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 March 31, 2026

or

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

Commission File Number: 001-43275

MOBIA MEDICAL, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-8573833**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2802 Flintrock Trace, Suite 226
Austin, TX
(Address of principal executive offices)

78738
(Zip Code)

(855) 628-9375
(Registrant's telephone number, including area code)

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value per share	MOBI	The Nasdaq Stock Market LLC

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 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 June 1, 2026, there were 33,249,006 shares of the registrant's common stock, par value $0.01 per share, outstanding.

Mobia Medical, Inc.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our expectations of future results of operations and financial condition, business strategy, solutions, technology, R&D costs, regulatory approvals, potential market opportunity, anticipated trends in our business, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these terms or other similar expressions, are intended to identify forward-looking statements. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- the expected growth of our business and our organization;
- our ability to continue as a going concern;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our expectations regarding the potential market size and size of the potential patient populations for treatment with our Vivistim Paired Vagus Nerve Stimulation System and any future products, if approved for commercial use;
- the expected use of our products by physicians and patients;
- our plans to conduct further clinical trials and patient registries;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or otherwise;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we create;
- our expected uses of the net proceeds from the initial public offering and our existing cash and cash equivalents;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to purchase sufficient quantities from manufacturers of our products with sufficient quality and at an acceptable price;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers;
- our ability to obtain, maintain and enforce intellectual property protection for our products;
- our ability to expand our business into new geographic markets;
- our compliance with extensive exchange requirements and government laws, rules, and regulations both in the United States and internationally;
- our estimates of our expenses, ongoing losses, future revenue, and capital requirements, as well as our need for, or ability to obtain, additional financing, and our future financial performance;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act");
- our ability to identify and develop new and planned products or acquire new products;
- developments and projections relating to our competitors or our industry; and
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in the section titled "Risk Factors" and elsewhere in this Quarterly Report and in other filings we make with the U.S. Securities and Exchange Commission (the "SEC") from time to time. Moreover, we operate in a competitive and rapidly changing environment.

New risks and uncertainties emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Although we believe that the expectations reflected in our forward-looking statements are reasonable based on the information available to us when they are made, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. 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 Quarterly 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 you are cautioned not to unduly rely upon these forward-looking statements. We undertake no obligation to update any forward-looking statements, which speak only as the date they are made, for any reason after the date of this Quarterly Report.

Regulation FD – Channel of Distribution

We periodically post information that may be important to investors on our investor relations website at https://ir.mobia.com. We intend to use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Accordingly, investors and potential investors are encouraged to consult our website regularly for important information, in addition to following our press releases, filings with the SEC and public conference calls and webcasts. The information contained on, or that may be accessed through, our website is not incorporated by reference into, and is not a part of, this Quarterly Report.

Summary Risk Factors

The risk factors summarized and detailed below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. A summary of the material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

- We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we ever achieve profitability, we may not be able to sustain it.
- If we fail to manage our growth effectively, our business could be materially and adversely affected.
- The commercial success of treatment with our Vivistim Paired Vagus Nerve Stimulation ("Paired VNS") System ("Vivistim Therapy") depends upon attaining significant market acceptance of our products by hospitals, healthcare providers, therapists, patients, caregivers and payors.
- Our success depends entirely on our currently marketed Vivistim Therapy. If we are unable to successfully market and sell Vivistim Therapy, our business prospects will be materially and adversely affected, and we may be unable to achieve revenue growth and to fund our operations.
- If we fail to effectively hire, train, and retain our direct sales force, increase our sales capabilities, or develop broad brand awareness in a cost-effective manner, our growth will be materially and adversely affected, and our business will suffer.
- Coverage and adequate reimbursement may not be available or may be subject to change for our Vivistim System, including any future products we commercialize, which could diminish our sales, increase our competition, or affect our ability to sell our currently marketed Vivistim Therapy and any future products profitably.
- We depend on a small number of third-party contract manufacturers and suppliers, some of which are single source, to produce and package all elements comprising our Vivistim Paired VNS System (the "Vivistim System") as well as certain implantation tools, and if these suppliers and manufacturers fail to supply our Vivistim System or its components or subcomponents in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition, and results of operations.
- The size of our market opportunity has not been established with precision and may be smaller than we estimate, possibly materially.

- Adverse events, product recalls, or other complications or customer satisfaction issues associated with Vivistim Therapy, including regarding the finite implanted pulse generator ("IPG") battery life, could limit its adoption.
- We have limited clinical data, evidence and experience regarding the safety and efficacy of Vivistim Therapy.
- If we are unable to maintain existing, and obtain additional, patent and other intellectual property protection for our technology and products, or if the scope of the patent protection we obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- Our products and operations are subject to extensive government regulation and oversight in the United States, and our failure to comply with applicable requirements could materially and adversely affect our business.
- Failure to maintain marketing authorizations for our products, or to timely obtain necessary marketing authorizations for our future products, may have a material and adverse effect on our business, financial condition and results of operations.
- We have identified a material weakness in our internal control over financial reporting.

The risks described above should be read together with the text of the full risk factors described below in the section entitled "Risk Factors" and the other information set forth in this Quarterly Report, including our condensed financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

Mobia Medical, Inc.
Condensed Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	March 31, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 55,725	$ 33,587
Accounts receivable	4,854	4,435
Inventory	6,049	5,457
Deferred offering costs	3,496	935
Other current assets	1,590	1,943
Total current assets	71,714	46,357
Property and equipment, net	738	669
Right-of-use assets — operating leases	1,001	1,068
Other assets	143	55
Total assets	$ 73,596	$ 48,149
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities		
Accounts payable	$ 3,033	$ 2,223
Operating lease liabilities, current	358	358
Product warranty liability	1,029	844
Accrued payroll, commissions, and bonuses	3,113	4,854
Accrued offering costs	2,641	935
Accrued and other current liabilities	1,660	992
Total current liabilities	11,834	10,206
Warrant liabilities	882	865
Notes payable, net of discount and deferred financing costs	7,257	7,130
Convertible notes payable	14,359	—
Convertible notes payable due to related parties	26,369	—
Operating lease liabilities, non-current	870	948
Total liabilities	61,571	19,149
Commitments and contingencies (Note 13)		
Redeemable convertible preferred issuable in series, stock, $0.01 par value, 67,174,403 shares authorized as of March 31, 2026 and December 31, 2025, respectively; 65,591,701 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively; aggregate liquidation value of $182,255 as of March 31, 2026 and December 31, 2025, respectively	179,773	179,773
Stockholders' deficit		
Common stock, $0.01 par value, 86,600,000 shares authorized as of March 31, 2026 and December 31, 2025; 1,003,256 and 884,030 shares outstanding as of March 31, 2026 and December 31, 2025, respectively	10	9
Additional paid-in capital	7,771	7,007
Accumulated deficit	(175,529)	(157,789)
Total stockholders' deficit	(167,748)	(150,773)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 73,596	$ 48,149

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

Mobia Medical, Inc.
Condensed Statements of Operations
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2026	**2025**
Revenue	$ 12,074	$ 5,661
Cost of goods sold	2,133	1,015
Gross profit	**9,941**	**4,646**
Operating expenses		
Research and development costs	1,692	1,354
Selling, general and administrative expenses	25,186	13,596
Total operating expenses	**26,878**	**14,950**
Loss from operations	**(16,937)**	**(10,304)**
Other income (expense)		
Change in fair value of convertible notes payable	(728)	—
Interest expense	(357)	(239)
Other income (expense), net	282	(109)
Total other expense, net	**(803)**	**(348)**
Loss before provision for income tax	**(17,740)**	**(10,652)**
Provision for income tax	—	(1)
Net loss attributable to common stockholders	**$ (17,740)**	**$ (10,653)**
Net loss per share attributable to common stockholders		
Basic	**$ (19.30)**	**$ (12.97)**
Diluted	**$ (19.30)**	**$ (12.97)**
Weighted average shares used to compute net loss per share attributable to common stockholders		
Basic	**918,935**	**821,160**
Diluted	**918,935**	**821,160**

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

Mobia Medical, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(Unaudited)
(in thousands, except share and per share data)

For the three months ended March 31, 2026

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance, December 31, 2025	65,591,701	$ 179,773	884,030	$ 9	$ 7,007	$ (157,789)	$ (150,773)
Net loss	—	—	—	—	—	(17,740)	(17,740)
Exercise of common stock options	—	—	119,226	1	357	—	358
Share-based compensation	—	—	—	—	407	—	407
Balance, March 31, 2026	65,591,701	$ 179,773	1,003,256	$ 10	$ 7,771	$ (175,529)	$ (167,748)

For the three months ended March 31, 2025

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance, December 31, 2024	40,892,855	$ 114,826	776,701	$ 8	$ 5,247	$ (111,291)	$ (106,036)
Net loss	—	—	—	—	—	(10,653)	(10,653)
Issuance of Series F redeemable convertible preferred stock, net of tranche liability of $625,628 and issuance costs of $264,065	11,351,970	28,985	—	—	—	—	—
Related Party Issuance of Series F redeemable convertible preferred stock, net of tranche liability of $54,972 and issuance costs of $23,202	997,453	2,547	—	—	—	—	—
Exercise of common stock options	—	—	65,105	1	210	—	211
Share-based compensation	—	—	—	—	201	—	201
Balance, March 31, 2025	53,242,278	$ 146,358	841,806	$ 9	$ 5,658	$ (121,944)	$ (116,277)

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

Mobia Medical, Inc.
Condensed Statements of Cash Flows
(Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (17,740)	$ (10,653)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	56	31
Share-based compensation	407	201
Change in fair value of convertible notes payable	728	—
Change in fair value of warrant liabilities	16	265
Amortization of debt discount and debt issuance costs	127	9
Changes in operating assets and liabilities		
Accounts receivable	(419)	409
Inventory	(593)	(486)
Other assets	(139)	(104)
Accounts payable	727	1,521
Accrued liabilities and other	(898)	(916)
Net cash used in operating activities	(17,728)	(9,723)
Cash flows from investing activities		
Purchases of property and equipment	(42)	(23)
Net cash used in investing activities	(42)	(23)
Cash flows from financing activities		
Exercise of common stock options	358	211
Proceeds from issuance of convertible notes payable	14,102	—
Proceeds from the related party issuance of convertible notes payable	25,898	—
Proceeds from issuance of Series F redeemable convertible preferred stock, net of issuance costs	—	29,611
Proceeds from the related party issuance of Series F redeemable convertible preferred stock, net of issuance costs	—	2,602
Payment of deferred offering costs	(450)	—
Net cash provided by financing activities	39,908	32,424
Net change in cash and cash equivalents	22,138	22,678
Cash and cash equivalents, beginning of period	33,587	14,620
Cash and cash equivalents, end of period	$ 55,725	$ 37,298
Supplemental disclosures of cash flows information		
Cash paid for interest	$ 230	$ 230

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

Note 1 – Description of Business

Mobia Medical, Inc. (the "Company") was incorporated in Delaware in March 2007. Effective February 23, 2026, the Company amended its articles of incorporation to change its name from MicroTransponder, Inc. to Mobia Medical, Inc. The change was solely a corporate name change and had no impact on the Company's financial statements.

The Company develops, markets, and sells devices for the treatment of medical conditions. The first device brought to market, the Vivistim Paired VNS System ("Vivistim System"), received U.S. Food and Drug Administration premarket approval in 2021 and is intended to be used by chronic ischemic stroke survivors with moderate to severe upper extremity impairments to reduce upper extremity motor deficits and improve motor function. The Vivistim System was first brought to market in 2022, with the first commercial implant in May 2022, and commenced full commercial launch in 2023.

Initial Public Offering – In May 2026, the Company completed its initial public offering ("IPO") in which it sold 10,000,000 shares of its common stock at a public offering price of $15.00 per share, for net proceeds of approximately $134.5 million, after deducting the underwriters' discounts and commissions, and estimated offering costs paid by the Company. In addition, immediately prior to the completion of the IPO, all the outstanding shares of the Company's redeemable convertible preferred stock were converted into an aggregate of 18,831,868 shares of common stock, and the Company's convertible promissory notes issued during the three months ended March 31, 2026 were converted into an aggregate of 3,333,324 shares of common stock.

Risks and Uncertainties – The Company's activities are subject to significant risks and uncertainties, including, but not limited to, failure to manage growth effectively, reliance on the success of the Vivistim System, new technological innovations, dependence upon third-party payers to provide adequate coverage and reimbursement to our customers, the absence of a national coverage determination or local coverage determinations applicable to its device administered by the Centers for Medicare and Medicaid Services (CMS), dependence on key personnel, dependence on key suppliers, protection of proprietary technology, product liability, and compliance with government regulations. The Company is also subject to risks relating to cybersecurity and the protection of confidential information and personal information, as well as risks relating to evolving regulatory requirements (including potential additional clinical evidence requirements) that could affect commercialization of existing or future products. These risks and uncertainties, as well as failure to secure additional funding, if needed, can adversely affect the Company's future financial results, financial position, and cash flow.

In addition, economic conditions in the United States, including any economic disruptions, inflationary, or supply chain pressures, may adversely impact the Company's future financial results. The Company uses contract manufacturers in Uruguay to supply key products. Political instability or the deterioration of trade relations, including implementation of new tariffs and trade restrictions, could adversely impact the Company's business.

Concentration of credit risk – The Company maintains its cash deposits with high credit quality financial institutions. At times, such deposits may be in excess of the Federal Deposit Insurance Corporation insured limits; however, management does not believe it is exposed to any significant credit risk. All such accounts are monitored by management to mitigate risk and cash equivalents are invested in highly rated money market funds.

Supplier concentration risk – The Company depends on a small number of third-party contract manufacturers and suppliers, some of which are single source, to produce and package all elements comprising our Vivistim System as well as certain implantation tools, and if these suppliers and manufacturers fail to supply the Vivistim System or its components or subcomponents in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition, and results of operations.

Note 2 – Liquidity and Going Concern

These condensed unaudited interim financial statements were prepared on a going concern basis. The going concern basis assumes that the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the normal course of business.

The Company has incurred operating losses and negative cash flows from operations since its inception. For the three months ended March 31, 2026, the Company had a net loss of $17.7 million and had an accumulated deficit of $175.5 million as of March 31, 2026. Additionally, the Company has generated negative cash flows from operations for the three months ended March 31, 2026.

Since inception, the Company has financed its activities principally from the issuance of preferred stock, debt financing arrangements, revenue from sales of the Vivistim System and, subsequent to March 31, 2026, net proceeds from the IPO completed in May 2026. The Company believes that its operating losses and negative operating cash flows will continue into the foreseeable future. There can be no assurance that the Company's products will generate sufficient revenue for the Company to achieve profitable operations.

Based on its current operating plan, the Company plans significant increases in marketing expenditures to facilitate further awareness and adoption of the Vivistim System, spending on research and development, including regulatory affairs and clinical studies, and costs related to scaling the Company's commercial operations and infrastructure. In addition, general and administrative expenses are expected to increase following the Company's IPO due to the additional costs associated with being a public company. As discussed in previous filings (including the Company's annual financial statements for the periods ended December 31, 2024 and 2025 included in the prospectus), the Company had previously concluded that the aforementioned factors raised substantial doubt about its ability to continue as a going concern. In May 2026, the Company completed its IPO and received net proceeds of approximately $134.5 million. As a result, the Company's cash on hand, together with the net proceeds received from the IPO, is now expected to be sufficient to fund the Company's operations for at least one year from the date these condensed unaudited interim financial statements are issued.

If future revenue is not sufficient or if sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail planned activities to significantly reduce its operating expenses. Failure to manage discretionary spending or raise additional financing, as needed, may have a material adverse effect on the Company's future viability and results of operations.

Note 3 – Summary of Significant Accounting and Reporting Policies

Basis of Presentation – The condensed unaudited interim financial statements do not include all disclosures, including certain notes required by accounting principles generally accepted in the United States of America ("GAAP") on an annual reporting basis. The condensed unaudited interim financial statements have been prepared on the same basis as the annual financial statements. In management's opinion, the condensed unaudited interim financial statements reflect all adjustments (consisting only of normal recurring adjustments) necessary for a fair statement of the condensed balance sheets, condensed statements of operations, condensed statements of redeemable convertible preferred stock and stockholders' deficit, and condensed statements of cash flows for the interim periods, but are not necessarily indicative of the results of operations to be anticipated for the full fiscal year or any future period. The condensed unaudited interim financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2025 included in the Company's prospectus dated May 7, 2026 filed pursuant to Rule 424(b)(4) with the U.S. Securities and Exchange Commission (the "SEC") on May 8, 2026.

The financial statements are presented in thousands, except for share and per share amounts. Certain prior period amounts presented in the Company's Registration Statement on Form S-1 have been rounded to the nearest thousand to conform to the current period's presentation. Accordingly, certain prior period figures may differ slightly from previously filed reports presented in whole dollars.

Reverse Stock Split – In connection with the IPO, on May 1, 2026 the Company effected a 1-for-3.483 reverse stock split of its issued and outstanding common stock. All references to common stock issued and outstanding, stock options, loss per share and per share amounts presented in the accompanying financial statements and notes thereto have been retroactively adjusted for all periods presented to reflect the reverse stock split. The per share par value, authorized numbers of shares of the Company's common stock and redeemable convertible preferred stock, issued and outstanding number of shares of redeemable convertible preferred stock, and redeemable convertible preferred stock warrants were not adjusted as a result of the reverse stock split. Instead, the conversion ratio was updated whereby each share of each series of Preferred Stock was convertible into shares of common stock on a 1-for-3.483 basis.

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, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions include, but are not limited to, stock compensation, valuation of common and preferred stock, valuation of warrant liability, product warranty liability, and redeemable convertible preferred stock tranche liability. Actual results could differ from those estimates.

Emerging Growth Company Status – The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), enacted in 2012. Under the JOBS Act, EGCs can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an EGC or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act.

Segment Reporting – The Company operates and manages its business as a single reportable and operating segment. Operating segments are defined as components of an enterprise where separate financial information is evaluated regularly by the chief operating decision maker (CODM) in deciding how to allocate resources and assess performance. The Company's CODM is the Chief Executive Officer, who reviews financial information on a company-wide basis for purposes of allocating resources and assessing financial performance and does not regularly review expenses or financial results on a more granular level. For additional segment reporting information, refer to Note 14.

Significant Accounting Policies – There have been no material changes to the Company's significant accounting policies as described in the Company's audited financial statements for the year ended December 31, 2025.

Deferred Offering Costs – Deferred offering costs consisted of legal and accounting fees incurred directly related to the Company's IPO. Upon completion of the IPO, these costs were recorded as a reduction of the offering proceeds included within additional paid-in capital. Unpaid offering costs during the three months ended March 31, 2026 were $2.2 million.

Inventory – Inventory costs are comprised primarily of finished goods and raw materials and include the acquisition costs of raw materials and components, in addition to direct labor and overhead. All inventory is stated at the lower of cost or net realizable value and is accounted for on a first in, first out (FIFO) basis.

The balance of inventory is as follows (in thousands):

	March 31, 2026	December 31, 2025
Raw materials	$ 1,188	$ 1,192
Finished goods	4,861	4,265
Total inventories	$ 6,049	$ 5,457

The Company performs an assessment of the recoverability of inventory during each reporting period, and, if applicable, writes down any excess and obsolete inventories to their estimated net realizable value in the period in which the impairment is first

identified. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required. There were no expenses recorded for excess inventory or other impairments for each of the three months ended March 31, 2026 and March 31, 2025.

Related Party Transactions – The Company's Chief Financial Officer held an indirect ownership interest in Exceller Hunt MicroTransponder 2017, LP ("Exceller Hunt") and the Curnes Fund 2001 ("Curnes Fund"), both of which are stockholders of the Company. Jordan Curnes, the Company's Co-founder and a former member of the Board of Directors, also held an indirect ownership interest in the Curnes Fund. Entities affiliated with U.S. Venture Partners, GPG Healthcare Opportunities Fund, LLC, and Osage University Partners are principal stockholders of the Company. Casey Tansey is a member of the Board of Directors.

During the three months ended March 31, 2026, Exceller Hunt and the Curnes Fund participated in the Company's issuance of convertible promissory notes discussed in Note 6 and purchased approximately $4.0 million and $2.1 million of such notes, respectively. Entities affiliated with U.S. Venture Partners, GPG Healthcare Opportunities Fund, LLC, Osage University Partners, and Casey Tansey also participated in the Company's issuance of convertible promissory notes discussed in Note 6 and purchased approximately $3.8 million, $7.4 million, $6.6 million and $2.0 million of such notes, respectively. The convertible promissory notes were issued on the same terms and conditions as those offered to other investors in the financing. Other transactions with related parties in the three months ended March 31, 2026 were immaterial.

During the three months ended March 31, 2025, Exceller Hunt and the Curnes Fund acquired 569,973 and 427,480 shares of the Company's Series F redeemable convertible preferred stock, respectively, at a price of $2.6317 per share. Entities affiliated with U.S. Venture Partners, GPG Healthcare Opportunities Fund, LLC, and Osage University Partners also participated in the Company's Series E and Series F redeemable convertible preferred stock financings on the same terms and conditions as other investors.

Recently Issued Accounting Standards – On December 14, 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires enhanced income tax disclosures, including specific categories and disaggregation of information in the effective tax rate reconciliation, disaggregated information related to income taxes paid, income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. This guidance is effective for annual periods beginning after December 15, 2024; however, as an EGC, the Company has elected to use the extended transition period for adopting new or revised accounting standards, and therefore the guidance will be effective for the Company for the year ended December 31, 2026. The adoption of ASU 2023-09 is expected to have a disclosure-only impact on the Company's financial statements for the year ended December 31, 2026. The Company is currently evaluating the impact of this pronouncement on the disclosures in its financial statements.

On November 4, 2024, the FASB issued ASU 2024-03, Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The amendments may be applied either (i) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (ii) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of this pronouncement on the disclosures in its financial statements.

On November 26, 2024, the FASB issued ASU 2024-04, Debt – Debt with Conversion and Other Options (Subtopic 470-20), which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion rather than as extinguishment of debt. The amendments may be applied on either a prospective or a retrospective basis. This ASU is effective for fiscal years beginning after December 15, 2025, and interim periods within those annual reporting periods. The Company adopted ASU 2024-04 as of January 1, 2026, on a prospective basis and it did not have a material impact on its financial statements.

On December 8, 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270) Narrow-Scope Improvements, which is intended to improve the navigability of interim disclosures, clarifies when Topic 270 applies, and provides additional interim disclosure guidance, including a principle to disclose material events since the most recent annual reporting period. The amendments do not change the underlying objectives of interim reporting but are designed to enhance clarity in application. This ASU is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027; however, as an EGC, the Company has elected to use the extended transition period for adopting new or revised accounting standards, and therefore the guidance will be effective for the Company for interim periods within annual periods beginning after December 15, 2028. The Company is currently evaluating the impact of this pronouncement on its financial statements.

