UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2026

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)*

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, 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, 2026, the registrant had 90,203,356 shares of common stock, par value $0.0001 per share outstanding.

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

FORM 10-Q
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical fact contained in this Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "project," "continue," "potential," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements about:

- our anticipated operating and financial performance, business plans, and prospects;
- expectations for our products, including anticipated regulatory submissions, study completion, approvals, clinical trial results and other developing data that become available, potential market size, and potential reimbursement pathways;
- the timing and likelihood of, and our ability to obtain and maintain, regulatory clearance of our Investigational New Drug ("IND") applications for and regulatory approval of our product candidates;
- our ability to successfully scale manufacturing operations in a manner that enables us to complete our clinical trials and, if our product candidates are approved, to meet commercial demand;
- our ability to create and maintain a pipeline of product candidates;
- our ability to advance any product candidate into, and successfully complete, clinical trials;
- our ability to initiate and successfully maintain operations of our subsidiary in Australia, including with respect to studies of our products and product candidates;
- the initiation, timing, design, progress and results of our clinical trials, and our research and development program;
- the anticipated receipt of proceeds from our tranched financings, including our ability to meet closing conditions at each closing;
- the success of the business, including future capital expenditures, expenses, synergies, economic performance, indebtedness, financial condition, losses, future prospects, and business strategies for the management, expansion and growth of the company's operations, and other conditions to the successful synergies of the business combination;
- the effect of unfavorable macroeconomic factors resulting from global economic conditions or geopolitical developments, including fluctuating interest rates and inflation and capital market disruptions, changes in governmental agencies, government shutdowns, international tariffs, trade protection measures, public health crises, economic sanctions and potential economic slowdowns or recessions, or similar events that could impact our business;
- the impact of laws and regulations in the United States and foreign countries on various aspects of our operations, including our regulatory and clinical strategy; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

Any forward-looking statements in this Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties, assumptions and other factors described under the "Risk Factors" section and elsewhere in this Form 10-Q, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements as predictions of future events. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

SUMMARY OF RISK FACTORS

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this Form 10-Q. These risks include, but are not limited to, the following:

- We are a clinical-stage company with a limited operating history, and have no products approved for commercial sale.
- We are dependent on the successful design, development, regulatory approval and commercialization of one or more product candidates; there can be no assurance we will achieve any of these objectives.
- Final marketing approval of NPM-139, NPM-133 or any of our other product candidates by the U.S. Food and Drug Administration ("FDA") or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.
- 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.
- Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing our product candidates, and our clinical development efforts may not yield favorable results.
- The commercial success of our product candidates, if approved, depends upon their market acceptance among physicians, patients, healthcare payors, and the medical community.
- We are subject to a multitude of complex manufacturing challenges and risks, including reliance on third parties, any of which could substantially increase our costs and limit supply of our product candidates.
- We may not be able to adequately protect our proprietary or licensed technology.
- We may infringe the intellectual property rights of others, which may prevent or delay our development efforts and prevent us from commercializing or increase the costs of commercializing our product candidates, if approved.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

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

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,591	$ 16,232
R&D tax credit incentive receivable	305	654
Prepaid expenses and other current assets	937	1,012
Total current assets	15,833	17,898
Property and equipment, net	2,763	2,879
Operating lease right-of-use assets, net	15,713	17,230
Restricted cash	892	1,338
Deposits and other assets	109	48
TOTAL ASSETS	$ 35,310	$ 39,393
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,210	$ 1,032
Accrued expenses	1,361	1,736
Litigation accrual	1,790	1,675
Accrued compensation expense	319	365
Lease liability, current portion	1,905	1,794
Total current liabilities	6,585	6,602
Lease liability, noncurrent portion	15,507	17,061
TOTAL LIABILITIES	22,092	23,663
Commitments and contingencies (Note 12)		
STOCKHOLDERS' EQUITY:		
Common stock, par value $0.0001 per share; 300,000 shares authorized; shares issued and outstanding: 90,300 and 76,428 at September 30, 2026 and December 31, 2025, respectively	9	8
Additional paid-in capital	182,110	164,225
Accumulated other comprehensive income	32	30
Accumulated deficit	(168,933)	(148,533)
TOTAL STOCKHOLDERS' EQUITY	13,218	15,730
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 35,310	$ 39,393

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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 5,021	$ 4,519	$ 13,978	$ 13,496
General and administrative	2,511	2,206	7,375	7,250
Total operating expenses	7,532	6,725	21,353	20,746
Loss from operations	(7,532)	(6,725)	(21,353)	(20,746)
Other income, net	282	195	953	770
Net loss	$ (7,250)	$ (6,530)	$ (20,400)	$ (19,976)
Net loss per common share - basic and diluted	$ (0.08)	$ (0.11)	$ (0.24)	$ (0.34)
Weighted average shares outstanding - basic and diluted	90,119	59,711	86,192	59,399

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)

Comprehensive loss	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Net loss	$ (7,250)	$ (6,530)	$ (20,400)	$ (19,976)
Other comprehensive income (loss):				
Foreign currency translation adjustments	-	60	2	93
Comprehensive loss	$ (7,250)	$ (6,470)	$ (20,398)	$ (19,883)

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 Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' 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

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance, January 1, 2026	76,428	$ 8	$ 164,225	$ 30	$ (148,533)	$ 15,730
Issuance of common stock to related party in connection with 2025 Private Sales Transactions, net of issuance costs	5,179	-	5,650	-	-	5,650
Issuance of common stock in connection with 2026 Registered Direct Offering, net of issuance costs	1,689	-	2,174	-	-	2,174
Issuance of common stock to related party in connection with 2026 Private Placement, net of issuance costs	1,351	-	1,997	-	-	1,997
Stock-based compensation expense	-	-	312	-	-	312
Foreign currency translation adjustments	-	-	-	2	-	2
Net loss	-	-	-	-	(6,780)	(6,780)
Balance, March 31, 2026	84,647	8	174,358	32	(155,313)	19,085
Issuance of common stock to related party in connection with 2025 Private Sales Transactions, net of issuance costs	4,763	1	5,938	-	-	5,939
Stock-based compensation expense	-	-	313	-	-	313
Net loss	-	-	-	-	(6,370)	(6,370)
Balance, June 30, 2026	89,410	$ 9	$ 180,609	$ 32	$ (161,683)	$ 18,967
Issuance of common stock to related party in connection with 2025 Private Sales Transactions, net of issuance costs	793	-	1,000	-	-	1,000
Exercise of stock options	97	-	123	-	-	123
Stock-based compensation expense	-	-	378	-	-	378
Net loss	-	-	-	-	(7,250)	(7,250)
Balance, September 30, 2026	90,300	$ 9	$ 182,110	$ 32	$ (168,933)	$ 13,218

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,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (20,400)	$ (19,976)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	387	309
Stock-based compensation	1,003	1,017
Non-cash lease expense	74	153
Gain on derecognition of contract liabilities	(335)	-
Changes in operating assets and liabilities:		
R&D tax credit incentive receivable	349	(411)
Prepaid expenses and other assets	14	1,062
Accounts payable	9	174
Accrued compensation expenses	(46)	14
Accrued expenses	324	57
Net cash used in operating activities	(18,621)	(17,601)
Cash flows from investing activities:		
Purchases of property and equipment	(102)	(899)
Net cash used in investing activities	(102)	(899)
Cash flows from financing activities:		
Issuance of common stock to related party in connection with 2025 Private Sales Transactions, net	12,589	2,593
Issuance of common stock in connection with 2026 Registered Direct Offering, net	2,174	-
Issuance of common stock to related party in connection with 2026 Private Placement, net	1,997	-
Exercise of stock options	123	-
Gross proceeds from insurance premium loan	-	355
Payments on insurance premium loan	(249)	(237)
Net issuance costs in connection with the Sales Agreement	-	(28)
Net cash provided by financing activities	16,634	2,683
Effect of exchange rate changes on cash and cash equivalents	2	93
Net decrease in cash, cash equivalents and restricted cash	(2,087)	(15,724)
Cash, cash equivalents and restricted cash balance at beginning of period	17,570	19,690
Cash, cash equivalents and restricted cash balance at end of period	$ 15,483	$ 3,966
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	$ 271	$ 443

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

VIVANI MEDICAL, INC.
AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements (Unaudited)

Note 1. Organization and Business Operations

Vivani Medical, Inc. ("Vivani," the "Company," "we," "us," "our" or similar terms) is a clinical-stage biopharmaceutical company that develops miniature, ultra long-acting subdermal drug implant candidates utilizing its proprietary NanoPortal™ technology, which is designed to enable reversible, 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.

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 candidate programs. In parallel, Vivani's management team remains committed to enabling further development of its pioneering neurostimulation systems from legacy company Second Sight which are aimed at helping patients recover critical body functions. Vivani subsequently contributed its Second Sight assets and certain liabilities to Cortigent, Inc. ("Cortigent"), its wholly owned subsidiary to advance its pioneering neurostimulation technology.

On July 1, 2026, the Company entered into a merger agreement between Cortigent and a wholly-owned subsidiary of Nasdaq-listed ClearOne, Inc. (Nasdaq: CLRO). In connection with that transaction, ClearOne is pursuing a financing which aims to raise $10 million to $15 million concurrently with the merger's closing.

Liquidity, Capital Resources and Going Concern

Our condensed consolidated 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, and which assumes timely execution for certain of management's plans including the transition of Cortigent to becoming a separate reporting company by the end of the fourth quarter of 2026.

From inception, our operations have been funded primarily through the sales of our common stock and warrants. We are subject to the risks and uncertainties associated with a business that does not generate revenue and that is developing novel biopharmaceutical products, 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 address these conditions, in March 2025, May 2025, and August 2025, we entered into three equity purchase agreements providing for up to $21.2 million of aggregate gross proceeds through 19 tranche closings occurring from August 13, 2025, through July 15, 2026. The final tranche closed on July 15, 2026 and no further proceeds are available under these agreements. 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.

We estimate that our existing cash and cash equivalents will be sufficient to fund our currently planned operations only through the first quarter of 2027. Accordingly, we will require additional capital to fund our operations beyond that period. Our plans include completing the transition of Cortigent to becoming a separate reporting company by the end of the fourth quarter of 2026 and obtaining additional financing. However, there can be no assurance that the transition will be completed within the anticipated timeframe or that additional financing will be available when needed or on acceptable terms. If we are unable to complete the transition or obtain sufficient additional funding, we would need to discontinue Cortigent's operations to preserve our available liquidity.

Our recurring operating losses and negative operating cash flows, together with our existing liquidity and need for additional capital to fund operations beyond the first quarter of 2027, raise substantial doubt about our ability to continue as a going concern for one year after the date these condensed consolidated financial statements are issued. Management's plans described above do not alleviate this substantial doubt.

Note 2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

These interim unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and following the requirements of the U.S. Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. In the Company's opinion, the interim unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of its financial position and its results of operations and cash flows for periods presented. These condensed consolidated financial statements do not include all disclosures required by GAAP and should be read in conjunction with the Company's consolidated financial statements and accompanying notes for the fiscal year ended December 31, 2025, included within its Annual Report on Form 10-K filed with the SEC on March 26, 2026 (the "2025 Form 10-K"). 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 interim unaudited 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 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 financial statements and the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole 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. Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. Significant estimates include those related to assumptions used in valuing equity instruments and stock-based compensation, and the realization of deferred tax assets. 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. The Company's chief operating decision-maker, its Chief Executive Officer, reviews financial information presented for each of its segments. The Company has 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 Cortigent's subsidiary in Switzerland, which was effectively closed in 2025.

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

Significant Accounting Policies

The Company's significant accounting policies are set forth in its audited consolidated financial statements for the year ended December 31, 2025, included within the 2025 Form 10-K.

The Company is eligible to receive a cash refund from the Australian Taxation Office for eligible research and development ("R&D") expenditures under the Australian Research and Development Tax Incentive program (the "Tax Incentive Program"). The Company recognizes the incentive when there is reasonable assurance that the eligible expenditures have been incurred, the amount can be reliably measured, and the Company will comply with all conditions of the program. Amounts earned under the program are recognized as a component of other income, net, in the condensed consolidated statements of operations in the period the eligible expenditures are incurred. Amounts recognized but not yet received are presented as an R&D tax credit incentive receivable in the condensed consolidated balance sheets.

