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, 2025

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)	*(Zip Code)*

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

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	VANI	The NASDAQ Capital Market

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

As of November 12, 2025, the registrant had 72,952,235 shares of common stock, par value $0.0001 per share outstanding.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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PART I. FINANCIAL STATEMENTS

Item 1. Financial Statements

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	September 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,628	$ 18,352
R&D tax credit incentive receivable	664	253
Prepaid expenses and other current assets	883	1,837
Total current assets	4,175	20,442
Property and equipment, net	2,726	1,693
Operating lease right-of-use assets, net	16,784	17,957
Restricted cash	1,338	1,338
Deposits and other assets	23	131
TOTAL ASSETS	$ 25,046	$ 41,561
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,434	$ 817
Accrued expenses	1,978	1,803
Litigation accrual	1,675	1,675
Accrued compensation expense	357	343
Lease liability, current portion	1,386	1,348
Total current liabilities	6,830	5,986
Lease liability, noncurrent portion	16,907	17,965
TOTAL LIABILITIES	23,737	23,951
Commitments and contingencies (Note 12)		
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:61,511 and 59,235 at September 30, 2025 and December 31, 2024, respectively	6	6
Additional paid-in capital	143,062	139,480
Accumulated other comprehensive income	141	48
Accumulated deficit	(141,900)	(121,924)
TOTAL STOCKHOLDERS' EQUITY	1,309	17,610
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 25,046	$ 41,561

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 September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development, net of grants	$ 4,519	$ 4,203	$ 13,496	$ 11,442
General and administrative, net of grants	2,206	2,106	7,250	6,775
Total operating expenses	6,725	6,309	20,746	18,217
Loss from operations	(6,725)	(6,309)	(20,746)	(18,217)
Other income, net	195	268	770	781
Net loss	$ (6,530)	$ (6,041)	$ (19,976)	$ (17,436)
Net loss per common share - basic and diluted	$ (0.11)	$ (0.11)	$ (0.34)	$ (0.32)
Weighted average common shares outstanding - basic and diluted	59,711	55,247	59,399	54,161

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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net loss	$ (6,530)	$ (6,041)	$ (19,976)	$ (17,436)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	60	29	93	(48)
Comprehensive loss	$ (6,470)	$ (6,012)	$ (19,883)	$ (17,484)

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

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balance, January 1, 2024	51,031	$ 5	$ 119,054	$ 140	$ (98,438)	$ 20,761
Issuance of common stock and warrants in connection with Securities Purchase Agreement, net of issuance costs $1,300	3,947	-	13,687	-	-	13,687
Stock-based compensation expense	-	-	353	-	-	353
Foreign currency translation adjustments	-	-	-	(52)	-	(52)
Net loss	-	-	-	-	(6,039)	(6,039)
Balance, March 31, 2024	54,978	5	133,094	88	(104,477)	28,710
Issuance of common stock in connection with At-the-Market offering, net of issuance costs $240	219	1	111	-	-	112
Stock-based compensation expense	-	-	383	-	-	383
Foreign currency translation adjustments	-	-	-	(25)	-	(25)
Net loss	-	-	-	-	(5,356)	(5,356)
Balance, June 30, 2024	55,197	6	133,588	63	(109,833)	23,824
Issuance of common stock in connection with At-the-Market offering, net of issuance costs $43	69	-	48	-	-	48
Stock-based compensation expense	-	-	472	-	-	472
Foreign currency translation adjustments	-	-	-	29	-	29
Net loss	-	-	-	-	(6,041)	(6,041)
Balance, September 30, 2024	55,266	$ 6	$ 134,108	$ 92	$ (115,874)	$ 18,332

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balance, January 1, 2025	59,235	$ 6	$ 139,480	$ 48	$ (121,924)	$ 17,610
Issuance of common stock in connection with the Sales Agreement, net of issuance costs of $37	9	-	(28)	-	-	(28)
Stock-based compensation expense	-	-	350	-	-	350
Foreign currency translation adjustments	-	-	-	(6)	-	(6)
Net loss	-	-	-	-	(6,302)	(6,302)
Balance, March 31, 2025	59,244	6	139,802	42	(128,226)	11,624
Stock-based compensation expense	-	-	391	-	-	391
Foreign currency translation adjustments	-	-	-	39	-	39
Net loss	-	-	-	-	(7,144)	(7,144)
Balance, June 30, 2025	59,244	6	140,193	81	(135,370)	4,910
Issuance of common stock in connection with the Private Sales Transaction, net of issuance costs of $57	2,267	-	2,593	-	-	2,593
Stock-based compensation expense	-	-	276	-	-	276
Foreign currency translation adjustments	-	-	-	60	-	60
Net loss	-	-	-	-	(6,530)	(6,530)
Balance, September 30, 2025	61,511	$ 6	$ 143,062	$ 141	$ (141,900)	$ 1,309

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,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (19,976)	$ (17,436)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	309	311
Stock-based compensation	1,017	1,208
Non-cash lease expense	153	216
Fixed assets write-off	-	34
Changes in operating assets and liabilities:		
R&D tax credit incentive receivable	(411)	-
Prepaid expenses and other assets	1,062	575
Accounts payable	174	274
Accrued compensation expenses	14	(25)
Accrued expenses	57	(131)
Net cash used in operating activities	(17,601)	(14,974)
Cash flows from investing activities:		
Purchases of property and equipment	(899)	(260)
Net cash used in investing activities	(899)	(260)
Cash flows from financing activities:		
Issuance of common stock and warrants in connection with the Securities Purchase Agreement, net of issuance costs	-	13,687
Issuance of common stock in connection with the 2025 Private Sales Transaction, net of issuance costs	2,593	-
Gross proceeds from insurance premium loan	355	379
Payments on insurance premium loan	(237)	-
Net proceeds from issuance of common stock in connection with the Sales Agreement, net of issuance costs	(28)	160
Net cash provided by financing activities	2,683	14,226
Effect of exchange rate changes on cash and cash equivalents	93	-
Net decrease increase in cash, cash equivalents and restricted cash	(15,724)	(1,008)
Cash, cash equivalents and restricted cash balance at beginning of period	19,690	21,992
Cash, cash equivalents and restricted cash balance at end of period	$ 3,966	$ 20,984
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during the period for:		
Income taxes	$ 2	$ 2
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 443	$ -

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

Note 1. Organization and Business Operations

Vivani Medical, Inc. ("Vivani," the "Company," "we," "us," "our" or similar terms) is a clinical stage biopharmaceutical company which develops miniature, ultra long-acting subdermal drug implants utilizing its proprietary NanoPortal™ technology, which is designed to enable ultra long-acting, 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 leading causes of poor clinical outcomes in the treatment of chronic diseases, including medication non-adherence, drug tolerability and administration challenges faced by certain patients.

According to the U.S. Centers for Disease Control and Prevention, adherence is defined as the extent to which an individual's behavior, including taking medications, corresponds to recommendations from a health care provider. An alarmingly high proportion of patients, approximately 50%, do not, or cannot, take their medicine as prescribed in the real world, a statistic that applies to both daily oral as well as weekly injectable medicines. For example, a recent study has shown that 64% of patients taking Wegovy® (semaglutide injection) discontinue treatment within the first year, a number that increases to 76% by the second year. Unfortunately, GLP-1 discontinuation may result in failure to achieve target outcomes and a quick reversal of the health benefits in the majority of patients.

At Vivani, we are developing a portfolio of miniature, ultra long-acting subdermal drug implant candidates based on our NanoPortal technology that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing medication adherence by delivering therapeutic drug levels for up to six months or longer. Our NanoPortal implant technology has the potential to reduce dosing administration frequency to 6 months or longer and allows for treatment to be discontinued at any time if necessary. In addition, we aim to minimize fluctuations in patients' drug levels which may improve the tolerability of medicines, including GLP-1 receptor agonists which produce side effects that are associated with fluctuating drug levels in the blood.

Our emerging portfolio of miniature, ultra long-acting drug implants have the potential to revolutionize the treatment of chronic diseases by directly addressing poor medication adherence and improving drug tolerability in patients, both of which have the potential to translate into better health outcomes for patients in the real-world setting. Vivani's lead program, NPM-139, is a miniature, six-month, GLP-1 (semaglutide) implant currently in development for chronic weight management in obese and overweight patients. NPM-139 recently achieved encouraging preclinical data in rats showing approximately 20% weight loss, as compared to a control group receiving sham implants, which was maintained for more than seven months. We are also developing NPM-133 (semaglutide implant) for the treatment of type-2 diabetes. Preliminary feasibility data support the additional potential benefit of once yearly dosing for both semaglutide implant programs, NPM-139 and NPM-133. In addition, we are also developing NPM-119 (exenatide implant) for the treatment of type 2 diabetes, NPM-115 (high-dose exenatide implant) for chronic weight management, and OKV-119, a GLP-1-based implant in development for chronic weight management and related conditions in companion cats and dogs. OKV-119 is being developed in collaboration with animal health partner Okava Pharmaceuticals, Inc. ("Okava").

Vivani resulted from the business combination of Second Sight Medical Products, Inc. ("Second Sight") and Nano Precision Medical, Inc. ("NPM"). On August 30, 2022, Second Sight and NPM completed their merger pursuant to which NPM became a wholly owned subsidiary of Second Sight and the combined company of NPM and Second Sight was renamed Vivani Medical, Inc. Vivani's main priority is the further development of its miniature, ultra long-acting drug implant programs. In parallel, Vivani's management team remains committed to identifying and exploring strategic options that will enable further development of its pioneering neurostimulation systems from legacy company Second Sight which are aimed at helping patients recover critical body functions. As noted below, we subsequently contributed our Second Sight assets and certain liabilities to Cortigent, Inc. ("Cortigent"), our wholly owned subsidiary to advance our pioneering neurostimulation technology.

Corporate Updates

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.

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

Preclinical and Platform Development

In February 2024, Vivani announced positive preclinical weight loss data with its exenatide implant, NPM-115, that was comparable to semaglutide, the active ingredient in Ozempic® and Wegovy®, and a strategic shift to prioritize the Company's obesity portfolio. In a study of high-fat diet-induced obese mice, the exenatide implant generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to the extent of weight loss observed in mice treated with semaglutide injections in the same study.