Note 4 – Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures*, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 – This level consists of quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2 – This level consists of directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

Level 3 – This level consists of unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

In determining the fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the unobservable inputs to the extent possible, as well as considers counterparty credit risk in its assessments of fair value.

Fair Value of Liabilities – The following tables represent the Company's financial liabilities according to the fair value hierarchy, measured at fair value (in thousands):

March 31, 2026	Level 1	Level 2	Level 3	Total
Liabilities				
Warrant liabilities	$ —	$ —	$ 882	$ 882
Convertible notes payable	—	—	40,728	40,728
Total liabilities, at fair value	$ —	$ —	$ 41,610	$ 41,610

December 31, 2025	Level 1	Level 2	Level 3	Total
Liabilities				
Warrant liabilities	$ —	$ —	$ 865	$ 865
Total liabilities, at fair value	$ —	$ —	$ 865	$ 865

The value of the warrants to purchase the Company's redeemable convertible preferred stock is dependent on inputs for which there is little or no market data, in particular the value of the Company's stock. As a result, the valuation of the warrants to purchase the Company's redeemable convertible preferred stock is categorized as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the lowest level of significance of the unobservable inputs to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable inputs, observable inputs (that is, components that are actively quoted and can be validated to external sources). The fair values could change significantly based on future market conditions.

The fair value of the warrant liability is estimated using the option-pricing model based on the Black-Scholes-Merton model with the following inputs:

	Preferred Warrants		
March 31, 2026	**Series B**	**Series D**	**Series E2 and F**
Strike price	$3.73744	$4.20700	$2.54430
Expected dividend yield	— %	— %	— %
Expected term (years)	6.8	7.2	7.8
Volatility	75%	75%	75%
Risk-free interest rate	3.465%	3.465%	3.465%

	Preferred Warrants		
December 31, 2025	**Series B**	**Series D**	**Series E2 and F**
Strike price	$3.73744	$4.20700	$2.54430
Expected dividend yield	— %	— %	— %
Expected term (years)	7.0	7.4	8.0
Volatility	80%	80%	80%
Risk-free interest rate	3.445%	3.445%	3.445%

The Company estimates volatility based upon analysis of the historical volatility of peer public companies as well as factors specific to the Company, including, but not limited to, size, expected growth and relative risk. The expected life assumption is based on the remaining contractual terms of the warrants. The risk-free rate as of March 31, 2026 and December 31, 2025 is based on the 1.5 year U.S. treasury bond yield. The expected dividend yield used is zero, because the Company has no present intention to pay cash dividends. The fair value of the warrant liability as of March 31, 2026 and December 31, 2025, was $0.9 million and $0.9 million, respectively. The change in fair value of the warrant liabilities was recorded within Other income (expense), net in the condensed statements of operations.

In January and February 2026, the Company issued convertible promissory notes in an aggregate principal amount of $40.0 million (the "Convertible Notes"). The Company elected the fair value option under ASC 825 for the Convertible Notes. At issuance, the fair value of the Convertible Notes was determined based on the transaction price, which the Company concluded represented an orderly transaction between market participants. Subsequent fair value measurements are determined using a scenario-based valuation model that incorporates probability-weighted outcomes across multiple potential scenarios, including an initial public offering, financing, change of control, maturity, and default. The model incorporates discounted cash flow techniques and option-pricing methodologies to reflect the embedded conversion features and is calibrated to the transaction price at issuance and updated at each reporting date. Significant unobservable inputs used in the valuation include discount rate (including a company-specific credit spread), equity volatility, and the probability and timing of potential liquidity events. The Convertible Notes are recurring Level 3 liabilities measured under the ASC 825 fair value option.

As of issuance, key assumptions included a discount rate of approximately 21.2%, equity volatility of approximately 85%, and expected term of 1.0 – 2.0 years. As of March 31, 2026, key assumptions included a discount rate of approximately 21.5%, equity volatility of approximately 80% and expected timing of liquidity events of 0.8 – 1.5 years. For each measurement date, the estimated probability of an initial public offering was 40% and a change of control was 20%.

The following table summarizes the change in the fair market value of the Convertible Notes (in thousands):

	Three Months Ended March 31, 2026
Beginning balance	$ —
Issuance of convertible notes payable	40,000
Change in fair value	728
Ending balance	$ 40,728

As of March 31, 2026, the aggregate principal amount of the Convertible Notes outstanding was $40.0 million and the estimated fair value of the Convertible Notes was $40.7 million.

Note 5 – Product Warranties

The Company provides an assurance-type warranty that its products will conform to agreed-upon technical and quality specifications. The warranty provides for repair or replacement of products that fail to meet specifications or become unusable during this period, which generally ranges from one to two years, depending on the product.

The Company maintains a warranty reserve for implanted pulse generators ("IPGs") and leads and began recording a warranty liability in 2024 based on historical product replacement experience. A warranty liability is recorded at the time revenue is recognized for all periods presented and is separately presented as product warranty liability on the face of the balance sheets. The warranty reserve is estimated based on historical product replacement experience. The Company establishes product replacement rates separately for IPGs and leads using historical replacement data beginning with the first full period of commercial shipments. The replacement rate represents the average historical rate of product replacement and is applied to units sold during each reporting period to estimate expected warranty obligations.

In developing its replacement rate assumptions, the Company evaluates historical replacement patterns over the expected product life cycle. The warranty accrual is calculated quarterly. The Company evaluates and updates its replacement rate assumptions annually, or more frequently if actual experience or product performance trends indicate that revisions are necessary. A reconciliation of the changes in the product warranty liability is as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Beginning balance	$ 844	$ 437
Accruals for warranties issued	328	133
Claims settled	(143)	(78)
Ending balance	$ 1,029	$ 492

Note 6 – Convertible Notes and Notes Payable

Convertible Notes

In January and February 2026, the Company issued Convertible Notes in an aggregate principal amount of $40.0 million. The Convertible Notes bear payment-in-kind ("PIK") interest at a rate of 7.0% per annum and mature two years from issuance unless earlier converted or repaid. The Convertible Notes are convertible into equity upon the occurrence of specified events, including a qualified financing, non-qualified financing, change of control, or initial public offering. The Convertible Notes bear no interest for the first six months following the date of issuance (the "Interest Free Period"), and in connection with an initial public offering, all accrued PIK interest is contractually waived immediately prior to conversion.

The Company elected the fair value option under ASC 825 for the Convertible Notes in order to account for the instrument as a single unit of account, which reflects the combined effect of the debt host and the embedded features within the overall fair value measurement. Accordingly, the Convertible Notes are initially recorded at fair value and subsequently remeasured at fair value at each reporting date, with changes in fair value recognized in the statement of operations within "Change in fair value of convertible notes

payable." This amount includes the impact of accrued PIK interest, and therefore no separate interest expense is presented for the Convertible Notes. The portion of the change in fair value attributable to changes in instrument-specific credit risk is recorded in other comprehensive income. There were no material changes in the fair value of the Convertible Notes during the period.

The Convertible Notes are presented as a separate line item on the balance sheet titled "Convertible notes payable". At issuance, the Company determined that the transaction price represented the best evidence of fair value and recorded the Convertible Notes at the proceeds received. As of March 31, 2026, the aggregate principal amount of Convertible Notes outstanding was $40.0 million and the estimated fair value was $40.7 million. See Note 4 – *Fair Value Measurements* for the discussion on the methodology and assumptions used in assessing the fair value of the Convertible Notes.

Immediately prior to the completion of the IPO, the Convertible Notes issued during the three months ended March 31, 2026 were converted into an aggregate of 3,333,324 shares of common stock.

Notes

On December 29, 2023, the Company entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Horizon Technology Finance Corporation. On June 1, 2024, Horizon Technology Finance Corporation assigned all of its right, title and interest in and to the loans outstanding under the Loan and Security Agreement and related warrants to Horizon Funding II, LLC, its wholly-owned subsidiary (together with Horizon Technology Finance Corporation, "Horizon"). The Loan and Security Agreement provides for term loans of up to an aggregate principal amount of $30.0 million, available in four equal tranches of $7.5 million. Each tranche comprises two equal loans of $3,750,000. As of December 31, 2025, the Company had $7.5 million in principal outstanding under the Loan and Security Agreement (the "Notes").

Borrowing under the Loan and Security Agreement accrue interest at an annual rate equal to the greater of (i) the Wall Street Journal (or any successor thereto) prime rate (subject to a floor of 8.50%) plus 3.75% and (ii) 12.25%. The Company is required to make monthly payment of interest through January 1, 2028, followed by amortizing principal and interest payments through the maturity date of January 1, 2029. The unpaid balance of principal and accrued interest is due at maturity. The borrowings are secured by substantially all of the Company's assets, excluding intellectual property.

In connection with the Company's draw down of the first tranche under the Loan and Security Agreement, the Company issued warrants to purchase such number of securities representing an aggregate of $262,500 to the lender. The warrants are exercisable at the election of the holder for (i) shares of Series E-2 redeemable convertible preferred stock at an exercise price of $2.5443 per share or, (ii) shares of Series F redeemable convertible preferred stock at an exercise price of $2.6317 per share, and expire ten years from the date of issuance. The warrants allow for settlement in shares and are transferable at the holder's discretion. The value of the warrants is capped at $2.5443 per share, a total of $262,500, but the number of shares is not limited. Immediately prior to the completion of the IPO, the warrants automatically converted into warrants to purchase 29,622 shares of common stock with an average exercise price of $8.8618 per share.

As of March 31, 2026 and December 31, 2025, the carrying value of the borrowings under the Loan and Security Agreement was $7.3 million and $7.1 million, net of unamortized debt discount and deferred financing costs. The Company amortizes deferred financing costs associated with the Notes to interest expense over the term of the Notes. The amortization of debt discount was not material for each of the three months ended March 31, 2026 and March 2025. The amortization of deferred financing costs was $0.1 million and immaterial for the three months ended March 31, 2026 and March 31, 2025, respectively.

There were no additional borrowings, repayments, or material modifications regarding the Loan and Security Agreement during the three months ended March 31, 2026 and March 31, 2025. Total interest expense was $0.2 million for each of the three months ended March 31, 2026 and March 31, 2025.

Note 7 – Leases

On March 7, 2023, the Company entered into a noncancellable operating lease for office space and warehouse space. The commencement date of this lease was July 1, 2023, with an end date of July 31, 2028. Leases for all prior years were month to month. The lease contains a renewal option to extend the term for a period of five years. Because the Company is reasonably certain to exercise its renewal option, the optional period is included in determining the lease term, and associated payments under these renewal options are included in lease payments. The Company's lease does not include termination options for either party to the lease or restrictive financial or other covenants. Payments due under the lease contract include fixed payments plus variable payments. The Company's office space lease requires it to make variable payments for the Company's proportionate share of the building's property taxes, and common area operating expenses. These variable lease payments are not included in lease payments used to determine lease liability and are recognized as variable costs when incurred.

On March 20, 2025 the Company entered into a modification of its existing operating lease. The modification extended the lease term to April 30, 2030, expanded the office space and revised the future lease payments. Although the modification grants the Company an additional right of use at a stand-alone price, the modification also changes the scope of the original lease by extending it two additional years while also removing the renewal option. As such, the modification has been accounted for as a single contract.

On August 8, 2025, the Company entered into an additional non-cancellable operating lease for office space. The commencement date of the lease was September 1, 2025, with an end date of August 31, 2028. Payments due under the lease contract include fixed payments plus variable payments. The Company's office space lease requires it to make variable payments for the Company's proportionate share of the building's property taxes, and common area operating expenses. These variable lease payments are not included in lease payments used to determine lease liability and are recognized as variable costs when incurred in accordance with ASC 842.

Supplemental lease cost information are as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Operating lease cost	$ 102	$ 25
Short-term lease cost	$ 6	$ 10
Variable lease cost	$ 16	$ 11
Total lease cost	$ 124	$ 46

The following table presents the lease balances within the balance sheet (in thousands):

	March 31, 2026	December 31, 2025
Operating Leases:		
Right-of-use asset	$ 1,001	$ 1,068
Operating lease liabilities, current	$ 358	$ 358
Operating lease liabilities, non-current	870	948
Total operating lease liabilities	$ 1,228	$ 1,306

The following table presents undiscounted future minimum lease payments as of March 31, 2026, which reconcile to the total lease liability as follows (in thousands):

Years Ending December 31	
2026, remaining months	$ 341
2027	467
2028	387
2029	206
2030	70
Total undiscounted future minimum lease payments	1,471
Less: Amounts representing interest	(243)
Total lease liabilities	$ 1,228

The weighted average lease terms and discounts rates are as follows:

Operating Lease Term and Discount Rate	March 31, 2026	December 31, 2025
Weighted-average remaining lease term	3.28 years	3.54 years
Weighted-average discount rate	10.82%	10.82%

Supplemental cash flow information related to leases was as follows (in thousands):

	Three Months Ended March 31,	
Cash paid for amounts included in the measurement of lease liabilities:	2026	2025
Operating cash flow from operating leases	$ 112	$ 25

Note 8 – Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes*. The income tax provision for interim periods is determined using an estimate of the Company's annual effective tax rate, adjusted for discrete items recognized in the period. The Company had an effective tax rate of 0% for each of the three months ended March 31, 2026 and March 31, 2025. The Company continues to incur operating losses.

For periods ended March 31, 2026 and 2025, the Company continued to maintain a full valuation allowance against its deferred tax assets as management believes it is more likely than not that these assets will not be realized based on the Company's history of operating losses. The Company's tax provision for interim periods primarily reflects state income taxes and other minimum taxes.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted, introducing various federal tax changes, including extensions of certain 2017 Tax Cuts and Jobs Act ("TCJA") provisions and updates to individual and business tax rules. Management evaluated the provisions applicable to the Company and determined that OBBBA did not have a significant impact on the Company's condensed unaudited interim financial statements for the as of and for the three months ended March 31, 2026.

Note 9 – Redeemable Convertible Preferred Stock

The Company has issued Series A redeemable convertible preferred stock ("Series A"), Series B redeemable convertible preferred stock ("Series B"), Series C redeemable convertible preferred stock ("Series C"), Series D redeemable convertible preferred stock ("Series D"), Series E-1 redeemable convertible preferred stock ("Series E-1"), Series E-2 redeemable convertible preferred stock ("Series E-2"), and Series F redeemable convertible preferred stock ("Series F"), collectively the ("Preferred Stock").

In March 2025, the Company entered into a Series F preferred stock purchase agreement (the "Series F Agreement") pursuant to which the Company issued 12,349,423 shares of Series F redeemable convertible preferred stock at a price of $2.6317 per share for gross cash proceeds of $32,499,977. The Series F Agreement also required the Company to issue, and the investors to purchase, an additional 12,349,423 shares of Series F redeemable convertible preferred stock at the same price per share on or around October 15, 2025 for additional gross cash proceeds of $32,499,977 (the "Series F preferred stock tranche obligation").

The Company classified the Series F preferred stock tranche obligation as a liability on its balance sheets as it represents a freestanding financial instrument that may require the Company to transfer assets to settle its obligation (upon events that are outside of its control). The Series F preferred stock tranche obligations were initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date until settlement. Changes in the fair value of the Series F preferred stock tranche obligation was recognized as a component of other income, net in the statements of operations.

The Series F preferred stock tranche obligation had an initial fair value of $680,600. As a result of the initial issuance of Series F in March 2025, 12,349,423 shares of Series F were recorded at their fair value of $31,532,110, net of issuance costs of $287,267. The Series F preferred stock tranche obligation was subsequently remeasured to a fair value of $797,908 as of June 30, 2025, and $915,216 as of September 30, 2025, with changes in fair value of $117,308 for the three months ended June 30, 2025 and $117,308 for the three months ended September 30, 2025 recognized as a component of other income, net in the statements of operations.

The Series F preferred stock tranche obligation was settled in October 2025, with the issuance of 12,349,423 shares of Series F at a price of $2.6317 per share for gross cash proceeds of $32,499,977. The fair value of the Series F preferred stock tranche obligation at settlement was $915,216. As a result of the October 2025 issuance of Series F, as well as the settlement of the Series F preferred stock obligation, 12,349,423 shares of Series F were recorded at their fair value of $33,415,193. Issuance costs related to the October 2025 Series F issuance were immaterial.

Preferred Stock consists of the following (in thousands, except for share and per share amounts):

	March 31, 2026				
	Number of Shares Authorized	Number of Shares Issued and Outstanding	Original Issue Price	Carrying Value	Liquidation Value
Series A	1,401,000	1,401,000	$ 1.91259	$ 2,694	$ 3,215
Series B	4,229,000	3,321,000	3.73744	10,849	14,894
Series C	1,362,000	1,362,000	4.20700	5,744	5,730
Series D	5,127,000	4,865,000	4.20700	19,989	20,467
Series E-1	6,361,753	6,361,753	2.03540	15,841	12,949
Series E-2	23,994,804	23,582,102	2.54430	59,709	60,000
Series F	24,698,846	24,698,846	2.63170	64,947	65,000
Total	67,174,403	65,591,701		$ 179,773	$ 182,255

	December 31, 2025				
	Number of Shares Authorized	Number of Shares Issued and Outstanding	Original Issue Price	Carrying Value	Liquidation Value
Series A	1,401,000	1,401,000	$ 1.91259	$ 2,694	$ 3,215
Series B	4,229,000	3,321,000	3.73744	10,849	14,894
Series C	1,362,000	1,362,000	4.20700	5,744	5,730
Series D	5,127,000	4,865,000	4.20700	19,989	20,467
Series E-1	6,361,753	6,361,753	2.03540	15,841	12,949
Series E-2	23,994,804	23,582,102	2.54430	59,709	60,000
Series F	24,698,846	24,698,846	2.63170	64,947	65,000
Total	67,174,403	65,591,701		$ 179,773	$ 182,255

Dividends

In the event dividends are declared by the Board of Directors on the common stock (except dividends on common stock payable in additional shares of common stock), the holders of the Preferred Stock shall be entitled to receive a dividend per share on the Preferred Stock, as applicable, pro rata with the shares of common stock, as if such shares of Preferred Stock had been converted to shares of common stock, assuming for this purpose only that shares of redeemable convertible preferred stock are convertible into

fractional shares, at the record date for the determination of stockholders entitled to such dividends. The right to receive dividends on shares of redeemable convertible preferred stock is non-cumulative, and no right to such dividends accrues to holders of redeemable convertible preferred stock by reason of the fact that dividends on such shares are not declared or paid in any years. No dividends have been declared or paid as of March 31, 2026 or December 31, 2025.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, or in the event of a deemed liquidation event (as defined below) the holders of Preferred Stock are entitled to liquidation preferences.

Payment of liquidation preferences rights to preferred stockholders are in the order of: first, the Series F redeemable convertible preferred stock, then the Series E-2 and Series E-1 redeemable convertible preferred stock, then the Series D redeemable convertible preferred stock, then the Series C redeemable convertible preferred stock, then the Series B and A redeemable convertible preferred stock. The liquidation values for the Series F, Series E-2, Series E-1, Series D, and Series C redeemable convertible preferred stock are equivalent to an amount equal to the respective original issue price per share, adjusted for any recapitalization, stock split and the like, plus any dividends declared but unpaid thereon. The liquidation values for the Series B and Series A redeemable convertible preferred stock are equivalent the greater of (i) an amount equal to 1.2 multiplied by the respective original issue price per share, adjusted for any recapitalization, stock split and the like, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series B and Series A redeemable convertible preferred stock been converted into common stock immediately prior to such liquidation, dissolution or winding up. The remaining assets, if any, shall be distributed among the holders of the shares of common stock, Series C Preferred Stock, Series D Preferred Stock, Series E-1 Preferred Stock, Series E-2 Preferred Stock, and Series F Preferred Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock pursuant to the terms of the Amended and Restated Certificate of Incorporation immediately prior to such liquidation, dissolution or winding up of the Corporation, or deemed liquidation event.

If upon the liquidation, dissolution, winding up of the Company, or deemed liquidation event, the assets of the Company legally available for distribution to the holders of the Preferred Stock are insufficient to permit the payment to such holders of the full liquidation preferences to which they are entitled, then the holders of the Company's common stock will receive nothing in respect of their equity holdings in the Company.

A deemed liquidation event is defined as a merger or consolidation of the Company that results in a change of control, or the sale, lease, transfer, exclusive license, or other disposition of substantially all of the assets of the Company to another entity that is less than a wholly owned subsidiary, unless the holders of at least a majority of the outstanding shares of Preferred Stock, voting together as a single class and on an as converted to common stock basis, and the holders of at least a majority of the outstanding shares of Series F, voting exclusively and as a separate class, elect otherwise by written notice sent to the Company prior to the effective date of any such event.

Subsequent to March 31, 2026, immediately prior to the completion of the IPO, all the outstanding shares of Preferred Stock converted into an aggregate 18,831,868 shares of common stock and the related liquidation preferences terminated.

Conversion Rights

Each share of Preferred Stock is convertible at the option of the holder and at any time into common stock as determined by dividing the applicable original issue price by the applicable Conversion Price. Conversion Price is defined as initially the applicable original issue price for the applicable series of Preferred Stock, subject to certain adjustments in the event of any recapitalizations, stock splits and the like, and for certain subsequent dilutive issuances of common stock or deemed dilutive issuances of common stock, at a price per share less than the then applicable conversion prices of the Preferred Stock. Each share of each series of Preferred Stock converts into shares of common stock on a 1:3.483 basis.

Each share of the Preferred Stock shall automatically be converted into fully paid and nonassessable shares of common stock at the above then-effective respective conversion price upon, (1) the closing of a sale of shares of common stock to the public at a specified price (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to common stock) in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $75,000,000 of gross proceeds to the Company, before deductions of underwriting discounts, commissions, and expenses, (2) the date and time, or the occurrence of an event, specified by vote or written consent of (x) the holders of at least a majority of the outstanding shares of Preferred Stock, voting together as a single class and on an as converted to common stock basis, and (y) the holders of at least a majority of the outstanding shares of Series F, voting exclusively and as a separate class, or (3) immediately prior to the closing of the IPO.

Subsequent to March 31, 2026, immediately prior to the completion of the IPO, all the outstanding shares of Preferred Stock converted into an aggregate 18,831,868 shares of common stock.

Voting Rights

Prior to the completion of the IPO, the holders of each share of Preferred Stock were entitled to one vote for each share of common stock into which such share could be converted on all matters presented to the shareholders for vote.

Redeemable Convertible Preferred Stock Warrants

As of March 31, 2026 and December 31, 2025, the Company had 908,000 warrants for Series B redeemable convertible preferred stock ("Series B Preferred Warrants") outstanding. These warrants were issued during 2012 and 2013 in connection with the issuances of Series B redeemable convertible preferred stock. In addition, as of March 31, 2026 and December 31, 2025, the Company had 258,000 warrants for Series D redeemable convertible preferred stock ("Series D Preferred Warrants") outstanding, respectively. These warrants were issued in connection with the promissory notes issued in 2017 which were exercised and converted to shares of Series D preferred stock in 2017.