Recently Issued Accounting Pronouncements Not Yet Adopted as of September 30, 2026

In November 2024, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update ("ASU") No. 2024-03 *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (“ASU No. 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 for 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 is currently evaluating the impact of this ASU on its condensed consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU No. 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*. This ASU provides authoritative guidance for the recognition, measurement and presentation of government grants received by a business entity. This ASU is effective for annual reporting periods beginning after December 15, 2028, and interim periods within those annual periods. The guidance can be applied on a modified prospective, modified retrospective, or retrospective approach; early adoption is permitted. The Company is currently evaluating the impact of this ASU on its condensed consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270) - Narrow-Scope Improvements.* This ASU clarifies interim disclosure requirements; it does not attempt to expand or reduce disclosures. ASU 2025-11 also includes a disclosure principle to help entities determine which events since the end of the last annual reporting period are material for disclosure. This ASU is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. The guidance can be applied on a prospective basis, or a retrospective basis for all or any prior periods, and early adoption is permitted. The Company is currently evaluating the impact of this ASU; however, it is not anticipated to have a material impact on its condensed consolidated financial statements.

Note 3. Concentration of Risk

Credit Risk

Financial instruments that subject the Company to concentrations of credit risk consist primarily of cash and money market funds. The Company maintains cash and money market funds with financial institutions that management deems credit worthy, and at times, cash balances may be in excess of Federal Deposit Insurance Corporation (“FDIC”) and Securities Investor Protection Corporation (“SIPC”) insurance limits of $250,000 and $500,000 (including cash of $250,000), respectively.

Foreign Operations

The accompanying interim unaudited condensed consolidated financial statements as of September 30, 2026 and December 31, 2025 include assets amounting to approximately $693,000 and $700,000, respectively, relating to the Company’s operations in Australia. Unanticipated events in foreign countries could disrupt the Company’s 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 the Company has 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 that 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.

The Company determines 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, the Company performs an analysis of the assets and liabilities at each reporting period end.

Cash equivalents, which include money market funds, are the only financial instruments measured and recorded at fair value on the condensed consolidated balance sheets, and are valued using Level 1 inputs. As of September 30, 2026 and December 31, 2025, the Company did not have any Level 1 financial liabilities or any Level 2 or Level 3 financial assets or liabilities measured at fair value on a recurring basis. The Company 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, 2026 and 2025.

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, 2026			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents:				
Money market funds	$ 13,333	$ 13,333	$ -	$ -
Total	$ 13,333	$ 13,333	$ -	$ -

	As of December 31, 2025			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents:				
Money market funds	$ 15,423	$ 15,423	$ -	$ -

Total	$ 15,423	$ 15,423	$ -	$ -

Note 5. Insurance Premium Financing

In September 2025, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance premiums for its professional liability policies. The amount financed was approximately $355,000 and incurred interest at an annual rate of 7.2%. The Company was required to make ten monthly payments of approximately $36,000 through July 2026. The amount had been fully repaid as of September 30, 2026.

Note 6. Selected Balance Sheet Detail

Property and Equipment, Net

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

	September 30, 2026	December 31, 2025
Property and equipment at cost:		
Equipment	$ 2,603	$ 4,161
Furniture and fixtures	380	380
Computer hardware	116	-
Computer software	30	30
Construction in progress	1,103	1,362
Total property and equipment	4,232	5,933
Accumulated depreciation	(1,469)	(3,054)
Property and equipment, net	$ 2,763	$ 2,879

Contract Liabilities

Contract liabilities of $335,000 as of December 31, 2025 were included in accrued expenses on the condensed consolidated balance sheet. This balance represented a reserve established in connection with a contract originally entered into by Second Sight Medical Products, Inc., a predecessor entity, related to a discontinued sales product. The Company could have been required to refund the purchase price of the product to the extent that certain contract provisions were unmet.

During the quarter ended June 30, 2026, the Company determined that the applicable contract provisions had expired and that the Company was no longer legally obligated under the contract. Accordingly, the Company concluded that the obligation was no longer enforceable and derecognized the liability. Because the arrangement relates to a discontinued product and does not reflect revenue from the Company's current operations, the Company recorded the $335,000 derecognition as a gain within other income, net in the interim condensed consolidated statement of operations, rather than as product revenue or as a reduction of operating expenses.

There was no balance of contract liabilities as of September 30, 2026.

Note 7. Equity Securities

The Company is authorized to issue 300,000,000 shares of common stock, par value $0.0001 per share, with 90,300,230 issued and outstanding as of September 30, 2026. In addition, the Company is authorized to issue 10,000,000 shares of preferred stock with none issued as of September 30, 2026.

Open Market 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 its 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 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.

During the nine months ended September 30, 2026, the Company did not issue any shares of common stock pursuant to the Sales Agreement. 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 $27,000.

2025 Private Sales Transactions

During 2025, the Company entered into multiple share purchase agreements with a related party entity affiliated with one of its independent directors and one share purchase agreement with one of its investors (collectively, the "2025 Private Sales Transactions") pursuant to which the Company agreed to sell shares of its common stock in multiple tranche closings at prices equal to the closing price of the Company's common stock on Nasdaq on the respective agreement dates, subject to customary adjustments for reverse and forward stock splits, stock dividends, stock combinations, and similar transactions.

On March 26, 2025, the Company entered into a share purchase agreement with an entity affiliated with one of its independent directors to sell an aggregate of 7,366,071 shares of common stock in five tranche closings at a price of $1.12 per share, representing the closing price of the Company's common stock on Nasdaq on that date. Gross proceeds from this transaction were approximately $8.25 million.

On May 12, 2025, the Company entered into a share purchase agreement with an entity affiliated with one of its independent directors to sell an aggregate of 2,912,621 shares of common stock in two tranche closings at a price of $1.03 per share, representing the closing price of the Company's common stock on Nasdaq on that date. Gross proceeds from this transaction were approximately $3.0 million.

On August 11, 2025, the Company entered into a share purchase agreement with an entity affiliated with one of its independent directors, and with another investor, to sell an aggregate of 7,936,507 shares of common stock in 12 tranche closings at a price of $1.26 per share, representing the closing price of the Company's common stock on Nasdaq on that date. Gross proceeds from this transaction were approximately $10.0 million.

During the nine months ended September 30, 2026, the Company issued 10,735,041 shares of common stock pursuant to the 2025 Private Sales Transactions, generating net proceeds of $12.6 million. All shares issuable under these agreements have been issued, with no further proceeds available thereunder.

2026 Private Placement and Registered Direct Offering

On January 25, 2026, the Company entered into a share purchase agreement with a related party entity affiliated with one of its independent directors for the purchase of an aggregate of 1,351,351 shares of common stock of the Company at a purchase price of $1.48 per share, the last reported sale price of the common stock on January 23, 2026 (the "2026 Private Placement"). This private placement of common stock resulted in net proceeds of approximately $2.0 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 1,689,200 shares of the Company's common stock in a registered direct offering, also at a purchase price of $1.48 per share (the "2026 Registered Direct Offering"). Net proceeds were $2.2 million after giving effect to $325,000 in issuance expenses.

Note 8. Warrants

In 2019, 2020 and 2021, NPM issued common stock and equity classified warrants (collectively, the "unit" or "units") for $3.15 per unit. Outstanding warrants to purchase common stock are shown in the table below and generally expire five years from the date of issuance at $3.15 per share exercise price, split adjusted, are transferable into one share of common stock and may be exercised on a cashless basis. The remaining warrants outstanding that were issued at $3.15 per unit will expire in December 2026, if not exercised sooner.

In connection with a securities purchase agreement entered on March 1, 2024, the Company issued equity classified 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 are exercisable for cash at an exercise price of $3.80 per share and, if exercised in full, could result in aggregate proceeds to the Company of approximately $15.0 million. In the absence of an effective registration statement covering the issuance of the shares underlying the warrants, the warrants may be exercised on a cashless basis in accordance with their terms.

The warrants outstanding as of September 30, 2026 have no intrinsic value.

A summary of warrant activity for the nine months ended September 30, 2026 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, 2025	7,619	$ 3.49	0.9
Issued	-	-	-
Exercised	-	-	-
Forfeited or expired	(2,297)	$ 3.15	-
Warrants outstanding as of September 30, 2026	5,322	$ 3.63	0.4
Warrants exercisable as of September 30, 2026	5,322	$ 3.63	0.4

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. On March 25, 2026, the Company's board of directors adopted and approved an amendment and restatement of the 2022 Plan (the "2022 Amended Plan"). The 2022 Amended Plan was approved by the Company's stockholders at the Annual Meeting on June 24, 2026, increasing the maximum number of shares authorized for issuance under the 2022 Amended Plan to 21,033,333 shares. No other provisions of the 2022 Plan were amended in the 2022 Amended Plan. 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, 2026, 10,360,029 shares of common stock were available for future issuance under the 2022 Amended 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 Amended Plan provides for accelerated vesting if there is a change of control, as defined in the 2022 Amended 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, 2025	8,366	$ 2.23	6.09
Granted	1,346	$ 1.27	
Exercised	(97)	$ 1.27	
Forfeited or expired	(494)	$ 2.22	
Options outstanding, vested and expected to vest as of September 30, 2026	9,121	$ 2.10	6.12
Options exercisable as of September 30, 2026	6,289	$ 2.47	4.97

The estimated aggregate intrinsic value of stock options exercisable as of September 30, 2026 was approximately $0.1 million.

Restricted Stock Units (RSUs)

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

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2025	800	$ 1.15
Granted	293	1.17
Vested and released	-	-
Forfeited or expired	-	-
Outstanding as of September 30, 2026	1,093	$ 1.16

During the nine months ended September 30, 2026, the Company granted 292,500 RSUs. During the nine months ended September 30, 2025 the Company granted 292,500 RSUs. Outstanding RSUs are subject to market conditions which require our closing stock price to equal or 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 anniversaries 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 condensed consolidated statements of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 195	$ 227	$ 497	$ 638
General and administrative	183	49	506	379
Total stock-based compensation expense	$ 378	$ 276	$ 1,003	$ 1,017

As of September 30, 2026, there was $2.5 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, 2026, there was $0.4 million of total unrecognized stock-based compensation expense related to outstanding RSUs that will be recognized over a weighted average period of 1.7 years.

Fair Value Assumptions

Stock Options (Service Vesting)

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2026 and 2025 was $1.02 and $0.91, respectively. The assumptions used in the Black-Scholes model for stock options are as follows:

	Nine Months Ended September 30,	
	2026	2025
Risk-free interest rate	3.76% to 4.41%	3.93% to 4.39%
Expected dividend yield	-%	-%
Expected volatility	100%	100%
Expected term	5.17 to 6.08 years	5.25 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, 2026 and 2025 was valued using a Monte Carlo simulation were as follows:

	Nine Months Ended September 30,	
	2026	2025
RSUs Granted	292,500	292,500
Valuation date stock price	$1.31	$1.03
Risk-free interest rate	4.28%	3.99%
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, the Company considered the two-year vesting period following achievement of the performance condition. Accordingly, the Company's 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 the Company's common stock value starting with its 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 the Company's stock price on a daily basis over the specified period assuming 252 trading days per year. The Monte Carlo simulation for the Particle Swarm Optimization ("PSO") utilized the following assumptions:

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

2. **Consideration of the Performance-Vesting Schedule.** As previously discussed, the Company's publicly traded common share price must equal or exceed the stock price hurdle amount of $3.15 over a three-consecutive-trading-day rolling period on or before the Performance Period End Date. If such performance condition is achieved, one-third of the award shall vest on the Hurdle Achievement Date, one-third of the award shall vest one year following the Hurdle Achievement Date, and one-third 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 the Monte Carlo simulation. For the purposes of calculating the weighted service

period associated with the RSUs, a separate simulation was performed using the Company's cost of equity as the drift rate. 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,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (7,250)	$ (6,530)	$ (20,400)	$ (19,976)
Denominator:				
Weighted average common shares outstanding - basic and diluted	90,119	59,711	86,192	59,399
Net loss per common share, basic and diluted	$ (0.08)	$ (0.11)	$ (0.24)	$ (0.34)

Because 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, 2026 and 2025, 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,	
	2026	2025
Stock options issued and outstanding	9,121	8,406
Unvested restricted stock units issued and outstanding	1,093	800
Warrants to purchase common stock	5,322	7,979
Total	15,536	17,185

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

The Company leases certain office, laboratory, research and development space for its use. Leases with an initial term of 12 months or less are not recorded on the condensed consolidated balance sheets. 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 condensed consolidated statements of operations. The lease agreements do not contain any material residual value guarantees or restrictive covenants. As most of the leases do not provide an implicit rate, the Company used its 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 right-of-use asset and lease liability because 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. During the period ended September 30, 2026, $0.4 million of previously restricted cash was released upon a reduction in the collateral requirements under the letter of credit. Restricted cash was $0.9 million and $1.3 million on the condensed consolidated balance sheets as of September 30, 2026 and December 31, 2025, respectively.

