

**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 March 31, 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)

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

02-0692322
(I.R.S. Employer Identification No.)

5858 Horton Street, Suite 280 Emeryville, CA 94608
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 May 10, 2023, the registrant had 50,793,799 shares of common stock, no par value per share and 7,680,938 warrants, outstanding.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

FORM 10-Q
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PART I. FINANCIAL STATEMENTS

Item 1. Financial Statements

**VIVANI MEDICAL, INC.
AND SUBSIDIARIES**

Condensed Consolidated Balance Sheets (unaudited)
(in thousands)

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 38,073	\$ 45,076
Prepaid expenses and other current assets	2,611	2,452
Total current assets	40,684	47,528
Property and equipment, net	1,111	1,182
Right-of-use assets	1,148	779
Restricted cash	1,366	1,366
Deposits and other assets	271	275
Total assets	<u>\$ 44,580</u>	<u>\$ 51,130</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 746	\$ 1,177
Accrued expenses	2,114	2,358
Litigation accrual	1,675	1,675
Accrued compensation expense	415	657
Current operating lease liabilities	913	955
Total current liabilities	5,863	6,822
Long term operating lease liabilities	349	—
Total liabilities	<u>6,212</u>	<u>6,822</u>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; none outstanding	—	—
Common stock, no par value; 300,000 shares authorized; shares issued and outstanding: 50,789 as of March 31, 2023 and 50,736 as of December 31, 2022, respectively	109,050	109,050
Additional paid-in capital	8,378	8,009
Accumulated other comprehensive loss	44	35
Accumulated deficit	(79,104)	(72,786)
Total stockholders' equity	<u>38,368</u>	<u>44,308</u>
Total liabilities and stockholders' equity	<u>\$ 44,580</u>	<u>\$ 51,130</u>

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

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	Three Months Ended	
	March 31,	
	2023	2022
Operating expenses:		
Research and development, net of grants	\$ 3,955	\$ 2,679
General and administrative, net of grants	2,646	1,228
Total operating expenses	6,601	3,907
Loss from operations	(6,601)	(3,907)
Other income (expense), net	283	(17)
Net loss	\$ (6,318)	\$ (3,924)
Net loss per common share – basic and diluted	\$ (0.12)	\$ (0.11)
Weighted average common shares outstanding – basic and diluted	50,755	36,806

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

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	Three Months Ended	
	March 31,	
	2023	2022
Net loss	\$ (6,318)	\$ (3,924)
Other comprehensive loss:		
Foreign currency translation adjustments	9	—
Comprehensive loss	\$ (6,309)	\$ (3,924)

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 Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, January 1, 2022	36,803	\$ 54,649	\$ 6,713	\$ —	\$ (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	\$ 54,650	\$ 7,053	\$ —	\$ (62,821)	\$ (1,118)
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2023	50,736	\$ 109,050	\$ 8,009	\$ 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	\$ 109,050	\$ 8,378	\$ 44	\$ (79,104)	\$ 38,368

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

**VIVANI MEDICAL, INC.
AND SUBSIDIARIES**

Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2023	2022
	(unaudited)	
Cash flows from operating activities:		
Net loss	\$ (6,318)	\$ (3,924)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	108	83
Stock-based compensation	369	340
Non-cash lease expense	(62)	27
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(153)	(61)
Accounts payable	(429)	192
Accrued compensation expenses	(243)	—
Accrued expenses	(238)	167
Net cash used in operating activities	<u>(6,966)</u>	<u>(3,176)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(37)	(30)
Net cash used in investing activities	<u>(37)</u>	<u>(30)</u>
Cash flows from financing activities:		
Proceeds from SAFE note	—	8,000
Net proceeds from sale of common stock and exercise of warrants	—	1
Net cash provided by financing activities	<u>—</u>	<u>8,001</u>
Effect of exchange rate changes on cash and cash equivalents	—	—
Cash, cash equivalents and restricted cash:		
Net increase (decrease)	(7,003)	4,795
Balance at beginning of period	46,442	2,178
Balance at end of period	<u>\$ 39,439</u>	<u>\$ 6,973</u>
Non-cash investing and financing activities:		
Establishment of operating right-of-use assets through operating lease obligations	\$ 668	\$ —

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

**VIVANI MEDICAL, INC.
AND SUBSIDIARY**
Notes to Condensed Consolidated Financial Statements (unaudited)

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 implant candidates, alone or in collaboration with pharmaceutical company partners to address a leading cause of poor clinical outcomes in the treatment of chronic disease, medication non-adherence. 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, sub-dermal drug implant candidates 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 the life of the implant. 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 Nano Precision Medical (“NPM” and Second Sight Medical Products (“SSMP”) was renamed Vivani Medical, Inc.