Subsequent to March 31, 2026, in connection with the IPO, the Company received exercises of the warrants noted above for shares of redeemable convertible preferred stock. Any remaining warrants have expired. As such, subsequent to the completion of the IPO, there remains no outstanding redeemable convertible preferred stock warrants.

Note 10 – Common Stock

In March 2025, the Company's Board of Directors amended and restated the Company's Certificate of Incorporation to increase the number of authorized shares of common stock to 86,600,000 shares at $0.01 per share. In May 2026, the Company's Board of Directors amended the Company's Certificate of Incorporation to increase the number of authorized shares of common stock to 950,000,000 shares at $0.01 per share.

Note 11 – Share-Based Compensation

On December 15, 2022, the Board of Directors approved the Corporation's 2022 Equity Incentive Plan (the "2022 Plan") providing for the grants of non-qualified stock options, incentive stock options and other stock-based awards up to an aggregate of 7,575,181 shares of common stock, $0.01 par value per share. This consisted of the available reserve from the 2007 Equity Incentive Plan (the "2007 Plan") plus all returned shares. The 2022 Plan serves as the successor to and continuation of the 2007 Plan, and all options that were granted under the 2007 Plan (unless forfeited, exercised or expired) remained outstanding as of December 31, 2022. Awards issued under the 2007 Plan remain subject to the terms of the 2007 Plan, and unissued authorized 2007 shares became available under the 2022 Plan. No issued 2007 Plan awards were converted. The 2007 Plan contained an antidilution provision. Following a 1,000-for-1 common stock split in June 2022, the number of option shares for prior periods was retrospectively adjusted to reflect the split. No other terms of these existing awards were changed except for the number of option shares and the exercise price

to reflect the stock split. Because the modification did not result in incremental fair value under ASC 718, no additional compensation expense was recognized in 2022.

Under the 2022 Plan, stock options generally vest and become exercisable in respect of 25% of the total number of Shares initially subject to the Options on the first anniversary of the Vesting Commencement Date, and in respect of 1/48th of the total number of Shares initially subject to the Option on each monthly anniversary of the Vesting Commencement Date thereafter, so that 100% of the Shares subject to the Option shall be vested on the fourth anniversary of the Vesting Commencement Date, in each case, subject to the Optionee remaining as a Service Provider (as defined in the Plan) through the applicable vesting date. Certain awards may vest immediately upon grant or may be subject to performance-based vesting conditions, as determined by the Board of Directors. During the year ended 2025, the Company granted two executive awards that include performance-based vesting conditions which are immaterial. The Board of Directors administers the 2022 Plan and determines the exercise prices of options based on the fair value of the Company's common stock as determined by an independent valuation, in certain instances, options have been granted with an exercise price in excess of fair market value at the date of grant.

The fair market value of stock options was estimated using the Black-Scholes valuation model. Since the Company does not have sufficient trading history of its common stock, it estimates the expected volatility of its stock options at their grant date by taking the weighted average historical volatility of a group of comparable publicly traded companies over a period of time equal to the expected life of the options. The Company uses the simplified method to calculate the expected term and contractual terms. Under the simplified method, the expected life is equal to the average of the share-based award's weighted average vesting period and its contractual term. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. There were no expected dividends. The following assumptions were used in estimating the fair value of option grants issued:

	Three Months Ended March 31,	
	2026	2025
Expected term (years)	6.0 - 6.1	3.3 - 6.1
Volatility	81.6% — 81.9%	51.5% — 52.9%
Risk-free interest rate	4.0% — 4.1%	4.0% — 4.2%
Dividend yield	—	—

Stock options - A summary of officer, employee, and non-employee options granted and outstanding, under the 2007 and 2022 Plans are presented below (in thousands, except for share and per share amounts):

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2025	4,046,266	$ 3.51	7.90	$ 1,611
Options Granted	524,180	$ 7.91		
Options Exercised	(119,226)	$ 3.01		
Options Forfeited, Cancelled, or Expired	(68,341)	$ 3.62		
Outstanding as of March 31, 2026	4,382,879	$ 4.08	7.93	$ 16,783
Vested and exercisable at March 31, 2026	1,915,208	$ 3.38	6.46	$ 8,683

The following table summarizes information about stock options outstanding as of March 31, 2026:

	Options Outstanding			Options Vested	
Exercise Price	Number of Shares	Weighted Average Remaining Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Number of Shares	Weighted Average Exercise Price
$1.39	22,968	$1.39	3.61	22,968	$1.39
$1.45	2,871	$1.45	0.03	2,871	$1.45
$2.66	61,728	$2.66	4.44	61,728	$2.66
$2.79	84,409	$2.79	2.77	84,409	$2.79
$2.88	43,066	$2.88	5.10	43,066	$2.88
$3.24	264,009	$3.24	7.93	123,154	$3.24
$3.38	1,207,080	$3.38	6.78	1,094,091	$3.38
$3.41	36,891	$3.41	6.87	22,798	$3.41
$3.73	1,510,824	$3.73	8.46	426,872	$3.73
$3.94	525,228	$3.94	9.56	2,512	$3.94
$4.11	99,606	$4.11	3.99	30,739	$4.11
$7.91	524,199	$7.91	9.97	—	$7.91
$1.39 — $7.91	4,382,879	$4.08	7.93	1,915,208	$3.37

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money at period end. The aggregate intrinsic value of all options exercised for the three months ended March 31, 2026 and 2025 was $0.5 million and $34,000, respectively. The total fair value of options vested for the three months ended March 31, 2026 and 2025 was $0.5 million and $0.2 million, respectively. The options granted for the three months ended March 31, 2026 and 2025 had a weighted average grant date fair value of $5.71 per share and $1.95 per share, respectively. The options forfeited during the three months ended March 31, 2026 and 2025 had a weighted average grant date fair value of $1.95 per share and $1.74 per share, respectively. The total compensation cost related to non-vested stock options to be recognized in the future as of March 31, 2026, was $6.5 million over a weighted-average period of approximately 3.1 years.

A summary of share-based compensation expense by line items in the statements of operations is as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Research and development costs	$ 68	$ —
Sales, general and administrative expenses	339	201
Total share based compensation expense	$ 407	$ 201

Note 12 – Net Loss Per Share

Net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share is calculated similarly but includes potential dilution from the exercise of stock options and stock awards and conversion of redeemable convertible preferred stock, except when the effect would be anti-dilutive.

The following is a reconciliation of the numerators and denominators of the basic and diluted net loss per share computations for the periods presented (in thousands, except for share and per share amounts):

	Three Months Ended March 31,	
	2026	2025
Net loss attributable to common stockholders	$ (17,740)	$ (10,653)
Share (denominator):		
Weighted average number of common shares outstanding used in basic computation	918,935	821,160
Common shares issuable upon the exercise of stock options	—	—
Common shares issuable upon conversion of redeemable convertible preferred stock and warrants on redeemable convertible preferred stock	—	—
Weighted average number of common shares outstanding used in diluted computation	918,935	821,160
Net loss attributable to common stockholders, per common share		
Basic	$ (19.30)	$ (12.97)
Diluted	$ (19.30)	$ (12.97)

The following table summarizes the as converted securities that were excluded from the diluted per share calculation because the effect of including these potential shares was anti-dilutive:

	Three Months Ended March 31,	
	2026	2025
Series A redeemable convertible preferred stock	402,239	402,239
Series B redeemable convertible preferred stock	953,488	953,488
Series C redeemable convertible preferred stock	391,042	391,042
Series D redeemable convertible preferred stock	1,396,784	1,396,784
Series E redeemable convertible preferred stock	8,597,145	8,597,145
Series F redeemable convertible preferred stock	7,091,256	3,545,628
Warrants on redeemable convertible preferred stock	364,390	364,390
Convertible notes payable	3,333,324	—
Common shares issuable upon the exercise of stock options	4,382,879	3,196,660
Potentially dilutive securities	26,912,547	18,847,376

In connection with the IPO, on May 1, 2026, the Company effected a 1-for-3.483 reverse stock split. All share and per share amounts for all periods presented have been retroactively adjusted to reflect this reverse stock split.

Note 13 – Commitments and Contingencies

From time to time, the Company may become a party to claims, legal actions, and complaints arising in the ordinary course of business. Management is not aware of any such matters which would have a material effect on its financial positions, results of operations, or cash flows. The Company relies on third-party manufacturers for the production of its IPGs and stimulation leads. Certain of these arrangements include non-cancelable purchase commitments and binding forecast obligations. The Company issues purchase orders based on production requirements, which are generally non-cancelable once accepted by the supplier. As of March 31, 2026, the Company had outstanding non-cancelable purchase orders totaling approximately $11.6 million, which are expected to be fulfilled in the next twelve months. As of December 31, 2025, the Company had outstanding non-cancelable purchase orders totaling approximately $7.1 million, which are expected to be fulfilled during 2026.

During September 2024, the Company entered into an updated IPG supply agreement that expanded the scope of its supply arrangements with the third-party manufacturer. The agreement includes minimum annual purchase commitments over a five-year period commencing upon the first commercial shipment of product under the agreement. The first commercial shipment is currently expected to occur in 2028. The agreement also requires the Company to provide rolling twelve-month forecasts, portions of which

may become binding. As of March 31, 2026, no binding forecast commitments had been established under this agreement. The aggregate minimum purchase obligation over the five-year commitment period totals approximately $5.8 million.

Note 14 – Segment Information

The Company's measure of segment profit or loss is net loss, which is used by the CODM to measure actual results versus expectations, set performance metrics, and during the Company's budgeting and forecasting process to assess profitability and enable decision making. Significant segment expenses within net loss include cost of goods sold, research and development, and selling, general and administrative expenses. The only segment asset regularly reviewed by the CODM is cash and cash equivalents, which is reported on the balance sheets. No sales to an individual customer accounted for more than 10% of the Company's total revenue for the three months ended March 31, 2026 and March 31, 2025, respectively.

The following table is representative of revenue and significant segment expense categories regularly provided to the CODM for purposes of managing the Company's single operating and reportable segment. Segment revenue and net loss are consistent with the statements of operations (in thousands).

	Three Months Ended March 31,	
	2026	2025
Revenue	$ 12,074	$ 5,661
Less:		
Cost of goods sold	2,133	1,015
Research and development costs	1,692	1,354
Selling, general and administrative expenses [(1)]	25,186	13,596
Other segment items [(2)]	803	349
Net loss	$ (17,740)	$ (10,653)

(1) Selling, general and administrative expenses include depreciation and amortization expense of $0.1 million and $31,000 for the three months ended March 31, 2026 and 2025, respectively.

(2) Other segment items are comprised of change in fair value of convertible notes payable, interest expense, other income, net, and provision for income taxes, as shown on the statements of operations.

Note 15 – Subsequent Events

In April 2026, the Board of Directors approved the Company's 2026 Incentive Award Plan (the "2026 Plan") and 2026 Employee Stock Purchase Plan (the "2026 ESPP"). The stockholders of the Company approved the 2026 Plan and the 2026 ESPP in May 2026. Both plans became effective in connection with the IPO. The 2026 Plan provides for the grant of equity-based awards and authorizes an initial share reserve based on a percentage of the Company's fully diluted capitalization at the pricing date, as well as annual increases in the number of shares available for issuance thereunder. The 2026 ESPP provides eligible employees with the opportunity to purchase shares of the Company's common stock and includes an initial share reserve and annual increases based on a percentage of outstanding shares. No awards have been granted under the 2026 Plan or the 2026 ESPP as of March 31, 2026.

On May 11, 2026, the Company completed its IPO, in which it sold 10,000,000 shares of its common stock at a public offering price of $15.00 per share, for net proceeds of approximately $134.5 million, after deducting underwriters' discounts and commissions and estimated offering costs paid by the Company. In addition, immediately prior to the completion of the IPO, all the outstanding shares of the Company's redeemable convertible preferred stock were converted into an aggregate of 18,831,868 shares of common stock and the Company's convertible promissory notes issued during the three months ended March 31, 2026 were converted into an aggregate of 3,333,324 shares of common stock.

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

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our condensed unaudited interim financial statements (the condensed financial statements) and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2025, included in our prospectus dated May 7, 2026, filed with the U.S. Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Prospectus") on May 8, 2026.

Overview

We are a commercial-stage medical device company redefining stroke recovery for survivors living with life-altering motor impairments. Our Vivistim Paired Vagus Nerve Stimulation (Paired VNS) System is the first and only clinically-validated, FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. Stroke is one of the leading causes of long-term disability in the United States. While advancements in acute stroke care over the past decade have significantly reduced mortality, innovation for chronic stroke recovery has lagged, resulting in a growing number of stroke survivors living with meaningful impairments. Our breakthrough Vivistim Paired VNS System (Vivistim System) addresses this unmet need. The Vivistim System includes an implanted pulse generator and lead that deliver stimulation to the vagus nerve when activated. During treatment (Vivistim Therapy), intentional bursts of stimulation are delivered during functional movement to increase neuroplasticity and durably restore motor function. Clinical data has demonstrated that Vivistim Therapy delivers meaningful improvements in upper limb function, which can help stroke survivors regain critical capabilities and independence and restore quality of life, regardless of the time elapsed since the patient's stroke. We believe we are setting a new standard of care in chronic stroke recovery, facilitating a new treatment pathway for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. We have experienced rapid growth since our full commercial launch in 2023, and as of December 31, 2025, physicians have performed over 1,000 implants, including approximately 700 in 2025.

Chronic stroke recovery presents a significant market opportunity. According to the American Heart Association (AHA), approximately 87% of the strokes in the United States are ischemic. This equates to approximately 9 million ischemic stroke survivors in the United States, of which we estimate that more than 4 million are chronic ischemic stroke survivors living with moderate to severe upper extremity impairment. This population falls within the current on-label indication for the Vivistim System. We believe that an initial market opportunity comprises approximately 1 million of those survivors that demonstrate the requisite overall health, cognition and motivation to participate in therapy and have received some amount of post-stroke therapy, which we estimate represents an initial market opportunity of over $30 billion based on the average selling price of the Vivistim System. Vivistim Therapy is effective for recent stroke survivors as well as patients who initiate treatment many years post-stroke. Based on a report published by the AHA in 2025, we estimate that each year approximately 200,000 new stroke survivors in the United States meet our indication for use, with 50,000 of these survivors representative of our initial market opportunity.

Our commercial strategy is designed to encourage Vivistim Therapy adoption at stroke centers and therapy sites through a coordinated, evidence-based approach. We sell the Vivistim System to customers, primarily stroke hospitals, in the United States, and our commercial organization is responsible for driving adoption of the Vivistim System through customer outreach, education, and relationship management activities. Our team includes Territory Managers (TMs), who support initial customer onboarding efforts at stroke centers and maintain commercial relationships with physicians and administrators, and Therapy Development Specialists (TDSs), who focus on outreach to therapy sites and provide general educational information regarding the clinical use of the Vivistim System. These activities are intended to facilitate customer adoption and utilization of the Vivistim System. Our commercial efforts are currently focused on primary and comprehensive stroke centers, which are hospitals that have cross-functional teams with the capabilities to treat acute stroke at the highest level of care and in compliance with AHA guidelines. These centers see significant volumes of acute stroke patients and are typically surrounded by a network of therapy sites with neurorehabilitation capabilities, providing the infrastructure necessary for efficient implementation of Vivistim Therapy. We work with these stroke centers to establish Vivistim Therapy as a treatment option for stroke survivors. Over time, we believe these centers will naturally integrate Vivistim Therapy into standard care pathways for stroke survivors upon discharge and establish self-sustaining care programs that use Vivistim Therapy. According to data from the stroke center accreditation organizations, there were approximately 1,500 primary and

comprehensive stroke centers in the United States as of December 2025. In addition, according to stroke claims data, approximately 70% of acute strokes in the United States are seen at 900 hospitals.

We rely on third-party contract manufacturers to manufacture the Vivistim System and accessories. We believe this strategy provides the expertise and capacity required to effectively and efficiently scale production based on demand, and helps to reduce our need for capital investment and reduce operational expenses.

To date, our primary sources of capital have been private placements of preferred stock, debt financing arrangements, revenue from sales of our Vivistim System and, subsequent to March 31, 2026, net proceeds from our initial public offering in May 2026 (the "IPO"). For the three months ended March 31, 2026, we generated revenue of $12.1 million, with a gross margin of 82.3%, and had a net loss of $17.7 million, compared to revenue of $5.7 million, with a gross margin of 82.1%, and a net loss of $10.7 million for the three months ended March 31, 2025. As of March 31, 2026, we had cash and cash equivalents of $55.7 million and an accumulated deficit of approximately $175.5 million. In May 2026, we completed our IPO and received net proceeds of approximately $134.5 million.

Key Factors and Trends Affecting our Business

We believe that our performance, results of operations and future success depend on several factors, including:

- ***Market development and awareness of Vivistim Therapy.*** Our mission is to redefine stroke recovery for survivors living with life-altering functional impairments by establishing Vivistim Therapy as the standard of care for chronic stroke recovery. As there are currently very limited options to support chronic stroke recovery, we are focused on developing this new market and driving awareness of Vivistim Therapy as a potential treatment option for stroke survivors. To accomplish this, we intend to continue to educate healthcare providers on the capabilities and benefits of Vivistim Therapy, work closely with hospitals to incorporate Vivistim Therapy as a treatment option, and activate care programs that use Vivistim Therapy at stroke centers and therapy sites. In addition, we intend to continue to expand our clinical evidence to support a robust cadence of publications regarding the benefits of Vivistim Therapy. We believe these efforts will support the growth of our business by generating broader awareness, which can support adoption and increase utilization of Vivistim Therapy. Candidates for Vivistim Therapy generally result from three primary sources: physician referrals, therapist referrals, and direct patient engagement. A diverse network of care providers, including stroke interventionalists, neurosurgeons, neurologists, physical medicine and rehabilitation physicians, occupational and physical therapists, stroke coordinators and nurses, support and interact with stroke survivors. We directly engage with each of these stakeholders through our field-based commercial team and specialized events, summits, and conferences. In addition, we engage in direct patient education activities, such as webinars, outreach through support groups, digital advertising and other targeted activities. We believe that establishing strong referral patterns between providers and engaging directly with stroke survivors and their caregivers will help to further market development, awareness and utilization. For example, we believe that as awareness and utilization increase, stroke centers will naturally integrate Vivistim Therapy into standard care pathways for stroke survivors upon discharge and establish self-sustaining care programs that use Vivistim Therapy over time. Our financial performance will be significantly impacted by the extent to which we can increase awareness and utilization, as well as the timing and rate of adoption of our products by healthcare providers.
- ***Growing our commercial organization.*** To promote awareness and utilization, we expect to continue to efficiently invest in and grow our commercial organization. For example, our selling, general and administrative expenses were $25.2 million for the three months ended March 31, 2026 compared to $13.6 million for the three months ended March 31, 2025. We intend to continue to make significant investments in our commercial organization by scaling our team, which we believe will broaden our geographic reach, drive penetration, and increase access to our products. We seek to scale deliberately and efficiently using our scalable commercial model, which initially targets a highly concentrated group of high-volume primary and comprehensive stroke centers. These stroke centers are typically surrounded by a network of therapy sites with neurorehabilitation capabilities, providing the infrastructure for efficient implementation of Vivistim Therapy. Historically, substantially all Vivistim System implants have been performed at primary and comprehensive stroke centers. While we aim

to expand strategically and efficiently, the rate at which we grow our commercial organization and the speed at which newly hired personnel become effective will impact our revenue growth and our costs incurred in anticipation of such growth.

- ***Reimbursement and expanding payor coverage.*** Healthcare providers generally rely on third-party payors, including Medicare, Medicaid, Medicare Advantage and commercial insurance plans, to cover and reimburse all or part of the cost of the Vivistim System. As a result, demand for our Vivistim System depends in part on the availability of reimbursement from such payors and the rates that such payors reimburse for implantation procedures with the Vivistim System. The Vivistim System implantation procedure falls under a long-established Category 1 CPT code. Effective January 1, 2026, this code was assigned to a New Technology Ambulatory Payment Classification (APC) by CMS, which established an elevated payment level. Future changes in payment levels could have a significant impact on patient access to the Vivistim System, and thus on our revenue, either positively or negatively. Medicare fee-for-service patients can typically access Vivistim Therapy when medically necessary, without prior authorization. Commercial insurance plans, Medicaid and Medicare Advantage generally require prior authorization. Our in-house market access team works to provide support in navigating the prior authorization process and facilitating positive coverage decisions by third-party payors, including by utilizing our robust clinical evidence, demonstrating economic value, and leveraging endorsements from key opinion leaders. Our recent growth was, and our future success will be, driven in part by our ability to facilitate streamlined prior authorization processes and increase coverage by third-party payors, and improve market access.
- ***Expanding our clinical evidence.*** We have built, and remain committed to expanding, a robust body of clinical evidence demonstrating the safety, efficacy and durability of Vivistim Therapy. We believe the extent of our clinical evidence is important for increasing awareness and adoption of, and driving broader coverage decisions for the Vivistim System. We are actively enrolling patients in our GRASP registry and plan to publish 12-, 24-, and 36-month outcomes. We anticipate that our real-world evidence will also support a robust cadence of publications in the future that will further validate our clinical trials and the direct experiences of patients and healthcare providers. We plan to build our base of clinical evidence by supporting new clinical studies.
- ***Continued investment in research and development.*** We focus on innovation to develop new products and product enhancements, including to improve clinical outcomes, optimize patient experience, enhance physician usability, increase utilization, and increase patient engagement. We expect to continue to invest in supporting these initiatives. Our near-term research and development activities are primarily directed toward continued technological advancement of the Vivistim System, and development of a next-generation Vivistim System with enhanced features. We also expect to invest in exploring expansions into other functional impairments (*e.g.*, lower limb) or stroke etiologies (*e.g.*, intracerebral hemorrhage).

Components of Results of Operations

Revenue

We currently generate all of our revenue from the sale of our Vivistim System to customers, mainly primary and comprehensive stroke centers, in the United States. Our customers typically purchase an initial stocking order and then reorder replenishment product as procedures are performed. No single customer accounted for 10% or more of our revenue during the three months ended March 31, 2026 or 2025. We expect revenue to increase as we expand our commercial organization and sales territories, add customers and expand patient and customer awareness. We have expanded our commercial organization to help us drive and support revenue growth and intend to continue this expansion. We also expect that demand, and thus revenue growth, will be positively impacted by, and to the extent that, we obtain additional positive coverage policies with payors. While we have experienced strong revenue growth, our revenue may fluctuate from quarter to quarter due to a variety of factors.

Cost of goods sold and gross margin

Cost of goods sold primarily consists of acquisition costs of finished goods and components, depreciation, warranty costs to replace aged, damaged or unusable items, product replacement costs, shipping costs, packaging costs, and allocated costs including facilities and information technology. We expect cost of goods sold to increase in absolute terms as our revenue grows.

We calculate gross margin as gross profit divided by revenue. Our gross profit has been and will continue to be affected by a variety of factors, including sales volumes, purchase volumes of inventory, cost of goods sold, tariffs, inflation, and product yields. Our gross margin will likely fluctuate from quarter to quarter.