The Company also maintains short-term leases for offices and storage space that are not material, individually or in the aggregate, and are not recorded on the condensed consolidated balance sheets.

On October 1, 2025, the Company entered into a long-term sublease agreement to lease a manufacturing facility that will support, among other activities, Good Manufacturing Practices 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.

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

	Balance Sheet Classification	September 30, 2026	December 31, 2025
Assets			
Non-current assets	Right-of-use assets	$ 15,713	$ 17,230
Liabilities			
Current	Current operating lease liabilities	$ 1,905	$ 1,794
Long-term	Long-term operating lease liabilities	$ 15,507	$ 17,061

Operating lease cost was $0.8 million and $0.8 million during the three months ended September 30, 2026 and 2025, respectively, and $2.4 million and $2.4 million during the nine months ended September 30, 2026 and 2025, respectively.

Variable lease cost, consisting 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, 2026 and 2025, respectively, and $0.4 million and $0.5 million during the nine months ended September 30, 2026 and 2025, respectively.

The following table summarizes a maturity analysis of the Company's lease liabilities showing the aggregate lease payments as of September 30, 2026 (in thousands except weighted average data):

Year Ending December 31,	Amount
2026 (remaining)	$ 815
2027	3,313
2028	3,180
2029	3,156
2030	3,252
Thereafter	9,453
Total lease payments	$ 23,169
Less imputed interest	5,757
Total lease liabilities	$ 17,412
Weighted average discount rate	8.35%
Weighted average remaining lease term	6.84 years

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cash paid for operating lease liabilities	$ 813	$ 710	$ 2,402	$ 2,204

Note 12. Commitments and Contingencies

Indemnification Agreements

The Company maintains indemnification agreements with its directors and officers that may require it 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

The Company contracted with various universities, hospitals, and medical practices to conduct an early feasibility clinical study of Orion which was completed in March 2025, a Phase 1 study of NPM-115 (LIBERATE-1) which was completed in August 2025, and a Phase 1 study of NPM-139 (SLIM-1) which was fully enrolled with all participants dosed in August 2026.

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, 2026 and 2025 were $539,000 and $0, respectively, and during the nine months ended September 30, 2026 and 2025 were $765,000 and $35,000, respectively.

Litigation, Claims and Assessments

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

Pixium

One opposition filed by Pixium Vision SA ("Pixium") was pending in the European Patent Office ("EPO") challenging the validity of a European patent owned by Cortigent. The Company 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 the Company's ability to protect Cortigent's neurostimulation technology in Europe related to this patent, the Company does not believe that it will have a material effect on its ability to manufacture and sell its products, or otherwise have a material effect on Cortigent's operations.

As described in the Company's Annual Report on Form 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 the Company and Pixium, the Company's Board of Directors determined that the business combination with Pixium was not in the best interest of its stockholders. On April 1, 2021, the Company gave notice to Pixium that it was 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. The Company 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 claims damages of approximately €5.1 million or about $5.6 million. The Company believes it has fulfilled its 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 had 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, a net amount payable of approximately €1,552,220. We recorded a charge of $1,675,000 for the year ended December 31, 2022, related to this matter but plan to continue our appeal against the preliminary judgment. 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 the Company 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, because the Company has failed to enforce the judgment, Pixium 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. As of September 30, 2026, the Company adjusted the litigation accrual to $1.79 million to reflect the amount paid on October 1, 2026, with the resulting foreign currency adjustment recognized within other income, net in the condensed consolidated statements of operations. On October 1, 2026, the Company paid the remaining balance of $1,790,000 to reinstate the case on the court's docket and prevent the appeal proceeding from lapsing. On November 2, 2026, the correspondent before the Paris Court of Appeal confirmed that the *Conseiller de la mise en état* had reinstated the appeal, and that the case will now proceed on the merits, as no objection was raised by the liquidator.

Oppenheimer

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 with respect to this matter, 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.

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 Neurostimulation Division. The Company's CODM is its Chief Executive Officer who reviews the Company between Biopharm and Neurostimulation divisions. The Company's primary focus is the Biopharm Division. The Company is pursuing the proposed sale of the Neurostimulation Division described in Note 1. The measure of segment loss is reported on the condensed consolidated statements of operations 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 since the merger of NPM and Second Sight. 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, 2026, the Biopharm Division and Neurostimulation Division incurred segment losses of $6.4 million and $0.9 million, respectively.

During the nine months ended September 30, 2026, the Biopharm Division and Neurostimulation Division incurred segment losses of $18.6 million and $1.8 million, respectively.

As of September 30, 2026, total assets for the Biopharm Division and the Neurostimulation Division were $34.7 million and $0.6 million, respectively.

The following table provides information related to the Company's operating segments based upon the Company's net loss for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,					
	2026			2025		
	Biopharm Division	Neurostimulation Division	Total	Biopharm Division	Neurostimulation Division	Total
Operating expenses:						
Personnel and related expenses	$ 2,927	$ 445	$ 3,372	$ 2,521	$ 296	$ 2,817
Office space rental related expenses	1,001	29	1,030	1,003	54	1,057
Development expenses	1,191	-	1,191	1,083	-	1,083
Professional services and insurance	984	285	1,269	1,201	172	1,373
Depreciation	129	-	129	101	4	105
Other general and administrative expenses	439	102	541	180	110	290
Other (income) expense, net	(280)	(2)	(282)	(237)	42	(195)
Segment net loss	$ 6,391	$ 859	$ 7,250	$ 5,852	$ 678	$ 6,530

	Nine Months Ended September 30,					
	2026			2025		
	Biopharm Division	Neurostimulation Division	Total	Biopharm Division	Neurostimulation Division	Total
Operating expenses:						
Personnel and related expenses	$ 8,175	$ 1,145	$ 9,320	$ 7,580	$ 815	$ 8,395
Office space rental related expenses	3,044	93	3,137	3,143	260	3,403
Development expenses	3,182	-	3,182	3,154	-	3,154
Professional services and insurance	3,202	626	3,828	4,018	638	4,656
Depreciation	387	-	387	299	8	307
Other general and administrative expenses	1,225	274	1,499	563	268	831
Other (income) expense, net	(614)	(339)	(953)	(894)	124	(770)
Segment net loss	$ 18,601	$ 1,799	$ 20,400	$ 17,863	$ 2,113	$ 19,976

Note 14. Subsequent Events

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

Pixium Appeal Reinstatement

On October 1, 2026, the Company paid the remaining judgment balance of $1,790,000 and requested that the Paris Court of Appeal reinstate the Pixium appeal before it would lapse. On November 2, 2026, the correspondent before the Paris Court of Appeal confirmed that the *Conseiller de la mise en état* had reinstated the appeal, and that the case will now proceed on the merits, as no objection was raised by the liquidator.

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

The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors. See "Cautionary Note Regarding Forward-Looking Statements." The consolidated results of operations for the three and nine months ended September 30, 2026 and 2025 are not necessarily indicative of the results that may be expected for any future period. The following discussion should be read in conjunction with the interim unaudited condensed consolidated financial statements and the notes thereto included in Item 1 of this Form 10-Q and the audited consolidated financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2025 (the "2025 Form 10-K") and in conjunction with the "Risk Factors" included in Part II, Item 1A of this Form 10-Q.

Business Overview

We are a clinical-stage biopharmaceutical company that develops miniature, ultra long-acting subdermal drug implant candidates utilizing our proprietary NanoPortal™ technology, which is designed to enable reversible, ultra long-acting, near constant-rate delivery of a broad range of medicines to treat chronic diseases. We use 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) reverse 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 enable patients to maintain continuous and therapeutic drug exposure levels with convenient once or twice-yearly administration while still offering patients the ability to rapidly discontinue GLP-1 drug exposure in patients when cessation of therapy is needed or desired. Reversibility can be an important clinical consideration in certain situations including when a woman becomes pregnant or when patients undergoing surgery have an increased aspiration risk. In addition, NanoPortal aims to minimize fluctuations in patients' drug levels which may improve the tolerability of medicines, including GLP-1 receptor agonists, that produce side effects that are associated with fluctuating drug levels in the blood.

Our emerging portfolio of miniature, ultra long-acting drug implant candidates has the potential to revolutionize the treatment of chronic diseases by directly addressing poor medication adherence and improving drug tolerability in patients, both of which may translate into better health outcomes for patients in the real-world setting. Our lead program, NPM-139, is a miniature GLP-1 (semaglutide) implant designed for once- or twice-yearly administration, currently in development for chronic weight management in obese and overweight patients. NPM-139 achieved encouraging preclinical data in rats showing approximately 20% weight loss, as compared to a control group receiving sham implants, which was maintained for a full year after a single administration. We are also developing NPM-133, a miniature, six-month, GLP-1 (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 developing OKV-119, a GLP-1-based implant in development for chronic weight management and related conditions in companion cats and dogs, 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. We subsequently contributed our Second Sight assets and certain liabilities to Cortigent, Inc. (“Cortigent”), our wholly owned subsidiary, to advance our pioneering neurostimulation technology.

Our main priority is the further development of our miniature, ultra long-acting drug implant candidate programs. In parallel, our management team remains committed to enabling further development of Cortigent’s pioneering neurostimulation systems from legacy company Second Sight which are aimed at helping patients recover critical body functions. To that end, on July 1, 2026, we entered into a merger agreement between Cortigent and a wholly-owned subsidiary of Nasdaq-listed ClearOne, Inc. (Nasdaq:CLRO). In connection with that transaction, ClearOne is pursuing a financing which aims to raise $10 million to $15 million concurrently with the merger’s closing.

On May 22, 2026, the Company entered into an agreement with Novo Nordisk ("Novo") that enables Novo to conduct a non-exclusive internal evaluation of NPM-139 semaglutide implants prepared by Vivani. There are no exclusivity provisions for NPM-139 or the Company's proprietary NanoPortal technology associated with this agreement.

On July 29, 2026, the Company treated the first patient in the SLIM-1 trial of NPM-139 (semaglutide) implant and subsequently completed dosing all patients in the study one week later. We currently anticipate topline data for the trial will be available in the first half of November.

Liquidity and Capital Resources

2025 Private Sales Transactions

During 2025, we entered into multiple share purchase agreements with an entity affiliated with one of our independent directors and one share purchase agreement with one of our investors (collectively, the “2025 Private Sales Transactions”) pursuant to which we agreed to sell shares of our common stock in multiple tranche closings at prices equal to the closing price of our common stock on Nasdaq on the respective agreement dates, subject to customary adjustments for reverse and forward stock splits, stock dividends, stock combinations, and similar transactions. For additional details, see Note 7 to our interim unaudited condensed consolidated financial statements included in Item 1 of this Form 10-Q.

During the nine months ended September 30, 2026, we issued 10,735,041 shares of our common stock pursuant to the 2025 Private Sales Transactions, generating net proceeds of $12.6 million.

2026 Private Placement and Registered Direct Offering

On January 25, 2026, we entered into a share purchase agreement with an entity affiliated with one of our independent directors for the purchase of an aggregate of 1,351,351 shares of our common stock at a purchase price of $1.48 per share, the last reported sale price of the common stock on January 23, 2026. This private placement of common stock resulted in net proceeds of approximately $2.0 million.

Concurrent with the private placement, we also entered into a Placement Agency Agreement with ThinkEquity, LLC relating to the sale of 1,689,200 shares of our common stock in a registered direct offering, also at a purchase price of $1.48 per share. Net proceeds were $2.2 million after giving effect to $325,000 in issuance 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, 2026 and 2025, total grants offset against operating expenses were $0 and $35,000, respectively.