In February 2024, the Company also disclosed that semaglutide, the active ingredient in Ozempic®, Wegovy® and Rybelsus®, is the active pharmaceutical ingredient in NPM-139, another miniature, ultra long-acting subdermal GLP-1 implant in development for chronic weight management, further prioritizing our obesity treatment portfolio. NPM-139 has the added potential benefit of once-yearly administration.

On May 28, 2024, Vivani announced the publication of positive weight loss data supporting the potential veterinary use of OKV-119, the Company's miniature, ultra long-acting GLP-1 implant under development with partner Okava for the treatment of pre-diabetes, diabetes and obesity in companion felines. The device is intended to be conveniently inserted under the skin during routine veterinary visits and is being designed to deliver six months of GLP-1 therapy with a single administration. We believe this six-month administration profile is important commercially in the veterinary setting due to the infrequent cadence of veterinary visits.

On September 4, 2024, Vivani announced positive preclinical liver fat results with its miniature, ultra long-acting GLP-1 implant currently under development for chronic weight management in obese and overweight individuals and type 2 diabetes. The Company's GLP-1 (exenatide) implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing. These liver fat data are consistent with published results from similar investigations with semaglutide.

Clinical Development

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

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

On July 11, 2024, the Company provided an update of the clinical development plans for NPM-115, the clinical program associated with the miniature, ultra long-acting GLP-1 (high-dose exenatide) implant for chronic weight management in obese and overweight individuals. The Company redesigned the first-in-human study, LIBERATE-1™, initially intended to explore the safety, tolerability and pharmacokinetics of its exenatide implant in patients with type 2 diabetes, to evaluate the implant in obese and overweight individuals.

On September 26, 2024, the Company reported receiving regulatory approval to initiate its first-in-human clinical trial with NPM-115, a miniature, ultra long-acting GLP-1 (exenatide) implant in obese and overweight individuals in Australia. This clinical trial, known as LIBERATE-1, investigated the safety, tolerability and full pharmacokinetic profile of our exenatide implant. The trial also represented the first clinical application of the Company's proprietary NanoPortal drug implant technology. LIBERATE-1 was redesigned to enroll participants who were titrated on weekly semaglutide injections for 8 weeks (0.25 mg/week for 4 weeks followed by 0.5 mg/week for 4 weeks) before being randomized to receive a single administration of Vivani's exenatide implant (n=8), weekly exenatide injections (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. The trial was initiated at the end of 2024 and top-line data was released in August 2025.

On December 19, 2024, Vivani announced that screening and enrollment of LIBERATE-1, the First-in-Human clinical trial with a GLP-1 implant in obese and overweight patients, was initiated at two study centers in Australia. The primary objective of the study was to investigate the safety, tolerability and full pharmacokinetic profile of an exenatide implant in obese or overweight individuals.

On March 13, 2025, the Company announced the successful administration of its first GLP-1 (exenatide) implant in the LIBERATE-1 clinical trial. This milestone marked a critical step toward addressing one of healthcare's most pressing challenges: medication adherence in metabolic diseases including chronic weight management and type 2 diabetes. The Company also announced full enrollment in the LIBERATE-1 study, which was achieved in just four weeks after enrollment of the first subject, signaling early potential interest for this six-month, subdermal GLP-1 implant.

On August 5, 2025, Vivani announced plans to support the rapid advancement of NPM-139, a novel semaglutide implant, based on promising results from the LIBERATE-1 clinical study and additional positive data from a preclinical study with a semaglutide implant. LIBERATE-1, the first-in-human application of Vivani's proprietary NanoPortal implant technology, demonstrated a positive safety and tolerability profile and encouraging performance data, thus meeting the study's primary objectives. This study provided information on the GLP-1 exposure levels obtained with an exenatide configuration, thereby paving the road for future clinical development of the technology, not only for exenatide implants (NPM-115 and OKV-119), but also for semaglutide implants (NPM-139 and NPM-133) and other applications of NanoPortal technology that the Company may pursue in the future. Vivani also announced new NPM-139 (semaglutide implant) preclinical feasibility data that demonstrated an approximately 20% weight loss with a single implant, which had been maintained for more than six months at the time of the announcement. This new semaglutide data also continues to support the potential for a semaglutide implant with annual dosing. Based on the LIBERATE-1 data supporting the clinical application of the NanoPortal platform technology, and the preclinical weight loss data with a semaglutide implant configuration, Vivani announced plans to prioritize advancement of NPM-139, with clinical development expected to begin in 2026.

On September 4, 2025, Vivani announced plans to initiate a Phase 1 clinical study for the NPM-139 semaglutide implant program in the first half of 2026, pending regulatory clearance, along with high-level details of the anticipated study design. The Company also announced parallel preparations to initiate a Phase 2 clinical study of NPM-139 pending enabling results from the Phase 1 study and regulatory feedback.

Cortigent, Inc.

In December 2022, we contributed our neurostimulation assets and certain liabilities from legacy company Second Sight to Cortigent, our wholly owned subsidiary to advance our pioneering neurostimulation technology. Cortigent had 5,000,000 shares of common stock outstanding, all owned by Vivani. On March 12, 2025, Vivani announced efforts to file a Form 10 with the U.S. Securities and Exchange Commission ("SEC") to support the spin-off of Cortigent into a fully independent, publicly traded company. Vivani announced the filing of the Cortigent Form-10 registration statement on May 29, 2025. The strategic goal of this transaction is to create two focused companies dedicated to driving current and future value in their respective therapeutic areas of expertise.

On August 25, 2023, the Company and Cortigent entered into an Amendment 1 (the "Amendment") to the Transition Funding, Support and Services Agreement dated March 19, 2023 (the "TFSSA"). Pursuant to the TFSSA, Vivani has agreed to advance funds and provide or cause to be provided to Cortigent the services and funding intended to cover salaries and related costs, rent and other overhead in order to permit Cortigent to operate in substantially the same manner as Second Sight prior to the formation of Cortigent. Efforts to support a successful initial public offering of Cortigent ceased in March 2025 and efforts are now focused on a potential spinoff with the filing of a Form 10 registration statement. The TFSSA terminated effective December 31, 2024. If the spinoff is successful, the loan payable from Cortigent to Vivani will be forgiven.

On May 29, 2025, Vivani announced that Cortigent had filed a Form 10 registration statement with the SEC to spin off Cortigent as an independent, publicly traded Nasdaq company. The strategic goal of this transaction is to create two focused companies dedicated to driving current and future value in their respective therapeutic areas of expertise. Vivani's board of directors authorized management to proceed with a plan to spin off its Cortigent neuromodulation business. The spin-off was planned to be completed during third or fourth quarter 2025, subject to the satisfaction of certain conditions, including, among others, final approval of Vivani's board of directors, receipt of a favorable opinion that the transaction will qualify for non-recognition of gain or loss as a result of receipt of Cortigent shares for U.S. Federal Income Tax purposes, and SEC and Nasdaq approval.

On September 17, 2025, Vivani announced that its board of directors had set a record date for the approved spin-off of Cortigent, Inc. Vivani stockholders holding common stock as of that record date would receive common stock in Cortigent. This record date was withdrawn on October 3, 2025, due to delays arising from the shutdown of the U.S. federal government. Vivani expects to reestablish a new record date as soon as possible.

Okava Pharmaceuticals, Inc.

On April 12, 2025, Vivani entered into an amendment to its License and Supply Agreement with Okava which expanded Vivani's ongoing collaboration to include dogs in the development of OKV-119, a long-acting GLP-1 therapy for weight management, type 2 diabetes, and other cardiometabolic conditions.

Liquidity and Capital Resources

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

Our financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We are subject to the risks and uncertainties associated with a business that does not generate revenue and 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.

To support our future operations, the Company entered into three equity purchase agreements in March 2025, May 2025 and August 2025. These agreements will bring an additional $18.6 million of committed capital into the Company between September 30, 2025 and July 15, 2026. For additional information, refer to Note 7 Equity Securities of the Notes to Condensed Consolidated Financial Statements and Note 14 Subsequent Event in this Quarterly Report on Form 10-Q.

We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations into 2027. Our ability to continue as a going concern is dependent on our ability to raise additional capital, however, there can be no assurances that we will be able to do so.

Note 2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

These unaudited interim financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and following the requirements of the SEC for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. In our opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of our financial position and our results of operations and cash flows for periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with our financial statements and accompanying notes for the fiscal year ended December 31, 2024, included within our Annual Report on Form 10-K filed with the SEC on March 31, 2025. The results of the interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

Principles of Consolidation

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

Use of estimates

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

Operating Segments

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

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

Significant Accounting Policies

Our significant accounting policies are set forth in our financial statements for the year ended December 31, 2024, included within our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed with the SEC on March 31, 2025.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued Accounting Standards Update No. 2024-03 *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which will improve the disclosures about a public business entity's expenses and requires detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions such as cost of sales, selling, general and administrative, and research and development on the face of the income statement. ASU 2024-03 is effective for the Company or fiscal years beginning on January 1, 2027, and for interim periods within fiscal years beginning on January 1, 2028. Early adoption is permitted. The guidance may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of ASU 2024-03 or (2) retrospectively to all prior periods presented in the financial statements. The Company does not expect the adoption of this guidance to have a material effect on its consolidated financial statements and continues to evaluate disclosure presentation alternatives.

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

Note 3. Concentration of Risk

Credit Risk

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

Foreign Operations

The accompanying condensed consolidated financial statements as of September 30, 2025 and 2024 include assets amounting to approximately $28,000 and $27,000, respectively, relating to our operations in Switzerland. The accompanying condensed consolidated financial statements as of September 30, 2025 and 2024 include assets amounting to approximately $702,000 and $85,000, respectively, relating to our operations in Australia. Unanticipated events in foreign countries could disrupt our operations and impair the value of these assets.

Note 4. Fair Value Measurements

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

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

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

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

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

Cash equivalents, which include certificates of deposit and money market funds, are the only financial instruments measured and recorded at fair value on our condensed consolidated balance sheet, and are valued using Level 1 inputs. As of September 30, 2025 and 2024, we did not have any Level 1 and Level 2 financial liabilities or Level 3 financial assets or liabilities measured at fair value on a recurring basis. We did not have any transfers between Level 1 and Level 2 or transfers in or out of Level 3 during the three or nine months ended September 30, 2025 and 2024.