Research and development costs

Research and development costs primarily consist of expenses related to product development, engineering, clinical studies related to new clinical indications, regulatory expenses, testing, consulting services and other costs associated with product improvements and next generation versions of our products. Other research and development expenses include salaries, employee benefits, stock-based compensation and other headcount-related costs, depreciation expense and allocated costs related to facilities and information technology. We expect our research and development costs to increase in absolute dollars in the future as we pursue product development initiatives, including product improvements and next-generation versions of our products, and continue to expand our clinical data. We expect research and development costs as a percentage of revenue to vary over time depending on the level and timing of initiating product development efforts and clinical development activities.

Selling, general and administrative expenses

Selling, general and administrative expenses primarily consist of compensation for personnel, including salaries, employee benefits, stock-based compensation, commissions associated with our commercial organization, spending related to sales and marketing, finance, information technology and human resource functions, expenses related to clinical studies and our registry for our current clinical indication, legal expenses related to regulatory matters, and training. Other expenses include travel expenses, advertising, conferences, trade shows, consulting and professional services fees, insurance costs, and general corporate expenses, including facilities-related expenses. The activities of our TMs and TDSs to facilitate customer adoption and utilization of the Vivistim System, and of our in-house market access team in facilitating the administrative prior authorization process, are included in selling, general and administrative expenses and do not represent contractual obligations or services provided to customers after product delivery. We expect selling, general and administrative expenses to continue to increase in absolute dollars as we expand our commercial organization, including with respect to TMs and TDSs, to both drive and support our planned growth in revenue, fund clinical studies and our registry for our current clinical indication, and incur additional expenses associated with operating as a public company, including costs related to legal, accounting, insurance, compliance with exchange listing and Securities and Exchange Commission requirements, and investor relations. We also expect an increase in our stock-based compensation expense with the establishment of the new equity plan in connection with our IPO and related grants thereunder. However, we expect selling, general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Other income (expense), net

Other income (expense), net consists primarily of interest expense on our debt obligations, including our Loan and Security Agreement, as well as amortization of debt issuance costs, interest income on our cash and cash equivalents and fair value adjustments related to our redeemable convertible preferred stock warrants and redeemable convertible preferred stock tranche liability. We expect our other income (expense), net to vary in future periods depending on the extent of our debt obligations.

Provision for Income Taxes

Provision for income taxes consists of income taxes in the United States and includes deferred taxes on temporary differences for tax and financial statement purposes.

Results of Operations

Comparison of the three months ended March 31, 2026 and 2025

The following table summarizes our results of operations for the three months ended March 31, 2026 and 2025.

(in thousands, except percentage)	Three Months Ended March 31, 2026	2025	Change $	%
Revenue	$ 12,074	$ 5,661	$ 6,413	113.3 %
Cost of revenue	2,133	1,015	1,118	110.1 %
Gross profit	9,941	4,646	5,295	114.0 %
Operating expenses:				
Research and development costs	1,692	1,354	338	25.0 %
Selling, general and administrative expenses	25,186	13,596	11,590	85.2 %
Total operating expenses	26,878	14,950	11,928	79.8 %
Loss from operations	(16,937)	(10,304)	(6,633)	64.4 %
Other income (expense)				
Change in fair value of convertible notes payable	(728)	—	(728)	N/A
Interest expense	(357)	(239)	(118)	49.4 %
Other income (expense), net	282	(109)	391	(358.7)%
Total other expense, net	(803)	(348)	(455)	130.7 %
Loss before provision for income tax	(17,740)	(10,652)	(7,088)	66.5 %
Provision for income taxes	—	(1)	1	(100.0)%
Net loss	$ (17,740)	$ (10,653)	$ (7,087)	66.5 %

Revenue. Revenue increased by $6.4 million, or 113.3%, to $12.1 million for the three months ended March 31, 2026, compared to $5.7 million for the three months ended March 31, 2025. The increase was driven entirely by higher adoption of the Vivistim System. Units of IPGs sold, a primary component of the Vivistim System, increased by 108.9% during the period. This revenue growth reflects our continued efforts to increase awareness and expand our commercial organization while maintaining a consistent average selling price of the Vivistim System.

Cost of goods sold and gross margin. Cost of goods sold increased by $1.1 million, or 110.2%, to $2.1 million for the three months ended March 31, 2026, compared to $1.0 million for the three months ended March 31, 2025. While the cost per unit of the underlying product remained relatively consistent year over year, the increase in cost of goods sold was primarily driven by higher sales volume of Vivistim Systems, as well as an increase in incoming freight and product warranty costs during the period ended March 31, 2026. Gross margin increased to 82.3% in the current period, from 82.1% in the three month period ended March 31, 2025. Gross margin improved slightly due to lower product warranty expense as a percentage of revenue, while per-unit product costs remained relatively consistent.

Research and development costs. Research and development costs increased by $0.3 million, or 24.9%, to $1.7 million for the three months ended March 31, 2026, compared to $1.4 million for the three months ended March 31, 2025. The increase was primarily due to an increase of $0.2 million of expenses related to increased headcount and related expenses and $0.1 million of expenses related to product and related software development efforts including external development services.

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $11.6 million, or 85.3%, to $25.2 million for the three months ended March 31, 2026, compared to $13.6 million for the three months ended March 31, 2025. The increase was primarily due to an increase of $6.4 million in personnel-related expenses as a result of increased headcount primarily in our commercial organization, as well as higher commissions related to increased sales of Vivistim Systems. Additional increases included $1.9 million in audit, legal and other professional fees, $1.1 million in travel and meeting expenses related to increased staffing, and $0.8 million in marketing and branding-related costs, including expenses associated with our name change. The increase also reflects $0.6 million related to the post-market GRASP clinical study.

Total other income (expense), net. Total other expense, net was $0.8 million for the three months ended March 31, 2026, compared to total other expense, net of $0.3 million for the three months ended March 31, 2025. The increase was primarily attributable to $0.7 million in changes in the fair value of our Convertible Notes, $0.2 million of higher interest income resulting from a higher average cash balance and $0.2 million in changes in the value of warrant liabilities, partially offset by $0.1 million of increased interest expense related to the amortization of debt discount.

Liquidity and Capital Resources

Overview

To date, our primary sources of capital have been private placements of preferred stock, debt financing arrangements and revenue from sales of our Vivistim System and, subsequent to March 31, 2026, net proceeds from our IPO. As of March 31, 2026, we had cash and cash equivalents of $55.7 million and an accumulated deficit of approximately $175.5 million. During the three months ended March 31, 2026, we issued Convertible Promissory Notes in an aggregate principal amount of $40.0 million. In May 2026, we completed our IPO and received proceeds of approximately $134.5 million.

Funding Requirements

We expect our operating expenses to continue to increase for the foreseeable future as we continue to make significant investments in our commercial organization, seek to expand our marketing programs to help facilitate further awareness and adoption of our Vivistim System, continue to make investments in research and development, including regulatory affairs and clinical studies, and as we continue to scale our infrastructure. Moreover, we expect to incur additional expenses associated with operating as a public company, including costs related to legal, accounting, insurance, exchange listing and SEC requirements, and investor relations.

Our future liquidity and capital requirements will depend on numerous factors, including:

- our revenue growth;
- the market awareness and adoption of Vivistim Therapy, including by patients and our customers;
- the scope, timing and costs of supporting the growth and expansion of our commercial organization and efforts;
- the availability and amount of reimbursement for procedures using our products;
- the adoption of private payor coverage of our products;
- changes in the acquisition costs of finished goods and components used in our products;
- the costs associated with securing additional suppliers and service providers;
- the timing and costs of our research and development efforts;
- the scope, rate of progress and costs of our current or future clinical trials and registries as well as costs associated with complying with regulatory requirements;
- the cost and timing of additional regulatory clearances or approvals;
- the costs of attaining, defending, and enforcing our intellectual property rights;
- whether we acquire third-party products or technologies;
- litigation or other claims against us for intellectual property infringement or otherwise;
- the emergence of competing or complementary technologies;
- our ability to raise additional funds to finance our operations;
- debt service requirements;
- our need to implement additional infrastructure and internal systems;
- general economic, industry and market conditions or extraordinary external events, such as a recession;
- the rate at which we expand internationally;
- the cost associated with being a public company;
- our reputation among physicians, hospitals, therapists and patients; and

- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

Based on our current operating plan, we believe that our cash and cash equivalents, which include the net proceeds from our IPO in May 2026, will be sufficient to fund our planned operating expenses for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations.

If these sources are insufficient to satisfy our liquidity requirements, we may seek additional financing or to raise any necessary additional capital through public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these or other funding sources. Additional funds may not be available to us on acceptable terms or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, we could be forced to delay, limit, reduce or terminate our commercial efforts, product development programs or other operations, and such failure would have a negative impact on our financial condition and our ability to execute our business plan. If we raise additional funds by issuing equity securities or convertible debt, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we raise additional capital through collaboration agreements, licensing arrangements or marketing and distribution or other similar arrangements, we may have to relinquish valuable rights, future revenue streams, research programs or product or grant licenses that may not be favorable to us. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2026 and 2025:

	Three Months Ended March 31,	
	2026	2025
(in thousands)		
Net cash provided by (used in)		
Operating activities	$ (17,728)	$ (9,723)
Investing activities	(42)	(23)
Financing activities	39,908	32,424
Net increase in cash and cash equivalents	$ 22,138	$ 22,678

Operating Activities

Net cash used in operating activities was $17.7 million for the three months ended March 31, 2026, compared to $9.7 million for the three months ended March 31, 2025. The increase in cash used was primarily due to a higher net loss of $17.7 million. Cash used in operating activities for the three months ended March 31, 2026 was also impacted by increases in inventory of $0.6 million and decreases in accrued liabilities and other of $0.9 million. These uses of cash were partially offset by increases in accounts payable of $0.8 million, as well as non-cash share-based compensation of $0.4 million and non-cash amortization of debt discount and debt issuance costs of $0.1 million.

Net cash used in operating activities was $9.7 million for the three months ended March 31, 2025. This was primarily due to net losses incurred during the period of $10.7 million, partially offset by increases in accounts payable of $1.5 million and accrued liabilities and other of $0.9 million, as well as non-cash share-based compensation of $0.2 million and changes in the fair value of warrant liabilities of $0.3 million.

Investing activities

Net cash used in investing activities was $42.0 thousand for the three months ended March 31, 2026, compared to $23.0 thousand for the three months ended March 31, 2025, in each case consisting of purchases of property and equipment.

Financing activities

Net cash provided by financing activities was $39.9 million for the three months ended March 31, 2026, attributable primarily to $14.1 million in proceeds from the issuance of our Convertible Notes, $25.9 million in proceeds from the related party issuance of our Convertible Notes, and $0.4 million received upon the exercise of stock options, offset by payment of deferred offering costs of $0.5 million.

Net cash provided by financing activities was $32.4 million for the three months ended March 31, 2025, attributable primarily to $29.6 million in net proceeds from the issuance of Series F redeemable convertible preferred stock, $2.6 million from the related party issuance of Series F redeemable convertible preferred stock, and $0.2 million received upon the exercise of stock options.

Loan and Security Agreement with Horizon

On December 29, 2023, we entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Horizon Technology Finance Corporation. On June 1, 2024, Horizon Technology Finance Corporation assigned all of its right, title and interest in and to the loans outstanding under the Loan and Security Agreement and related warrants to Horizon Funding II, LLC, its wholly-owned subsidiary (together with Horizon Technology Finance Corporation, "Horizon"). The Loan and Security Agreement provides for term loans of up to an aggregate principal amount of $30.0 million, available in four equal tranches of $7.5 million. Each tranche comprises two equal loans of $3,750,000. As of December 31, 2025, there was $7.5 million outstanding under the Loan and Security Agreement, representing the full available aggregate principal amount under the Loan and Security Agreement, and no additional tranches are available to draw down under the Loan and Security Agreement in the future.

The tranches are subject to various conditions and requirements set out in the Loan and Security Agreement. The availability of the first tranche was subject to, among other things, our completing an equity offering of at least $15.0 million on or before December 31, 2023. We satisfied the conditions of the first tranche and drew down $7.5 million in December 2023. The availability of the second tranche was subject to, among other things, our completing an equity offering of at least $15.0 million on or before December 31, 2024. We did not draw down this second tranche. The availability of the third tranche was subject to, among other things, (i) our achievement of at least $20.0 million of trailing 12-month revenue as of the funding date and (ii) our completing an equity offering of at least $30.0 million on or before June 20, 2025. We did not draw down this third tranche. The availability of the fourth tranche is subject to, among other things, (i) our achievement of at least $25.0 million of trailing 12-month revenue as of the funding date and (ii) our completing an equity offering of at least $30.0 million on or before December 31, 2025. We did not draw down this fourth tranche. Our ability to draw additional loans under the Loan and Security Agreement expired on December 31, 2025.

Pursuant to the Loan and Security Agreement, we are required to issue a warrant to purchase shares of our securities in the event that we draw down a tranche following satisfaction of the applicable conditions. In connection with our draw down of the first tranche under the Loan and Security Agreement, we issued first tranche warrants to purchase such number of securities representing an aggregate of $262,500 to Horizon. The first tranche warrants are exercisable, at the election of Horizon, for (i) shares of Series E-2 redeemable convertible preferred stock at an exercise price of $2.5443 per share or (ii) shares of Series F redeemable convertible preferred stock at an exercise price of $2.6317 per share, and expire ten years from the date of issuance.

The Loan and Security Agreement matures on January 1, 2029. Borrowings under the Loan and Security Agreement accrue interest at an annual rate equal to the greater of (i) The Wall Street Journal (or any successor thereto) prime rate (subject to a floor of 8.50%) plus 3.75% and (ii) 12.25%. We are required to make monthly payments of interest only through January 1, 2028. Following such date, we are required to make monthly payments of principal and accrued interest through maturity. The unpaid balance of principal and accrued interest is due at maturity.

The Loan and Security Agreement provides that we can at any time prepay, in whole but not in part, amounts outstanding under the Loan and Security Agreement, subject to a prepayment premium on the outstanding principal amount of the loans being repaid equal to (i) 3.0% if such prepayment occurs on or prior to the second anniversary of the Loan and Security Agreement; (ii) 2.0% if such prepayment occurs after the second anniversary, and on or prior to the fourth anniversary, of the Loan and Security Agreement; and (iii) 1.0% if such prepayment occurs after the fourth anniversary of the Loan and Security Agreement and prior to maturity.

We are required to make a final payment of $131,250 for each loan funded on the earlier of (i) the date that we prepay all of the outstanding principal of such loan, (ii) the date of acceleration of the balance of such loan by the Lender, and (iii) the maturity.

Amounts outstanding under the Loan and Security Agreement are secured by substantially all of our assets, excluding intellectual property.

The Loan and Security Agreement includes customary affirmative and negative covenants and events of default. Upon the occurrence and continuance of an event of default, Horizon may demand immediate repayment of all principal and unpaid interest under the Loan and Security Agreement, and exercise remedies against us and the collateral securing our obligations under the Loan and Security Agreement. Events of default under the Loan and Security Agreement include, among other things: (i) insolvency, bankruptcy or similar proceedings subject to a certain grace period in respect of any involuntary insolvency, bankruptcy or similar proceedings; (ii) failure to pay any debts due under the Loan and Security Agreement or other indebtedness on a timely basis; (iii) failure to observe any covenant or other terms under the Loan and Security Agreement or the other Loan Documents (as defined in the Loan and Security Agreement), some of which are subject to a certain cure period; (iv) occurrence of a material adverse change; (v) material misrepresentations; and (vi) entry of certain final, non-appealable judgments against us in excess of $250,000 not paid or bonded within 10 days of such entry.

As of March 31, 2026, we were in compliance with all covenants contained in the Loan and Security Agreement.

2026 Convertible Notes

From January 30, 2026 through February 11, 2026, we issued convertible promissory notes to certain investors in an aggregate principal amount of $40.0 million (the "Convertible Notes"). The Convertible Notes mature on January 30, 2028 (the "Maturity Date"). The Convertible Notes bear no interest for the first six months following the date of issuance (the "Interest Free Period"). Following such Interest Free Period, the Convertible Notes accrue interest at a rate of 7.0% per annum through the Maturity Date, which interest payments shall be paid in kind. Pursuant to the terms of the Convertible Notes, immediately prior to the completion of the public offering, the Convertible Notes and any accrued interest will automatically convert into shares of our common stock at the applicable conversion price. The conversion price is the lower of (a) 80% of the initial public offering price per share in the initial public offering and (b) the valuation of the Company immediately prior to the closing of the initial public offering divided by the number of fully diluted shares of capital stock (on an as-converted basis) outstanding immediately prior to the initial public offering but excluding the Convertible Notes (the "Fully Diluted Capitalization"), provided, that in no event shall such conversion price be less than the quotient obtained by dividing $226.0 million by the Fully Diluted Capitalization or greater than the quotient obtained by dividing $750.0 million by the Fully Diluted Capitalization. Immediately prior to the closing of our IPO, the Convertible Notes and any accrued paid-in-kind interest automatically converted into an aggregate of 3,333,324 shares of the Company's common stock.

Contractual Obligations and Commitments

As of March 31, 2026, our contractual obligations and commitments consist primarily of obligations under our Loan and Security Agreement, Convertible Notes, operating leases and purchase commitments with third-party suppliers.

As of March 31, 2026, we had approximately $7.5 million in principal outstanding under the Loan and Security Agreement. Borrowings under the Loan and Security Agreement accrue interest at an annual rate equal to the greater of (i) The Wall Street Journal (or any successor thereto) prime rate (subject to a floor of 8.50%) plus 3.75% and (ii) 12.25%. We are required to make monthly payments of interest only through January 1, 2028. Following such date, we are required to make monthly payments of principal and accrued interest through maturity. The unpaid balance of principal and accrued interest is due at maturity. Amounts outstanding under the Loan and Security Agreement are secured by substantially all of our assets, excluding intellectual property. Because the interest

rate is variable, future interest obligations are not fixed. For additional information, see Note 6 – *Convertible Notes and Notes Payable* to our condensed financial statements included in this Quarterly Report.

In January and February 2026, we issued Convertible Notes in an aggregate principal amount of $40.0 million. The Convertible Notes bear no interest for the first six months following the date of issuance, after which the Convertible Notes accrue interest at a rate of 7.0% per annum through maturity, which interest payments shall be paid in kind, unless earlier converted or repaid. Immediately prior to the closing of our IPO, the Convertible Notes and any accrued paid-in-kind interest automatically converted into 3,333,324 shares of the Company's common stock. For additional information, see Note 6 – *Convertible Notes and Notes Payable* to our condensed financial statements included in this Quarterly Report.

We lease office and warehouse space under non-cancellable operating lease agreements. These leases require fixed monthly payments and may also include variable payments for our proportionate share of property taxes and common area operating expenses. Variable lease payments are not included in the measurement of lease liabilities and are recognized as incurred. For additional information, see Note 7 – *Leases* to our condensed financial statements included in this Quarterly Report.

We rely on third-party contract manufacturers and suppliers and enter into purchase commitments in the ordinary course of business. These arrangements are generally executed through purchase orders and, in certain cases, include non-cancelable purchase commitments and binding forecast obligations. As of March 31, 2026, we had outstanding non-cancelable purchase commitments expected to be fulfilled within the next twelve months. For additional information, see Note 13 – *Commitments and Contingencies* to our condensed financial statements included in this Quarterly Report.

From time to time, we may become a party to claims, legal actions and complaints arising in the ordinary course of business. As of March 31, 2026, we are not aware of any material pending legal proceedings that we believe would have a material adverse effect on our financial condition, results of operations or cash flows. For additional information, see Note 13 – *Commitments and Contingencies* to our condensed financial statements included in this Quarterly Report.

Off-Balance Sheet Arrangements

Through March 31, 2026, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies, Significant Judgments and Use of Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires us to make estimates and judgments that affect the amounts reported in the financial statements and related notes thereto. Critical accounting estimates are those estimates that, in accordance with GAAP, involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial statements. Management has determined that our most critical accounting estimates are those relating to stock compensation and valuation of common stock. Although we believe that the estimates we use are reasonable, due to the inherent uncertainty involved in making these estimates, actual results reported in future periods could differ materially from those estimates. For further discussion about our accounting policies, see Note 3 to our condensed financial statements included in this Quarterly Report and the section titled "Management's Discussion and Analysis of Financial Conditions and Results of Operations" in our Prospectus. There have been no significant or material changes in our critical accounting policies with which estimates and judgments are developed since December 31, 2025.

Emerging Growth Company and Smaller Reporting Company Status

The JOBS Act permits EGCs such as us to take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for any other new or revised accounting

standards during the period in which we remain an EGC; however, we may adopt certain new or revised accounting standards early. As a result, we will not be subject to the same new or revised accounting standards as other public companies that are not EGCs and our financial statements may not be comparable to other public companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO (*i.e.*, the fiscal year ended December 31, 2031); (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an EGC. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. We cannot predict if investors will find our shares of common stock less attractive because we may rely on these exemptions. If some investors find our shares of common stock less attractive as a result, there may be a less active trading market for shares of our common stock and our share price may be more volatile.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of March 31, 2026, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that the Company's disclosure controls and procedures were not effective as of March 31, 2026 due to the material weakness in internal control over financial reporting described below.

Material Weakness in Internal Control over Financial Reporting

Our management identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Specifically, we did not design and maintain effective controls over the review of the inputs in the calculation of net loss per share attributable to common stockholders. The material weakness resulted in a revision to the weighted average number of shares and net loss per share attributable to common stockholders within the statement of operations and related disclosures as of and for the year ended December 31, 2025. Additionally, this material weakness could result in misstatements to net loss per share attributable to common stockholders and related disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

Plan to Remediate the Material Weakness

In response to the identified material weakness, our management has implemented and is continuing to enhance our internal control over financial reporting. These remediation measures include the design and implementation of a control over the calculation of weighted-average shares outstanding and net loss per share, including additional review by qualified accounting personnel. We have applied this control in connection with the preparation of our financial information for the quarter ended March 31, 2026. Our management is in the process of evaluating the effectiveness of these remediation efforts and will continue to monitor the design and operating effectiveness of the new control. The material weakness will not be considered remediated until the applicable controls have been designed, implemented, and operated effectively for a sufficient period of time.

Changes in Internal Control over Financial Reporting

As described in the "Plan to Remediate the Material Weakness" section above, there were changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired 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 judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings. From time to time, we are and may in the future be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our other public filings. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock. Certain statements below are forward-looking statements. See the section titled "Special Note Regarding Forward-Looking Statements" appearing elsewhere in this Quarterly Report.

Risks Related to Our Business and Industry

We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we ever achieve profitability, we may not be able to sustain it.