Liquidity

Our condensed consolidated 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 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. We estimate that currently available cash will provide sufficient funds to enable us to meet our planned obligations through the first quarter of 2027. Our ability to operate as planned beyond such date is dependent on our ability to raise additional capital, however, there can be no assurances that we will be able to do so. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date these condensed consolidated financial statements are issued.

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 novel biopharmaceutical product 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 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 that we can generate product revenues, if ever, we anticipate that we will fund our operations through public or private equity sales 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.

Results of Operations

Operating Expenses. We recognize our operating expenses as incurred in two general operational categories: research and development and general and administrative. Our operating expenses also include a non-cash component related to the recognition 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 NIH, 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 income 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, and are net of grants. 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, 2026 and 2025

Research and development expense. Research and development expense during the three months ended September 30, 2026 was $5.0 million, compared to $4.5 million during the three months ended September 30, 2025. The increase of $0.5 million, or 11%, was primarily attributable to an increase in the clinical trial related expense from our Biopharm Division.

General and administrative expense. General and administrative expense during the three months ended September 30, 2026 was $2.5 million, compared to $2.2 million during the three months ended September 30, 2025. The increase of $0.3 million, or 14%, was primarily attributable to an increase in personnel and related expenses from our Neurostimulation Division and our Biopharm Division.

Other income, net. Other income, net during the three months ended September 30, 2026 was $0.3 million, compared to $0.2 million during the three months ended September 30, 2025. The increase of $0.1 million was primarily attributable to amounts recognized under the Australian R&D Tax Incentive Program and higher interest income earned during the period.

Net loss. For the foregoing reasons, we had a net loss of $7.3 million during the three months ended September 30, 2026 compared to $6.5 million during the three months ended September 30, 2025.

Comparison of the Nine Months Ended September 30, 2026 and 2025

Research and development expense. Research and development expense during the nine months ended September 30, 2026 was $14.0 million, compared to $13.5 million during the nine months ended September 30, 2025. The increase of $0.5 million, or 4%, was primarily attributable to an increase in the clinical trial related expense from our Biopharm Division.

General and administrative expense. General and administrative expense during the nine months ended September 30, 2026 was $7.4 million, compared to $7.3 million during the nine months ended September 30, 2025. The increase of $0.1 million, or 1%, was primarily attributable to an increase in personnel and related expenses from our Neurostimulation Division and our Biopharm Division.

Other income, net. Other income, net during the nine months ended September 30, 2026 was $1.0 million, compared to $0.8 million during the nine months ended September 30, 2025. The increase of $0.2 million was primarily attributable to the derecognition of a contract liability previously held by the Neurostimulation Division and amounts recognized under the Australian R&D Tax Incentive Program.

Net loss. For the foregoing reasons, we had a net loss of $20.4 million during the nine months ended September 30, 2026 compared to $20.0 million during the nine months ended September 30, 2025.

Cash Flows from Operating Activities

During the nine months ended September 30, 2026, we used $18.6 million of cash in operating activities, consisting primarily of a net loss of $20.4 million, partially offset by a $0.7 million net change in operating assets and liabilities, and non-cash items totaling $1.1 million.

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 a $0.9 million net change in operating assets and liabilities, and non-cash items totaling $1.5 million for stock-based compensation, lease expense, and depreciation of property and equipment.

Cash Flows from Investing Activities

Cash used for investing activities during the nine months ended September 30, 2026 and 2025 was $0.1 million and $0.9 million, respectively, for the purchase of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities was $16.6 million during the nine months ended September 30, 2026, primarily attributable to net proceeds of $2.2 million from a registered direct offering with a placement agent and $14.6 million from other securities purchase agreements with an affiliate of one of our independent directors and another investor, partially offset by $0.2 million of principal payments for the insurance premium loan.

Cash provided by financing activities was $2.7 million during the nine months ended September 30, 2025, primarily attributable to net proceeds of $2.6 million from securities purchase agreements with an affiliate of one of our independent directors and $0.4 million from insurance premium financing, partially offset by $0.2 million of principal payments for the insurance premium loan, and $28,000 net financing costs associated with the common stock sales in connection with the Sales Agreement.

Recently Issued Accounting Pronouncements Not Yet Adopted as of September 30, 2026

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our interim unaudited condensed consolidated financial statements included in Item 1 of this Form 10-Q.

Recently Adopted Accounting Standards

There were no accounting standards adopted during the nine months ended September 30, 2026, that had a material effect on the Company's condensed consolidated financial statements.

Critical Accounting Policies and Estimates

The following discussion and analysis of financial condition and results of operations is based upon our interim unaudited condensed consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States of America. Certain accounting policies and estimates are particularly important to the understanding of our financial position and results of operations and require the application of significant judgment by our management or can be materially affected by changes from period to period in economic factors or conditions that are outside of our control. As a result, they are subject to an inherent degree of uncertainty. In applying these policies, our management uses their judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical operations, our future business plans and projected financial results, the terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. See Note 2 to our interim unaudited condensed consolidated financial statements included in Item 1 of this Form 10-Q for a more complete description of our significant accounting policies. During the nine months ended September 30, 2026, there were no material changes to our critical accounting policies from those described in the 2025 Form 10-K.

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. 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, 2026, our cash equivalents consisted of money market funds deposited at Merrill Lynch. Separately, we held 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

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports filed or submitted 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 in reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow for timely decisions regarding required disclosure. Due to inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Further, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

As of September 30, 2026, management has concluded that our disclosure controls and procedures were effective based upon testing of our key internal controls.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during or subsequent to the quarter ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

The design of any system of control is based upon certain assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated objectives under all future events, no matter how remote, or that the degree of compliance with the policies or procedures may not deteriorate. Because of its inherent limitations, disclosure controls and procedures may not prevent or detect all misstatements. Accordingly, even effective disclosure controls and procedures can provide only reasonable assurance of achieving their control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

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 outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Pixium

One opposition filed by Pixium Vision SA ("Pixium") in the European Patent Office (the "EPO") challenged 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. Although the abandonment may 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 our annual report on Form 10-K for the year ended December 31, 2020, we 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 our offers, but retained the $1,000,000 payment. On May 19, 2021, Pixium filed suit in the Paris Commercial Court, and currently claims 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, we received notice that the Paris Commercial Court had rendered its judgment, including finding that our termination of the MOU was not valid. In the judgment, we were ordered to pay to Pixium the amount of €2,500,000 minus a €947,780 credit for the $1,000,000 already paid, a net amount payable of approximately €1,552,220. We recorded a charge of $1,675,000 for the year ended December 31, 2022, related to this matter but plan to continue our appeal against the preliminary judgment. On May 24, 2023, we 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 us to pay it a sum of €480,693 relating to the alleged time spent by its teams, (ii) Pixium's application to order us 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 and converted into euros on 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, we 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.

We filed our brief in reply with the Paris Court of Appeal on April 17, 2024. Proceedings before the Paris Court of Appeal are pending. In parallel, because we have failed to enforce the judgment, Pixium requested the pre-trial judge to strike out our 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 our appeal for failure to enforce the decision. As of September 30, 2026, the Company adjusted the litigation accrual to $1.79 million to reflect the amount paid on October 1, 2026, with the resulting foreign currency adjustment recognized within other income, net in the condensed consolidated statements of operations. On October 1, 2026, the Company paid the remaining $1,790,000 balance to reinstate the case on the court's docket and prevent the appeal proceeding from lapsing. On November 2, 2026, the correspondent before the Paris Court of Appeal confirmed that the *Conseiller de la mise en état* had reinstated the appeal, and that the case will now proceed on the merits, as no objection was raised by the liquidator.

Oppenheimer

On January 26, 2024, Oppenheimer & Co. Inc. ("Oppenheimer") filed a complaint asserting breach of contract and other claims against us and an unrelated party with respect to this matter, ThinkEquity LLC (the "Third Party"), arising from a placement agent agreement dated November 5, 2020, executed by and between our 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, we 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 our 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. We and Oppenheimer are now commencing discovery on the Claim, which seeks the monetary damages referenced above. We and Oppenheimer have each filed notices of appeal. We have defenses to the Claim and intend to defend ourselves vigorously, but there can be no assurance as to the outcome of the litigation.

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 condensed consolidated financial statements and the related notes, the disclosures and audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2025 (the "2025 Form 10-K"), and in our other filings with the Securities and Exchange Commission ("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. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements" in this Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Risks Related to Our Financial Position and Need for Additional Capital

We are a clinical-stage company with a limited operating history, and have no products approved for commercial sale.

We are a clinical-stage biopharmaceutical company. In August 2022, we completed a business combination of Second Sight and NPM, to form our current company. Following the business combination, we are focusing primarily on the development of our proprietary NanoPortal technology and the development of miniaturized, subdermal drug implant candidates capable of the long-term delivery of medicine in patients with chronic diseases with high unmet medical need. Our pipeline includes our current product candidates NPM-139, NPM-133 and OKV-119. We have partnered with Okava for the development of product candidate OKV-119. OKV-119 is in development for use in treating cardiometabolic disorders in dogs and cats. None of our drug candidates have been approved for marketing or sale in any country or territory.

As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and we have not yet demonstrated an ability to obtain marketing approval for any of our product candidates or otherwise successfully overcome the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. We have not generated any revenues to date, and we continue to incur significant research and development and other expenses. As a result, we

have not been profitable and have incurred operating losses in every reporting period since our inception. During the nine months ended September 30, 2026 and 2025, we reported net losses of $20.4 million and $20.0 million, respectively, and during the years ended December 31, 2025 and 2024, we reported net losses of $26.6 million and $23.5 million, respectively. We had an accumulated deficit of $168.9 million as of September 30, 2026.

For the foreseeable future, we expect to continue to incur significant and increasing losses as we expand our research and development activities, seek regulatory approvals for our product candidates and begin to commercialize them if they are approved by the FDA or comparable foreign regulatory authorities. Even if one or more of our product candidates complete their clinical development, achieve marketing approval and are commercialized, we may never become profitable.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies in rapidly evolving fields. If one or more of our product candidates receive marketing approval, we also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition.

We do not anticipate generating revenue from product sales for the foreseeable future and may never be profitable.

The viability of our business depends on our ability to generate revenue from product sales. Our current pipeline is focused on the development of our proprietary NanoPortal technology and the development of miniaturized, subdermal drug implant candidates capable of the long-term delivery of medicine in patients with chronic diseases with high unmet medical need. However, we may never be able to develop or commercialize marketable products from our current pipeline or achieve profitability. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is obtained, the accepted price for the product, the acceptance of the product by physicians and patients, the ability to obtain reimbursement at any price and whether we own the commercial rights for that territory. In addition, if the market size for our product candidates is smaller than estimated, the indication or intended use approved by regulatory authorities is narrower than expected, or the target patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable. Even if we achieve profitability in the future, such profitability may not be sustained in subsequent periods.

Our ability to generate revenue and achieve profitability depends significantly on our ability, either independently or in collaboration with third parties, to achieve several objectives, including:

- successful completion of preclinical studies resulting in data that is supportive of advancing to an IND submission;
- successful submission and acceptance of INDs or comparable applications;
- successful initiation of clinical trials;
- successful and timely completion of nonclinical and clinical development of our product candidates;
- establishing and maintaining relationships with contract research organizations (CROs) and clinical sites for the clinical development of our product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing an efficient and scalable manufacturing process for our candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing, and developing new product candidates;
- obtaining, maintaining, and expanding patent protection, trade secret protection and regulatory exclusivity in the United States and target international markets;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing, or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring, and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve or maintain profitability. Any failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, and continue our operations.

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue to 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 or other foreign regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we may not be able to reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate. We are not permitted to market or promote any product candidate before it receives marketing approval from the regulatory authorities. Accordingly, we will need to obtain substantial additional funding in order to continue our operations and pursue our business objectives.

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

Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, preclinical studies, and other related activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates;
- the number and characteristics of the product candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates;
- the cost of commercialization activities if any of our current or future product candidates are approved for sale, including marketing, sales, and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

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

Our ability to utilize our net operating loss ("NOL") carry-forwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code") if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change NOL carry-forwards and other pre-change tax attributes to offset its post-change income may be limited. Past, current and future ownership changes may limit our ability to utilize remaining tax attributes.

