September 30, 2023 was $24.8 million which excludes $3.2 million of reimbursable tenant improvements recorded in our prepaid account. We expect our cash runway to extend into early 2025.

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. In particular, we expect to incur increased expenses as we initiate our planned first-in-human (FIH) clinical trial of NPM-119, also known as LIBERATE-1. On August 18, 2023, FDA provided written notification that the LIBERATE-1 study was on Full Clinical Hold exclusively due to CMC information to assess the risk to human subjects. Vivani remains actively engaged in discussions with FDA as part of its efforts to lift the Clinical Hold and enable the expeditious initiation of LIBERATE-1. If we are required to conduct additional nonclinical or clinical activities preclinical or IND-enabling activities such as additional pre-clinical, our overall expenditures relating to our NPM-119 program 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 decreased by $20.2 million from $46.4 million as of December 31, 2022 to $26.2 million as of September 30, 2023. Working capital was $23.2 million as of September 30, 2023 compared to $40.7 million as of December 31, 2022, a decrease of $17.5 million. We use our cash and cash equivalents and working capital to fund our operating activities.

Cash Flows from Operating Activities

During the nine months ended September 30, 2023, we used $20.2 million of cash in operating activities, consisting primarily of a net loss of $19.6 million and a net increase in net operating assets of $3.0 million, partially offset by non-cash charges of $2.4 million for depreciation and amortization of property and equipment, stock-based compensation and change in right of use assets. During the first nine months of 2022, we used $13.6 million of cash in operating activities, consisting primarily of a net loss of $6.6 million increased by non-cash charges which used cash of $5.4 million for depreciation and amortization of property and equipment, stock-based compensation and change in right of use assets and the gain from the bargain purchase and a net change in operating assets and liabilities of $1.6 million.

Cash Flows from Investing Activities

Cash used for investing activities in the nine months ended September 30, 2023 and 2022 was $144,000 and $297,000, respectively. In 2023 $144,000 was used for the purchase of property and equipment. In 2022, $297,000 was used for the purchase of property and equipment and intangibles.

Cash Flows from Financing Activities

Financing activities was $110,000 in the nine months ended September 30, 2023 from the net proceeds from exercise of stock options. Financing activities provided $63.4 million of cash in the nine months ended September 30, 2022, $55.4 million for cash acquired in the merger for stock consideration and $8.0 million from the funding of the SAFE agreement.

Off-Balance Sheet Arrangements

As of September 30, 2023, 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 money market funds. As of September 30, 2023, our investments consisted solely of money market funds.

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 September 30, 2023, 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 the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the nine months ended September 30, 2023, 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

Three oppositions filed by Pixium Vision SA ("Pixium") are pending in the European Patent Office, each challenging the validity of a European patent owned by Second Sight. The outcomes of the challenges are not certain, however, if successful, they may affect our ability to block competitors from utilizing our 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 our 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 Vision SA ("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. On April 1, 2021, we remitted $1,000,000 to Pixium for liquidated damages as contemplated by the MOU. 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 9, 2022, the Company received notice that the Paris Commercial Court has rendered its judgement, including finding that the Company's termination of the MOU was not valid. In the judgement, 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. The Company filed an appeal with the Appeals Court of Paris on May 24, 2023. The Company recorded a charge of $1,675,000 for the year ended December 31, 2022 related to this matter but plans to raise any and all legal challenges to this preliminary judgement.

From time to time, we may be involved in a variety of legal proceedings and claims relating to securities laws, product liability, patent infringement, contract disputes, employment matters and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. It is our opinion that the outcome of such matters will not have a material adverse effect on our results of operations, however, the results of litigation, proceedings, disputes 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 Form 10-K that we filed on March 31, 2023. There have been no material changes from the risk factors previously disclosed in such filing, other than those as discussed below.

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 (CROs) and clinical trial sites;
- manufacturing sufficient quantities of a product candidate or other materials necessary to conduct clinical trials;
- 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 August 18, 2023, FDA provided written notification that the LIBERATE-1 study was on Full Clinical Hold exclusively due to insufficient Chemistry, Manufacturing, and Controls ("CMC") information to assess the risk to human subjects. Vivani remains actively engaged in discussions with FDA as part of its efforts to lift the clinical hold and enable the expeditious initiation of LIBERATE-1. However, there can be no assurance that we can address the issues identified by the FDA in a timely manner or at all, and we may incur additional expenses in connection with our efforts to advance NPM-119 into the clinic.

In addition, once a clinical trial has begun, it may be suspended or terminated by us or our collaborators, institutional review boards, or, if applicable, data safety monitoring boards charged with overseeing our clinical trials, the FDA, the EMA, or comparable foreign authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA, the EMA or comparable foreign authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the development of product candidates will be impaired. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development process and our anticipated timelines for seeking marketing approval. Such delays could also allow our competitors to obtain marketing approval for their own product candidates before we do or may shorten the patent protection period during which we may have the exclusive right to commercialize our product, if approved. Any of these occurrences may harm our business, financial condition, and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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 August 18, 2023, FDA provided written notification that the LIBERATE-1 study was on Full Clinical Hold exclusively due to insufficient Chemistry, Manufacturing, and Controls ("CMC") information to assess the risk to human subjects. Vivani remains actively engaged in discussions with FDA as part of its efforts to lift the clinical hold and enable the expeditious initiation of LIBERATE-1. However, there can be no assurance that we can address the issues identified by the FDA in a timely manner or at all, and we may incur additional expenses in connection with our efforts to advance NPM-119 into the clinic.

Even if we experience success in early development for any product candidate, that experience may not be replicated in later development or with respect to any other product candidates. For example, in our industry, product candidates in later-stage clinical trials routinely fail to demonstrate adequate safety and efficacy despite having progressed through initial clinical trials or preclinical testing.