While the primary focus of Vivani is to develop and ultimately commercialize the 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 former legacy company Second Sight which includes development of its pioneering neurostimulation systems to help patients recover critical body functions. On December 28, 2022, the neuromodulation assets and certain of its liabilities were contributed to Cortigent, Inc. a newly formed wholly owned subsidiary of Vivani, in exchange for 20 million shares of common stock of Cortigent. 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 is expected to continue to be majority-owned by Vivani immediately following the 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. Vivani plans to file an Investigational New Drug (IND) application with the US Food and Drug Administration to support a first in human (FIH) study with lead asset NPM-119 (GLP-1 implant). Following an acceptable IND submission, Vivani plans to initiate the FIH study, named LIBERATE-1, which is a Randomized, Phase 2, 12-week investigation of NPM-119 in patients with type 2 diabetes. The IND filing and the initiation of LIBERATE-1 remain on track to occur mid-2023.

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

On February 4, 2022, Second Sight Medical Products, Inc. (“Second Sight”) entered into an agreement and plan of merger (the “Merger Agreement”) with Nano Precision Medical, Inc. (“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 successful 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 805”), *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, Medical, Inc. 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	\$	<u>53,262</u>

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		<u>(53,262)</u>
Gain on bargain purchase	\$	<u>6,877</u>

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 costs.”

Pro forma consolidated net loss as if Second Sight had been included in the consolidated results was \$6.1 million for the three months ended March 31, 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 Medical Products, Inc. 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 the second half of 2024.

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 generally accepted accounting principles (“GAAP”) and following the requirements of the United States Securities and Exchange Commission (“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 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 March 31, 2023, and 2022 (in thousands):

	March 31, 2023	March 31, 2022
Shares underlying warrants outstanding	10,311	9,074
Shares underlying stock options outstanding	6,055	4,583

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 March 31, 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):

	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
March 31, 2023 (unaudited):				
Money market funds	<u>\$ 36,527</u>	<u>\$ 36,527</u>	<u>\$ —</u>	<u>\$ —</u>
December 31, 2022:				
Money market funds	<u>\$ 44,417</u>	<u>\$ 44,417</u>	<u>\$ —</u>	<u>\$ —</u>

5. Selected Balance Sheet Detail

Property and equipment

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

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
Equipment	\$ 3,557	\$ 3,520
Furniture and fixtures	10	10
Software	51	51
Leasehold improvements	12	12
	<u>3,630</u>	<u>3,593</u>
Accumulated depreciation and amortization	(2,519)	(2,411)
Property and equipment, net	<u>\$ 1,111</u>	<u>\$ 1,182</u>

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.

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.

<u>Assets</u>	<u>Classification</u>	March 31, 2023 (in thousands)	December 31, 2022 (in thousands)
Non-current assets	Right-of-use assets	\$ 1,148	\$ 779
Liabilities			
Current	Current operating lease liabilities	\$ 913	\$ 955
Long term	Long term operating lease liabilities	\$ 349	\$ —
		For the three months ended March 31, 2023	For the three months ended March 31, 2022
Cash paid for operating lease liabilities in thousands:		\$ 377	\$ 221

Rent expense, including common area maintenance charges, was \$0.3 million and \$0.2 million during the three-month periods ended March 31, 2023 and 2022, respectively.

6. Equity Securities

We are authorized to issue 300,000,000 shares of common stock with 50,788,799 issued as of March 31, 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 three months ended March 31, 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 March 31, 2023	<u>10,311</u>	\$ 11.13	2.06
Warrants exercisable as of March 31, 2023	<u>10,311</u>	\$ 11.13	2.06

The warrants outstanding as of March 31, 2023, had no intrinsic value.