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

	As of September 30, 2025			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents:				
Money market funds	$ 29	$ 29	$ -	$ -
Total	$ 29	$ 29	$ -	$ -

	As of December 31, 2024			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents:				
Certificates of deposit	$ 9,996	$ 9,996	$ -	$ -
Money market funds	7,441	7,441	-	-
Total	$ 17,437	$ 17,437	$ -	$ -

Note 5. Insurance Premium Financing

In September 2025, we entered into a finance agreement with First Insurance Funding in order to fund a portion of our insurance premiums for our professional liability policies. The amount financed is approximately $355,000 and incurs interest at a rate of 7.2%. The Company is required to make nine monthly payments of approximately $39,000 through May 2026. There was an outstanding balance of $355,000 as of September 30, 2025.

In September 2024, we entered into a finance agreement with First Insurance Funding in order to fund a portion of our insurance premiums for our professional liability policies. The amount financed is approximately $426,000 and incurs interest at a rate of 7.2%. The Company is required to make nine monthly payments of approximately $47,000 through May 2025. The amount has been fully repaid as of September 30, 2025.

Note 6. Selected Balance Sheet Detail

Property and Equipment, Net

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

	September 30, 2025	December 31, 2024
Property and equipment at cost:		
Equipment	$ 4,043	$ 3,937
Furniture and fixtures	380	367
Computer software	30	30
Construction in progress	1,223	-
Total property and equipment	5,676	4,334
Accumulated depreciation and amortization	(2,950)	(2,641)
Property and equipment, net	$ 2,726	$ 1,693

Note 7. Equity Securities

We are authorized to issue 300,000,000 shares of common stock with 61,510,768 issued and outstanding as of September 30, 2025. In addition, we are authorized to issue 10,000,000 shares of preferred stock with none issued as of September 30, 2025.

Securities Purchase Agreement

On March 1, 2024, the Company entered into a securities purchase agreement ("Securities Purchase Agreement") with an institutional investor to purchase 3,947,368 shares of common stock, par value $0.0001 per share (the "Common Stock") and warrants to purchase up to an aggregate of 3,947,368 shares of common stock at a purchase price of $3.80 per share and accompanying warrant in a registered direct offering (the "Offering"). The warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance, and will expire three years following the date of issuance. The Company also entered into a Placement Agency Agreement with Maxim Group LLC ("Maxim" and such agreement, the "Placement Agency Agreement," and together with the Securities Purchase Agreement, the "Agreements") who acted as the sole placement agent for the Offering. In connection with the Placement Agency Agreement, the Company agreed to pay Maxim an aggregate cash fee of 7.0% of the aggregate proceeds raised from the sale and issuance of the shares of common stock and accompanying warrants. Pursuant to the Placement Agency Agreement, the Company also agreed to reimburse Maxim up to $65,000 for its legal expenses. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other estimated offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million.

The Sales Agreement

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

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

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

During the nine months ended September 30, 2025, the Company issued 9,215 shares of common stock for gross proceeds of $10,000 pursuant to the Sales Agreement. The Company paid expenses of $37,000, resulting in negative net proceeds of $28,000. During the nine months ended September 30, 2024, the Company issued 287,970 shares of common stock for gross proceeds of $504,000 pursuant to the Sales Agreement. The Company paid expenses of $344,000, resulting in net proceeds of $160,000.

2024 Private Sale Transaction

On November 8, 2024, the Company entered into a private sale transaction with one of its directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company's common stock on Nasdaq or the 5-day average closing price of the Company's common stock on Nasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

2025 Private Sale Transaction

On March 26, 2025, the Company entered into a share purchase agreement with an entity affiliated with one of its directors whereby the Company shall sell an aggregate of 7,366,071 shares of the Company's common stock to the entity, in five tranche closings as provided in such share purchase agreement, at a price of $1.12 per share, which was the closing price of the Company's common stock on Nasdaq, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the share purchase agreement. The gross proceeds from this share purchase agreement will be approximately $8.25 million. The Company has concluded that the share purchase agreement is classified as equity instruments since it does not contain any (i) exercise contingencies based on observable markets or indices besides those related to the market for the Company's own stock price and operations and (ii) settlement provisions that would preclude the share purchase agreement from being indexed to the Company's own stock. The share purchase agreement also does not contain any provisions that would preclude equity classification under ASC 815-40. The Company will record the proceeds from the share purchase agreement in equity upon the issuance of the underlying common stock.

On May 12, 2025, the Company entered into a share purchase agreement with an entity affiliated with one of its directors whereby the Company shall sell an aggregate of 2,912,621 shares of the Company's common stock to the entity, in two tranche closings as provided in such share purchase agreement, at a price of $1.03 per share, which was the closing price of the Company's common stock on Nasdaq, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the share purchase agreement. The gross proceeds from this private sale transaction will be approximately $3.0 million. The Company concluded that the private sale transaction on May 12, 2025 would have the same accounting treatment as the private sale transaction that was entered into on March 26, 2025.

On August 11, 2025, the Company entered into a share purchase agreement with an entity affiliated with one of its directors and another investor whereby the Company shall sell an aggregate of 7,936,507 shares of the Company's common stock to the entity and other investor, in twelve tranche closings as provided in such share purchase agreement, at a price of $1.26 per share, which was the closing price of the Company's common stock on Nasdaq on August 11, 2025, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the share purchase agreement. The gross proceeds from this private sale transaction will be approximately $10.0 million.

During the nine months ended September 30, 2025, the Company issued 2,266,865 shares of common stock pursuant to these share purchase agreements (collectively, "2025 Private Sales Transactions"), generating gross proceeds of $2.6 million. The remaining shares issuable under the 2025 Private Sales Transactions are expected to be issued in 2025 and 2026 upon completion of the applicable tranche closings.

Note 8. Warrants

A summary of warrant activity for the nine months ended September 30, 2025 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, 2024	9,340	$ 3.42	1.6
Issued	-	$ -	
Exercised	-	$ -	-
Forfeited or expired	(1,361)	$ 3.15	-
Warrants outstanding as of September 30, 2025	7,979	$ 3.47	1.1
Warrants exercisable as of September 30, 2025	7,979	$ 3.47	1.1

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

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

The warrants outstanding as of September 30, 2025 had no intrinsic value.

Note 9. Stock-Based Compensation

Equity Incentive Plan

The Vivani Medical, Inc. 2022 Omnibus Incentive Plan (the "2022 Plan") became effective on August 30, 2022. Under the 2022 Plan, 10,033,333 shares were authorized for issuance at its effective date. The maximum number of shares with respect to which stock awards could be granted is offset and reduced by stock awards previously granted under the 2022 Plan. As of September 30, 2025, 463,674 shares of common stock were available for future issuance under the2022 Plan pursuant to stock awards that had not previously been granted.

For stock option grants, the option price is determined by the Board of Directors but cannot be less than the fair value of the shares at the grant date. Generally, the options vest ratably over four years and expire ten years from the grant date. The 2022 Plan provides for accelerated vesting if there is a change of control, as defined in the 2022 Plan.

Stock Options

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

	Number of Shares		Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)
Options outstanding as of December 31, 2024	6,809	$	2.52	6.55
Granted	1,815	$	1.13	
Exercised	-	$	-	
Forfeited or expired	(218)	$	1.78	
Options outstanding, vested and expected to vest as of September 30, 2025	8,406	$	2.24	6.41
Options exercisable as of September 30, 2025	5,701	$	2.68	5.24

The estimated aggregate intrinsic value of stock options exercisable as of September 30, 2025 was $198,987.

Restricted Stock Units (RSUs)

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

	Number of Shares		Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2024	695	$	1.25
Granted	293	$	0.87
Vested and released	-	$	-
Forfeited and canceled	(188)	$	1.07
Outstanding as of September 30, 2025	800	$	1.15

During the nine months ended September 30, 2025 and 2024, the Company granted 292,500 RSUs each period, subject to market conditions which required our stock price to exceed $3.15 per share for three consecutive days in the four years from grant date for the RSUs to vest. Upon achievement of the market condition, one-third of the award will vest, and thereafter, one-third of the award will vest on the first and second anniversary of the achievement date, subject to the recipient's continued service through each applicable vesting date.

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 227	$ 275	$ 638	$ 757
General and administrative	49	197	379	451
Total stock-based compensation expense	$ 276	$ 472	$ 1,017	$ 1,208

As of September 30, 2025, there was $2.3 million of total unrecognized stock-based compensation expense related to outstanding stock options that will be recognized over a weighted average period of 1.5 years. As of September 30, 2025, there was $0.3 million of total unrecognized compensation expense related to outstanding RSUs that will be recognized over a weighted average period of 1.4 years.

Stock Options (Service Vesting)

During the nine months ended September 30, 2025, 1,814,890 stock options subject to service vesting, were issued and valued at $1.6 million using the Black-Scholes option-pricing model. During the nine months ended September 30, 2024, 1,092,836 stock options subject to service vesting, were issued and valued at $1.4 million using the Black-Scholes option-pricing model. The calculated value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions.

	Nine Months Ended September 30,	
	2025	2024
Risk-free interest rate	3.93% to 4.39%	3.79% to 5.53%
Expected dividend yield	-%	-%
Expected volatility	100%	100%
Expected term	5.25 to 6.08 years	5.04 to 6.08 years

Restricted Stock Units (RSUs)

The assumptions used to estimate the fair value of the performance-based restricted stock units granted during the nine months ended September 30, 2025 and September 30, 2024 and valued using a Monte Carlo simulation were as follows:

	Nine Months Ended September 30,	
	2025	2024
RSUs Granted	292,500	292,500
Valuation date stock price	$1.03	$1.81
Risk-free interest rate	3.99%	4.53%
Expected dividend yield	0%	0%
Expected volatility	100%	100%
Simulation term	4 Years	4 Years

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

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

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

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

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

3. Performance-Based RSU Value Conclusion The proceeds from the vesting of common shares were then discounted to the Valuation Date using the applicable risk-free rate, which is consistent with the assumption utilized to project stock prices in our Monte Carlo simulation. The service period was then determined based on the median Hurdle Achievement Date.