We have incurred losses since our inception and expect to continue to incur losses for the foreseeable future. We reported net losses of $17.7 million and $10.7 million for the three months ended March 31, 2026 and 2025, respectively. As a result of these losses, as of March 31, 2026, we had an accumulated deficit of approximately $175.5 million. We expect to continue to incur significant sales and marketing, research and development, clinical and regulatory, and other expenses as we expand our commercial organization, increase marketing efforts to drive adoption of Vivistim Therapy, expand existing relationships with our customers, conduct clinical trials on our existing and future products and develop new products or add new features to our existing products, pursue any required regulatory clearances or approvals, and seek to establish broader commercial coverage. In addition, we expect our general and administrative expenses to increase due to the additional costs associated with being a public company. Additionally, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown obstacles as we continue to build and scale our business. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any period of time.

If we fail to manage our growth effectively, our business could be materially and adversely affected.

We have experienced recent rapid growth and anticipate further growth. For example, for the three months ended March 31, 2026, our revenue was $12.1 million compared to revenue of $5.7 million for the three months ended March 31, 2025, an increase of 113% year-over-year. This growth has placed significant demands on our management, financial, operational, technological and other resources, and we expect that our future growth will continue to place significant demands on our management and other resources and will require us to continue developing and improving our operational, financial and other internal controls. In particular, continued growth increases the challenges involved in a number of areas, including managing our third-party manufacturers and supplier relationships and ensuring adequate inventory is available, recruiting and retaining sufficient skilled personnel for leadership positions, sales force and other functions, providing adequate training and supervision to maintain our high-quality standards and preserving our culture and values. We may not be able to address these challenges in a cost-effective manner, or at all.

To achieve our business objectives, we must also successfully increase our supply of products and components from third-party manufacturers to meet expected demand. If demand decreases, we will need to implement capacity and cost reduction measures involving restructuring costs. If demand increases, we will be required to make capital expenditures related to increased production. This would also put pressure on our third-party manufacturing capabilities. For example, a sudden increase in demand could require increased production of components, such as the implantable pulse generator (IPG) or stimulation lead. Adapting to changes in

demand inherently involves a delay because it takes time to identify the change the market is undergoing and to implement any measures to take as a result. Finally, capacity adjustments are inherently risky because there is imperfect information, and sales trends may rapidly intensify, ebb, or even reverse. We may be unable to accurately or timely predict trends in demand and customer behavior or to take appropriate measures to mitigate risks and react to opportunities resulting from such trends. Any inability in the future to identify or to adequately and effectively react to changes in demand could have a material adverse effect on our business, financial condition and results of operations.

In addition, we may experience challenges managing the inventory of components of our Vivistim System, which can lead to excess inventory. Inventory levels in excess of customer demand may result in inventory obsolescence or expiration, which could potentially result in inventory write-downs or write-offs, which could be substantial and could impact our gross margins. Actual future demand could be less than our forecast, which may result in additional reserves and write-downs in the future, or actual demand could be stronger than our forecast, which may result in a reduction to previously recorded reserves and write-downs in the future and increase the volatility of our operating results.

In the future, we may also experience difficulties with quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability, product quality issues, delays in our ability to reach our sales potential, delays in the development and launch of new products and increases in expenses. Any such delays, issues or increased expenses could adversely affect our business, financial condition and results of operations. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure, particularly as a newly public company. In order to manage our operations and growth, we will need to continue to improve our operational and management controls, hiring process, reporting and information technology systems and financial internal control procedures. If we do not effectively manage our growth, we may not be able to execute on our business plan, respond to competitive pressures, take advantage of market opportunities, reach our sales potential, satisfy customer requirements or maintain high-quality product offerings, which could have a material adverse effect on our business, financial condition and results of operations.

Our success depends entirely on our currently marketed Vivistim Therapy. If we are unable to successfully market and sell Vivistim Therapy, our business prospects will be materially and adversely affected, and we may be unable to achieve revenue growth and to fund our operations.

To date, all of our revenue has been derived, and we expect it to continue to be derived, from sales of our Vivistim System. Our future financial success will depend entirely on our ability to effectively and profitably market and sell Vivistim Therapy. The commercial success of Vivistim Therapy and any of our future products we develop will depend on a number of factors, including the following:

- our revenue growth;
- the market awareness and adoption of Vivistim Therapy, including by patients and our customers;
- the scope, timing and costs of supporting the growth and expansion of our commercial organization and efforts;
- the availability and amount of reimbursement for procedures using our products;
- the adoption of private payor coverage of our products;
- changes in the acquisition costs of finished goods and components used in our products;
- the costs associated with securing additional suppliers and service providers;
- the timing and costs of our research and development efforts;
- the scope, rate of progress and costs of our current or future clinical and registries as well as costs associated with complying with regulatory requirements;
- the cost and timing of additional regulatory clearances or approvals;
- the costs of attaining, defending, and enforcing our intellectual property rights;
- whether we acquire third-party products or technologies;
- litigation or other claims against us for intellectual property infringement or otherwise;
- the emergence of competing or complementary technologies;
- our ability to raise additional funds to finance our operations;
- debt service requirements;

- our need to implement additional infrastructure and internal systems;
- general economic, industry and market conditions or extraordinary external events, such as a recession;
- the rate at which we expand internationally;
- the cost associated with being a public company;
- our reputation among physicians, hospitals and therapists; and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

If we fail to successfully market and sell our products, we will not be able to achieve profitability, which will have a material adverse effect on our business, financial condition and results of operations.

If we fail to effectively hire, train, and retain our direct sales force, increase our sales capabilities, or develop broad brand awareness in a cost-effective manner, our growth will be materially and adversely affected, and our business will suffer.

We have a direct sales team with substantial applicable medical device and clinical experience, as well as sales management. In order to generate future growth, we must continue to add highly qualified personnel to our commercial organization, with a strategic mix of TMs and TDSs, to drive further awareness and penetration within healthcare providers that interact with stroke survivors. Identifying and recruiting qualified commercial personnel and training them on our product, applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense, and attention. Once hired, the training process is lengthy because it requires significant education for new TMs and TDSs to achieve the level of clinical competency with our products expected by physicians and therapists. Upon completion of the training, our TMs and TDSs typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our products may involve limited, non-contractual support activities provided in connection with initial education and setup prior to or at the time of implantation. The Company does not have an ongoing obligation to provide programming, reprogramming, or customer or technical support after implantation, and any such activities, if performed, are incidental and not considered significant. Also, to the extent we hire personnel from our competitors, we may have to wait until applicable non-competition or non-solicitation provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories, and we may be subject to future allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Our business may be harmed if our efforts to expand and train our sales force and any future efforts to engage in direct-to-patient programs and direct-to-consumer marketing do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Moreover, the members of our direct sales force are at-will employees. The loss of these personnel to competitors or otherwise could have a material adverse effect on our business, financial condition, and results of operations. If we are unable to attract, train and retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, if we are unable to successfully instill technical expertise in replacement personnel, or if our direct sales force personnel are unable to reach the productivity levels we expect on the timeline we expect for any reason, our revenue and results of operations could be materially and adversely affected.

The commercial success of Vivistim Therapy depends upon attaining significant market acceptance of our products by hospitals, healthcare providers, therapists, patients, caregivers and payors.

Our success depends, in part, on the acceptance of Vivistim Therapy as safe, effective and cost-effective. We cannot predict how quickly, if at all, hospitals, healthcare providers, therapists, patients, caregivers or payors will adopt Vivistim Therapy or, if adopted, how frequently Vivistim Therapy will be used. Vivistim Therapy and any future products we may develop or market may never gain broad market acceptance for some or all of our targeted indications. It is important to our success, future growth, and profitability that we are able to increase healthcare provider awareness of Vivistim Therapy and that hospitals, healthcare providers, therapists, patients, caregivers and payors believe that our products offer benefits over alternative treatment methods, and that they adopt our products. These parties may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations, and other analyses, that our products are safe, effective and cost-effective on a stand-alone basis and relative to competitors' products. If physicians or payors do not find our body of published clinical evidence and data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for or prescribe our product. Currently, there are a number of large third-party payers that have determined that our Vivistim Therapy is experimental or investigational and therefore do not cover it at this time. In addition, the long-term effects of our Vivistim Therapy beyond our current clinical trials are not yet known. Certain physicians, hospitals, therapists and payers may prefer to see longer-term safety and efficacy data than we have produced. Even if we are able to raise awareness, physicians and therapists may be slow in changing their medical treatment practices and may be hesitant to select our products for recommendation to their patients for a variety of reasons, including:

- long-standing relationships with competing companies and distributors that sell other products;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting reliability, safety, clinical or economic benefits;
- lack of third-party coverage or adequate reimbursement, particularly from private payors;
- lack of experience with our products and concerns that we are relatively new to market; and
- time commitment and skill development that may be required to gain familiarity and proficiency with our products and implantation procedures.

Stroke survivors interact with a diverse network of care providers, including stroke interventionalists, neurosurgeons, neurologists, physical medicine and rehabilitation physicians, occupational and physical therapists, stroke coordinators and nurses. Each of these providers can play a role in identifying and evaluating potential Vivistim Therapy candidates. We directly engage each of these stakeholders through our field-based commercial team, as well as through specialized events, summits, and conferences. As a result, our success depends, in large part, on effectively marketing Vivistim Therapy to these healthcare providers. We aim to educate these healthcare providers regarding the patient population that would benefit from Vivistim Therapy. Acceptance of Vivistim Therapy depends upon our education of healthcare providers as to the distinctive characteristics, clinical benefits, safety, durability and ease of use of Vivistim Therapy as compared to other therapy options and any future competitor VNS devices and upon our effective communication to healthcare providers of the proper use of Vivistim Therapy as well as our ability to provide effective and timely physician, therapist and patient support, including in connection with device education and addressing any technical, quality or other concerns. However, we cannot assure you that we will achieve broad market acceptance among these practitioners. Healthcare providers may be reluctant or unwilling to invest time to learn about the benefits of Vivistim Therapy, and to deviate from practices or therapy programs which they consider to be more established. If we are not able to effectively demonstrate that the use of Vivistim Therapy is beneficial in a broad range of patients, some healthcare providers may choose to utilize Vivistim Therapy on only a subset of their total eligible patient population or not at all, and adoption of our product will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations.

Most of our customers are hospitals, which may require us to enter into contracts regarding our devices. This process can be lengthy and time-consuming and may require extensive negotiations and management time with an uncertain degree of success. If we do not receive access to hospital facilities via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, we may not achieve our sales and revenues goals, and our results of operations may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

In addition, certain characteristics and features of Vivistim Therapy may prevent widespread market adoption. For example, some patients have reported pain, discomfort, bruising, swelling and infection after implantation as well as device related issues, such as low or high impedance (a measure of the lead's resistance to current), which have led to explant or revision requests. These and any similar future explants or revisions could deter potential candidates from pursuing treatment or prompt physicians to favor alternative therapies. Even if physicians recommend Vivistim Therapy to patients, patients may not adopt it for a variety of reasons, including because they do not want to or are unable to undergo the implantation procedure (which involves typical risks associated with such procedures, including infection), do not perceive our device as safe, effective or cost-effective, prefer any future competitive devices or therapies (including as a result of competitive patient marketing) or because Vivistim Therapy is not reimbursed by their health insurance provider.

Also, screening patients for Vivistim Therapy requires a clinical assessment of a patient's motor impairments, which is typically done based on the Fugl-Meyer Assessment of Upper Extremity (FMA-UE) score. The FMA-UE assessment can take about 30 minutes or more to complete, which can be longer than other clinical assessments. Follow-up assessments take about the same time. Healthcare providers that use other clinical assessments that are shorter may not want to learn how to use the FMA-UE scoring system or invest the time in a longer assessment process generally, which may impact adoption of Vivistim Therapy.

Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products, therapies or technologies are considered safer, more effective, more cost-effective or otherwise superior. Any failure of our products to generate sufficient demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations.

Coverage and adequate reimbursement may not be available or may be subject to change for our Vivistim System, including any future products we commercialize, which could diminish our sales, increase our competition, or affect our ability to sell our currently marketed Vivistim Therapy and any future products profitably.

Our customers are generally reimbursed by third-party payors for the procedures that are required to implant our device. Because there is no separate reimbursement for supplies used in surgical procedures, including our device, the additional cost associated with the use of our products can affect the profit margin of the hospital where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of potential additional associated cost. In addition, customers that perform the procedure may be subject to reimbursement claim denials upon submission of the claim. These events, or any other decline in the amount payors are willing to reimburse our customers, could make it difficult for existing customers to continue using or to adopt our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

Based on our experience to date, third-party payors generally reimburse for the surgical procedures in which our products are used only if the patient meets the established medical necessity criteria for surgery. Some payors are moving toward a managed care system and control their healthcare costs by limiting authorizations for surgical procedures, including elective procedures using our devices. Although no uniform policy of coverage and reimbursement among payors exists and coverage and reimbursement for procedures can differ significantly from payor to payor, reimbursement decisions by particular third-party payors may depend upon a number of factors, including the payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational.

Third-party payors are increasingly auditing and challenging the prices charged for medical products and services with concern for upcoding, miscoding, using inappropriate modifiers, or billing for inappropriate care settings. Some third-party payors must approve coverage for new or innovative devices or procedures before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution by the FDA, we may find limited demand for the product unless and until reimbursement approval has been obtained from governmental and private third-party payors.

Medicare, which is administered by the Centers for Medicare and Medicaid Services (CMS), does not currently have a national coverage determination or local coverage determinations applicable to our device. As a result, coverage determinations are made on a case-by-case basis for Medicare beneficiaries. Medicaid programs are funded by both federal and state governments, and coverage and reimbursement policies vary from state to state and from year to year. Effective July 1, 2023, the New York State Medicaid fee-for-service program covers FDA-cleared vagus nerve stimulator, or VNS, devices used for stroke therapy in conjunction with rehabilitation to recover function in hands and arms after an ischemic stroke. Most commercial payors currently consider Vivistim Therapy as experimental or investigational and require prior authorization.

Obtaining and maintaining coverage and reimbursement can be a time-consuming and expensive process. For example, payors typically require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products before providing coverage. We may not be able to provide data sufficient to satisfy third-party payors that procedures using our products should be covered and reimbursed, and even if we are, such data may be time-consuming and costly to obtain and the incremental revenue from the positive coverage decisions it generates (if any) may not be sufficient to recoup the expense associated with data collection. Payors also continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. While some payors currently cover and provide reimbursement for procedures using our currently cleared or approved products on a case-by-case basis, we can give no assurance that these third-party payors will continue to provide coverage and adequate reimbursement for the procedures using our products, or that additional third-party payors will provide coverage for our products in the future. If we are not successful in reversing any non-coverage policies, or if third-party payors that currently cover or reimburse procedures in which our products are used reverse or limit their coverage in the future, or if other third-party payors issue similar non-coverage policies, this could have a material adverse effect on our business.

Third-party payors are also increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. It is uncertain whether our current products or any future products will be viewed as sufficiently cost effective by payors to warrant coverage and adequate reimbursement levels for procedures using such products in any given jurisdiction. For example, there can be no assurance that payors will find Vivistim

Therapy attractive from a cost/benefit perspective, or that they will deem our data on economic benefits of Vivistim Therapy sufficiently persuasive.

High rates of coverage denials or prolonged, burdensome prior authorization processes by commercial and government payors may discourage physicians from recommending Vivistim Therapy to their patients. Certain of our customers have, from time to time, experienced coverage denials and extended prior authorization requirements for Vivistim Therapy, and there can be no assurance that payor behavior will improve or that such denials will not persist or increase in the future. If medical centers and physicians perceive that reimbursement is uncertain or routinely denied, they may be less willing to invest the time required to pursue appeals or recommend Vivistim Therapy to their patients, which could reduce utilization of Vivistim Therapy. Persistent denial trends could also influence hospital committees and practice groups to deprioritize Vivistim Therapy in their care protocols, further limiting adoption and adversely affecting our revenue, reputation and growth prospects.

In addition, government payors, such as CMS, have increased their efforts to control the cost, utilization and delivery of healthcare services. CMS establishes Medicare payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities. The Vivistim System is typically implanted in the hospital outpatient setting, and all items and services paid under the Medicare hospital outpatient prospective payment system, or OPPS, are assigned to payment groups called Ambulatory Payment Classifications, or APCs, which group together items and services that are similar clinically and in terms of resource use. Reimbursement for professional services performed by physicians are reported using CPT codes and based on a different payment methodology. Implantation of the Vivistim System falls under CPT Code 64568 ("Incision for implantation of a cranial nerve (e.g., vagus) neurostimulator electrode array and pulse generator"). From January 1, 2023 through December 31, 2025, CMS granted transitional pass-through payment status for the Vivistim System under HCPCS code C1827 ("Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller") when used in combination with CPT code 64568. This status is granted by CMS to facilitate access to innovative devices that significantly improves clinical outcomes as compared to currently available treatment options. Effective January 1, 2026, CPT code 64568 is assigned to New Technology APC 1580. A service is not paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. CMS generally expects this to occur within two to three years. We cannot provide any assurances that CPT code 64568 will continue to be assigned to APC 1580 during this time, or that reimbursement amount associated with any subsequent assignment to a clinical APC group will be adequate to cover the costs associated with our device. Individual states may also enact legislation that impacts Medicaid payments to hospitals and physicians.

The marketability of our products may suffer if government and commercial third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

We depend on a small number of third-party contract manufacturers and suppliers, some of which are single source, to produce and package all elements comprising our Vivistim System as well as certain implantation tools, and if these suppliers and manufacturers fail to supply our Vivistim System or its components or subcomponents in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition, and results of operations.

We utilize a small number of qualified medical device contract manufacturers and suppliers, some of which are single source, to produce and package all elements comprising our Vivistim System as well as certain implantation tools. In certain cases, these third parties also perform design engineering activities for specific components. We generally do not have long-term contracts with our suppliers, and our supply arrangements generally do not include minimum manufacturing or purchase obligations. For these arrangements, we primarily order products through the use of purchase orders, do not have any obligation to purchase any given quantity of products, and our suppliers generally have no obligation to sell to us or to manufacture for us any given quantity of our products or components of our systems. Certain supplier arrangements include non-cancelable purchase commitments and binding forecast obligations. For these arrangements, we primarily order products through the use of purchase orders that are generally non-cancelable once accepted by the respective supplier. Although we continue to fortify our supply chain by seeking additional sourcing channels, all of the critical components of the Vivistim System, including the IPG and lead, are supplied to us from single sources that are qualified medical device contract manufacturers and suppliers. Our lead is manufactured by Cirtec Medical. Our IPG is manufactured by Integer Holdings Corporation (Integer).

We entered into supply agreements with Integer pursuant to which Integer agreed to manufacture our IPG component for us. Our first supply agreement with Integer provides that we may order from Integer on a non-exclusive, purchase order basis with no minimum purchase requirements. The agreement includes, among other provisions, customary representations and warranties by the parties, ordering and payment and shipping terms, customary provisions with respect to the ownership of any intellectual property and customary confidentiality provisions. The agreement continues until termination by the parties. Either party may terminate the

agreement upon written notice in the event of a material breach that is not cured within 30 days of the other party's written notice of such breach; upon bankruptcy, insolvency or reorganization that has not been dismissed within 30 days after commencement; or in the event that the other party commits a crime, intentionally imparts material information or misappropriates intellectual property. In addition, we may terminate the agreement if Integer fails to meet our specifications or is unable to manufacture products, or for our convenience if we are current in our payment obligations to Integer. To further support our anticipated growth and IPG supply needs, we also entered into a second supply agreement (the IPG Supply Agreement), effective September 24, 2024, with Greatbatch Ltd., a subsidiary of Integer. The IPG Supply Agreement contains, among other provisions, customary representations and warranties by the parties, ordering and payment and shipping terms, customary provisions with respect to the ownership of any intellectual property created during the term of the IPG Supply Agreement, certain indemnification rights in favor of both parties, limitations of liability and customary confidentiality provisions, and minimum purchase requirements. The minimum purchase requirements are expected to commence in 2028. Under the minimum purchase requirements, we are obligated to purchase a high double-digit fixed percentage of our IPG supply requirements from Integer and must purchase a minimum number of IPGs from Integer per year. The aggregate minimum purchase obligation for the initial five-year period is approximately $5.8 million. The IPG Supply Agreement has an initial five-year term commencing upon the first commercial shipment of product, and will automatically renew for one-year periods unless either party delivers a notice of non-renewal prior to the renewal date. Either party may terminate the IPG Supply Agreement upon written notice in the event of a material breach of the IPG Supply Agreement that is not cured within 60 days of the other party's written notice of such breach, subject to certain conditions; or upon bankruptcy, insolvency or reorganization that has not been dismissed within 60 days after commencement. We may terminate the IPG Supply Agreement if Integer fails to adequately supply non-defective products, if the products are subject to repeating failures over time that fail to meet our specifications, or if Integer is unable to manufacture products for a specified period of time.

Where we rely on a single-source supplier, alternative second-source suppliers may not be readily available or qualifying them may take significant time and expense. The level of inventory we maintain for certain of our sole-sourced supplies may not be sufficient to support our customer demand for the length of time that may be required to qualify an alternative supplier should this become necessary. We seek to strategically maintain sufficient levels of inventory to help mitigate supply disruption, to accommodate varying demand mix and to achieve more efficient volume-based pricing on our components; however, we may not be accurate in our estimates which could result in insufficient inventory to meet demand or excess inventory and the risk of inventory obsolescence and expiration. If our estimates result in carrying insufficient levels of inventory to meet customer demand, this may lead to customer backorders due to a lack of manufacturing capacity or supply chain challenges, which could result in delays or inability to reach sales potential, cause reputational harm or otherwise have a material adverse effect on our business, financial condition and results of operations.

Where these third parties perform design engineering work, we are additionally reliant on their design engineering capacities and proprietary know-how, and we may have reduced visibility and control over design decisions and related changes. This reliance can increase the time and cost to implement, validate and transfer design changes, complicate second-sourcing efforts, and heighten the risk of disputes over intellectual property ownership, licensing scope, and access to design files and documentation necessary to manufacture and support our device.

Our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our reliance on a third-party manufacturer and third-party suppliers also subjects us to other risks that could harm our business that we would not be subject to if we manufactured products ourselves, including:

- we may not be a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of Vivistim Therapy or cause delays in shipment or product recalls;
- we may have difficulty locating and qualifying alternative suppliers;
- the capacity, technical capabilities and qualifications of our suppliers may not expand in line with our future volume requirements or support the manufacture of new products on our desired schedule, or at all;
- switching components or suppliers may require product redesign and possibly submission to FDA or other regulatory bodies, which could significantly impede or delay our commercial activities;

- one or more of our single-source suppliers may be unwilling or unable to supply components of our Vivistim System;
- other customers may use fair or unfair negotiation tactics or pressures to impede our use of the suppliers;
- the occurrence of a fire, natural or man-made disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner or at all;
- our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements;
- our suppliers may not maintain the confidentiality of our confidential information; and
- higher manufacturing and product costs than more vertically integrated companies.