8. Stock-Based Compensation

A summary of stock option activity for the three months ended March 31, 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	993	\$ 1.22	
Exercised	(91)	\$ 0.43	
Forfeited or expired	(119)	\$ 2.93	
Options outstanding, vested and expected to vest as of March 31, 2023	<u>6,055</u>	\$ 2.81	7.26
Options exercisable as of March 31, 2023	<u>3,784</u>	\$ 3.30	6.16

The estimated aggregate intrinsic value of stock options exercisable as of March 31, 2023, was \$0.2 million. As of March 31, 2023, there was \$2.9 million of total unrecognized compensation cost related to outstanding stock options that will be recognized over a weighted average period of 1.4 years.

During the quarter ended March 31, 2023, we granted stock options to purchase 993,333 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 \$0.90 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 these options, calculated using the Black-Scholes option-pricing model, was determined to be \$0.9 million using the following assumptions: expected term of 4.00 to 6.02 years, volatility of 100%, risk-free interest rate of 4.22% to 4.45%, and expected dividend rate of 0.0%. We also granted 402,500 RSU's (as defined below) during the quarter. 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 following table summarizes restricted stock unit ("RSU") activity for the three months ended March 31, 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 March 31, 2023	<u>403</u>	<u>\$ 0.93</u>

As of March 31, 2023, there was \$0.4 million of total unrecognized compensation cost related to the outstanding RSUs that will be recognized over a weighted average period of 3.1 years.

Stock-based compensation expense recognized for stock-based awards in the condensed consolidated statements of operations for the three months ended March 31, 2023, and 2022 was as follows (in thousands):

	Three Months Ended	
	March 31,	
	2023	2022
Research and development	\$ 248	\$ 190
General and administrative	121	150
Total	<u>\$ 369</u>	<u>\$ 340</u>

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 charged to expense for the three months ended March 31, 2023 were \$26,000.

Lease Agreement

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 March 31, 2023. The current lease expires on September 30, 2023.

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. We accrued \$1,000,000 of liquidated damages as contemplated by the MOU in accounts payable as of March 31, 2021, and remitted that amount to Pixium in April 2021. Pixium indicated that it considered this termination wrongful, rejected the Company’s offers, but retained the \$1,000,000 payment. On May 19, 2021, Pixium filed suit in the Paris Commercial Court, and currently claim damages of approximately €5.1 million or about \$5.6 million. We believe we have fulfilled our obligations to Pixium with the liquidated damages payment of \$1,000,000. On December 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 may appeal the decision within three months from the date of service which was February 28, 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.

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, 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 recent 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 implant candidates, alone or in collaboration with pharmaceutical company partners to address a leading cause of poor clinical outcomes in the treatment of chronic disease, medication non-adherence. 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, sub-dermal drug implant candidates 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 the life of the implant. 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 Nano Precision Medical (“NPM” and Second Sight Medical Products (“SSMP”) was renamed Vivani Medical, Inc.

While the primary focus of Vivani is to develop and ultimately commercialize the 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 former legacy company Second Sight which includes development of its pioneering neurostimulation systems to help patients recover critical body functions. On December 28, 2022, the neuromodulation assets and certain of its liabilities were contributed to Cortigent, Inc. a newly formed wholly owned subsidiary of Vivani, in exchange for 20 million shares of common stock of Cortigent. 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 is expected to continue to be majority-owned by Vivani immediately following the 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. Vivani plans to file an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) to support a first in human (FIH) study with lead asset NPM-119 (GLP-1 implant). Following an acceptable IND submission, Vivani plans to initiate the FIH study, named LIBERATE-1, which is a randomized, Phase 2, 12-week investigation of NPM-119 in patients with type 2 diabetes. The IND filing and the initiation of LIBERATE-1 remain on track to occur mid-2023.

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 NIH five-year grant (with annual reviews) from the National Institutes of Health (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. 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 the second half of 2024.

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. 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 successful 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 three months ended March 31, 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 March 31, 2023 and 2022

Research and development expense. Research and development expense increased by \$1.3 million, or 48%, to \$4.0 million in the first quarter of 2023 from \$2.7 million in the first 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 \$0.6 million. The remainder of the increase was primarily due to subdermal drug implants development costs.