Note 10. Net Loss Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net loss	$ (6,530)	$ (6,041)	$ (19,976)	$ (17,436)
Denominator:				
Weighted average common shares outstanding - basic and diluted	59,711	55,247	59,399	54,161
Net loss per common share, basic and diluted	$ (0.11)	$ (0.11)	$ (0.34)	$ (0.32)

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

During the periods ended September 30, 2025 and 2024, the following common stock equivalents were excluded from the computation of diluted net loss per share because including them would have been antidilutive (in thousands).

	September 30,	
	2025	2024
Stock options issued and outstanding	8,406	6,809
Unvested restricted stock units issued and outstanding	800	695
Warrants to purchase common stock	7,979	9,912
Total	17,185	17,416

Note 11. Right-of-use Assets and Operating Lease Liabilities

We lease certain office, laboratory, research and development space for our use. Leases with an initial term of twelve months or less are not recorded on the balance sheet. Operating lease cost for the operating lease is recognized on a straight-line basis over the lease term and is included in operating expenses on the consolidated statements of operations and comprehensive loss. Our lease agreements do not contain any material residual value guarantees or restrictive covenants. As most of our leases do not provide an implicit rate, we used our estimated incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

On November 21, 2022, Vivani entered into a triple net lease agreement for a single building with 43,645 square feet of space in Alameda, California. The stated term of the lease commenced on June 1, 2023 and terminates on September 30, 2033, ten years and four months. The lease term is based on the non-cancellable period in the lease agreement. There are two options to extend the lease, each for a term of five years; however, the extension options were not included in the measurement of the ROU asset and lease liability since it is not reasonably certain that the Company will exercise such extension options. Payments increase annually from $2,676,311 to $3,596,784, or 124 monthly payments less the first four which are abated, totaling approximately $31.0 million. Vivani is responsible for insurance, property taxes and common area maintenance charges. Vivani deposited $1.3 million to guarantee a letter of credit to secure the lease and this amount is recorded as restricted cash, long-term on the balance sheets as of September 30, 2025 and December 31, 2024.

On February 1, 2023, we entered into a lease agreement, effectiveMarch 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 sublease has a term of two years and two months. The sublease expired on April 30, 2025. We also entered into a leasefor storage space on January 25, 2023, in the same building at a cost of $6,775 per month for a term of two years and one month. The lease expired on March 31, 2025. We did not renew the current office lease. However, we entered into another lease in the same building for a smaller space at a cost of $1,700 per month for six months. We renewed the lease of the storage unit. These new and renewal leases were short-term leases with immaterial monthly costs and both expired as of September 30, 2025.

On July 3, 2024, we entered into a short-term sublease agreement to lease a manufacturing facility which terminated onJune 30, 2025.

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

	Balance Sheet Classification	September 30, 2025	December 31, 2024
Assets			
Non-current assets	Right-of-use assets	$ 16,784	$ 17,957
Liabilities			
Current	Current operating lease liabilities	$ 1,386	$ 1,348
Long-term	Long-term operating lease liabilities	$ 16,907	$ 17,965

Operating lease cost was $0.8 million and $0.8 million during the three months ended September 30, 2025 and 2024, respectively, and $2.4 million and $2.5 million during the nine months ended September 30, 2025 and 2024, respectively.

Variable lease cost, comprising primarily of common area maintenance charges and taxes, for the operating lease was $0.1 million and $0.1 million during the three months ended September 30, 2025 and 2024, respectively, and $0.5 million and $0.3 million during the nine months ended September 30, 2025 and 2024, respectively.

The following table summarizes a maturity analysis of our lease liabilities showing the aggregate lease payments as ofSeptember 30, 2025 (in thousands except weighted average data):

Year Ending December 31,	Amount
2025	$ 710
2026	2,889
2027	2,976
2028	3,065
2029	3,156
Thereafter	12,704
Total lease payments	$ 25,500
Less imputed interest	(7,206)
Total lease liabilities	$ 18,294
Weighted average discount rate	8.38%
Weighted average remaining lease term	8.00 years

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Cash paid for operating lease liabilities	$ 710	$ 776	$ 2,204	$ 2,294

Note 12. Commitments and Contingencies

Indemnification Agreements

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

Clinical Trial Agreements

Based upon FDA approval of Argus II, which was obtained in February 2013, we were required to collect follow-up data from subjects enrolled in our pre-approval trial for a period of up to ten years post-implant, which was extended through the year 2019. This requirement to collect follow-up data was halted in 2020 with FDA approval. In addition, we conducted three post-market studies to comply with U.S. FDA, French, and European post-market surveillance regulations and requirements and are conducting an early feasibility clinical study of Orion. We have contracted with various universities, hospitals, and medical practices to provide these services. Payments are based on procedures performed for each subject and are charged to clinical and regulatory expense as incurred. Total amounts expensed during the three months ended September 30, 2025 and 2024 were $0 and $3,000, respectively and during the nine months ended September 30, 2025 and 2024 were $35,000 and $13,000, respectively.

Litigation, Claims and Assessments

One opposition filed by Pixium Vision SA ("Pixium") was pending in the European Patent Office challenging the validity of a European patent owned by Cortigent. We decided to allow the patent to be abandoned by the EPO, which occurred in February 2025. As a result, this opposition is no longer pending. While this abandonment could impact our ability to protect Cortigent's neurostimulation technology in Europe related to this patent, we do not believe that it will have a material effect on our ability to manufacture and sell our products, or otherwise have a material effect on Cortigent's operations.

As described in the Company's 10-K for the year ended December 31, 2020, the Company had entered into a Memorandum of Understanding ("MOU") for a proposed business combination with Pixium. In response to a press release by Pixium dated March 24, 2021, and subsequent communications between us and Pixium, our Board of Directors determined that the business combination with Pixium was not in the best interest of our stockholders. On April 1, 2021, we gave notice to Pixium that we were terminating the MOU between the parties and seeking an amicable resolution of termination amounts that may be due, however no assurance can be given that an amicable resolution will be reached. We accrued $1,000,000 of liquidated damages as contemplated by the MOU in accounts payable as of March 31, 2021 and remitted that amount to Pixium in April 2021. Pixium indicated that it considered this termination wrongful, rejected the Company's offers, but retained the $1,000,000 payment. On May 19, 2021, Pixium filed suit in the Paris Commercial Court, and currently claim damages of approximately €5.1 million or about $5.6 million. We believe we have fulfilled our obligations to Pixium with the liquidated damages payment of $1,000,000. On December 8, 2022, the Company received notice that the Paris Commercial Court has rendered its judgment, including finding that the Company's termination of the MOU was not valid. In the judgment, the Company was ordered to pay to Pixium the amount of €2,500,000 minus a €947,780 credit for the $1,000,000 already paid for, a net amount payable of approximately €1,552,220. On May 24, 2023, the Company filed an appeal against the judgment from the Paris Commercial Court except in so far as such prior judgment dismissed (i) Pixium's claim for the Company to pay it a sum of €480,693 relating to the alleged time spent by its teams, (ii) Pixium's application to order the Company to pay it a sum of €1,500,000 in respect to alleged loss of opportunity and (iii) deducted the sum of $1,000,000 that we already paid Pixium and which Pixium retained converted into euros at the date of the judgment. Thereafter Pixium filed its brief with Paris Court of Appeal and filed a cross-appeal on January 18, 2024. Meanwhile, the Company received notice that the Paris Commercial Court had opened safeguard proceedings against Pixium by judgment dated October 9, 2023, then in its judgment dated November 13, 2023, converted safeguard proceedings into receivership, and in its judgment dated January 31, 2024, converted Pixium's receivership proceedings to liquidation proceedings, the transfer plan being rejected. As a result, Pixium's liquidator intervened on behalf of Pixium in the pending proceedings before the Paris Court of Appeal and filed its brief on March 21, 2024. The Company filed its brief in reply with the Paris Court of Appeal on April 17, 2024. Proceedings before the Paris Court of Appeal are pending. In parallel, since the Company has failed to enforce the judgment, Pixium has requested the pre-trial judge to strike out the Company's appeal for failure to enforce the judgment. The hearing took place on June 4, 2024 and on October 23, 2024, the pre-trial judge issued his order, striking out Vivani's appeal for failure to enforce the decision. Within two years, Vivani will have to request that the case be reinstated on the court's docket, providing evidence that the judgment has been fully enforced or, at the very least, that an agreement has been reached. Failing this, the appeal proceedings will lapse.

The Company recorded a charge of $1,675,000 for the year ended December 31, 2022, related to this matter but plans to continue its appeal against the preliminary judgment.

On January 26, 2024, Oppenheimer & Co. Inc. ("Oppenheimer") filed a complaint asserting breach of contract and other claims against the Company and a party unrelated to the Company, ThinkEquity LLC (the "Third Party"), arising from a placement agent agreement dated November 5, 2020, executed by and between the Company and Pixium in connection with a proposed business combination transaction with Pixium. The complaint, filed in the Supreme Court of the State of New York, County of New York, Index No. 650421/2024, seeks recovery of no less than $1,625,000 in damages, plus costs and fees. On April 3, 2024, the Company filed a motion to dismiss the complaint. On May 3, 2024, the Third Party filed its own motion to dismiss. On June 12, 2025, the Court granted the Company's motion in part and denied it in part, dismissing all claims except the first cause of action for breach of contract (the "Claim"), and the Court dismissed the complaint as against the Third Party. Oppenheimer and the Company are now commencing discovery on the Claim, which seeks the monetary damages referenced above. Each of the Company and Oppenheimer have filed notices of appeal. The Company has defenses to the Claim and intends to defend itself vigorously, but there can be no assurance as to the outcome of the litigation.

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.

Note 13. Segment Information

Operating segments are defined as components of an enterprise for which separate financial information is available for evaluation by the chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. The Company has two operating and reporting segments, the Biopharm Division and the Neuromodulation Division. The Company's CODM is its Chief Executive Officer who reviews the Company between Biopharm and Neuromodulation divisions. Our primary focus is the Biopharm Division. We are trying to spin off the Neuromodulation Division. The measure of segment loss is reported on the Consolidated Statements of Operations and Comprehensive Loss as net loss. The measure of segment assets is reported on the Consolidated Balance Sheets as total assets.

The Company has not generated any product revenue to date. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it is a clinical stage biopharmaceutical company.

During the three months ended September 30, 2025, the Biopharm Division and Neurostimulation Division incurred operating expenses of $6.1 million and $0.6 million, respectively. During the three months ended September 30, 2025, net loss for the Biopharm Division was $5.9 million and for the Neurostimulation Division was $0.7 million.