Any of these factors could cause delays or suspension of commercialization and marketing, clinical trials, regulatory submissions or required approvals, cause us to incur higher costs, inability to meet customer demand, and product quality issues or recalls. Furthermore, if our contract manufacturers fail to deliver the required commercial quantities of finished products of an acceptable quality on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. Any difficulties in locating and hiring third-party manufacturers, or in the ability of third-party manufacturers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business. It may take a significant amount of time and resources (including costs) to establish an alternative source of supply for our products and to have any such new source approved by the FDA. Given our reliance on certain single-source suppliers, we are especially susceptible to supply shortages because we do not have alternate suppliers currently available, which can result in increased costs and production delays and potentially adversely impact our ability to meet demand for our products in a timely manner or at all.

Moreover, some third parties or their facilities are or may in the future be located in markets subject to political, social and economic risk, corruption, infrastructure problems, tariffs and natural or man-made disasters, in addition to country-specific intellectual property protection, privacy and data security and tax risks and the risk of nationalization and expropriation, given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may have a material adverse effect on our business, financial condition and results of operations. Because we rely on some suppliers in countries outside of the United States, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or the governments in the countries these suppliers are located, including changes in tariff policies, political or social unrest, or unstable economic conditions. Any of these matters could materially and adversely affect our business, financial condition and results of operations.

The size of our market opportunity has not been established with precision and may be smaller than we estimate, possibly materially.

We estimate that there are more than 4 million chronic ischemic stroke survivors living with moderate to severe upper extremity impairment in the United States and that are within the current on-label indication for our Vivistim System. We believe that an initial market opportunity comprises approximately 1 million of those survivors, which equates to an initial market opportunity of over $30 billion based on the average selling price of the Vivistim System. This initial market represents the total overall revenue opportunity that we believe is available if we achieve 100% market share for Vivistim Therapy among these survivors, and is not a representation that we will achieve any such market share. The market share we achieve is subject to a number of assumptions, risks and uncertainties, including our ability to execute on our commercial strategy and the extent of adoption of Vivistim Therapy. Further, these estimates are based on a number of internal and third-party estimates which may prove to be inaccurate. The actual size of our addressable markets may be smaller than our estimates for a number of reasons. The Vivistim System is currently the first and only FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairment. As such, we will have to expend significant resources to educate and promote awareness of this solution among patients, caregivers and healthcare providers. If we are not able to successfully drive adoption of our solution, we may not be able to access a significant part of this estimated market opportunity.

Our Vivistim System implantation procedure falls under Category 1 CPT code. Medicare fee-for-service patients can typically access Vivistim Therapy when medically necessary, without prior authorization. Commercial insurance, Medicaid and Medicare Advantage generally require prior authorization. As such, commercial insurance coverage represents the largest gap in coverage and continues to evolve, and may never become widely available. Medicare reimbursement rates may also be reduced. The foregoing may slow or prevent broad adoption of our solution or require us to reduce our average selling prices to accommodate reduced reimbursement rates. We have determined our serviceable addressable market using an assumed average selling price for our Vivistim System. A decrease or increase in our assumed average selling price would change our serviceable addressable market.

Additionally, the market for our solution may be slow to develop as a result of physician concerns associated with Vivistim Therapy due to the limited long term clinical data, limited or challenges regarding commercial reimbursement, and limited network of referral sources that may take some time to develop, if they develop at all. In order to generate future growth, we are building out a dedicated group of field-based TMs and TDSs focused on developing our market, including driving awareness of Vivistim Therapy and its clinical benefits as well as supporting VNS-specific professional education, but our efforts to do so may not be successful. Moreover, our total market opportunity could decrease if preventive therapies, drugs or devices that broadly reduce stroke incidence (such as glucagon-like peptide agonists, or GLP-1 drugs, if proved to be effective for such purpose) are prescribed or utilized more widely or if stroke incidence generally decreases due to, among other reasons, the population in the United States becoming healthier or new drugs being developed.

Any of the foregoing could cause our total addressable market and serviceable addressable market to be lower than we currently estimate. If our market does not continue to develop at the rate we expect, our business, financial condition, and results of operations could be materially and adversely affected.

Adverse events, product recalls, or other complications or customer satisfaction issues associated with Vivistim Therapy, including regarding the finite IPG battery life, could limit its adoption.

Risks of using our products include risks that are common to any surgical procedure. Adverse events that have been experienced in connection with our device in clinical trials and clinical practice include infection, pain and discomfort, migration of the implanted device, irritation, bruising, swelling and non-healing wounds. Certain of these procedure or device related adverse events have, in some cases, required device explantations or revisions; in some of these cases, patients have not been re-implanted. Complications or adverse events could result from improper implantation and lack of adequate physician experience or training with our products as well as other user errors, pre-existing patient conditions or anatomical factors and manufacturing defects.

In addition, since the IPG battery is indicated for approximately five years of service life under continuous use conditions, long-term use past five years have in the past, and may in the future, require one or more replacement procedures when the IPG battery reaches its end-of-life. Replacement of the IPG necessarily involves surgical intervention (such as explant or replacement) and is subject to the risk of additional adverse reactions, including infection, pain and discomfort, irritation, bruising, swelling, non-healing wounds and adverse reactions to general anesthesia. The prospect of having to eventually explant or replace our Vivistim System, which would involve additional surgery and its associated risks (which may be heightened at the more advanced age of any such explant or replacement procedure), may dissuade patients from using Vivistim Therapy in the first instance.

In addition to the adverse events described above, users have in the past experienced, and may in the future experience, issues with the SAPS interface and accessories and their interactions with the IPG, and we have received, and may in the future receive, complaints regarding these issues. These issues have included SAPS screen anomalies and connection errors between the SAPS user interface and the wireless transmitter, which are typically resolved by rebooting SAPS or replacing the respective laptop, and connection issues between the wireless transmitter and the IPG, which are typically resolved by reconnecting or repositioning the wireless transmitter. Our device manual includes detailed instructions regarding how to resolve these issues, and a team of field-based clinical engineers are available to provide remote and in-person support to clinicians and therapists. While these issues have not been material or presented significant risks or issues for our business to date, if any such issues become systemic, persist, or we are unable to remediate them promptly, or if they otherwise inconvenience or frustrate users, they could impair device performance, disrupt therapy, necessitate replacement procedures, dissuade patients and physicians from using Vivistim Therapy and damage our reputation. Customers may attribute these or similar issues to our products even if caused by reasons not directly related to our products, such as pre-existing conditions, complications associated with the surgical procedure or related anesthesia itself, implantation of the device too deep in the tissue, making a larger-than-necessary incision that results in device migration, movement in the body or other types of user error or patient anatomical features. Even if these types of events are not directly attributable to the devices, they could decrease acceptance of our products by our customers, including hospitals, physicians, therapists, patients or caregivers, and result in a material adverse effect on our business, financial condition, and results of operations. Our reputation among our current or potential customers and referral sources, including but not limited to, stroke interventionalists, neurosurgeons, neurologists, physical medicine and rehabilitation physicians, occupational and physical therapists, stroke coordinators and nurses could also be materially and adversely affected by safety or customer satisfaction issues involving us or our products. For example, our customer service and clinical representatives may be unable to, or be perceived to be unable to, provide technical and customer service support effectively and in a timely manner or at all. These or other customer satisfaction issues, in addition to any product recalls or other safety or efficacy issues, could materially and adversely affect our reputation and our ability to establish or maintain broad adoption of our products, which would harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations. Additionally, any unfavorable publicity or news coverage regarding our Vivistim System, whether or not accurate, may dissuade patients from using our Vivistim System.

Screening procedures designed to identify patients who are contraindicated for use of Vivistim Therapy may be inconsistently or incorrectly applied by healthcare providers or may otherwise fail to identify individuals who should not have been eligible for Vivistim Therapy, resulting in customer dissatisfaction by such patients. Also, hospitals and physicians may not prescribe our products due to potential interference or complications with other medical procedures. For example, because our products include implantation of certain medical-grade metals, our labeling our Vivistim System is designated as MR Conditional and includes specific considerations for procedures using magnetic resonance imaging, or MRI. Any of these events could materially and adversely affect our ability to commercialize our products and to compete with other products in stroke recovery.

We operate in a competitive industry that is subject to technological change and significantly affected by new product introductions and market activities of other industry participants.

We operate in a competitive industry that is subject to technological change and significantly affected by new product introductions and market activities of other industry participants. For example, industry participants include medical device manufacturers and robotics companies, including a significant number of companies focused on stroke prevention and acute stroke care. To the extent these companies decide to focus on longer term stroke care, particularly in the chronic phase, we may face increased competition. Many of these companies have longer, more established operating histories, and significantly greater name recognition and financial, technical, marketing, sales, distribution and other resources. In addition, certain companies have several competitive advantages, including significant scale and established relationships with healthcare providers and third-party payors. Irrespective of their current focus, we also compete with these companies for personnel, including qualified personnel that are necessary to grow our business, including TMs and TDSs.

Competitors may be able to offer products similar or superior to ours, including products that may, or may be perceived to, have improved features, such as smaller form factors, improved ease of use, longer battery life or rechargeable battery, aesthetics, reliability, safety and effectiveness; have improved reimbursement; be better supported by clinical evidence; more widely recognized and adopted by healthcare providers and patients; or be more cost-efficient. For example, competitors may utilize existing or newly developed products to enter the VNS market in the future, which would increase our competition and could materially and adversely affect demand for Vivistim Therapy. Increased competition may result in price reductions, reduced gross margins and loss of market share. To the extent we expand internationally, we will face additional competition in geographies outside the United States. In addition, we face competition from pharmaceutical companies that produce drugs which aim to aid in stroke recovery, and other companies that produce other devices or therapies that aim to assist in stroke recovery. Further, if medical research were to lead to the discovery of alternative therapies or technologies that address chronic stroke impairments in a way that is or is perceived to be more accurate, reliable, cost-effective, or otherwise improved relative to Vivistim Therapy, for example through alternative monitoring or testing technologies, medication, or therapies, the demand for our products could decrease significantly. For example, some of our patients have experienced pain and discomfort associated with the surgical implantation of our product, and some prospective patients have been reluctant to undergo surgery; if competitors develop or commercialize minimally invasive or non-surgical alternatives that avoid implantation, patients and providers may prefer those options over Vivistim Therapy, which could further reduce demand for our products. There can be no assurance that we will be able to compete successfully against our current or future competitors, or that competitive pressures will not have a material adverse effect on our business, financial condition and results of operations.

In addition, many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for our products. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease, which could have a material adverse effect on our business, financial condition, and results of operations.

If rising prices or limited availability of raw materials continues to persist, our business and results of operations may be adversely affected.

Volatility in raw material prices and availability can occur due to numerous factors beyond our control, including general, domestic, and international economic conditions, labor costs, production levels, competition, consumer demand, import duties, tariffs and taxes, inflation and currency exchange rates. This volatility can significantly affect the availability and cost of raw materials that our suppliers purchase and are ultimately used in our systems, and may therefore have a material adverse effect on our business, financial condition and results of operations.

In addition, the current U.S. administration has expressed strong concerns about imports from countries that it perceives as engaging in unfair trade practices, and has imposed tariffs or other restrictions on products, components or raw materials sourced from those countries. The legal basis for some of these tariffs have been challenged, and recent judicial decisions, including from the U.S. Supreme Court, have invalidated or called into question certain tariff measures. However, other tariffs remain in place, new or

additional tariffs have been and may continue to be imposed, and the overall trade policy environment remains fluid and subject to rapid change. Moreover, changes in U.S. trade policy have triggered and may in the future trigger retaliatory actions, countermeasures, or trade restrictions by affected countries. For example, there have been and continue to be further indications that there may be an increase in tariff rates on various types of goods imported from Canada, Mexico, South America and Europe that could apply to the raw materials we require in our products, including certain types of metal powders used for coating our products as well as entire components of our Vivistim System. In the event that any such possible tariff increases remain in place or become enacted in the future, they could significantly increase the cost of materials and components that our suppliers import and use in our systems, which in turn could increase our supply costs. At this time, there can be no assurance that we will be able to pass any portion of such increases on to customers. We currently do not hedge against our exposure to changing raw material prices and are not aware as to whether our suppliers hedge. As a result, fluctuations in raw material prices could have a material adverse effect on our business, results of operations and financial condition. Supply shortages or changes in availability for any particular type of raw material can delay supplier volume and production capabilities or cause increases in the cost of manufacturing our products. We may be materially and adversely affected by changes in availability and pricing of raw materials, which could materially and adversely affect our results of operations.

In order to support our continued operations and the growth of our business, we may seek to raise additional capital, which may not be available to us on acceptable terms, or at all.

We expect our operating expenses to continue to increase for the foreseeable future as we continue to make significant investments in our commercial organization; seek to expand our marketing programs to help facilitate further awareness and adoption among healthcare providers and patients; seek payor reimbursement; continue to make investments in research and development, regulatory affairs, and clinical trials to develop future generations of products based on Vivistim Therapy, support regulatory submissions, and demonstrate the clinical efficacy of our products; and as we continue to scale the business infrastructure and manufacturing capacity. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations, and other expenses. In addition, we may in the future seek to acquire or invest in, additional businesses, products, or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities, or otherwise offer growth opportunities.

As of March 31, 2026, we had $55.7 million in cash and cash equivalents. After giving effect to the net proceeds from our IPO, we believe that our cash and cash equivalents will be sufficient to fund our planned operating expenses for at least the next 12 months from the date of this Quarterly Report. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Because of these and other factors, we expect to continue to incur substantial net losses and negative cash flows from operations for at least the next several years. Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our revenue growth;
- the market awareness and adoption of our Vivistim System, including by our customers and their patients, and the extent to which we are able to successfully educate patients and customers about our current and future indications, and the benefits of our Vivistim Therapy in treating such conditions;
- our ability to expand our sales, marketing, and distribution capabilities in a timely and cost efficient manner, or at all;
- the availability and amount of reimbursement for procedures using our products;
- the new adoption and continued acceptance of private payor coverage of Vivistim Therapy;
- the emergence of competing, complementary or alternative technologies or therapies, including from other VNS neurostimulation device manufacturers or other stroke rehabilitation alternatives;
- the timing and extent of our research and development efforts;
- our ability to sustain meaningful clinical benefits for our patients;
- our ability to retain our current employees and the need and ability to hire additional management, sales, scientific, and clinical personnel;
- our need to implement additional infrastructure and internal systems;
- our ability to raise additional funds to finance our operations;
- general economic, industry and market conditions or extraordinary external events, such as a recession;

- the timing and success or failure of clinical trials or post-approval studies for our products or competing products;
- litigation or other claims against us for intellectual property infringement or otherwise; and
- our ability to hire additional personnel and undertake initiatives to support our operations as a public company.

To the extent that we need additional capital to continue to fund our operations, we intend to obtain such capital through public or private equity offerings or debt financings, credit or loan facilities, or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In the case of an insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our corporate assets. Any debt financing or additional equity that we raise may also contain terms that are not favorable to us or our stockholders. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our current or future product candidates, or grant licenses on terms that are not favorable to us. We may also seek additional financing opportunistically. We may be unable to raise additional funds on favorable terms, or at all.

Volatility in the capital markets and general economic conditions may be a significant obstacle to raising the required funds. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from factors that include but are not limited to, tariffs, trade and socioeconomic tensions, inflation, the conflict between Russia and Ukraine and in the Middle East, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise sufficient capital on acceptable terms, or at all, our ability to finance our planned operations and support business growth, our business, financial condition and results of operations will be materially and adversely affected.

We have limited clinical data, evidence and experience regarding the safety and efficacy of Vivistim Therapy.

Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes. Because Vivistim Therapy is relatively new in the treatment of upper extremity impairment for chronic stroke survivors, we have performed clinical trials only with limited patient populations relevant to our FDA-approved indication. The trials conducted to date have involved relatively small sample sizes, which may limit the statistical power of the findings and the precision of estimated treatment effects. For example, the largest population we studied was 108 participants in our pivotal REHAB trial. As a result, there is uncertainty as to whether the observed safety, efficacy and other outcomes will be applicable across broader patient populations and other, different sub-groups, including for variations in age, sex, race and ethnicity. The effects of using Vivistim Therapy in a large number of patients have not been studied extensively or over a long-term period, and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. While we have one year efficacy data from our pivotal REHAB trial and three year efficacy data from our pilot trial, these results were based on a small number of participants of 74 and 14, respectively. Moreover, clinical benefits may not persist in various circumstances, including if the patient discontinues or pauses occupational or physical therapy, does not otherwise adhere to the prescribed treatment regimen, or experiences an intervening medical or functional setback, and we have not studied the durability of effect in these scenarios.

After patients complete their initial in-clinic therapy protocol, they are expected to continue Vivistim Therapy at home with functional movements for at least 90 days. At-home Vivistim Therapy sessions last thirty minutes and follow the same principles as the in-clinic therapy. Patients who do not use the device as directed, such as not turning the device on during such sessions, or who fail to engage in the recommended task-specific therapy with the appropriate frequency or at all, may experience limited or no improvement from the completion of the in-clinic therapy, may be dissatisfied with their outcomes, and may attribute such poor results to Vivistim Therapy. We have no clinical data that indicates whether functional gains from the in-clinic therapy would be reversed if patients do not complete the home therapy sessions properly or sufficiently. As such, it is possible that patient noncompliance could lead to reversal of the functional gains during in-clinic therapy. Negative patient experiences – whether due to misuse, noncompliance, or unrealistic expectations – could reduce physician and patient acceptance, harm our reputation, and adversely affect demand.

In addition, the clinical outcomes supporting Vivistim Therapy have primarily been evaluated using the FMA-UE and the Wolf Motor Function Test (WMFT). Clinicians and therapists who rely on different outcome measures or standards may view our trial results as less relevant or may not accept these endpoints, and patients implanted with our device who are treated in settings that emphasize alternative scoring systems may not experience similar levels of observed benefits. Variability in accepted assessment

methodologies among physicians and therapists could reduce the perceived effectiveness of, and limit adoption of Vivistim Therapy, which could have a material adverse effect on our business, financial condition and results of operations.

The results of preclinical trials and clinical trials of our product conducted to date and ongoing or future trials of our current or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results, because they may include assumptions, calculations and conclusions that may prove to be inaccurate and because we may not have received or had the opportunity to fully and carefully evaluate all data. Data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations, indications or in the commercial use of our products. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical trials and earlier clinical trials have nonetheless failed to replicate results in later clinical trials and subsequently failed to obtain marketing approval or commercial acceptance. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through non-clinical trials and earlier clinical trials. We incur substantial expenses for, and devote significant time to, clinical trials but cannot be certain that the trials will continue to support positive commercial payor reimbursement coverage or result in commercial revenue. Failure can occur at any stage of clinical testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations, including our revenue, profitability, and cash flow, may vary significantly in the future, and period-to-period comparisons of our results of operations may not be meaningful. Accordingly, the results of any one quarter or other period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- the level of demand for our products, which may vary significantly from period to period;
- the rate at which we grow our sales force and the speed at which newly hired TMs and TDSs become effective, and the cost and level of investment therein;
- expenditures that we may incur to acquire, develop, or commercialize additional products and technologies;
- the degree of competition in our industry and any change in the competitive landscape of our industry;
- the timing and cost of obtaining regulatory approvals or clearances for future products;
- coverage and reimbursement policies with respect to the procedures using our products and potential future products that compete with our products;
- the timing and success or failure of clinical trials for our current or future products or any future products we develop or competing products;
- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to our products, which may change from time to time;
- the timing of customer orders or medical procedures, the number of available selling days in a particular period, which can be impacted by a number of factors, such as holidays or days of severe inclement weather in a particular geography, the mix of products sold, and the geographic mix of where products are sold;
- timing and adequacy of supply chain to meet demand;
- natural or man-made disasters, outbreaks of disease or public health crises;
- the timing and nature of any future acquisitions or strategic partnerships; and
- future accounting pronouncements or changes in our accounting policies.

Because our quarterly and annual results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

In addition, this variability and unpredictability could result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or results of operations fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it may result in a decrease in the price of our common stock.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be materially and adversely affected.

We are currently engaged in ongoing clinical trials of Vivistim Therapy and we may pursue other clinical trials in the future. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory authorization to commence a trial, in reaching an agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval at each site, in recruiting patients to participate in a trial, or in obtaining sufficient supplies of clinical trial materials. We cannot provide any assurance that we will successfully, or in a timely manner, enroll our clinical trials, that our clinical trials will meet their primary endpoints, or that such trials or their results will be accepted by the FDA or foreign regulatory authorities or lead to more positive reimbursement coverage decisions from commercial payors.

The initiation and completion of any clinical trials may be prevented, delayed, or halted, or the integrity of data collected may be compromised, for numerous reasons. We may experience delays in our ongoing clinical trials for a number of reasons, which could adversely affect the costs, timing, or successful completion of our clinical trials, including new indications for our existing product, including:

- we may be required to submit an Investigational Device Exemption (IDE) application to FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or conduct of our clinical trials;
- regulators or institutional review boards (IRBs) or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate, each resulting in significant delays;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with our clinical trial, consent or screening protocols;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical testing which may be expensive and time-consuming;
- trial results may not meet the level of statistical significance required by the FDA, other regulatory authorities, or payors;
- the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB or regulatory authorities for re-examination;
- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- clinical sites may not adhere to our clinical protocol or may drop out of a clinical trial;
- we may have trouble finding patients to enroll in our trials;
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply

of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate, or not available at an acceptable cost, or we may experience interruptions in supply;

- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects, and negatively affect our reputation and competitive position.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post treatment procedures, monitoring or follow-up to assess the safety and efficacy of a product, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

From time to time, we engage outside parties to perform services related to certain of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates or obtain positive commercial reimbursement coverage for our products.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations, or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under Quality Systems Regulations (the QSR) requirements and other regulations. From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical trials, and we may have limited influence over their actual performance. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to conduct clinical trials and monitor and analyze data from these trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, such as GCP guidelines, the Common Rule, and FDA human subject protection regulations. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant, or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness, or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical trials or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional trials, which would significantly increase our costs.

Our long-term growth depends in part on our ability to innovate and enhance our Vivistim System, expand our approved indications and develop and commercialize additional products in a timely manner. If we fail to identify, acquire, or develop other products, we may be unable to grow our business.

The market for Vivistim Therapy is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop products that compete directly with ours. Demand for Vivistim Therapy and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete, and our revenue would decline as our customers purchase our competitors' products. Developing products is expensive and time-consuming and could divert management's attention away from our core business. The success of any new product offering or product enhancements to our solution will depend on several factors, including our ability to:

- develop an effective and dedicated commercial team;
- assemble sufficient resources to acquire or discover additional products;
- receive adequate coverage and reimbursement for procedures performed with our products;
- develop and introduce new products and product enhancements in a timely manner;

- properly identify and anticipate physician and patient needs;
- anticipate and respond to competitive developments;
- avoid infringing upon the intellectual property rights of third-parties and protect our own intellectual property rights;
- demonstrate, if required, the safety and efficacy of new products or new indications with data from preclinical trials and clinical trials;
- obtain and maintain the necessary regulatory clearances or approvals for expanded indications, new products, or product modifications;
- be fully FDA-compliant with marketing of new devices or modified products;
- provide timely and effective customer and technical support;
- produce new products of an acceptable quality, in commercial quantities at an acceptable cost; and
- provide adequate training to physicians implanting and patients using of our products.