As of December 31, 2025, we had federal and apportioned state NOLs and federal and state R&D credit carry-forwards available to offset future taxable income and income taxes as follows (in thousands):

	As of December 31, 2025
Pre TCJA (Tax Cuts and Jobs Acts of 2017) period federal NOL carry-forward, begin expiring 2030	$ 47,353
Post TCJA period federal NOL carry-forward, with no carry-forward limitation	206,727
Total federal NOL carry-forward	$ 254,080
State NOL carry-forward, begin expiring 2030	$ 167,590
Federal R&D tax credit carry-forward, begin expiring in 2036	$ 4,428
State R&D carry-forward, no expiration date	$ 9,048
Reserve for uncertain income tax positions	--

Furthermore, tax losses generated in taxable years ending on or before December 31, 2017 are generally deductible to the extent of the lesser of the NOL carryover for taxable years ending before January 1, 2018 or 100% of the taxable income and are available for 20 years from the period the loss was generated. Tax losses generated in taxable years beginning after December 31, 2017 do not expire but may only be utilized to offset 80% of taxable income annually. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Changes in tax law may adversely affect our business and financial condition.

The laws and rules dealing with U.S. federal, state and local income taxation are routinely being reviewed and modified by governmental bodies, officials and regulatory agencies, including the Internal Revenue Service ("IRS") and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to NOLs and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many changes to tax laws have been made and changes are likely to occur in the future. For example, the July 2025 One Big Beautiful Bill Act made significant changes to U.S. federal tax law. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, that could result in an increase in our or our stockholders' tax liability. Future changes in tax law could have a material adverse effect on our business, cash flow, financial condition or results of operations.

Risks Related to Product Development, Clinical Testing and Commercialization

We are dependent on the successful design, development, regulatory approval and commercialization of one or more of our product candidates, there can be no assurance that we may achieve any of these objectives.

We have spent significant time, money and effort on our proprietary NanoPortal implant technology which will require additional design and development to support our emerging portfolio of drug/device combination product candidates, including NPM-139 (semaglutide implant), NPM-133 (semaglutide implant), and OKV-119 (exenatide implant for companion animals). All of our product candidates will require additional design and development, including further enhancements to our NanoPortal technology, clinical trials as well as further preclinical studies to evaluate their safety, tolerability and pharmacokinetics, and to optimize their formulation. Our product candidates may require significant additional design and testing before advancing to pivotal clinical trials that are designed to generate sufficient safety and efficacy data to support a marketing application. Even if we conduct and complete such testing of our product candidates, there can be no assurance that we will obtain marketing approval for one or more of these candidates. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory approvals will be obtained. Our drug development efforts may not lead to commercially viable products for any number of reasons, including because our product candidates fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities to support marketing approval, or because we have inadequate financial or other resources to advance our product candidates through development and approval processes. If any of our product candidates fail to demonstrate sufficient safety or efficacy data at any time to support their continued development, or we encounter other challenges in the development of our product candidates, we would experience potentially significant delays in, or be required to abandon, development of the product candidate.

We do not anticipate that any of our product candidates will be eligible to receive regulatory approval from the FDA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these product candidates, we may be unable to commercialize them successfully for a variety of reasons, either independently or in collaboration with third parties. These include, for example, the availability of alternative treatments, lack of cost-effectiveness, the cost of manufacturing the product on a commercial scale and competition with other drugs. The success of our product candidates may also be limited by the prevalence and severity of any adverse side effects or the willingness of patients and healthcare providers to use or administer our drug implants. If we fail to develop, obtain approval for and commercialize one or more of our product candidates, our business would be materially and adversely impacted.

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

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

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

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

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

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

Our product candidates may have serious adverse, undesirable or unacceptable side effects that could delay, pause or terminate our clinical trials, or prevent us from obtaining regulatory approval for or commercialize such product candidates. If such side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

Undesirable side effects observed in preclinical studies or clinical trials of our product candidates could interrupt, delay, or halt their development and could result in the denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or adversely affect the marketability of any such product candidates that receive regulatory approval.

Our product candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. Our product candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study, and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug or could be limited to a more restricted patient population. Any risk management program required for approval of our product candidates could potentially have an adverse effect on our business, financial condition, and results of operations.

Undesirable side effects involving our product candidates may have other significant adverse implications on our business, financial condition, and results of operations. For example:

- our collaborators may terminate any development agreements covering these product candidates;
- if any development agreements are terminated, we may determine not to further develop the affected product candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all;
- if we were to later continue the development of these product candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization; and
- we may be subject to product liability or stockholder litigation.

In addition, even if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by such products (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the product, or we may decide to cease marketing and sale of the product voluntarily;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- regulatory authorities may impose conditions under a risk evaluation and mitigation strategy ("REMS"), including distribution of a medication guide to patients outlining the risks of such side effects or imposing distribution or use restrictions and/or requiring special training for prescribers of the product;
- change the way the product is administered, conduct additional clinical trials or preclinical studies regarding the product, change the labeling of the product, or change the product's manufacturing facilities;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to recall or remove such products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates;
- we may fail to secure acceptance of our product candidates from physicians, healthcare payers, patients and the medical community; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

Our efforts to identify and develop product candidates beyond those in our current pipeline may not succeed, and any product candidates that we select for clinical development may not actually begin clinical trials.

We intend to expand our current pipeline of core assets by continuing to advance drug implant candidates from future and ongoing feasibility programs into preclinical and clinical development. However, the process of identifying and developing drug implant candidates is expensive, time-consuming, and unpredictable. Data from our current preclinical programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds that we select for clinical development may not generate sufficient safety and efficacy data that would support advancement into clinical trials or to continue clinical trials that are ongoing. Such findings would potentially impede our ability to maintain or expand our development pipeline. Our ability to identify new drug implant candidates and advance them into preclinical and clinical development also depends upon our ability to fund our research and development operations, and there can be no assurance that additional funding will be available on acceptable terms, or at all.

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

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

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

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

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

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

Results of clinical trials or preclinical studies may not be predictive of the results of later-stage clinical trials, and many product candidates fail to achieve regulatory approval despite showing initial promise in early-stage testing.

The results of preclinical studies of product candidates may not be predictive of the results of clinical trials, and results from early-stage clinical testing may not be replicated in later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. We may experience similar setbacks in our development programs for these or other reasons.

As product candidates are developed through preclinical, early-stage clinical and late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late-stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could make the results of our planned clinical trials or other future clinical trials less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay or prevent approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We may also make assumptions, estimations, calculations and conclusions as part of our analyses of preliminary or topline data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may experience delays in the enrollment of patients in our clinical trials, which would adversely affect our ability to initiate, conduct and complete such trials on our anticipated timelines.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Difficulty or delays in patient recruitment into our trials could result in increased costs, delays in advancing our product development, or termination of the clinical trials altogether. Patient enrollment depends on many factors, including:

- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- identifying and enrolling eligible patients, including those willing to discontinue use of their existing medications;
- the design of the clinical protocol and the patient eligibility and exclusion criteria for the trial;
- safety profile, to date, of the therapeutic candidate under study;
- the willingness or availability of patients to participate in our trials, including due to the perceived risks and benefits, stigma or other side effects of use of a controlled substance;
- perceived risks and benefits of our approach to treatment of indication;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions of the potential advantages of the drug being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient informed consents.

If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which may impair the significance of such results and cause regulatory authorities to require additional testing. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, delay our development timelines or force us to abandon one or more of our programs altogether.

We may experience difficulty identifying, training and/or certifying an adequate number of healthcare professionals to properly implant and, when appropriate, explant our drug implant candidates, which may impair our ability to conduct our clinical trials.

Our drug implant candidates require properly trained healthcare professionals, which may include doctors, nurse practitioners and nurses, for subdermal placement into patients. These healthcare professionals would also be responsible for removal and replacement of a new drug implant candidate. There can be no assurance that sufficient numbers of trained and/or certified healthcare professionals will be available or that the training or certification requirements will not be more burdensome than anticipated. Both factors could lead to difficulties in conducting our clinical trials and impair our development efforts for our product candidates.

If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile, or are demonstrated to be more effective than our own, our commercial opportunity may be reduced or eliminated.

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience, and scientific resources enable us to compete in our industry, we face competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Any product candidates that we develop and, if approved, commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals, and marketing approved products. Some of our competitors in the GLP-1 receptor agonist drug class include companies such as Novo Nordisk, AstraZeneca, and Eli Lilly. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than those of our own, or that would render our product candidates obsolete and non-competitive. Even if we obtain regulatory approval for any of our product candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

We believe that the key competitive factors affecting the viability of product candidates, if approved, are likely to be their efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third-party payors.

Multiple GLP-1 receptor agonist products have been proven effective to reduce cardiovascular morbidity and mortality, including Trulicity® (dulaglutide), Ozempic®/Wegovy® (semaglutide injection), and Victoza® (liraglutide), medical guidelines may recommend preferential use of GLP-1 receptor agonists that have positive cardiovascular morbidity and mortality data in the products approved labeling.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the sales of our product candidates, if approved, could be adversely affected.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered becomes a "listed drug" which can be cited by potential competitors in support of approval of an abbreviated new drug application ("ANDA"). FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidate (and in some cases even this limited bioequivalence testing can be waived by the FDA). Competition from generic equivalents to our product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates.

We are subject to a multitude of complex manufacturing challenges and risks, including reliance on third parties, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated, and subject to numerous risks. For example, the process of manufacturing our product candidates is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, including but not limited to wildfires, earthquakes and floods, power failures and numerous other factors.

In addition, any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls, or other interruptions in the supply of our product candidates. We also may need to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts, or seek costlier manufacturing alternatives.

The commercial success of our product candidates, if approved, depends upon their market acceptance among physicians, patients, healthcare payors, and the medical community.

Even if our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our product candidates, if approved, will depend on several factors, including:

- the effectiveness of our approved product candidates as compared to competitive products;
- adequately trained healthcare professionals willing to administer our product candidates;
- patient willingness to adopt our approved product candidates rather than competitive therapies;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- restrictions on use in combination with other products;
- availability of alternative treatments;
- pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our product candidates and target markets;
- effectiveness of our sales and marketing strategy;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- potential product liability claims.

In addition, the potential market opportunity for our product candidates is difficult to estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of their potential market opportunity. If the actual market for our product candidates is smaller than we expect, the market potential for our product candidates may be limited. If we fail to achieve market acceptance of our product candidates, the viability of our business may be limited.

If we fail to obtain and sustain an adequate level of reimbursement by third-party payors for our product candidates, if approved, potential future sales would be materially adversely affected.

Even if our product candidates receive marketing approval, there will be no viable commercial market without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our product candidates. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan, and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. Third-party payors may also limit the covered indications. Cost-control initiatives could decrease the price that we might establish for products, which could result in product revenues being lower than anticipated. If we are unable to show a significant benefit over existing therapies, Medicare, Medicaid, and private payors may not be willing to provide reimbursement for our product candidates, if approved, which would significantly reduce the likelihood of such product candidates gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety, and tolerability of our product candidates in determining whether to approve reimbursement for such product candidates and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive adequate reimbursement of our product candidates, if approved, from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our product candidates.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that generates cost-effectiveness or health economics data of our product candidates in comparison to other available therapies.

If the prices for our product candidates, if approved, are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our products, our future revenue, cash flows and prospects for profitability will suffer.

Since our product candidates are designed to deliver active medication for up to six months or longer, there may be additional risks associated with the third-party payor's willingness or desire to reimburse the full product cost at the time of purchase. We may develop customized reimbursement practices or policies to address potential concerns from payors if appropriate. There are no assurances that customized reimbursement practices or policies, if needed, will be effective and the potential impact on revenues and profits is difficult to project.

Risks Related to Regulatory Approval and Other Legal and Compliance Matters

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

The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. Any guidance that may result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. In addition, with respect to our current pipeline, we have been granted only one U.S. IND and one Australian human research ethics committee ("HREC") request. We have submitted no NDAs with the FDA or similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our product candidates.