During the nine months ended September 30, 2025, the Biopharm Division and Neurostimulation Division incurred operating expenses of $18.7 million and $2.0 million, respectively. During the nine months ended September 30, 2025, net loss for the Biopharm Division was $17.9 million and for the Neurostimulation Division was $2.1 million.

As of September 30, 2025, total assets for the Biopharm Division and the Neurostimulation Division were $24.6 million and $0.4 million, respectively.

The following table provides information related to our operating segments based upon the Company's net loss for the three and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,					
	2025			2024		
	Biopharma Division	Neuromodulation Division	Total	Biopharma Division	Neuromodulation Division	Total
Operating expenses:						
Personnel and related expenses	$ 2,521	$ 296	$ 2,817	$ 2,588	$ 270	$ 2,858
Office space rental related expenses	1,003	54	1,057	1,049	112	1,161
Development expenses	1,083	-	1,083	772	-	772
Professional services and insurance	1,201	172	1,373	987	120	1,107
Depreciation and amortization	101	4	105	99	8	107
Other general and administrative expenses	180	110	290	251	47	298
Other income (expense), net	(237)	42	(195)	(306)	44	(262)
Segment net loss	$ 5,852	$ 678	$ 6,530	$ 5,440	$ 601	$ 6,041

	Nine Months Ended September 30,					
	2025			2024		
	Biopharma Division	Neuromodulation Division	Total	Biopharma Division	Neuromodulation Division	Total
Operating expenses:						
Personnel and related expenses	$ 7,580	$ 815	$ 8,395	$ 7,567	$ 560	$ 8,127
Office space rental related expenses	3,143	260	3,403	2,916	247	3,163
Development expenses	3,154	-	3,154	1,823	111	1,934
Professional services and insurance	4,018	638	4,656	3,448	396	3,844
Depreciation and amortization	299	8	307	286	24	310
Other general and administrative expenses	563	268	831	573	246	819
Other income (expense), net	(894)	124	(770)	(896)	135	(761)
Segment net loss	$ 17,863	$ 2,113	$ 19,976	$ 15,717	$ 1,719	$ 17,436

Note 14. Subsequent Event

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:

Private Placement

The Company entered into a Share Purchase Agreement, dated October 26, 2025 (the "Purchase Agreement"), with an entity affiliated with one of its board of directors (the "Purchaser") for the purchase of an aggregate of 3,703,703 shares of common stock of the Company at a purchase price of $1.62 per share (the "Private Placement Shares"), the last reported sale price of the Common Stock on October 24, 2025. This private placement of Common Stock resulted in gross proceeds of approximately $6.0 million to the Company. No warrants or discounts were provided and no placement agent or investment banking fees were incurred in connection with the private placement. The Private Placement Shares will be issued pursuant to an exemption from registration under Rule 506 of Regulation D, which is promulgated under the Securities Act of 1933, as amended (the "Securities Act"). The Company relied on this exemption from registration based in part on representations made by the Purchaser.

Registered Direct Offering

Concurrent with the private placement, the Company also entered into a Placement Agency Agreement, dated October 26, 2025 (the "Placement Agency Agreement") with ThinkEquity LLC (the "Agent") relating to the sale by the Company of 6,000,000 shares of the Company's common stock (the "Registered Shares") in a registered direct offering (the "Registered Offering"). The gross proceeds from the Registered Offering were approximately $9.7 million, before placement agent fees and other estimated offering expenses. In connection with the Placement Agency Agreement, the Company agreed to pay the Agent an aggregate cash fee of 7.0% of the aggregate proceeds raised from the sale and issuance of the shares of Common Stock. Pursuant to the Placement Agency Agreement, the Company also agreed to reimburse the Agent for up to $125,000 for its legal and total reimbursable expenses.

Sublease Agreement

On October 1, 2025, the Company entered into a long-term sublease agreement for access to a manufacturing facility that will support, among other activities, GMP with the Company's clinical study test article. The stated term of the sublease commenced on October 1, 2025 and terminates on April 30, 2028. The Company's rental payment amounts to $35,000 per month plus operating expenses.

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

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

Business Overview

Vivani Medical, Inc. ("Vivani," the "Company," "we," "us," "our" or similar terms) is a clinical stage biopharmaceutical company which develops miniature, ultra long-acting subdermal drug implants utilizing its proprietary NanoPortal™ technology, which is designed to enable ultra long-acting, 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 leading causes of poor clinical outcomes in the treatment of chronic diseases, including medication non-adherence, drug tolerability and administration challenges faced by certain patients.

According to the U.S. Centers for Disease Control and Prevention, adherence is defined as the extent to which an individual's behavior, including taking medications, corresponds to recommendations from a health care provider. An alarmingly high proportion of patients, approximately 50%, do not, or cannot, take their medicine as prescribed in the real world, a statistic that applies to both daily oral as well as weekly injectable medicines. For example, a recent study has shown that 64% of patients taking Wegovy® (semaglutide injection) discontinue treatment within the first year, a number that increases to 76% by the second year. Unfortunately, GLP-1 discontinuation may result in failure to achieve target outcomes and a quick reversal of the health benefits in the majority of patients.

At Vivani, we are developing a portfolio of miniature, ultra long-acting subdermal drug implant candidates based on our NanoPortal technology that, unlike most oral and injectable medicines, are designed with the goal of guaranteeing medication adherence by delivering therapeutic drug levels for up to six months or longer. Our NanoPortal implant technology has the potential to reduce dosing frequency to 6 months or longer and allows for treatment to be discontinued at any time if necessary. In addition, we aim to minimize fluctuations in patients' drug levels which may improve the tolerability of medicines, including GLP-1 receptor agonists which produce side effects that are associated with fluctuating drug levels in the blood.

Our emerging portfolio of miniature, ultra long-acting drug implants have the potential to revolutionize the treatment of chronic diseases by directly addressing poor medication adherence and improving drug tolerability in patients, both of which have the potential to translate into better health outcomes for patients in the real-world setting. Vivani's lead program, NPM-139, is a miniature, six-month, GLP-1 (semaglutide) implant currently in development for chronic weight management in obese and overweight patients. NPM-139 recently achieved encouraging preclinical data in rats showing approximately 20% weight loss, as compared to a control group receiving sham implants, which was maintained for more than seven months. We are also developing NPM-133 (semaglutide implant) for the treatment of type-2 diabetes. Preliminary feasibility data support the additional potential benefit of once yearly dosing for both semaglutide implant programs, NPM-139 and NPM-133. In addition, we are also developing NPM-119 (exenatide implant) for the treatment of type 2 diabetes, NPM-115 (high-dose exenatide implant) for chronic weight management, and OKV-119, a GLP-1-based implant in development for chronic weight management and related conditions in companion cats and dogs. OKV-119 is being developed in collaboration with animal health partner Okava Pharmaceuticals, Inc. ("Okava").

Vivani resulted from the business combination of Second Sight Medical Products, Inc. ("Second Sight") and Nano Precision Medical, Inc. ("NPM"). On August 30, 2022, Second Sight and NPM completed their merger pursuant to which NPM became a wholly owned subsidiary of Second Sight and the combined company of NPM and Second Sight was renamed Vivani Medical, Inc. Vivani's main priority is the further development of its miniature, ultra long-acting drug implant programs. In parallel, Vivani's management team remains committed to identifying and exploring strategic options that will enable further development of its pioneering neurostimulation systems from legacy company Second Sight which are aimed at helping patients recover critical body functions. As noted below, we subsequently contributed our Second Sight assets and certain liabilities to Cortigent, Inc. ("Cortigent"), our wholly owned subsidiary to advance our pioneering neurostimulation technology.

Corporate Updates

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.

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

Preclinical and Platform Development

In February 2024, Vivani announced positive preclinical weight loss data with its exenatide implant, NPM-115, that was comparable to semaglutide, the active ingredient in Ozempic® and Wegovy®, and a strategic shift to prioritize the Company's obesity portfolio. In a study of high-fat diet-induced obese mice, the exenatide implant generated weight loss of approximately 20% compared to a sham implant control after a 28-day treatment duration, comparable to the extent of weight loss observed in mice treated with semaglutide injections in the same study.

In February 2024, the Company also disclosed that semaglutide, the active ingredient in Ozempic®, Wegovy® and Rybelsus®, is the active pharmaceutical ingredient in NPM-139, another miniature, ultra long-acting subdermal GLP-1 implant in development for chronic weight management, further prioritizing our obesity treatment portfolio. NPM-139 has the added potential benefit of once-yearly administration.

On May 28, 2024, Vivani announced the publication of positive weight loss data supporting the potential veterinary use of OKV-119, the Company's miniature, ultra long-acting GLP-1 implant under development with partner Okava for the treatment of pre-diabetes, diabetes and obesity in companion felines. The device is intended to be conveniently inserted under the skin during routine veterinary visits and is being designed to deliver six months of GLP-1 therapy with a single administration. We believe this six-month administration profile is important commercially in the veterinary setting due to the infrequent cadence of veterinary visits.

On September 4, 2024, Vivani announced positive preclinical liver fat results with its miniature, ultra long-acting GLP-1 implant currently under development for chronic weight management in obese and overweight individuals and type 2 diabetes. The Company's GLP-1 (exenatide) implant produced sham-implant adjusted liver fat reduction of 82% in an obese mouse model from a single administration with expected twice-yearly dosing. These liver fat data are consistent with published results from similar investigations with semaglutide.

Clinical Development

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

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

On July 11, 2024, the Company provided an update of the clinical development plans for NPM-115, the clinical program associated with the miniature, ultra long-acting GLP-1 (high-dose exenatide) implant for chronic weight management in obese and overweight individuals. The Company redesigned the first-in-human study, LIBERATE-1™, initially intended to explore the safety, tolerability and pharmacokinetics of its exenatide implant in patients with type 2 diabetes, to evaluate the implant in obese and overweight individuals.