Even if our clinical trials generate data that we believe are promising, such data may not be sufficient to support seeking marketing approval by the FDA, the EMA, or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, the EMA or comparable foreign authorities may interpret such data in different ways than we do. If we fail to generate data that adequately demonstrate the safety and efficacy of our product candidates to support marketing approval from regulatory authorities, we will not be able to market and commercialize these product candidates.

From time to time, in addition to or as an alternative to raising capital through equity or debt offerings, we may seek to selectively and opportunistically enter into collaborations with third parties to assist in the development and potential future commercialization of some or all of our product candidates. However, there can be no assurance that we will be able to establish such collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations. Even if we enter into one or more of such collaborations, the risks associated with the development of product candidates still remain, and there can be no assurance that our potential collaborators will successfully develop, seek approval for and commercialize any of our product candidates.

The recent furloughing of certain Cortigent employees may adversely impact its ability to achieve its business objectives and result in the incurrence of additional expenses by us or Cortigent.

While Cortigent continues to pursue its efforts towards its initial public offering, in October 2023, certain of its employees have been furloughed as an expense reduction measure. This action, as well as other measures that may be taken in the future, may adversely affect the operations of Cortigent, including its ability to conduct its initial public offering, particularly if such furloughed employees determine to seek employment elsewhere. In addition, certain such employees have asserted and others in the future may assert their entitlement to payments or other benefits in connection with their furlough or, if applicable, termination, which may cause the Company or Cortigent to incur additional expenses if the Company determines to, or is required to, satisfy such asserted entitlements. We or Cortigent may also lose the services of these employees even if the furlough were ended, if they determine not to remain with us or Cortigent in the long term. As a result, there can be no assurance that Cortigent can complete its initial public offering on favorable terms, in a timely manner or at all. In addition, certain such employees have asserted and others in the future may assert their entitlement to payments or other benefits in connection with their furlough or, if applicable, termination, which may cause us or Cortigent to incur additional expenses if we determine to, or are required to, satisfy such asserted entitlements.

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 European Medicines Agency (EMA) or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. For example, on August 18, 2023, FDA provided written notification that the LIBERATE-1 study was on Full Clinical Hold exclusively due to insufficient CMC information to assess the risk to human subjects. Vivani remains actively engaged in discussions with FDA as part of its efforts to lift the clinical hold and enable the expeditious initiation of LIBERATE-1. If we are required to conduct additional nonclinical and/or clinical activities, our overall expenditures relating to our NPM-119 program would increase. 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.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit, or eliminate one or more of our business objectives, and our competitiveness, and business, financial condition and results of operations may be materially adversely affected. If we are unable to continue our business, including due to inadequate funding, you could lose your investment.

Vivani's future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of its clinical trials, preclinical studies, and other related activities;
- its ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of its current or future product candidates;
- the number and characteristics of the product candidates it seeks to develop or commercialize;

- the cost of manufacturing clinical supplies, and establishing commercial supplies, of its product candidates;
- the cost of commercialization activities if any of its current or future product candidates are approved for sale, including marketing, sales, and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the amount of revenue, if any, received from commercial sales of its product candidates, should any of its product candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

We may raise capital in the form of equity or debt financing, partnerships, collaborations, licensing, spin-offs or other strategic transactions. If we raise additional capital by issuing equity securities, the ownership of our existing shareholders may be reduced, and accordingly these shareholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences, and privileges senior to those of its common stock. If we raise funding through debt instruments or facilities, lenders may require us to pledge some or all of our assets as collateral. We may also be required to observe financial, operational and other covenants that constrain our business and operations. If we enter into partnerships, collaborations, licensing or other strategic transactions, we may be required to grant rights to third parties, including rights to develop and market product candidates, that we would otherwise have retained.

Inadequate funding for the FDA, the SEC, and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and the acceptance of user fees payments, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. If a prolonged government shutdown occurs, if the FDA is required to furlough review staff or necessary employees, or if the agency operations are otherwise impacted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The impact of the Russian invasion of Ukraine and the Israel-Hamas war on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.

The short and long-term implications of Russia's invasion of Ukraine and the Israel-Hamas war are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the Israel-Hamas war may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, a prolonged conflict in Ukraine or Israel may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. To the extent the wars in Ukraine or Israel may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

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

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Exhibit Description
2.1	Plan of Conversion of Vivani Medical, Inc. (a California corporation) to Vivani Medical, Inc. (a Delaware corporation), dated July 5, 2023 and effective July 5, 2023 (incorporated by reference to Exhibit 99.1 in the Company's Current Report on Form 8-K filed with the SEC on July 10, 2023).
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 Company's Current Report on Form 8-K filed with the SEC on July 10, 2023)
3.2	Bylaws of Vivani Medical, Inc. (a Delaware Corporation) effective July 6, 2023 (incorporated by reference to Exhibit 3.2 in the Company's Current Report on Form 8-K filed with the SEC on July 10, 2023)
10.1*	Amendment 1 to the Transition Funding, Support and Services Agreement dated August 28, 2023, (incorporated by reference to Exhibit 10.1 in the Company's Current Report on Form 8-K filed with the SEC on August 28, 2023)
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)*

* Indicates the exhibit is being furnished, not filed, with this report.

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)	November 13, 2023
/s/ Brigid A. Makes Brigid A. Makes	Chief Financial Officer (Principal Financial and Accounting Officer)	November 13, 2023

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13a14(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 13a15(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: November 13, 2023

/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 A. 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 13a15(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: November 13, 2023

/s/ Brigid A. Makes
Brigid A. 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 the nine months ended September 30, 2023, 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: November 13, 2023

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

/s/ Brigid A. Makes
Brigid A. 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.