Despite the time and expense invested, and even if we observe promising results from clinical testing of our product candidates, regulatory approval is never guaranteed. In our industry, many companies have experienced significant setbacks when seeking marketing approval from regulatory agencies, despite having generated promising data from clinical testing of their product candidates. For example, the FDA has rejected both original and resubmitted NDAs from Intarcia Therapeutics for its exenatide implant candidate for the treatment of type 2 diabetes. Based on public correspondence from the FDA, the agency asserted that the data submitted in the applications did not show that the product would be safe under the proposed conditions of use and that the methods used in, and the facilities and controls used for, the manufacture, processing, or packing of the product were not shown to be adequate to preserve its identity, strength, quality, and purity. Further correspondence disclosed additional deficiencies, including that data that did not demonstrate adequate device reliability in regard to dose delivery. While we seek to avoid such outcomes in developing our product candidates based on our proprietary NanoPortal technology, there can be no assurance that such product candidates will not experience similar setbacks if and when we apply for regulatory approval. Similar results would significantly jeopardize the approvability of our product candidates that employ the NanoPortal technology.

Any inability to obtain these approvals would prevent us from commercializing our product candidates. The FDA or comparable foreign regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- the FDA could determine that we cannot rely on the Section 505(b)(2) regulatory pathway or other pathways we have selected, as applicable, for our lead product candidate or other product candidates;
- agency officials of the FDA or comparable foreign regulatory authorities may find the data from non-clinical or preclinical studies, chemistry, manufacturing, and controls, and/or clinical trials generated during development is inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our product candidate for any indication;
- the FDA or comparable foreign regulatory authorities may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidate outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for our product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously approved drugs with the same conditions of approval as our product candidate, as applicable;
- the FDA or comparable foreign regulatory authorities may not approve the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacture of our product candidates;
- the FDA or comparable foreign regulatory authorities may audit some or all of our clinical research study sites to determine the integrity of our data and may reject any or all of such data;
- the FDA or comparable foreign regulatory authorities may approve our lead product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- the FDA or comparable foreign regulatory authorities may change their approval policies or adopt new regulations; or
- the FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our lead product candidate.

With respect to our lead program, NPM-139 (semaglutide implant) in development for chronic weight management in obese or overweight individuals, we have consulted the FDA's recent draft guidance document "Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction" issued in January 2025. In addition, we are preparing briefing materials to gain further clarity from the FDA on our proposed NPM-139 development program.

We plan to seek regulatory approval in the United States by filing an NDA under Section 505(b)(2) of the Food, Drug and Cosmetic Act ("FDCA"), which is referred to as the 505(b)(2) pathway. The 505(b)(2) pathway allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. For NPM-139 and NPM-133, we intend to rely on certain information from the Wegovy® and Ozempic® applications, respectively. If we are unable to reference data generated for Wegovy® and/or Ozempic®, additional clinical studies, including a cardiovascular outcomes ("CVOT") study, may be required and would add significant additional costs and a significant delay in our efforts to seek and secure marketing approval. Further, if a CVOT study were conducted, there can be no assurance that the study would generate favorable results and support U.S. registration.

Although we have discussed our intention to use the 505(b)(2) regulatory pathway with the FDA, there can be no assurance that this pathway will be acceptable, and there can be no assurance that the FDA will not require additional testing to support seeking approval in the United States. If the 505(b)(2) regulatory pathway is not available, the costs of development may significantly increase and the projected timeline to approval and launch would be significantly delayed.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials and/or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for the approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions.

Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidate.

We may utilize the 505(b)(2) pathway for the regulatory approval of NPM-139, NPM-133, and, potentially, other of our product candidates. Final marketing approval of any of our product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

We may pursue a regulatory pathway pursuant to Section 505(b)(2) of the FDCA for the approval of NPM-139, NPM-133, and other product candidates, which allows us to rely on existing preclinical and/or clinical data for the drug. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could refuse to file our NDA submissions, request additional information before accepting our submissions for filing or require additional information to sufficiently demonstrate safety and efficacy to support approval.

Final marketing approval of NPM-139 or any of our other product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could refuse to file our NDA submissions, request additional information before accepting our submissions for filing or require additional information to sufficiently demonstrate safety and efficacy to support approval.

In the case of NPM-139, if the FDA does not agree that the 505(b)(2) regulatory pathway is appropriate or scientifically justified for our product candidates, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. Even if we are allowed to pursue the 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Notwithstanding the approval of many products by the FDA pursuant to 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Moreover, the FDA adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's interpretation, the approval of NPM-139 or other of our product candidates may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with NPM-139 or our other product candidates, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Even if we are successful in pursuing the 505(b)(2) regulatory pathway for NPM-139, or other of our product candidates, we cannot assure you that we will receive the requisite or timely approval for commercialization of NPM-139 or other of our product candidates. Although the Section 505(b)(2) pathway allows us to rely in part on the FDA's prior findings of safety or efficacy for approved listed drugs or on published literature for which we do not have a right of reference, the FDA may determine that prior findings by the FDA or the published literature that we believe supports the safety or efficacy of NPM-139 or other of our product candidates is insufficient or not applicable to our application or that additional studies will need to be conducted. To the extent that we are relying on the 505(b)(2) regulatory pathway based on the approval of a listed drug for a similar indication, the FDA may require that we include in the labeling of NPM-139 or another of our product candidates, if approved, some or all of the safety information that is included in the labeling of the approved listed drug. Moreover, even if any of our product candidates are approved via the 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, such as a REMS, which is a risk mitigation plan which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.

Some of our product candidates are drug-device combination products which require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug and device is sought under a single application, there could be delays in the approval process due to the increased complexity of the review process and the lack of a well-established review process and criteria. In the European Union, depending on the nature of the drug-device combination product, an opinion may be required from a notified body on the device element of the product (for single integral products) or from the EMA on the medicinal product element (for medical devices with an ancillary medicinal substance), as part of the approval process for the applicable product. Any issues identified in such opinion or any delays in the provision of such opinion could independently affect our ability to market our combination products in the European Union. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with current Good Manufacturing Practices ("cGMPs") and Quality Management System Regulation ("QMSR") requirements, as applicable. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application ("MAA") on a timely basis and must adhere to good laboratory practices ("GLP"), cGMP regulations, and QMSR regulations enforced by the FDA, the EMA or comparable foreign regulatory authorities through their facilities inspection program. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we plan to oversee the contract manufacturers that we use, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition, and results of operations.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA, the EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product candidate, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially and adversely affected.

Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, and our development efforts would be impaired.

Even if one or more of our product candidates receive regulatory approval in the United States, we may never receive comparable approvals outside of the United States.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among countries and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these risk factors regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to commercialize our product candidates in territories outside of the United States.

Even if any of our product candidates receive regulatory approval, we will be subject to ongoing legal and regulatory compliance requirements, and regulatory agencies may impose post-approval requirements or, under certain circumstances, withdraw such approval. We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval.

Even if one or more of our product candidates receive regulatory approval, the FDA or comparable foreign regulatory authorities may still impose significant restrictions on the indicated uses or marketing of the product candidates or impose ongoing requirements for potentially costly post-approval studies and trials. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to QMSR regulations, cGMP regulations and applicable product tracking and tracing requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, on our company or on any of our collaborators, including requiring withdrawal of the product from the market.

Our product candidates will also be subject to ongoing FDA or comparable foreign regulatory authorities' requirements, including those related to the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our product candidates that are approved for commercialization. If our product candidates fail to comply with applicable regulatory requirements, or there is later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, a regulatory agency may:

- issue FDA Form 483s, warning or untitled letters or other notices of possible violations;
- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- withdraw any regulatory approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations;
- refuse to approve pending applications or supplements to approved applications that we submit;
- recall our products;
- refuse to permit the import or export of products; or
- seize or detain products or require a product recall.

Additionally, under the Food and Drug Omnibus Reform Act of 2022, sponsors of approved drugs must provide six months' notice to the FDA of any changes in marketing status, or for discontinuing or interrupting supply of certain drugs, including the withdrawal of a drug. Failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

The FDA, the EMA and comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA, the EMA and comparable foreign authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign regulatory authorities as reflected in the product's approved labeling. If we receive marketing approval for one or more of our product candidates for any particular indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal, or administrative penalties, and seek fines against us. The FDA, the EMA or comparable foreign regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed, or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition, and results of operations.

Current and future legislation may increase the difficulty and cost of commercializing our product candidates and may affect the prices that we may obtain if our product candidates are approved for commercialization.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict, or regulate post-approval activities and affect our ability to profitably sell any product candidates that obtain regulatory approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we, or any of our collaborators, may receive for any approved products. For more information, see the section titled "*Business-Government Regulation – Healthcare Reform & the Patient Protection and Affordable Care Act"* in the 2025 Form 10-K.

Current and future legislation may increase the difficulty and cost to commercialize our product candidates, if approved, and affect the prices obtained, including changes in coverage and reimbursement policies in certain market segments for our product candidates, which could make it difficult to sell our product candidates, if approved, profitably. Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our product candidates, if approved, profitably.

Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the Affordable Care Act ("ACA"). In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the current administration will impact our business, financial condition, and results of operations. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, which, among other things, created measures for spending reductions by Congress, and automatic reduction to several government programs (including aggregate reductions of Medicare payments to providers, including hospitals and cancer treatment centers), and increased the statute of limitations period for the government to recover overpayments to providers.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. 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 approved;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we will be required to pay; and
- the availability of capital.

We expect that the ACA, the Inflation Reduction Act of 2022, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any product candidates, if approved. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

At the state level, individual states are also increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through Centers for Medicare Services as well as local state Medicaid programs could have a significant impact on our business.

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

The current United States administration is focused on reducing costs of the federal government generally, including significantly reducing the number of government employees at various federal agencies, including the FDA. Currently, most federal agencies in the United States are funded through December 11, 2026. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the United States market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and the acceptance of user fees payments, layoffs, and statutory, regulatory, leadership and policy changes. Average review times at the agency have fluctuated in recent years as a result. If a prolonged government shutdown occurs, if the FDA is required to furlough review staff or necessary employees, if there are substantial leadership or policy changes, or if agency operations are otherwise impacted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. 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, future government shutdowns or other disruptions at the SEC could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Additionally, disruptions at the National Institutes of Health ("NIH") or changes to the NIH's budget may negatively impact our operations and ongoing clinical trials. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Also, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

We may be exposed to product liability risks which could place a substantial financial burden on our business.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing, and marketing of medical products and the subsequent sale of these products. In addition, the use in our clinical trials of pharmaceutical and related products and the subsequent sale of these products may cause us to bear a portion of or all product liability risks. If a products liability claim is brought against us, we will be required to expend significant time and resources in defending against such a claim, and such defense may not ultimately be successful. We currently have clinical trial liability insurance coverage in connection with our ongoing SLIM-1 clinical trial supporting our NPM-139 program. There can be no assurance that we will secure clinical trial liability insurance on commercially reasonable terms or at all. As a result, products liability risks could have a material adverse effect on our business, financial condition, and results of operations.

Our research and development activities involve the use of hazardous materials, which are subject to regulation, related costs and delays and potential liabilities.

Our research and development activities may involve the controlled use of hazardous materials and chemicals. If an accident occurs, we could be held liable for resulting damage, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Additional federal, state, and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations.

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 – Government Regulation – Healthcare Reform & the Patient Protection and Affordable Care Act*" in the 2025 Form 10-K.

Risks Relating to Our Intellectual Property

We may not be able to adequately protect our proprietary or licensed technology.

Our business depends on our ability to protect our proprietary technology. We rely on a combination of trade secret, patent, copyright and trademark laws, and confidentiality, licensing, and other agreements with employees and third parties, all of which offer only limited protection. We may also in-license additional intellectual property rights in the future. We cannot be certain that patent enforcement activities by our current or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that our current or future licensors will allocate sufficient resources or prioritize enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from continuing to license intellectual property that we may need to operate our business.

We plan to seek, through prosecution of patent applications covering our owned technology, adequate patent protection for our proprietary drug technology. If we are compelled to spend significant time, money and resources protecting or enforcing our patents and future patents that we may possess, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition, and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in-license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition, and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our product candidates, if approved.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection for licensed patents, pending patent applications and potential future patent applications and patents could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the United States Patent and Trademark Office (the "USPTO") and various governmental patent agencies outside of the United States in several stages over the lifetime of the applicable patent and/or patent application. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs with respect to our in-licensed patents or patent applications that we may file in the future, our competitors might be able to use our technologies, which would have a material adverse effect on our business, financial condition, and results of operations.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the United States and many jurisdictions outside of the United States is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our product candidates may prevent us from obtaining or enforcing patents relating to these product candidates.