On September 26, 2024, the Company reported receiving regulatory approval to initiate its first-in-human clinical trial with NPM-115, a miniature, ultra long-acting GLP-1 (exenatide) implant in obese and overweight individuals in Australia. This clinical trial, known as LIBERATE-1, investigated the safety, tolerability and full pharmacokinetic profile of our exenatide implant. The trial also represented the first clinical application of the Company's proprietary NanoPortal drug implant technology. LIBERATE-1 was redesigned to enroll participants who were titrated on weekly semaglutide injections for 8 weeks (0.25 mg/week for 4 weeks followed by 0.5 mg/week for 4 weeks) before being randomized to receive a single administration of Vivani's exenatide implant (n=8), weekly exenatide injections (n=8), or weekly 1 mg semaglutide injections (n=8) for a 9-week treatment duration. The trial was initiated at the end of 2024 with top-line data was released in August 2025.

On December 19, 2024, Vivani announced that screening and enrollment of LIBERATE-1, the First-in-Human clinical trial with a GLP-1 implant in obese and overweight patients, was initiated at two study centers in Australia. The primary objective of the study was to investigate the safety, tolerability and full pharmacokinetic profile of an exenatide implant in obese or overweight individuals.

On March 13, 2025, the Company announced the successful administration of its first GLP-1 (exenatide) implant in the LIBERATE-1 clinical trial. This milestone marked a critical step toward addressing one of healthcare's most pressing challenges: medication adherence in metabolic diseases including chronic weight management and type 2 diabetes. The Company also announced full enrollment in the LIBERATE-1 study, which was achieved in just four weeks after enrollment of the first subject, signaling early potential interest for this six-month, subdermal GLP-1 implant.

On August 5, 2025, Vivani announced plans to rapidly advance NPM-139, a novel semaglutide implant, based on promising results from the LIBERATE-1 clinical study and additional positive data from a preclinical study with a semaglutide implant. LIBERATE-1, the first-in-human application of Vivani's proprietary NanoPortal implant technology, demonstrated a positive safety and tolerability profile and encouraging performance data, thus meeting the study's primary objectives. This study provided information on the GLP-1 exposure levels obtained with an exenatide configuration, thereby paving the road for future clinical development of the technology, not only for exenatide implants (NPM-115 and OKV-119), but also for semaglutide implants (NPM-139 and NPM-133) and other applications of NanoPortal technology that the Company may pursue in the future. Vivani also announced new NPM-139 (semaglutide implant) preclinical feasibility data that demonstrated an approximately 20% weight loss with a single implant, which had been maintained for more than six months at the time of the announcement. This new semaglutide data also continues to support the potential for a semaglutide implant with annual dosing. Based on the LIBERATE-1 data supporting the clinical application of the NanoPortal platform technology, and the preclinical weight loss data with a semaglutide implant configuration, Vivani announced plans to prioritize advancement of NPM-139, with clinical development expected to begin in 2026.

On September 4, 2025, Vivani announced plans to initiate a Phase 1 clinical study for the NPM-139 semaglutide implant program in the first half of 2026, pending regulatory clearance, along with high-level details of the anticipated study design. The Company also announced parallel preparations to initiate a Phase 2 clinical study of NPM-139 pending enabling results from the Phase 1 study and regulatory feedback.

Cortigent, Inc.

In December 2022, we contributed our neurostimulation assets and certain liabilities from legacy company Second Sight to Cortigent, our wholly owned subsidiary to advance our pioneering neurostimulation technology. Cortigent had 5,000,000 shares of common stock outstanding, all owned by Vivani. On March 12, 2025, Vivani announced efforts to file a Form 10 with the U.S. Securities and Exchange Commission ("SEC") to support the spin-off of Cortigent into a fully independent, publicly traded company. Vivani announced the filing of the Cortigent Form-10 registration statement on May 29, 2025. The strategic goal of this transaction is to create two focused companies dedicated to driving current and future value in their respective therapeutic areas of expertise.

On August 25, 2023, the Company and Cortigent entered into an Amendment 1 (the "Amendment") to the Transition Funding, Support and Services Agreement dated March 19, 2023 (the "TFSSA"). Pursuant to the TFSSA, Vivani has agreed to advance funds and provide or cause to be provided to Cortigent the services and funding intended to cover salaries and related costs, rent and other overhead in order to permit Cortigent to operate in substantially the same manner as Second Sight prior to the formation of Cortigent. Efforts to support a successful initial public offering of Cortigent ceased in March 2025 and efforts are now focused on a potential spinoff with the filing of a Form 10 registration statement. The TFSSA terminated effective December 31, 2024.If the spinoff is successful, the loan payable from Cortigent to Vivani will be forgiven.

On May 29, 2025, Vivani announced that Cortigent had filed a Form 10 registration statement with the SEC to spin off Cortigent as an independent, publicly traded Nasdaq company. The strategic goal of this transaction is to create two focused companies dedicated to driving current and future value in their respective therapeutic areas of expertise. Vivani's board of directors authorized management to proceed with a plan to spin off its Cortigent neuromodulation business. The spin-off was planned to be completed during fourth quarter 2025, subject to the satisfaction of certain conditions, including, among others, final approval of Vivani's board of directors, receipt of a favorable opinion that the transaction will qualify for non-recognition of gain or loss as a result of receipt of Cortigent shares for U.S. Federal Income Tax purposes, and SEC and Nasdaq approval.

On September 17, 2025, Vivani announced that its board of directors had set a record date for the approved spin-off of Cortigent, Inc. Vivani stockholders holding common stock as of that record date would receive common stock in Cortigent. This record date was withdrawn on October 3, 2025, due to delays arising from the shutdown of the U.S. federal government. Vivani expects to reestablish a new record date as soon as possible.

Okava Pharmaceuticals, Inc.

On April 12, 2025, Vivani entered into an amendment to our License and Supply Agreement with Okava which expanded our ongoing collaboration to include dogs in the development of OKV-119, a long-acting GLP-1 therapy for weight management, type 2 diabetes, and other cardiometabolic conditions.

Liquidity and Capital Resources

Capital Funding

On March 1, 2024, the Company entered into the Securities Purchase Agreement relating to the issuance of 3,947,368 shares of the Company's common stock, par value of $0.0001 per share (the "common stock") and warrants to purchase up to an aggregate of 3,947,368 shares of common stock (the "Warrants"), at a purchase price of $3.80 per share and accompanying warrants in a registered direct offering (the "Offering"). The Warrants have an exercise price of $3.80 per share, are exercisable immediately upon issuance and will expire three years following the date of issuance. Simultaneously, the Company also entered into a placement agency agreement with Maxim Group LLC ("Maxim" and such agreement, the "Placement Agency Agreement," and together with the Securities Purchase Agreement, the "Agreements"), who acted as the sole placement agent for the Offering. The gross proceeds of $15.0 million from the Offering, before paying the placement agent fees and other offering costs, were received on March 5, 2024. In connection with the Securities Purchase Agreement, the Company paid issuance costs of $1.3 million, resulting in net proceeds of $13.7 million. For additional information, refer to Note 7. Equity Securities of the Notes to Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q.-

On April 22, 2024, the Company entered into an Open Market Sale Agreement^{SM} (the "Sales Agreement") with Jefferies LLC ("Jefferies"), under which the Company may offer and sell, from time to time at its sole discretion, shares of the common stock, having an aggregate offering price of up to $75.0 million through Jefferies as its sales agent. Also on April 22, 2024, the Company filed a Registration Statement on Form S-3, which was declared effective on May 3, 2024, including a sales agreement prospectus relating to the offering of up to $75.0 million shares of its common stock in accordance with the Sales Agreement. For additional information, refer to Note 7. Equity Securities of the Notes to Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q. During the three months ended September 30, 2025 the Company incurred no costs and realized no proceeds from issuing common stocks under the Sales Agreement with Jefferies.

On November 8, 2024, the Company entered into a private sale transaction with one of its directors whereby the Company sold an aggregate of 3,968,253 shares of the Company's common stock to the director at a price of $1.26 per share, which was the lower of the closing price of the Company's common stock on Nasdaq or the 5-day average closing price of the Company's common stock on Nasdaq, each immediately prior to the closing date, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction were $5.0 million.

On March 26, 2025, the Company entered into a private sale transaction with an entity affiliated with one of its directors whereby the Company shall sell an aggregate of 7,366,071 shares of the Company's common stock to the entity, in five closings as provided in the purchase agreement, at a price of $1.12 per share, which was the closing price of the Company's common stock on Nasdaq, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction will be approximately $8.25 million.

On May 12, 2025, the Company entered into a private sale transaction with an entity affiliated with one of its directors whereby the Company shall sell an aggregate of 2,912,621 shares of the Company's common stock to the entity, in two closings as provided in the purchase agreement, at a price of $1.03 per share, which was the closing price of the Company's common stock on Nasdaq, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the private sale transaction. The gross proceeds from this private sale transaction will be approximately $3.0 million.

On August 11, 2025, the Company entered into a share purchase agreement with an entity affiliated with one of its directors and another investor whereby the Company shall sell an aggregate of 7,936,507 shares of the Company's common stock to the entity and other investor, in twelve closings as provided in the share purchase agreement, at a price of $1.26 per share, which was the closing price of the Company's common stock on Nasdaq on August 11, 2025, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the share purchase agreement. The gross proceeds from this private sale transaction will be approximately $10.0 million.

On October 26, 2025, the Company entered into a share purchase agreement with an entity affiliated with one of its board of directors for the purchase of an aggregate of 3,703,703 shares of common stock of the Company at a purchase price of $1.62 per share, the last reported sale price of the Common Stock on October 24, 2025. This private placement of Common Stock resulted in gross proceeds of approximately $6.0 million to the Company. Concurrent with the private placement, the Company also entered into a Placement Agency Agreement with ThinkEquity LLC relating to the sale by the Company of 6,000,000 shares of the Company's common stock in a registered direct offering. The gross proceeds from the Registered Offering will be approximately $9.7 million, before placement agent fees and other estimated offering expenses.

Non-Capital Funding

From time to time, we receive grants that help fund specific development programs. Any amounts received pursuant to grants are offset against the related operating expenses as the costs are incurred. Commencing in January 2018, we were awarded a grant from the National Institutes of Health (the "NIH") to fund the "Early Feasibility Clinical Trial of a Visual Cortical Prosthesis". The final year of the grant ended in March 2024, however the NIH issued us a no-cost extension allowing us to utilize the unfunded amount through March 2025. During the nine months ended September 30, 2025 and 2024 total grants offsetting against operating expenses were $0.0 million and $0.2 million, respectively. As of September 30, 2025, we expect $0 will be available to offset future operating expenses.