General and administrative expense. General and administrative expense increased \$1.4 million, or 115%, to \$2.6 million in the first quarter of 2023 from \$1.2 million in the same period of 2022. This increase is primarily attributable to increased costs associated with the inclusion of our acquired company Second Sight which totaled \$1.1 million in the first quarter of 2023. Approximately \$0.1 million of costs were incurred related to the Cortigent IPO in the quarter.

Other income. Other income was impacted by the merger acquisition of cash which increased our interest income for the three months ended March 31, 2023 as compared to the same period in 2022 before the merger.

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.

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 Phase 2 clinical trial of NPM-119, for which we plan to file an IND with the FDA. 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 \$7.0 million from \$46.4 million as of December 31, 2022 to \$39.4 million as of March 31, 2023. Working capital was \$34.9 million as of March 31, 2023 compared to \$40.7 million as of December 31, 2022, a decrease of \$5.8 million. We use our cash and cash equivalents and working capital to fund our operating activities.

Cash Flows from Operating Activities

During the three months ended March 31, 2023, we used \$7.0 million of cash in operating activities, consisting primarily of a net loss of \$6.3 million and a net increase in net operating assets of \$1.1 million, partially offset by non-cash charges of \$0.4 million for depreciation and amortization of property and equipment, stock-based compensation and change in right of use assets. During the three months ended March 31, 2022, we used \$3.2 million of cash in operating activities, consisting primarily of a net loss of \$3.9 million, offset by non-cash charges which provided cash of \$0.4 million for depreciation and amortization of property and equipment, stock-based compensation, change in right of use and partially offset by a net decrease in net operating assets of \$0.3 million.

Cash Flows from Investing Activities

Cash used for investing activities in the three months ended March 31, 2023 and 2022 was minimal for both periods. In 2023 \$37,000 was used for the purchase of property and equipment. In 2022, \$30,000 was used for the purchase of property and equipment.

Cash Flows from Financing Activities

Financing activities was zero in the three months ended March 31, 2023. Financing activities provided \$8.0 million of cash in the three months ended March 31, 2022 from the funding of the SAFE agreement.

Off-Balance Sheet Arrangements

As of March 31, 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 March 31, 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 March 31, 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 quarter ended March 31, 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. We accrued \$1,000,000 of liquidated damages as contemplated by the MOU in accounts payable as of March 31, 2021 and remitted that amount to Pixium in April 2021. Pixium indicated that it considered this termination wrongful, rejected the Company’s offers, but retained the \$1,000,000 payment. On May 19, 2021, Pixium filed suit in the Paris Commercial Court, and currently claim damages of approximately €5.1 million or about \$5.6 million. We believe we have fulfilled our obligations to Pixium with the liquidated damages payment of \$1,000,000. On December 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 may appeal the decision within three months from the date of service which was February 28, 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.

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
3.1	Restated Articles of Incorporation of the Registrant as amended (incorporated by reference to Exhibit 3.1 in the Company's Registration Statement on Form S-1 filed with the SEC on September August 12, 2014)
3.2	Amendment to Restated Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 in the Company's Registration Statement on Form S-4 filed with the SEC on September May 13, 2022)
3.3	Second Amendment to Restated Articles of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 in the Company's Current Report on Form 8-K filed with the SEC on January 3, 2020)
3.4	Certificate of Amendment, filed August 25, 2022, and effective August 30, 2022 changing the name of the Company to "Vivani Medical, Inc." (incorporated by reference Exhibit 3.1 in the Company's Current Report on Form 8-K filed with the SEC on September 2, 2022)
3.5	Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 in the Company's Registration Statement on Form S-1 filed with the SEC on September August 12, 2014)
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	XBRL Instant Document.*
101.SCH	XBRL Taxonomy Extension Schema Document.*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	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
<u>/s/ Adam Mendelsohn</u> Adam Mendelsohn	Chief Executive Officer (Principal Executive Officer)	May 15, 2023
<u>/s/ Brigid Makes</u> Brigid Makes	Chief Financial Officer (Principal Financial and Accounting Officer)	May 15, 2023

**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: May 15, 2023

/s/ Adam Mendelsohn

Adam Mendelsohn
Chief Executive Officer
(Principal Executive Officer)

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

I, Brigid Makes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vivani Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 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: May 15, 2023

/s/ Brigid A. Makes

Brigid A. Makes
Chief Financial Officer
(Principal Financial and Accounting Officer)

**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 three months ended March 31, 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: May 15, 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.