Patents that we currently own or license and patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following:

- the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our own product candidates;
- there can be no assurance that the term of a patent can be extended under the provisions of patent term extensions afforded by United States law or similar provisions in foreign countries, where available;
- the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the market for our product candidates;
- we or our licensors may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;
- if the patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents that we may own that adversely affects the scope of our patent rights;
- a court could determine that a competitor's technology or product does not infringe our licensed patents, or any future patents we may own; and
- the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing. If we encounter delays in our development efforts or clinical trials, the period of time during which we could market our product candidates, if approved, under patent protection would be reduced.

Our competitors may be able to circumvent our licensed patents or future patents we may own by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable, or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our licensed patents, or any future patents we may own, including by filing lawsuits alleging patent infringement by such third parties. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development efforts before it is too late to obtain patent protection. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity, or enforceability. In this regard, third parties may challenge our licensed patents, or any future patents we may own in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

We may not be successful in obtaining or maintaining necessary rights to develop and commercialize our product candidates.

We utilize our NanoPortal technology to develop long-term drug implant candidates that are designed to deliver active compounds to patients. Some of our product candidates may deliver active compounds that are proprietary to one or more third parties. For example, from our current pipeline, NPM-139 delivers an active ingredient that is proprietary to another company, although we do not anticipate submitting an application for marketing approval with NPM-139 until the relevant intellectual property owned by another company has expired. Similarly, in the future, we may develop one or more additional product candidates that utilize active ingredients that are proprietary to another third party. If we advance future programs utilizing compounds that are proprietary to another company for further development, we will need to negotiate and enter into one or more licenses with the relevant third parties in order to conduct such activities. However, there can be no assurance that we can enter into such agreements on commercially reasonable terms or at all.

We may also need to partner, acquire or in-license additional intellectual property in the future with respect to other product candidates. Moreover, we may be unable to acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for our product candidates. We may face competition with regard to acquiring and in-licensing third-party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property rights to us. We also may be unable to acquire or in-license third-party intellectual property rights on commercially acceptable terms or at all.

If we are unable to successfully obtain required third-party intellectual property rights or maintain our existing intellectual property rights, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected.

We may infringe the intellectual property rights of others, which may prevent or delay our development efforts and prevent us from commercializing or increase the costs of commercializing our product candidates, if approved.

Our business depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our product candidates infringe. There also could be patents that we believe are not infringed, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made, and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our product candidates infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our product candidates infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our activities either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our activities, the holders of any of these patents may be able to block our ability to commercialize our product candidates, if approved, unless we acquire or obtain a license under the applicable patents or until the patents expire.

We may not be able to enter into licensing arrangements or make other arrangements on reasonable terms or at all. Any inability to secure licenses or alternative technology could result in delays in the commercialization of our product candidates, if approved, or lead to the prohibition of their manufacture or sale. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition, and results of operations.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates.

We expect to submit NDAs under Section 505(b)(2) of the FDCA for our product candidates. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA enables the applicant to reference published literature for which the applicant does not have a right of reference and the FDA's previous findings of safety and effectiveness for a previously approved drug. For 505(b)(2) NDAs, the patent certification and related provisions of the Hatch-Waxman Amendments apply.

Accordingly, if the applicant relies for approval on the safety or effectiveness on information for a previously approved drug, referred to as a listed drug, the applicant is required to include patent certifications in its 505(b)(2) NDA regarding any applicable patents covering the listed drug. If there are applicable patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and the applicant seeks to obtain approval prior to the expiration of one or more of those patents, the applicant is required to submit a Paragraph IV certification indicating its belief that the relevant patents are invalid or unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Otherwise, the 505(b)(2) NDA cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug.

If we submit any Paragraph IV certification that may be required, we will be required to provide notice of that certification to the NDA holder and patent owner. Under the Hatch-Waxman Amendments, the patent owner may file a patent infringement lawsuit after receiving such notice. If a patent infringement lawsuit is filed within 45 days of the patent owner's or NDA holder's receipt of notice (whichever is later), a one-time, automatic stay of the FDA's ability to approve the 505(b)(2) NDA is triggered, which typically extends for 30 months unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) NDA will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505(b)(2) NDAs and require us to submit traditional NDAs under Section 505(b)(1), which would require extensive data to establish safety and effectiveness of the product for the proposed use and could cause delay and additional costs. In addition, the FDA could reject any future 505(b)(2) application and require us to submit a Section 505(b)(1) NDA or a Section 505(j) ANDA if, before the submission of our 505(b)(2) application, the FDA approves an application for a product that is pharmaceutically equivalent to ours and determines that our product is inappropriate for review through the 505(b)(2) pathway. These factors, among others, may limit our ability to commercialize our product candidates successfully.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on maintaining and protecting our intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming, and inherently uncertain. For example, the United States previously enacted and implemented wide-ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law and included a number of significant changes to U.S. patent law, and many of the provisions became effective in March 2013. However, it may take the courts years to interpret the provisions of the Leahy-Smith Act, and the implementation of the statute could increase the uncertainties and costs surrounding the prosecution of our patents and future patent applications and the enforcement or defense of our licensed and future patents.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all jurisdictions throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the United States, these products may compete with our product candidates in jurisdictions where we do not have any issued or licensed patents and any future patent claims, or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the United States and abroad. For example, China currently affords less protection to a company's intellectual property than some other jurisdictions. As such, the lack of strong patent and other intellectual property protection in China may significantly increase our vulnerability regarding unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

To protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We expect to employ individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, and to date none our employees have been subject to such claims, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of such third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.

Depending upon the timing, duration, and specifics of FDA regulatory approval for our product candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Hatch-Waxman Amendments. In certain instances, the Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an investigational new drug application IND (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method of manufacturing it may be extended. However, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will not be lengthened and third parties, including our competitors, may obtain approval to market competing therapies sooner than we expect. As a result, our revenue from applicable therapies could be materially reduced and our business, financial condition, results of operations, and prospects could be materially harmed.

Risks Related to Our Reliance on Third Parties

Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for supply of the active pharmaceutical ingredients ("API") in our product candidates, and our other drug components, as well as the device components of our drug-device combination product candidates. Our current strategy is to outsource all manufacturing of our product candidates and products to third parties.

We currently engage, or plan to engage, third-party manufacturers to manufacture our product candidates and related supplies and packaging. There is no guarantee that we can maintain our relationships with these manufacturers and we may incur added costs and delays in identifying and qualifying any replacements for such manufacturers. There is no assurance that we will be able to timely secure further needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could impair our ability to commercialize our product candidates.

Reliance on third-party manufacturers entails additional risks, including:

- reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us.

If we do not maintain our key manufacturing relationships or if our third-party manufacturers fail to comply with applicable regulations, we may need to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers and enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA, the EMA and other foreign regulatory authorities.

If any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our product supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Third-party manufacturers may not be able to comply with the regulatory requirements, known as cGMP, applicable to drug-device combination products, including applicable provisions of the FDA's drug cGMP regulations, device quality requirements embodied in the QMSR or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA.

We have limited control over the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMPs and QMSRs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not regard these facilities as satisfactory for the manufacture of our product candidates, we may need to find alternative manufacturing facilities, which could cause significant delays in our operating timelines and would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QMSR requirements. Any failure to comply with cGMP or QMSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with applicable cGMPs and QMSRs. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP or QMSR requirements. Any failure to comply with cGMP or QMSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully perform their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates on the timelines that we anticipate or at all.

We have relied and intend to continue to rely upon third-party CROs, medical institutions, clinical investigators, and contract laboratories to monitor and manage data for our ongoing research and development efforts. Nevertheless, we remain responsible for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our responsibilities. We and our CROs and other vendors are required to comply with cGMP, GCP and GLP, which are a collection of laws and regulations enforced by the FDA, the EMA, and comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of clinical trials, preclinical studies and clinical trial sponsors, principal investigators, preclinical study sites and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated from our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials. We cannot guarantee that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations and QMSR regulations, as applicable. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

We may not be able to enter into arrangements with CROs on commercially reasonable terms, or at all. In addition, our CROs are not our own employees, and except for remedies available to us under our agreements with such CROs, we will not be able to control whether they devote sufficient time and resources to our ongoing research and development activities. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and our development activities will be impaired. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be harmed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition, or results of operations.

Our efforts to seek, secure and maintain partnerships, collaborations or other strategic initiatives with respect to one or more of our programs may not be successful.

As part of our business strategy, we have entered into, and seek to enter into partnerships, collaborations and other strategic initiatives with respect to one or more of our programs, with the goal of maximizing the value of such assets. For example, we have a collaboration with Okava with respect to OKV-119. However, there can be no assurance that these arrangements will yield their intended benefits or that we will receive any return on our efforts and resources invested into these arrangements.

In addition, we may from time to time in the future enter into additional arrangements with biopharmaceutical companies for the development or commercialization of our product candidates. We face significant competition in seeking such transactions with such collaborators. Moreover, collaboration arrangements are complex, and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, and the terms of these arrangements may not be favorable to us. If we collaborate with a third party for development and commercialization of a product candidate, we may be required to relinquish some or all of the control over that product candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable product candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect our business, financial condition, and results of operations.

If we are unable to develop our own commercial organization or enter into agreements with third parties to sell and market our product candidates, if approved, we may be unable to generate significant revenues.

We currently do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing, and distribution of approved products. If any of our product candidates are approved for commercialization, we may be required to develop our sales, marketing, and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force is expensive and time-consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force that we do establish may not be capable of generating sufficient demand for our product candidates, if approved. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, we may be required to relinquish a portion of the revenues from product sales to those third parties. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

Our current and future relationships with investigators, healthcare professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws. Failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

Although we do not currently have any products on the market, our operations may be directly, or indirectly through our prescribers, consultants, customers, and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates for which we obtain marketing approval. For more information, see the section titled "*Business – Government Regulation – Healthcare Laws & Reimbursement"* in the 2025 Form 10-K.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If we are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, reputational harm, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, and individual imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Ownership of Our Common Stock

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of December 31, 2025, our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 45.4% of our common stock. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

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

Our current company resulted from the business combination of Second Sight and NPM, completed in August 2022. Our main priority is the further development of our lead programs NPM-139 and NPM-133, which are miniature, 6-month, GLP-1 implant candidates for the treatment of chronic weight management and patients with type 2 diabetes, respectively. In parallel, our management team remains committed to identifying and exploring strategic options for our Neurostimulation Division (formerly Second Sight) that will enable further development of its pioneering neurostimulation systems to help patients recover critical body functions.

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

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. In addition, any future debt financing arrangement we enter into may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

The designation of our common stock as "penny stock" would limit the liquidity of our common stock.

Our common stock may be deemed a "penny stock" (as that term is defined under Rule 3a51-1 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) in any market that may develop in the future. Generally, a "penny stock" is a common stock that is not listed on a securities exchange and trades for less than $5.00 a share. Prices often are not available to buyers and sellers and the market may be very limited. Penny stock in start-up companies is among the riskiest equity investments. Broker-dealers who sell penny stock must provide purchasers with a standardized risk-disclosure document prepared by the SEC. The document provides information about penny stock and the nature and level of risks involved in investing in the penny stock market. A broker must also provide purchasers with bid and offer quotations and information regarding broker and salesperson compensation and make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser's written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. If our common stock is deemed "penny stock", because of penny stock rules, there may be less trading activity in any market that develops for our common stock in the future and stockholders are likely to have difficulty selling their shares.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our common stock.

The Financial Industry Regulatory Authority ("FINRA") has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, they may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

The market price of our common stock may be highly volatile, and may be influenced by numerous factors, some of which are beyond our control.

The market price for our common stock may from time to time fluctuate substantially due to a variety of factors, including market perception of our ability to meet our growth projections and expectations, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our business and the business of others in our industry. In addition, the stock market itself is subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons related and unrelated to their operating performance and could have the same effect on our common stock. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of clinical trials of our product candidates;
- the timing of the release of results of our clinical trials;
- results of clinical trials of our competitors' products;
- safety issues with respect to our products or our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

General Risk Factors

If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, our ability to conduct our business will be impaired.

Our business depends on our ability to attract, retain, and motivate highly qualified management and scientific personnel. However, competition for qualified personnel is intense. We may not be successful in attracting qualified personnel to fulfill our current or future needs and there is no guarantee that any of these individuals will join our company. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our product candidates, and may have difficulty in meeting our obligations as a public company. We currently do not maintain "key person" insurance on any of our employees.