Liquidity

We have experienced 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. To date, we have financed our working capital requirements through the recurring sale of our equity securities. Our financial statements have been presented on the basis that our business is a going concern and contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

We estimate that currently available cash will provide sufficient funds to enable the Company to meet its planned obligations into 2027. Our ability to continue as a going concern is dependent on our ability to raise additional capital, however, there can be no assurances that we will be able to do so.

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 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 expect our operating expenses to increase significantly as we continue our business operations, particularly as we prepare to initiate additional clinical trials and conduct our other research and development activities. Conducting clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval. We do not expect revenues until we are successful in completing the development and obtaining marketing approval for our products. We expect expenses to increase in connection with our ongoing activities, particularly as we initiate clinical trials, initiate new research and development projects and seek marketing approval for any product candidates that we successfully develop. If we are required to conduct additional nonclinical or clinical activities, or IND-enabling activities, our overall expenditures would increase. In addition, if we obtain marketing approval, we expect to incur significant additional expenses related to sales, marketing, distribution and other commercial infrastructure to commercialize such product. In addition, our product candidates, if approved, may not achieve commercial success. We incur significant costs associated with operating as a public company in a regulated industry.

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

Cash, cash equivalents and restricted cash decreased by $15.7 million from $19.7 million as of December 31, 2024 to $4.0 million as of September 30, 2025. Working capital decreased by $17.1 million from $14.5 million as of December 31, 2024 to negative $2.7 million as of September 30, 2025. We use our cash and cash equivalents and working capital to fund our operating activities.

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 thethree months ended September 30, 2025 compared to those disclosed in our Form 10-K for the year ended December 31, 2024.

Results of Operations

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

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

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

Comparison of the Three Months Ended September 30, 2025 and 2024

Research and development expense. Research and development expense during the three months ended September 30, 2025 was $4.5 million, compared to $4.2 million during the three months ended September 30, 2024. The increase of $0.3 million, or 8%, was primarily attributable to increased research and development expense from our Biopharma division.

General and administrative expense. General and administrative expense during the three months ended September 30, 2025 was $2.2 million, compared to $2.1 million during the three months ended September 30, 2024. The increase of $0.1 million, or 5%, was primarily attributable to increased professional services from our Biopharma division.

Other income, net. Other income, net during the three months ended September 30, 2025 was $0.2 million, compared to $0.3 million during the three months ended September 30, 2024. The decrease of $0.1 million was due to lower interest income.

Comparison of the Nine Months Ended September 30, 2025 and 2024

Research and development expense. Research and development expense during the nine months ended September 30, 2025 was $13.5 million, compared to $11.4 million during the nine months ended September 30, 2024. The increase of $2.1 million, or 18%, was primarily attributable to increased research and development expense from our Biopharma division .

General and administrative expense. General and administrative expense during the nine months ended September 30, 2025 was $7.3 million, compared to $6.8 million during the nine months ended September 30, 2024. The increase of $0.5 million, or 7%, was primarily attributable to increased professional services from both Neurostimulation Division and Biopharma division.

Other income, net. Other income, net during the nine months ended September 30, 2025 was $0.8 million, compared to $0.8 million during the nine months ended September 30, 2024. The change was not significant.

Cash Flows from Operating Activities

During the nine months ended September 30, 2025, we used $17.6 million of cash in operating activities, consisting primarily of a net loss of $20.0 million, partially offset by $0.9 million provided by a net change in operating assets and liabilities, and non-cash items totaling $1.5 million for depreciation and amortization of property and equipment, stock-based compensation and lease expense.

During the nine months ended September 30, 2024, we used $15.0 million of cash in operating activities, consisting primarily of a net loss of $17.4 million, partially offset by $0.7 million provided by a net change in operating assets and liabilities and non-cash items totaling $1.8 million for depreciation and amortization of property and equipment, stock-based compensation and lease expense.

Cash Flows from Investing Activities

Cash used for investing activities during the nine months ended September 30, 2025 and 2024 was $0.9 million and $0.3 million respectively, primarily attributable to the purchase of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities was $2.7 million during the nine months ended September 30, 2025, primarily attributable to $2.6 million from the issuance of common stocks in private financing agreements and $0.1 million net proceeds for the insurance premium loans. For additional information, refer to Note 7. Equity Securities of the Notes to Condensed Consolidated Financial Statements in this quarterly report on Form 10-Q.

Cash provided by financing activities was $14.2 million during the nine months ended September 30, 2024, primarily attributable to a securities purchase agreement with an institutional investor.

Off-Balance Sheet Arrangements

As of September 30, 2025, 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 and short-term certificates of deposits. In general, money market funds are not considered to be subject to interest rate risk because the interest paid on such funds fluctuates with the prevailing interest rate. As of September 30, 2025, our cash equivalents consisted of money market funds deposited at Merrill Lynch and restricted cash as collateral for our lease.

Exchange Rate Sensitivity

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, including our Chief Executive Officer ("CEO") and our Chief Financial Officer ("CFO"), evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. As of September 30, 2025, based on the evaluation of these disclosure controls and procedures, our CEO and CFO have concluded that our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter endedSeptember 30, 2025, that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We are updating our internal control environment to address changes in our risks in financial reporting to accommodate our operating activities, staffing levels, and segregation of duties. Such changes may result in new or reduced controls.

Inherent Limitations on Effectiveness of Controls

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

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

One opposition filed by Pixium Vision SA ("Pixium") was pending in the European Patent Office challenging the validity of a European patent owned by Cortigent. We decided to allow the patent to be abandoned by the EPO, which occurred in February 2025. As a result, this opposition is no longer pending. While this abandonment could impact our ability to protect Cortigent's neurostimulation technology in Europe related to this patent, we do not believe that it will have a material effect on our ability to manufacture and sell our products, or otherwise have a material effect on Cortigent's operations.

As described in the Company's 10-K for the year ended December 31, 2020, the Company had entered into a Memorandum of Understanding ("MOU") for a proposed business combination with Pixium. In response to a press release by Pixium dated March 24, 2021, and subsequent communications between us and Pixium, our Board of Directors determined that the business combination with Pixium was not in the best interest of our stockholders. On April 1, 2021, we gave notice to Pixium that we were terminating the MOU between the parties and seeking an amicable resolution of termination amounts that may be due, however no assurance can be given that an amicable resolution will be reached. We accrued $1,000,000 of liquidated damages as contemplated by the MOU in accounts payable as of March 31, 2021 and remitted that amount to Pixium in April 2021. Pixium indicated that it considered this termination wrongful, rejected the Company's offers, but retained the $1,000,000 payment. On May 19, 2021, Pixium filed suit in the Paris Commercial Court, and currently claim damages of approximately €5.1 million or about $5.6 million. We believe we have fulfilled our obligations to Pixium with the liquidated damages payment of $1,000,000. On December 8, 2022, the Company received notice that the Paris Commercial Court has rendered its judgment, including finding that the Company's termination of the MOU was not valid. In the judgment, the Company was ordered to pay to Pixium the amount of €2,500,000 minus a €947,780 credit for the $1,000,000 already paid for, a net amount payable of approximately €1,552,220. On May 24, 2023, the Company filed an appeal against the judgment from the Paris Commercial Court except in so far as such prior judgment dismissed (i) Pixium's claim for the Company to pay it a sum of €480,693 relating to the alleged time spent by its teams, (ii) Pixium's application to order the Company to pay it a sum of €1,500,000 in respect to alleged loss of opportunity and (iii) deducted the sum of $1,000,000 that we already paid Pixium and which Pixium retained converted into euros at the date of the judgment. Thereafter Pixium filed its brief with Paris Court of Appeal and filed a cross-appeal on January 18, 2024. Meanwhile, the Company received notice that the Paris Commercial Court had opened safeguard proceedings against Pixium by judgment dated October 9, 2023, then in its judgment dated November 13, 2023, converted safeguard proceedings into receivership, and in its judgment dated January 31, 2024, converted Pixium's receivership proceedings to liquidation proceedings, the transfer plan being rejected. As a result, Pixium's liquidator intervened on behalf of Pixium in the pending proceedings before the Paris Court of Appeal and filed its brief on March 21, 2024. The Company filed its brief in reply with the Paris Court of Appeal on April 17, 2024. Proceedings before the Paris Court of Appeal are pending. In parallel, since the Company has failed to enforce the judgment, Pixium has requested the pre-trial judge to strike out the Company's appeal for failure to enforce the judgment. The hearing took place on June 4, 2024, and on October 23, 2024, the pre-trial judge issued his order, striking out Vivani's appeal for failure to enforce the decision. Within two years, Vivani will have to request that the case be reinstated on the court's docket, providing evidence that the judgment has been fully enforced or, at the very least, that an agreement has been reached. Failing this, the appeal proceedings will lapse.

The Company recorded a charge of $1,675,000 for the year ended December 31, 2022, related to this matter but plans to continue its appeal against the preliminary judgment.

On January 26, 2024, Oppenheimer & Co.Inc. ("Oppenheimer") filed a complaint asserting breach of contract and other claims against the Company and a party unrelated to the Company, ThinkEquity LLC (the "Third Party"), arising from a placement agent agreement dated November 5, 2020, executed by and between the Company and Pixium in connection with a proposed business combination transaction with Pixium. The complaint, filed in the Supreme Court of the State of New York, County of New York, Index No. 650421/2024, seeks recovery of no less than $1,625,000 in damages, plus costs and fees. On April 3, 2024, the Company filed a motion to dismiss the complaint. On May 3, 2024, the Third Party filed its own motion to dismiss. On June 12, 2025, the Court granted the Company's motion in part and denied it in part, dismissing all claims except the first cause of action for breach of contract (the "Claim"), and the Court dismissed the complaint as against the Third Party. Oppenheimer and the Company are now commencing discovery on the Claim, which seeks the monetary damages referenced above. Each of the Company and Oppenheimer have filed notices of appeal. The Company has defenses to the Claim and intends to defend itself vigorously, but there can be no assurance as to the outcome of the litigation.