If we are unable to develop or improve products, applications or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills, or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

In addition, we may choose to focus our efforts and resources on potential products or indications that ultimately prove to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other potential products or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such potential products through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights, which could adversely impact our business, financial condition and results of operations.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must continue to recruit, retain, manage, and motivate qualified executives as we build out the management team, and we face significant competition for experienced personnel. We are highly dependent on executive officers, other members of senior management, as well as on our sales personnel, which includes TMs and TDSs. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our results of operations. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the medical device and neurostimulation field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other medical device, life science, and technology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If our business performance declines, we may be unable to offer competitive compensation packages, which could make it difficult to retain our current sales personnel. Additionally, if our competitors increase the compensation offered to their sales personnel, we may be required to increase our own compensation levels, which could increase our operating expenses and negatively impact our profitability. If we fail to increase our own compensation levels to match that of competitors, we may be unable to attract or retain our existing TMs and TDSs, or to attract new TMs or TDSs, which would prevent us from expanding our business and generating sales. If we are unable to continue to attract and retain high-quality sales personnel, the rate and success at which we can discover, develop, and commercialize our current and future products will be limited and the potential for successfully growing our business will be materially and adversely affected.

In addition, job candidates and existing employees often consider the value of the share awards they receive in connection with their employment. If the perceived value of our share awards declines, it may harm our ability to recruit and retain highly skilled

employees. Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock underlying options. Our employees may be more likely to leave our company if the common stock they own has significantly depreciated in value relative to the original purchase prices of the common stock, or if the exercise prices of the options that they hold are significantly above the market price of our common stock.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our Vivistim System. The expense and potential unavailability of insurance coverage for liabilities resulting from our Vivistim System could harm us and our ability to sell our Vivistim System.

We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians to implant our Vivistim System in patients. If these physicians are not properly trained, do not appropriately screen out patients who are contraindicated or otherwise not well-suited for an implant procedure or general anesthesia, or are negligent, the capabilities of our products may be diminished, or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- initiation of investigations by regulators;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to market and sell our products.

Although we carry product liability insurance, it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition, and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales.

Some of our customers and prospective customers may also have difficulty in procuring or maintaining liability insurance to cover their operations and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential customers may opt against purchasing our products due to the cost or inability to procure insurance coverage.

The terms of our loan and security agreement places restrictions on our operations and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On December 29, 2023, we entered into a loan and security agreement (the Loan and Security Agreement) with Horizon Technology Finance Corporation as lender and collateral agent. On June 1, 2024, Horizon Technology Finance Corporation assigned all of its right, title and interest in and to the loans outstanding under the Loan and Security Agreement and related warrants to Horizon Funding II, LLC, its wholly-owned subsidiary (together with Horizon Technology Finance Corporation, Horizon). The Loan and Security Agreement provides for term loans of up to an aggregate principal amount of $30.0 million, available in four equal tranches of $7.5 million available at various dates (the Commitments). The Company's ability to draw additional loans under the Loan and Security Agreement expired on December 31, 2025. The Loan and Security Agreement matures on January 1, 2029. As of March 31, 2026, there was $7.5 million outstanding under the Loan and Security Agreement, representing the full available aggregate principal amount under the Loan and Security Agreement, and no additional tranches are available to draw down under the Loan and Security Agreement in the future.

Borrowings under the Loan and Security Agreement bear interest at an annual rate equal to the greater of (i) The Wall Street Journal (or any successor thereto) prime rate (subject to a floor of 8.50%) plus 3.75%, and (ii) 12.25%. Amounts outstanding under the Loan and Security Agreement are secured by substantially all of our assets, excluding intellectual property. We must make interest payments under the Loan and Security Agreement, which have diverted and will continue to divert resources from other activities. The Loan and Security Agreement includes customary affirmative and negative covenants and events of default. The covenants related to the Loan and Security Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies.

While we have not previously breached and are not currently in breach of these or any other covenants contained in the Loan and Security Agreement, there can be no guarantee that we will not breach these covenants or any covenants under any other debt arrangements in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the Loan and Security Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the Loan and Security Agreement to become immediately due and payable and terminate commitments to extend further credit and foreclose on the collateral granted to it to collateralize such indebtedness. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

If we default under the Loan and Security Agreement, Horizon will be able to declare all obligations immediately due and payable and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. The lenders could declare a default under the Loan and Security Agreement upon the occurrence of specific events such as our failure to pay or our failure to comply with specified covenants, thereby requiring us to repay the loan immediately. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common shares to decline.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral or force us into bankruptcy or liquidation.

Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our business, financial condition and results of operations.

In an effort to reduce costs, many hospitals and ambulatory surgery centers (ASCs) in the United States have become members of group purchasing organizations (GPOs) and integrated delivery networks (IDNs). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals, ASCs and other members.

GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Accordingly, even if we secure a contract with a GPO or an IDN, we nonetheless need to negotiate contracts or purchase orders with individual GPO or IDN members, which can further increase the length of our sales cycle, increase sales costs and means that our sales success is uncertain even if we contract with a GPO or IDN. Furthermore, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue.

If we or our third-party providers fail to protect confidential information and/or experience data security incidents, there may be damage to our brand and reputation, material financial penalties, and legal liability, which could materially and adversely affect our business, results of operations and financial condition.

We rely on computer systems, hardware, software, technology infrastructure and online sites and networks for both internal and external operations that are critical to our business (collectively, IT Systems). We own and manage some of these IT Systems but also rely on third parties for a range of IT Systems and related products and services, including but not limited to financial records, facilitate our research and development initiatives, manage our manufacturing operations, maintain quality control, fulfill customer orders, maintain corporate records, communicate with staff and external parties and operate other critical functions. We and certain of our third-party providers collect, maintain and process data about customers, employees, business partners and others, including information about individuals, as well as confidential or proprietary information belonging to our business such as trade secrets (collectively, Confidential Information).

Cyberattacks are expected to accelerate on a global basis in frequency and magnitude as threat actors are becoming increasingly sophisticated in using techniques and tools—including AI—that circumvent security controls, evade detection and remove forensic evidence. As a result, we may be unable to detect, investigate, remediate or recover from future attacks or incidents, or to avoid a material and adverse impact to our IT Systems, Confidential Information or business. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our IT Systems and Confidential Information. Furthermore, given the nature of complex systems, software and services like ours, and the scanning tools that we deploy across our networks and products, we regularly identify and track security vulnerabilities. We are unable to comprehensively apply patches or confirm that measures are in place to mitigate all such vulnerabilities, or that patches will be applied before vulnerabilities are exploited by a threat actor. If attackers are able to exploit critical vulnerabilities before patches are installed or mitigating measures are implemented, significant compromises could impact our IT Systems and/or Confidential Information.

We and certain of our third-party providers regularly experience cyberattacks and other incidents, and we expect such attacks and incidents to continue in varying degrees. While to date no incidents have had a material impact on our operations or financial results, we cannot guarantee that material incidents will not occur in the future. Any adverse impact to the availability, integrity or confidentiality of our IT Systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. Any or all of the foregoing could materially and adversely affect our business, results of operations and financial condition. Finally, we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all.

To the extent we expand sales of our products internationally in the future, we will be exposed to additional risks associated with international business.

While we do not currently market outside of the United States, sales of products internationally will be subject to foreign regulatory requirements governing clinical trials and marketing approval. To the extent we expand sales of our products internationally in the future, we will incur substantial expenses. Additional risks related to operating in foreign countries include:

- differing and evolving regulatory requirements and reimbursement regimes in foreign countries;

- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- weaker intellectual property protections in certain foreign markets;
- compliance with tax, employment, immigration, and labor laws for employees living, working, or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act (FCPA) or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- there may be intellectual property held by third parties specific to one or more of those jurisdictions that would limit our ability to distribute the product without a license; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially and adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, there can be no guarantee that we will receive marketing authorization to sell our products in every international market we target, nor can there be any guarantee that any sales would result even if such authorization is received. Regulatory requirements can vary widely from country to country and could delay the introduction of our products in those countries. Our inability to successfully enter all our desired international markets and manage business on a global scale could materially and adversely affect our business, financial results and results of operations.

We may acquire other companies' technologies or intellectual property, which could fail to result in a commercial product or net sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and materially and adversely affect our results of operations.

We may in the future seek to acquire or invest in businesses, applications, technologies or intellectual property that we believe could complement or expand our portfolio, enhance our technical capabilities, or otherwise offer growth opportunities. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product, or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating, and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment. We may also be unable to identify all material liabilities associated with companies we acquire and any indemnities which we receive from the target in connection with an acquisition may be unavailable or insufficient to cover such liabilities.

To date, the growth of our operations has been organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations, and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could materially and adversely affect our results of operations. In addition, if an acquired business fails to meet our expectations, our business, financial condition and results of operations may be materially and adversely affected.

Risks Related to Intellectual Property

If we are unable to maintain existing, and obtain additional, patent and other intellectual property protection for our technology and products, or if the scope of the patent protection we obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

Our success depends in large part on our ability to maintain existing, and obtain additional, patent and other intellectual property protection in the United States and other countries with respect to our products and technology we develop.

We have protected and seek to protect our position by in-licensing intellectual property relating to our products and filing patent applications in the United States and abroad related to our technologies and products that are important to our business. Our ability to protect our products from unauthorized copying or recreation by third parties may be limited by the extent that such products are covered by valid and enforceable patents or include information that is effectively maintained as a trade secret. The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent and the scope of its coverage. For example, we rely on patents covering how the Vivistim System is used, commonly referred to as method patents.

We also rely on a combination of contractual provisions, confidentiality procedures and copyright, trademark, trade secret, and other intellectual property rights to protect the proprietary aspects of our brand, technologies, and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and Confidential Information. Our success will depend, in part, on obtaining and maintaining patents, preserving our trade secrets, maintaining the security of our data and know-how, and obtaining other intellectual property rights.

We may not be able to obtain and maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. For example, our trade secrets, data, and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality or other restrictive covenant agreements with our employees, consultants, contractors, clients, and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. In addition, the patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our intellectual property at all. Despite our efforts to protect our intellectual property, unauthorized parties may be able to obtain and use information that we regard as proprietary. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, contractors, collaborators, vendors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were or will be the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were or will be the first to file for patent protection of such inventions.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, or invalidated by third parties. Additionally, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Third parties may also have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products that are similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable, or not infringed, in which case, our competitors and other third

parties may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Given that patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel, or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, given the amount of time required for the development, testing, and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future, be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interests in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Our other intellectual property, including our trademarks, could also be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic, or found to be infringing on other marks, in which case we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote significant resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion.

We may in the future also be subject to claims by our current or former employees, consultants, or contractors asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants, contractors, and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Failure to obtain and maintain patents, trademarks, and other intellectual property rights necessary to our business and failure to protect, monitor, and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation, or misappropriation of our patents, trademarks, data, technology, and other intellectual property, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, this could arise if the research resulting in certain of our owned or in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our Confidential Information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could materially and adversely affect our competitive position, business, financial condition, and results of operations.

Any intellectual property litigation or administrative proceedings can be costly and could interfere with our ability to sell and market our products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It

is possible that United States and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit, or otherwise interfere with our ability to make, use, sell, or export our products or to use product names. Because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. We may receive inquiries regarding our intellectual property, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others.

The defense of intellectual property litigation can be time consuming and costly, can divert management's attention and resources, damage our reputation and brand, and cause us to incur significant expenses or make substantial payments, whether or not we receive a determination favorable to us.

Even if we believe a third party's intellectual property claims are without merit, there is no assurance that a court would find in our favor, including on questions of infringement, validity, enforceability, or priority of patents. The strength of our defenses will depend on the patents asserted, the interpretation of these patents, and our ability to invalidate the asserted patents. In the United States, in order to successfully challenge the validity of a patent in federal court, we would need to overcome a presumption of validity. This standard of proof is a high one, requiring us to present clear and convincing evidence of the invalidity of each asserted claim of the patent. There is no assurance that the court would agree that we had met that standard. Conversely, the patent owner needs only to prove infringement by a preponderance of the evidence, which is a lower standard of proof. If a court of competent jurisdiction should hold that third-party patents are valid, enforceable, and infringed, this could materially and adversely affect our ability to commercialize any products or technology we may develop, and any other products or technologies covered by the asserted third-party patents.

Further, if patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from developing, manufacturing, or selling our products or offering certain therapies with Vivistim Therapy, or result in obligations to pay license fees, damages, attorney fees, and court costs, which could be significant. In addition, if we are found to willfully infringe third-party patents or trademarks or to misappropriate trade secrets, we could be required to pay treble damages in addition to other penalties.

In addition, vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third party's patent or trademark or of misappropriating a third party's trade secret, or any indemnification granted by such vendors may not be sufficient to address any liability and costs we incur as a result of such claims. Additionally, we may be obligated to indemnify our customers or business partners in connection with litigation and to obtain licenses or refund subscription fees, which could further exhaust our resources.

Although patent, trademark, trade secret and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. In addition, if any license we obtain is non-exclusive, we may not be able to prevent our competitors and other third parties from using the intellectual property or technology covered by such license to compete with us. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement, and we could be forced to cease some aspects of our business operations. Any of these events could materially and adversely affect our business, financial condition, and results of operations.

Similarly, interference proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office (the USPTO), may be necessary to determine priority of, or ownership rights in, our patents, patent applications, trademarks, or trademark applications. We may also become involved in other proceedings, such as reexamination, inter partes review, derivation or opposition proceedings relating to our or a third party's patents or patent applications, or cancellation or opposition proceedings relating to our or a third party's registered trademarks, before the USPTO or the equivalent body in other jurisdictions. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a material adverse effect on our business, financial condition, and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual

property, which we may not always be able to detect. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe on their intellectual property or alleging that our intellectual property is invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise challenges to the validity of certain of our owned or in-licensed patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In any such lawsuit or other proceedings, a court or other administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail over a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or products that we may develop. If our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Any of these events could materially and adversely affect our business, financial condition, and results of operations.

Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. Uncertainties resulting from the initiation and continuation of patent and other intellectual property litigation or other proceedings could have a material adverse effect on our business, financial condition, and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or any of our current or future licensors fail to maintain the patents and patent applications that we in-license, our competitors may be able to enter the market, which would have a material adverse effect on our business.

The terms of our patents may not be sufficiently long to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date but can be shorter due to terminal disclaimers or similar term reductions in other jurisdictions. Although various extensions may be available, the term of a patent, and the protection it affords, are limited. Even if patents covering our technologies or products are obtained, once the patent term has expired, we may be open to competition. In addition, although upon issuance in the United States, a patent's term can be increased based on certain delays caused by the USPTO, this increase can be

reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing, and regulatory review of products, patents protecting such product candidates might expire before or shortly after such products are commercialized. If we do not have sufficient patent life to protect our technologies and products, our business, financial condition, and results of operations will be materially and adversely affected.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope, or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products in any jurisdiction.

The scope of a patent claim is a legal conclusion that rests upon consideration of the written disclosure in a patent, the patent's prosecution history, and usage by artisans in the relevant field. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may materially and adversely impact our ability to develop and market our products.

Reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

If we rely on third parties to manufacture Vivistim Therapy, or any future products, or if we collaborate with third parties on future developments for Vivistim Therapy, or other future products, we may need to, at times, share trade secrets with them. We may also conduct research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our trade secrets and other proprietary technology in part by entering into confidentiality agreements with third parties prior to disclosing Confidential Information. These agreements typically limit the rights of the third parties to use or disclose our Confidential Information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other Confidential Information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors, and other service providers to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our Confidential Information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the third parties who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. A competitor's discovery of our trade secrets would impair our competitive position and have a material adverse effect on our business.

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

Many of our employees, consultants, and contractors were previously employed at or engaged by other medical device, biotechnology, or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and contractors may have executed proprietary rights, non-disclosure, non-competition or other restrictive covenant agreements in connection with such previous employment or engagement. Although we try to ensure that our employees and consultants do not use the intellectual property, confidential information, know-how, or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other confidential information of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees, consultants, or contractors have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other confidential information of the former employers.

An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition, and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent TMs or TDSs. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to claims challenging the inventorship or ownership of our future patents and other intellectual property.

We may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising from, for example, conflicting obligations of consultants, contractors, or others who are involved in developing our products. Our success depends in part on our ability to obtain, maintain, protect, and enforce our intellectual property rights, including our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating, or otherwise violating the intellectual property rights of others. We rely on a combination of patents, trademarks, trade secrets, and other intellectual property rights to protect the products and technology that we consider important to our business.

Although it is our policy to require our employees and contractors who may be involved in the conception or development of products, technology, know-how, and other proprietary materials (collectively, the Technology) to execute agreements assigning all intellectual property rights in and to such Technology to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops Technology that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely, in part, upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our products and technology. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be materially and adversely affected.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could materially and adversely affect our business, financial condition, and results of operations.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. In spite of our best efforts, our licensors might also conclude that we have materially breached our license agreements and terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors will have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could materially and adversely affect our business, financial condition and results of operations.

In the future, we may enter agreements involving licenses or collaborations that provide for access or sharing of intellectual property. If we fail to comply with our obligations under any license, collaboration, or other agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our current and future products.

We currently, and in the future may continue to, license from third parties certain intellectual property relating to our current and future products. In the event we do so, we may have certain obligations to such licensors. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any of our future licensors and us and our partners.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected products, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor’s express consent in order for an assignment or transfer to take place.

Further, we or our future licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our future licensors fail to establish, maintain, or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business.

In addition, even where we have the right to control patent prosecution of patents and patent applications under future license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed in the future from various third parties may be subject to retained rights. Our predecessors or licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or future licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (Bayh-Dole Act). The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. If we choose to collaborate with academic institutions to accelerate our preclinical research or development, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be materially and adversely affected.

If we are limited in our ability to utilize acquired or future licensed technologies, or if we lose our rights to critical future in-licensed technology, we may be unable to successfully develop, out-license, market, and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies, and possibly in the future licensed technology, into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license, or market and sell our products.

We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in-licenses.

We may need to obtain additional licenses from our existing licensors or otherwise acquire or in-license any intellectual property rights from third parties that we identify as necessary for our products. It is possible that we may be unable to obtain any additional licenses or acquire such intellectual property rights at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital 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 rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. In that event, we may be required to expend significant time and resources to redesign our technology, products, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could have a material adverse effect on our business, financial condition, and results of operations.

Any collaboration or partnership arrangements that we may enter into in the future may not be successful, which could materially and adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current and future products;

- a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or Confidential Information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or Confidential Information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development, or commercialization of our current or future products, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.

If we are unable to protect the confidentiality of our other Confidential Information, our business and competitive position may be materially and adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other Confidential Information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and Confidential Information, we rely heavily on confidentiality provisions and other restrictive covenants that we have in contracts with our employees, consultants, collaborators, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other Confidential Information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other Confidential Information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could materially and adversely affect our ability to expand to international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other Confidential Information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect, and enforce our intellectual property rights could materially and adversely harm the value of our products, brand, and business. The theft or unauthorized use or publication of our trade secrets and other Confidential Information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced, and third parties might make claims against us related to losses of their confidential information. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets, and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other Confidential Information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of Confidential Information and enforcing a claim that a party illegally disclosed or misappropriated Confidential Information is difficult, expensive, and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of our patents in general, thereby impairing our ability to protect our products and could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our current or future patents.

Our ability to obtain patents and the breadth of any patents obtained is uncertain in part because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and other countries. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection, which in turn could diminish the commercial value of our products, services, and technologies.

The United States has enacted and implemented wide-ranging patent reform legislation, and further patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. 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 with regard to 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 actions by 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 have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, or changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, in June 2023, the European Unitary Patent system and the European Unified Patent Court (UPC) were launched. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system began and granted thereafter, are subject to the jurisdiction of the UPC, unless actively opted out. This was a significant change in European patent practice, and deciding whether to opt-in or opt-out of Unitary Patent practice entails strategic and cost considerations. The UPC provides third parties with a new forum to centrally revoke our European patents and makes it possible for a third party to obtain pan-European injunctions against us. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court's existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.

We cannot predict future changes in the interpretation of patent laws in the United States and other countries or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially and adversely affect our patents or patent applications and our ability to obtain additional patent protection in the future. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, and results of operations.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, and defending patents covering Vivistim Therapy, and any of our future products throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may have or obtain patent protection, but where patent enforcement is not as strong as that in the United States. These unauthorized products may compete with our products in such jurisdictions and take away our market share 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.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our current or future products we intend to commercialize that are not covered by the patents that we exclusively licensed and have the right to enforce;
- an in-license necessary for the manufacture, use, sale, offer for sale, or importation of one or more of our current or future products may be terminated by the licensor;
- we or any of our current or future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we or any of our current or future licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- the patents of others may have an adverse effect on our business; and
- we may not develop additional proprietary technologies that are patentable.

Our use of "open source" software could subject the proprietary software we use to general release, materially and adversely affect our ability to sell our products and subject us to possible litigation.

We use "open source software" in a portion of the products or technologies licensed, developed, or distributed by us, including as incorporated into software we receive from third-party commercial software vendors, and we may incorporate open source software into other products in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of the software we utilize in connection with open source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our products that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their products. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could materially and adversely affect our business, financial condition, and results of operations.

If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be materially and adversely affected.

We rely on trademarks, service marks, tradenames, and brand names to distinguish our products from the products of our competitors and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to

those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands.

For example, we have not registered the name "MicroTransponder," "Mobia" or "Mobia Medical" as a word trademark in the United States on the principal register, although we have obtained registration of the name "MicroTransponder" on the supplemental register. Registration on the principal register offers certain protections not provided to registrations on the supplemental register, including the right to obtain statutory damages and attorneys' fees in connection with third party infringement of the trademark, the right to register a mark with U.S. Customs to prevent the importation of goods that contain infringing marks and the ability to seek incontestability status after five years of registration on the primary register. Without a registered trademark on the principal register, we may encounter difficulty in enforcing, or be unable to enforce, the name "MicroTransponder," "Mobia" or "Mobia Medical" against third parties in the United States, which could adversely affect our business and our ability to effectively compete in the marketplace.

At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be materially and adversely affected.

Risks Related to Government Regulation

Our products and operations are subject to extensive government regulation and oversight in the United States, and our failure to comply with applicable requirements could materially and adversely affect our business.

Our products are regulated as medical devices in the United States. Medical devices and their manufacturers and product developers are subject to extensive regulation in the United States, including by the FDA. The FDA regulates, among other things, with respect to medical devices: design, development, and manufacturing; testing, labeling, content, and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales, and distribution; premarket clearance, classification, and approval or certification; recordkeeping procedures; complaint procedures and protocols, including documentation thereof; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export.