In addition, competitors and others are likely in the future to attempt to recruit our employees. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management, and other technical personnel, could materially and adversely affect our business, financial condition and results of operations. In addition, the replacement of key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives.

From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to our company. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us.

We will need to increase the size of our organization and may not successfully manage our growth.

We are an early-stage biopharmaceutical company with a relatively small number of employees, and our management systems currently in place are not likely to be adequate to support our growth in the future. Our ability to grow and to manage that growth effectively will require us to hire, train, retain, manage, and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems, it could have a material adverse effect on our business, financial condition, and results of operations.

Our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations (collectively, the "Trade Laws") prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Our business is heavily regulated and therefore involves significant interaction with public officials. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"). We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. In particular, our operations will be subject to FCPA, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government-owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could also result in prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), our management is required to annually report upon the effectiveness of our internal control over financial reporting. If we lose our status as a "smaller reporting company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. As we grow, we expect to hire additional personnel and may utilize external temporary resources to implement, document and modify policies and procedures to maintain effective internal controls. However, it is possible that we may identify significant deficiencies and/or material weaknesses in our internal controls. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Although we have determined that our internal control over financial reporting was effective as of December 31, 2025, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We will continue to incur increased costs as a result of being a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), was enacted. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced coverage or incur substantially higher costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a smaller reporting company and for as long as we remain a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including the ability to present only the two most recent fiscal years of audited financial statements in our annual reports on Form 10-K, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our registration statements, if applicable, and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We are a "smaller reporting company" and may continue to be a "smaller reporting company" until (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million as of the prior June 30.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. In 2023, a number of banks were placed into receivership. Even though we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors affecting the financial services industry or economy in general, such as these recent bank failures. These factors could also include, among others, liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry and the supervision thereof. In addition, investor concerns regarding the United States or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, which could have a material adverse effect on our liquidity and on our business, financial condition or results of operations.

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 what impact a future outbreak of any highly infectious or contagious disease will have on our business operations in the future, which will depend on a variety of factors and future developments and are highly uncertain and cannot be predicted with confidence. In addition, the short and long-term implications of military conflict, including recent U.S. and Israeli actions in Iran and Lebanon, 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 these and other conflicts and related actions 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. To the extent the wars in Iran, 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, 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 European Union, 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.

Rising inflation rates could negatively impact our expenses.

Inflation rates, particularly in the United States, have increased recently to levels not seen in years. Increased inflation may result in increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

We depend on sophisticated information technology systems and data processing to operate our business. If we experience security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, we may face costs, significant liabilities, harm to our brand and business disruption.

We rely on information technology systems and data processing that we and our service providers, collaborators, consultants, contractors or partners operate to collect, process, transmit and store electronic information in our day-to-day operations, including a variety of personal data, such as name, mailing address, email addresses, phone number and potentially clinical trial information. Additionally, we, and our service providers, collaborators, consultants, contractors or partners, do or will collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect and share personal information, health information and other information to host or otherwise process some of our anticipated future clinical data and that of users, develop our products, to operate our business, for clinical trial purposes, for legal and marketing purposes, and for other business-related purposes. Our internal computer systems and data processing and those of our third-party vendors, consultants, collaborators, contractors or partners, including future CROs may be vulnerable to a cyber-attack (including supply chain cyber-attacks), malicious intrusion, breakdown, destruction, loss of data privacy, denial-of-service attacks (such as credential stuffing), business email compromises, attacks enhanced or facilitated by artificial intelligence, wrongful intrusions, and data breaches, social engineering (including phishing), ransomware attacks, actions or inactions by our employees or contractors that expose security vulnerabilities, theft or destruction of intellectual property or other confidential or proprietary information, business interruption or other significant security incidents. As the cyber-threat landscape evolves, these attacks are growing in frequency, level of persistence, sophistication and intensity, and are becoming increasingly difficult to detect. In addition to traditional computer "hackers," threat actors, software bugs, malicious code (such as viruses and worms), wrongful conduct by insider employees or vendors, employee theft or misuse, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). These risks may be increased as a result of any lingering effects or impacts from the COVID-19 pandemic, owing to an increase in personnel working remotely and higher reliance on internet technology. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period.

While we have not directly experienced any material system failure, accident or cybersecurity incident or breach to date, like others in our industry, we and our vendors have, and may in the future continue to experience, threats and cybersecurity incidents and other attempts to disrupt or gain unauthorized access to our and our third-party vendors' information systems. There can be no assurance that we, our service providers, collaborators, consultants, contractors or partners will be successful in efforts to detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks or breaches of systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data. Attempts to disrupt or gain unauthorized access to our and our third-party service providers' information systems from malicious third parties or insider threats may incorporate widely varying and frequently changing tactics, which may be enhanced or facilitated by AI. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach. Any failure by us or our service providers, collaborators, consultants, contractors or partners to detect, prevent, respond to or mitigate security breaches or improper access to, use of, or inappropriate disclosure of any of this information or other confidential or sensitive information, including patients' personal data, or the perception that any such failure has occurred, could result in claims, litigation, regulatory investigations and other proceedings, significant liability under state, federal and international law, and other financial, legal or reputational harm to us. Further, such failures or perceived failures could result in liability and a material disruption of our development programs and our business operations, which could lead to significant delays or setbacks in our research, delays to commercialization of our product candidates, lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flow. For example, the loss or alteration of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Additionally, applicable laws and regulations relating to privacy, data protection or cybersecurity, external contractual commitments and internal privacy and security policies may require us to notify relevant stakeholders if there has been a security breach, including affected individuals, business partners and regulators. Such disclosures are costly, and the disclosures or any actual or alleged failure to comply with such requirements could lead to a materially adverse impact on the business, including negative publicity, a loss of confidence in our services or security measures by our business partners or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or other data protection obligations related to information security or security breaches.

We may be subject to a range of privacy and data protection laws across jurisdictions, which could present compliance challenges and regulatory risk.

Numerous federal and state laws and regulations govern the collection, use, disclosure, storage and transmission of personal information, including health information. These laws and regulations, including their interpretation by governmental agencies, are subject to frequent change and could have a negative impact on our business. Further, these varying interpretations could create complex compliance issues for us and our partners, potentially expose us to additional expense, liability, and penalties, negatively impact our client relationships, and lead to adverse publicity, and all of these risks could adversely affect our business.

At the federal level, HIPAA regulates "protected health information" (or "PHI") and imposes rigorous privacy and security standards. While we are not a "covered entity" under HIPAA, we may receive PHI from our partners and be bound to protect such PHI in accordance with HIPAA pursuant to our contracts. In addition, we are subject to consumer protection regulation by the U.S. Federal Trade Commission ("FTC") under its authority pursuant to Section 5 of the FTC Act. The FTC has used such authority to require businesses to adhere to reasonable privacy and security practices, and it has placed particular enforcement emphasis on protecting information relating to consumer health. At the state level, a wide range of privacy and security laws may apply to our business. For example, we may be subject to regulation by the California Consumer Privacy Act ("CCPA") and similar state consumer privacy laws, which impose transparency and in some instances consent requirements, as well as granting consumers rights to access, correct, and delete their personal information, and opt out of certain uses and disclosures of such information. We may also be subject to state and federal laws imposing data breach notification requirements and other security standards. State laws regulating certain categories of data or activities, such as Washington's My Health My Data Act, which governs consumer health data, and other state laws regulating biometric data, genetic data, neural data, and electronic eavesdropping may impose similar or more stringent requirements than the CCPA. Some state laws afford consumers a private right of action, and privacy litigation is a growing risk area, particularly in the health sector. Some, but not all, of these laws have carveouts for PHI regulated by HIPAA and health information we collect in the course of clinical trials. However, even the laws that have such carveouts may nonetheless apply to some of our activities, including in our website, marketing, patient recruitment, and engagements with our business partners.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), United Kingdom's GDPR ("UK GDPR") (collectively, the "GDPR"), and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data. We expect that there will continue to be new or amended laws, regulations, standards and obligations proposed and enacted in various foreign jurisdictions. Such laws impose a wide range of requirements on our business, including: (i) providing information to individuals regarding data processing activities; (ii) ensuring a legal basis or condition applies to the processing of personal data and, where applicable, obtaining consent from individuals to whom the data processing relates; (iii) responding to data subject requests; (iv) imposing requirements to notify the competent national data protection authorities and data subjects of personal data breaches; (v) implementing safeguards in connection with the security and confidentiality of the personal data; (vi) accountability requirements; and (vii) taking certain measures when engaging third-party processors. Failure, or even perceived failure, to comply with such requirements may lead to costly investigations, steep administrative penalties, litigation and harm to our reputation. We may also be subject to more damaging remedies, including requirements to delete unlawfully collected data, which could have deleterious effects on our business.

In addition, pursuant to such laws, we may be unable to transfer personal data across international borders in the conduct of our business. In particular, the GDPR and similar laws restrict the transfer of personal data to countries whose privacy laws do not meet similar standards, including the United States, unless a derogation exists or adequate international transfer safeguards are put in place. To date, such laws have permitted transfers to proceed where reasonable safeguards are in place, but such transfers remain the subject to legislative and regulatory debate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. If we are unable to transfer personal data internationally, we could face significant adverse consequences, including by limiting our ability to conduct clinical trial activities outside the U.S., the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business.

Regulators and legislators in the U.S. are also increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

Our use of new and evolving technologies, such as artificial intelligence, may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence ("AI") into our business processes both in our own development and implementation of AI and through the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, environmental harms, and other harms may flow from any development, use, or deployment of AI technologies. If we enable or use solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability.

A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the European Union's Artificial Intelligence Act ("AI Act") is now in effect and is expected to undergo amendments, as introduced in the European Union's November 2025 Digital Omnibus. As enacted, the AI Act imposes significant obligations on providers and deployers of AI systems, and encourages providers and deployers of AI systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines.

In the U.S., the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the current administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued guidance on the use of AI in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to meet various standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The use of certain AI technologies can also give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools.

Our vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. The integration of AI systems, by us or by our vendors, may increase cybersecurity risk. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

We may not be able to complete the proposed merger of Cortigent on the terms anticipated, or at all.

On July 1, 2026 we entered into a merger agreement with Cortigent, ClearOne, Inc. and CLRO Merger Sub, Inc. for the proposed merger of Cortigent and CLRO Merger Sub, Inc. Currently, this approach, and potentially others in the future, are being considered to generate an opportunity for our stockholders to potentially realize value in Cortigent's assets. Completion of this proposed merger will be subject to a number of factors and conditions, and there can be no assurance that the merger will be completed as anticipated, or as currently or potentially proposed, or at all. A failure to complete the merger or similar transaction could negatively affect the price of the shares of our common stock.

The proposed Cortigent merger may not have the benefits we anticipate.

The proposed Cortigent merger may not have the full, or any, strategic and financial benefits that we expect, or such benefits may be delayed or may not materialize at all. The anticipated benefits of the merger are based on a number of assumptions, which may prove incorrect. In the event that the merger does not have expected benefits, the costs associated with the transaction, including an expected increase in operating expenses, could have a negative effect on our financial condition. In addition, we cannot predict the effect of the merger on the trading price of shares of our common stock, and the market value of shares of our common stock may be less than, equal to or greater than the market value of shares of our common stock prior to the completion of the merger.

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

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.
(b) None.
(c) None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Exhibit Description
2.1	Agreement and Plan of Merger dated July 1, 2026 by and among Vivani Medical, Inc., Cortigent, Inc., ClearOne, Inc. and CLRO Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 in the Registrant's Current Report on Form 8-K filed with the SEC on July 7, 2026).
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	Amended and Restated 2022 Omnibus Incentive Plan (incorporated by reference to Annex A in the Registrant's Definitive Proxy Statement on Form DEF 14A filed with the SEC on April 29, 2026)
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 Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101)
*	Filed herewith.
**	This certification will not be deemed "filed" for purposes of Section 18 of 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.

Vivani Medical, Inc.

Date: November 12, 2026

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

Date: November 12, 2026

By: /s/ Anthony Baldor
Chief Financial Officer
(Principal Accounting and Financial Officer)

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 12, 2026

/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 12, 2026

/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 the three months ended September 30, 2026, 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 12, 2026

/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.