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

Item 1A. Risk Factors

Our business is subject to numerous material and other risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Form 10-Q, including our consolidated financial statements and the related notes, and in our other filings with the SEC. If any of the stated risks actually occur, our business, prospects, operating results, and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment. The material risks associated with our business were most recently discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 that we filed on March 31, 2025.There have been no material changes from the risk factors previously disclosed in such filing, expect as noted below:

Risks Related to Our Financial Position and Need for Additional Capital

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that can take 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 or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. For example, on June 13, 2024, the FDA lifted the full clinical hold that they had implemented on the LIBERATE-1™ study on August 18, 2023 and cleared the LIBERATE-1 Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of NPM-119 (exenatide implant) in development for the treatment of type 2 diabetes. We subsequently revised the LIBERATE-1 study, study population and study location, and on September 26, 2024, we received regulatory approval to initiate the revised LIBERATE-1 study of NPM-115 (exenatide implant) in obese and overweight patients in Australia. Additionally, on August 5, 2025, we announced a strategic transition to prioritize and accelerate the development of NPM-139 (semaglutide implant) and reported results from the LIBERATE-1 Phase 1 study of NPM-115 (exenatide implant). On September 4, 2025, we announced plans to initiate a Phase 1 clinical study of NPM-139 (semaglutide implant) in the first half of 2026, pending regulatory clearance. 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 candidates. We are not permitted to market or promote any product candidates 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.

General Risk Factors

Our business, results of operations and future growth prospects could be materially and adversely affected by global economic and political developments, including inflation and capital market disruption, global geopolitical disruptions, including various armed conflicts, economic sanctions and economic slowdowns or recessions, potential global health crises, or the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we may conduct business.

Any global financial crisis or slowdown could cause volatility and disruptions in the capital and credit markets. Similarly, any global health epidemic could cause disruptions in our operations and in the operations of third-party manufacturers, CROs, and other third-parties on whom we rely. More recently, the global economy has been impacted by increasing interest rates and high inflation, as well as by global geopolitical disruptions, including various armed conflicts. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, or at all. Additionally, a weak or declining economy or international trade disputes could strain our suppliers, some of whom are located outside the United States, potentially resulting in supply disruption. Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third-parties on which we rely. We cannot precisely determine or quantify the lingering impact the COVID-19 pandemic, or the future outbreak of any other highly infectious our contagious diseases, will have on our business operations in the future, which will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate geographic spread of the disease, the duration, scope and severity of the pandemic, the duration and extent of travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and the pandemic. In addition, the short and long-term implications of military conflict, including the Russia's invasion of Ukraine and/or 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.

We face risks associated with tariffs and other trade restrictions, which may have a material adverse impact on our results of operations and financial condition.

We face risks related to tariffs and other trade protection measures – including those that have been or may be imposed by the United States or other countries – as well as import or export licensing requirements, trade embargoes, sanctions (including those administered by the U.S. Department of the Treasury's Office of Foreign Assets Control), and other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade). These risks include protectionist or retaliatory measures that may limit or complicate the sourcing of raw materials, equipment, and other components critical to our research and development activities.

The United States has recently imposed significant tariffs on a range of imported goods, including a baseline tariff of 10% and higher rates targeting specific countries. In response, several countries have enacted retaliatory measures, and the situation remains unpredictable. While pharmaceutical end-products are currently excluded from certain tariffs, many of the raw materials, active pharmaceutical ingredients (APIs), and other components used in the development and production of our product candidates may be subject to such tariffs. In addition, the U.S. Department of Commerce has initiated a Section 232 investigation to assess the national security implications of pharmaceutical and API imports. The outcome of this investigation could result in additional trade restrictions, including tariffs, consistent with ongoing efforts to reshore pharmaceutical manufacturing. Further, the United States and the European Union have announced the framework of a trade agreement that could impose a 15% tariff on most imports from the EU, including pharmaceutical products and inputs. However, the details of this trade agreement remain uncertain, including whether and to what extent such agreement may be impacted by the results of the Section 232 investigation.

We may face increased costs and operational disruptions if existing or future tariffs are applied to materials or components used in the development and production of our product candidates. These risks also extend to indirect effects, such as retaliatory tariffs imposed by other countries or additional non-tariff trade barriers. As a result, our research and development activities, production timelines, and overall financial condition could be materially adversely affected.

Disruptions at the FDA, the SEC and other government agencies caused by reduction in staffing, funding shortages or global health concerns 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 staffing levels, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund R&D activities is subject to the political process, which is inherently fluid and unpredictable. The Trump Administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the SEC and the FDA. Any such reduction in personnel may result in longer review times by the FDA or SEC.

Disruptions and personnel turnover, as a result of leadership changes, staff reductions or otherwise, at the FDA and other government agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition to the potential reduction in staffing, a government shutdown could adversely affect the FDA review process. Over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, 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.

Similar consequences would also result in the event of another significant shutdown of the federal government. Currently, federal agencies in the U.S. are operating under a federal government shutdown due to the expiration of the continuing resolution on September 30, 2025. The duration of the current government shutdown is unknown. In addition, the current U.S. administration is focused on reducing costs of the federal government generally, including significantly reducing the number of government employees. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could materially adversely affect our business, financial condition, results of operations and prospects. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact Vivani's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. If the FDA is constrained in its ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. For more information, see the section of titled "*Business – Healthcare Laws and Regulations – Healthcare Reform & the Patient Protection and Affordable Care Act*" in the Annual Report on Form 10-K for the year ended December 31, 2024.

For example, the Medicare Drug Price Negotiation Program, administered by CMS as part of the Inflation Reduction Act of 2022, commonly referred to as the IRA, may apply to our products if they are selected for negotiation, which could materially reduce the amount of revenue we can generate from our products if they are approved. Prior to the enactment of the One Big Beautiful Bill Act of 2025 ("OBBBA"), orphan drugs were exempt from Medicare price negotiation under the IRA only if they had received a single orphan designation and were approved solely for the corresponding rare disease or condition. The OBBBA amended this exemption to apply more broadly: now, any orphan-designated drug is exempt from price negotiation, regardless of the number of orphan designations it has received, provided the drug's approved indications are exclusively for those rare diseases. The OBBBA also included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our future product candidates or business is unknown, any decrease in the number of insured patients or reimbursement levels for our products could adversely affect our potential for revenue and our commercial prospects.

In addition, multiple executive actions in the first half of 2025 signal the federal government's increasing focus on lowering prescription drug prices, adding to the uncertainty surrounding future drug pricing and reimbursement frameworks. For example:

- On May 12, 2025, President Trump signed the executive order titled "Delivering Most-Favored-Nation Prescription Drug Pricing," which directs the Secretary of Health and Human Services ("HHS") to identify and communicate most-favored-nation price targets for prescription drugs and to propose a rulemaking plan to impose such pricing if "significant progress" is not made. The order also directs the federal government to explore regulatory pathways that would facilitate direct-to-patient sales for manufacturers that meet these price targets. Additionally, it signals potential further action against manufacturers that fail to offer most-favored-nation pricing, including evaluating whether to modify or rescind marketing approvals or allow individual drug importation waivers. In July 2025, President Trump sent letters to pharmaceutical companies demanding further reduced prices more in line with most-favored-nation pricing. On September 30, 2025, the White House announced the first MFN agreement (Pfizer), and reports indicate additional negotiations are ongoing. The scope, timing, and ultimate impact of any further actions or agreements remain uncertain. Further, in September and October 2025, multiple drug manufacturers announced plans to, for certain of their drugs, lower prices to reflect similar pricing around the world, and to sell these reduced-price drugs on a direct-to-consumer purchasing platform that is yet to be developed by the federal government.

- Previously, on April 15, 2025, President Trump issued the executive order "Lowering Drug Prices by Once Again Putting Americans First," which contains a broad set of directives aimed at reducing drug costs. Among other actions, the order directs HHS to revise guidance under the Inflation Reduction Act ("IRA") to eliminate the so-called "pill penalty," which currently subjects small molecule drugs to Medicare price negotiation four years earlier than biologics. The order also calls for a comprehensive evaluation of the role played by pharmacy benefit managers ("PBMs") in drug pricing and market access.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

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

On August 11, 2025, the Company entered into a share purchase agreement with an entity affiliated with one of its directors and another investor whereby the Company shall sell an aggregate of 7,936,507 shares of the Company's common stock to the entity and other investor, in twelve closings as provided in the share purchase agreement, at a price of $1.26 per share, which was the closing price of the Company's common stock on Nasdaq on August 11, 2025, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock that occur after the date of the share purchase agreement. The gross proceeds from this private sale transaction will be approximately $10.0 million.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(c) *Rule 10b5-1 Trading Plan Disclosure*

No Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements were adopted, modified, or terminated by officers or directors of the Company, nor were there any material changes to the procedures by which security holders may recommend nominees to the Company's Board of Directors, during the quarter ended September 30, 2025.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Exhibit Description
2.1	Agreement and Plan of Merger by and among Second Sight Medical Products, Inc. and Nano Precision Medical, Inc., dated February 4, 2022 (incorporated by reference to Exhibit 2.1 in the Registrant's Current Report on Form 8-K filed with the SEC on February 8, 2022).
3.1	Certificate of Incorporation of Vivani Medical, Inc., filed with the Secretary of State of Delaware and effective, July 6, 2023 (incorporated by reference to Exhibit 3.1 in the Registrant's Current Report on Form 8-K filed with the SEC on July 10, 2023).
3.2	Bylaws of Vivani Medical, Inc. effective July 6, 2023 (incorporated by reference to Exhibit 3.2 in the Registrant's Current Report on Form 8-K filed with the SEC on July 10, 2023).
10.1	Share Purchase Agreement, dated August 11, 2025, between the Registrant and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 13, 2025).
31.1*	Certification of Principal Executive Officer of Vivani Medical, Inc. pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial and Accounting Officer of Vivani Medical, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certifications of Principal Executive Officer and Principal Financial and Accounting Officer of Vivani Medical, Inc. pursuant to Rule 13a-14(b) under the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instant Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

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

Name	Title	Date
/s/ Adam Mendelsohn Adam Mendelsohn	Chief Executive Officer (Principal Executive Officer)	November 13, 2025
/s/ Anthony Baldor Anthony Baldor	Chief Financial Officer (Principal Financial and Accounting Officer)	November 13, 2025

Exhibit 31.1

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

I, Adam Mendelsohn, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 13, 2025

/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, Anthony Baldor, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 13, 2025

/s/ Anthony Baldor
Anthony Baldor
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 Anthony Baldor, 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 thenine months ended September 30, 2025, 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, 2025

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

/s/ Anthony Baldor
Anthony Baldor
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.