The regulations to which we are subject are complex, burdensome to understand and apply, and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces its regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we or any of our contract manufacturers will be found compliant in connection with any future FDA or foreign inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: FDA inspectional observations; warning letters; fines; injunctions; civil penalties; termination of distribution; import alerts; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties. For example, following a routine FDA inspection in March 2026, we received a notice of inspectional observations, or Form 483, with one observation involving two events for which a medical device report was not submitted within 30 days of receiving or otherwise becoming aware of information regarding such events. These events have since been reported and we believe we have since addressed this observation with a corrective and preventative action plan, which included streamlined procedures for evaluating potential adverse events and training for relevant personnel at the Company regarding these procedures and reporting. We submitted a formal written response to FDA in April 2026. To date, the FDA has not taken any further action with respect to the inspection or its findings.

Failure to maintain marketing authorizations for our products, or to timely obtain necessary marketing authorizations for our future products, may have a material and adverse effect on our business, financial condition and results of operations.

Our products are subject to extensive regulation by the FDA and the Federal Communications Commission (the FCC) in the United States and by regulatory agencies in other countries where we do business. For medical devices involving radio frequency (RF)

wireless technologies, the FDA's policies on wireless medical devices coordinate with the FCC. In the United States, before we can market a new medical device, or a new use of, or other significant modification to an existing, marketed medical device, we must first receive either clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act (the FDCA), approval of a premarket approval (PMA) application, or grant of a de novo classification request from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices.

In the de novo classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the de novo classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

The PMA approval, 510(k) clearance and de novo classification processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Clinical data may also be required in connection with an application for 510(k) clearance or a de novo classification request. Despite the time, effort and cost, a device may not obtain marketing authorization by the FDA. We have obtained PMA approval for Vivistim Therapy, and we must obtain marketing authorization for any future devices we develop or future additional indications for Vivistim Therapy, unless they are exempt. Marketing authorizations for any of our future products, if granted, may include significant limitations on the indicated uses for the device, which may limit the potential commercial market for the device.

In the United States, any modification to a medical device for which we have obtained a PMA may require us to submit a new PMA or PMA supplement and obtain FDA approval. For example, certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. We have made modifications to our approved Vivistim Therapy and submitted and received approval of PMA supplements in the past. We may make modifications or add additional features in the future to Vivistim Therapy that we believe do not require a new approval of a PMA or PMA supplement. If the FDA disagrees with our determination and requires us to seek new marketing authorizations for the modifications for which we have concluded that new marketing authorizations are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain such marketing authorization, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business.

The FDA can delay, limit or deny marketing authorization of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA that our products are substantially equivalent to a predicate device or are safe and effective for their intended uses;
- the disagreement of the FDA with the design or implementation of clinical trials or the interpretation of data from preclinical trials or clinical trials;
- serious and unexpected adverse device effects experienced by participants in clinical trials;
- the data from preclinical trials and clinical trials may be insufficient to support clearance, de novo classification, or approval, where required;

- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for marketing authorization regulations of the FDA to change significantly in a manner rendering our clinical data or regulatory filings insufficient for marketing authorization.

We are subject to ongoing regulatory review and scrutiny. Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

We are subject to ongoing and extensive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. For example, medical device manufacturers must submit certain reports to the FDA and keep required records as a condition of obtaining and maintaining marketing authorization. These reports include information about failures and certain adverse events potentially associated with the device after its marketing authorization. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. We have ongoing responsibilities under FDA regulations, and the FDA and state regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state regulatory authorities, which may include any of the following or other sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees, and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement, or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances, de novo classifications or approvals, or comparable foreign marketing authorizations of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of any granted marketing authorizations, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in negative publicity, higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

In addition, the FDA may change its marketing authorization policies which may affect future products. The FDA may adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of any products under development or impact our ability to modify any products authorized for market on a timely basis. Such changes may also occur in foreign jurisdictions where we may market our products in the future. Such changes could impose additional requirements upon us that could delay our ability to obtain future marketing authorizations, increase the costs of compliance, or restrict our ability to maintain any marketing authorizations we have obtained.

The misuse or off-label use of our products may result in injuries that harm patients and lead to product liability suits, harm our reputation in the marketplace, or result in costly investigations, fines, or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Vivistim Therapy, and any marketing authorization we may receive for future products, is, and will be, limited to specified indications for use. We train our commercial team, including our direct sales force, to not promote our device for use outside of the FDA-authorized indications for use, known as "off-label uses." However, this training may not be effective in preventing all instances of off-label promotion. We cannot, in addition, prevent a healthcare professional from using our devices off-label, when in the healthcare professional's independent professional judgment he or she deems it appropriate. There may be increased risk of injury to

patients if healthcare professionals attempt to use our devices off-label, which could harm our reputation in the marketplace among healthcare professionals and patients.

If the FDA determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal or state enforcement authorities might take action under other regulatory authority, such as false advertising and consumer protection laws, or false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil, and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations.

In addition, healthcare professionals may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, even if we are ultimately successful in our defense, product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizeable damage awards against us that may not be covered by insurance, all of which would have a material adverse effect on our business, financial condition and results of operations.

Our products must be manufactured in accordance with applicable laws and regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.

In the United States, the methods used in, and the facilities used for, the manufacture of medical devices must comply with the FDA's Current Good Manufacturing Practices for medical devices, known as the Quality System Regulation (QSR), which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of medical devices. On February 23, 2024, the FDA issued a final rule to amend the QSR to align more closely with the International Organization for Standardization (ISO) standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, replaces the QSR with the Quality Management System Regulation (QMSR), and among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create market pressure that may negatively affect our business. Furthermore, we are required to verify that our suppliers maintain facilities, procedures, and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR, and is expected to enforce the QMSR, through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations governing manufacturing.

Despite our efforts to ensure compliance, we or our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our medical devices. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions, or civil penalties; suspension or withdrawal of marketing authorizations; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products or similar decisions by foreign regulatory authorities or notified bodies; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees. Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs. We are also subject to similar state requirements and licenses.

Our products have in the past, and may in the future cause or contribute to adverse medical events or be subject to failures or malfunctions which we may be required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could materially and adversely affect our reputation, business, financial condition and results of operations. In addition, the discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA, could have a material adverse effect on us.

There have been, and there may continue to be side effects and adverse events associated with the use of our medical devices or any future devices we develop. The FDA's medical device reporting regulations require us to assess reportability of adverse events that come to our attention and report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction

were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. The FDA may also disagree with our determinations that an event was not reportable. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our marketing authorizations, seizure of our products, or delay in obtaining marketing authorizations for our future products.

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could in the future occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects, or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new marketing authorizations for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may in the future initiate voluntary withdrawals or corrections for our products that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could materially and adversely affect our reputation with customers, potentially lead to product liability claims against us, and materially and adversely affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may materially and adversely affect our reputation, business, financial condition and results of operations and could expose us to material claims and losses.

Healthcare reform initiatives and other administrative and legislative proposals in the United States may materially and adversely affect our business, financial condition and results of operations.

There have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the United States healthcare system. Outside of the United States, foreign governments and regulatory authorities may implement new requirements that could impact our business and market acceptance. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition and results of operations.

For example, in the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together, the Affordable Care Act (the ACA) was enacted. The ACA made a number of substantial changes to the way healthcare is financed by both governmental and private insurers, including the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. More recently, the One Big Beautiful Bill Act (the OBBBA) was signed into law on July 4, 2025, and contains provisions that, among other changes, are expected to reduce the number of individuals enrolled in state Medicaid programs and ACA marketplace plans, which could adversely affect commercialization of Vivistim Therapy. We cannot predict how other litigation or legislative efforts, or the healthcare reform measures of the Trump administration will impact our business. The Trump administration is currently pursuing policies to reduce regulations and expenditures across government including at the U.S. Department of Health and Human Services, the FDA, the CMS, and related agencies. It is possible that certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our customers for procedures in which our products are utilized from governmental agencies or

third-party payors. We cannot assure you that the ACA or the OBBBA, as currently enacted or as amended in the future, will not harm our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers, which went into effect on April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032, unless additional congressional action is taken.

Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 (the MACRA) enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs may have on our business, financial condition, results of operations, or cash flows. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and accordingly, our financial operations.

There likely will continue to be legislative and regulatory proposals at the 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 or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. While some of these measures may require additional authorization to become effective, Congress and the Federal administration have each indicated that it will continue to seek new legislative or administrative measures to control product costs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability. Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services and could have a material adverse effect on our business, financial condition and results of operations.

If we fail to comply with U.S. federal and state fraud and abuse and other healthcare laws and regulations, we could face substantial penalties and our business operations and financial condition could be materially and adversely affected. In addition, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could materially and adversely affect our business.

The U.S. healthcare industry is heavily regulated and closely scrutinized by foreign, federal, state and local authorities. We are subject to various state and federal fraud and abuse, anti-kickback, false claims, transparency requirements, consumer protection and other healthcare laws and regulations. These laws constrain the business and financial arrangements and relationships through which we research, sell, market, and distribute our products, such as our arrangements with hospitals, physicians, therapists, customers and third-party payors. Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute (AKS), which prohibits the knowing and willful offer, payment, solicitation or receipt of any bribe, kickback, rebate or other remuneration for referring an individual, in return for ordering, leasing, purchasing or recommending or arranging for or to induce the referral of an individual or the ordering, purchasing or leasing of items or services covered, in whole or in part, by any federal healthcare program, such as Medicare and Medicaid. "Remuneration" includes the transfer of anything of value, in cash or in kind and directly or indirectly. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act (FCA), which imposes civil and criminal liability on individuals or entities that knowingly submit false or fraudulent claims for payment to the government or knowingly making, or causing to be made, a false statement in order to have a false claim paid, including qui tam or whistleblower suits. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the criminal healthcare fraud provisions of HIPAA and related rules, which prohibit knowingly and willfully executing a scheme or artifice to defraud any healthcare benefit program or falsifying, concealing or covering up a material fact or making any material false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal transparency requirements under the Physician Payments Sunshine Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal and state anti-inducement laws, which prohibit the offer or transfer of remuneration that would influence the patient to order or receive a healthcare item or service; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers or patients, state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state and local laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their TMs or other sales personnel.

Due to the breadth of these laws and the narrowness of statutory exceptions and regulatory safe harbors available, it is possible that some of our current or future practices, such as our commercial activities, interactions with physicians and patients, and reimbursement support activities might be challenged, by regulatory authorities, our competitors or others, under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between medical device and pharmaceutical manufacturers and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations and qui tam actions can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, manufacturers may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business, financial condition and results of operations. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm and disgorgement and we could be required to curtail, restructure or cease our operations. Any of the foregoing consequences will materially and adversely affect our business, financial condition and results of operations.

Legislative or regulatory reforms in the United States may make it more difficult and costly for us to manufacture, market, or distribute our products, or to obtain marketing authorizations for any future products.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of any future products under development or impact our ability to modify any products for which we have already obtained marketing authorizations on a timely basis. For example, on January 31, 2024, the FDA issued a final rule to amend the QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the ISO standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, replaces the QSR with the QMSR, and among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the existing QSR, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create market pressure that may materially and adversely affect our business. It is unclear to what extent any other legislative or regulatory proposal, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may materially and adversely affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may make it more difficult and costly to manufacture, market, or distribute our commercialized products, or may impose additional costs, lengthen marketing authorization review times, or make it more difficult to obtain marketing authorizations for any future products we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

We are subject to numerous laws and regulations related to anti-bribery and anti-corruption laws, such as the FCPA, anti-money laundering laws, and economic and trade sanctions, in which violations of these laws could result in substantial penalties and prosecution.

We are similarly subject to various heavily enforced anti-bribery and anti-corruption laws, such as the FCPA, anti-money laundering laws, and similar laws around the world. The FCPA or other anti-corruption and anti-bribery laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing, or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third-party business partners and intermediaries, fail to comply with the FCPA or other anti-corruption and anti-bribery laws. Certain suppliers of components of our devices are located in countries known to experience corruption. Business activities in these countries create the risk of unauthorized payments or offers of payments by one of our employees, consultants, contractors, or agents that could be in violation of various laws, including the FCPA and anti-bribery laws in these countries, even though these parties are not always subject to our control. While we have implemented policies and procedures designed to discourage these practices by our employees, consultants, contractors and agents and to identify and address potentially impermissible transactions under such laws and regulations, we cannot assure you that none of our employees, consultants, contractors and agents will take actions in violation of our policies, for which we may be ultimately responsible.

We are also subject to certain economic and trade sanctions programs, including those administered by the U.S. Department of the Treasury's Office of Foreign Assets Control, which prohibit or restrict transactions or dealings with or involving specified countries, their governments, and in certain circumstances, their nationals, or with individuals and entities that are specially-designated nationals, narcotics traffickers, terrorists or terrorist organizations, or otherwise blocked or sanctioned pursuant to applicable regulations. In addition, we are subject to export controls and similar trade restrictions, which restrict or prohibit the export, re-export, and transfer of certain goods, software, technology, and services to specified countries, governments, entities, and individuals. For example, in December 2021, the U.S. Congress enacted the Uyghur Forced Labor Prevention Act in an effort to prevent what it views as forced labor and human rights abuses in the Xinjiang Uyghur Autonomous Region, or XUAR, of China. If it is determined that our

third-party suppliers and manufacturers produce or manufacture our components or products wholly or in part from the XUAR, or certain designated entities, then we could be prohibited from importing such components or products into the United States. Similarly, the U.S. government has increasingly issued new restrictions limiting access to federal contracts or funds for companies that source certain types of equipment or services from designated companies in China or other so-called countries of concern.

Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti-bribery or anti-corruption laws, anti-money laundering laws, or sanctions could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and suspension or debarment from U.S. government contracts, which could have a material adverse effect on our business, financial condition and results of operations.

Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as supply chain disruption, significant costs, and negative publicity.

Our business is subject to significant risks associated with manufacture, distribution, and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead in the future to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and result in significant costs, negative publicity, and adverse competitive pressure. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition and results of operations.

We provide a limited warranty that our products are free of material defects in workmanship and materials and conform to specifications, and offer to repair or replace defective products. Although we have had very few warranty claims to date, we bear the risk of potential warranty claims on our products. If we receive a significant number of warranty claims or our products require significant amounts of service after sale, our operating expenses may substantially increase and our business and financial results will be adversely affected. We have a limited history of commercial placements from which to judge our rate of warranty claims, and we expect that the number of warranty claims we receive may increase as we scale our operations and as our existing commercial placements age. If product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated reductions in sales or additional operating expenditures for parts and service. In addition, our reputation could be damaged and our products may not achieve the level of market acceptance that we are targeting in order to achieve and maintain profitability. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors or that any recovery from such vendor or supplier would be adequate.

The medical device industry has historically been subject to extensive litigation over product liability claims. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, ASCs, physicians, or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any claims to avoid fault and complication not due to failure of our products. An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls, or market withdrawals.

We are required to file adverse event reports under Medical Device Reporting (MDR) regulations with the FDA that are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require our time and capital, distract management from operating our business and may harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

Our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, commercial team, consultants, commercial partners, distributors, and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct, or disclosure of unauthorized activities to us that violates: (i) FDA laws and laws of other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws, including anti-kickback law and patient inducement laws, in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing, and education programs. In particular, the promotion, sales, and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities 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 be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, imposition of a corporate integrity agreement, additional integrity reporting, compliance and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could materially and adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

Environmental and health safety laws may result in liabilities, expenses, and restrictions on our operations. Failure to comply with environmental laws and regulations could subject us to significant liability.

Our research and development and supply chain operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment, and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could materially and adversely our business, financial condition and results of operations.

Federal, state, local, and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Using hazardous substances in our operations exposes us to the

risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our business, financial condition, and results of operations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive, and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure, or other causes. The expense associated with environmental regulation and remediation could materially and adversely affect our business, financial condition and results of operation.

We are subject to, or may in the future become subject to, ever-evolving federal, state, and foreign laws and regulations imposing obligations on how we collect, store, use and process information collected from or about individuals or their procedures using our products. Our or our vendors' actual or perceived failure to comply with such obligations could materially and adversely our business. Ensuring compliance with such legal requirements could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In the conduct of our business, we may at times process personal information, including health-related personal information including from and about patients, as well as our employees and business contacts. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as the Common Rule, GCP guidelines, or FDA human subject protection regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. In addition to specific healthcare laws and regulations, the U.S. federal government and various states have adopted or proposed laws, regulations, guidelines, and rules with respect to the collection, distribution, use, and storage of personal information of patients. We also depend on a number of third party vendors in relation to the operation of our business, a number of which process personal information on our behalf.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA imposes data privacy, security and breach notification obligations, on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities and business associates to, among other things, develop and maintain policies with respect to the protection of, use and disclosure of protected health information (PHI). To the extent we create, receive, maintain or transmit PHI on behalf of covered entity customers or other third parties as a business associate under HIPAA, we are required to comply with applicable provisions of the HIPAA privacy, security and breach notification rules. HIPAA imposes, among other things, certain standards relating to the privacy, security, and breach reporting of individually identifiable health information. To the extent we are found to be out of compliance with HIPAA, we could face significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Furthermore, violation of consumers' privacy rights or failure to take appropriate steps to keep consumers' personal information secure may constitute unfair and/or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, including entities subject to HIPAA. The Federal Trade Commission (FTC) expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits particularly strong safeguards.

In addition, in recent years, certain states have adopted or modified data privacy and security laws and regulations that may apply to our business. For example, the California Consumer Privacy Act (CCPA) requires businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt-out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. The enactment of the CCPA is prompting a wave of similar legislative developments in other states in the United States, which creates a patchwork of

overlapping but different state laws. For example, since the CCPA went into effect, comprehensive privacy statutes that share similarities with the CCPA are now in effect and enforceable in numerous states, and will soon be enforceable in several other states as well. Similar laws have been proposed in many other states and at the federal level as well. Certain states have also enacted new laws regulating specific types of personal information, such as health data, including the Washington My Health My Data Act and Nevada's Senate Bill 370. In the event we are subject to such laws, they impose, among other things, onerous notice and consent obligations, and prohibit certain personal information processing. To the extent we are found to be out of compliance with such laws, we could face negative publicity, government investigations and enforcement actions, claims by third parties (including class action lawsuits and private litigation) and damage to our reputation, any of which could have a material adverse effect on our business, financial condition and results of operations. As a result, our processing of health data in such states may subject us to additional compliance obligations and expose us to increased risk of liability.

Additionally, laws, regulations, and standards covering marketing, advertising, and other activities conducted by telephone, email, mobile devices, and the internet may be or become applicable to our business. If we fail to comply with these laws, regulations, and standards, we could face liability, reputational harm, and experience other impacts that could have a material adverse effect on our business.

Further, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach may be difficult and costly. We also may be contractually required to notify consumers or other counterparties of a security breach. Regardless of our contractual protections, any actual or perceived security breach or breach of our contractual obligations could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach.

We also expect that there will continue to be new laws, regulations, and industry standards concerning privacy, data protection, and information security proposed and enacted in various jurisdictions in which we do business. These laws are in some cases relatively new and the interpretation and application of these laws are uncertain, may be inconsistent with or restrict our collection, storage, transfer, use and disclosure of personal information, and may require changes to our data processing practices and policies, including the acceptance of more onerous obligations in our contracts or additional costs, and we may be unable to make such changes and modifications in a commercially reasonable manner, or at all.

This risk is enhanced in certain jurisdictions and, as we expand our operations domestically and internationally, we may be subject to additional laws in other jurisdictions. Any actual or perceived failure by us or the third parties with whom we work to comply with privacy or security laws, policies, legal obligations, or industry standards, or any security incident that results in the unauthorized release or transfer of personally identifiable information, may result in governmental enforcement actions and investigations by U.S. federal and state regulatory authorities, fines and penalties, claims, proceedings or actions against us by individuals, consumer rights groups, government agencies, or others and we could incur significant costs in investigating and defending such claims, orders to make changes to our business, and/or adverse publicity, including by consumer advocacy groups and other private parties, and could cause our customers, their patients, and other healthcare professionals to lose trust in us, which could materially and adversely affect our reputation and have a material adverse effect on our business, financial condition and results of operations.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, government shutdowns or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could materially and adversely affect our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to be approved or cleared by necessary government agencies, which would materially and adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Ownership of Our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The price of our stock may be volatile, and you could lose all or part of your investment. The stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the timing and results of preclinical trials and clinical trials of our current and future products or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations, or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the medical device sector;
- changes in the structure of healthcare payment systems;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or our other stockholders;
- the concentration in ownership of our common stock;
- expiration of lock-up agreements;
- lawsuits threatened or filed against us, including litigation by current or former employees, alleging wrongful termination, sexual harassment, whistleblower, or other claims; and
- general economic, industry and market conditions.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock, which could also cause you to lose all or part of your investment.

In addition, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could materially and adversely affect our business.

Although our common stock is listed on Nasdaq, an active, liquid and orderly trading market for our shares may not be sustained. The trading market for our common stock has been, and may continue to be, volatile. The lack of a sustained active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of a sustained active market may also reduce the fair market value of your shares. Furthermore, a less active market may also impair our

ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies, or other assets by using our shares of common stock as consideration.

We may fail to satisfy the continued listing requirements of Nasdaq.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

The clear market restrictions and lock-up agreements entered into in connection with our IPO will expire 180 days after May 7, 2026. When this restricted period expires, we and our securityholders subject to lock-up agreements will be able to sell shares in the public market. In addition, BofA Securities, Inc., J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. Sales of a substantial number of such shares upon expiration of the lock-up agreement, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

Moreover holders of an aggregate of approximately 22.0 million shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also aim to register all shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

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

As of May 31, 2026, our executive officers, directors, holders of 5% or more of our capital stock, and their respective affiliates beneficially owned a significant percentage of our outstanding common stock. As a result, such persons, to the extent they act together, will have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. We are an “emerging growth company,” and a “smaller reporting company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our public disclosures;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our public disclosures, including in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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 will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering (*i.e.*, the fiscal year ended December 31, 2031).

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

We have identified a material weakness in our internal control over financial reporting. If we are unable to design and maintain effective internal control over financial reporting, our investors may lose confidence in the accuracy and completeness of our financial reports, which could adversely affect our stock price.

We identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

We did not design and maintain effective controls over the review of inputs in the calculation of net loss per share attributable to common stockholders. The material weakness resulted in a revision to the weighted average number of shares and net loss per share attributable to common stock holders within the statement of operations and related disclosures as of and for the year ended December 31, 2025. Additionally, this material weakness could result in misstatements to net loss per share attributable to common stockholders and related disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

We are taking steps to remediate the material weakness and to strengthen our internal control over financial reporting, including reviewing and prioritizing this control deficiency for remediation. The material weakness will not be considered remediated until management completes the design and implementation of the controls and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The measures we will take may not be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not remediate the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected.

Our management will be required to evaluate the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2027. As part of that evaluation, we may identify additional control deficiencies that are determined to constitute one or more material weaknesses. In addition, there can be no assurance that our remediation efforts will be successful, that our internal control over financial reporting will be effective as a result of these efforts, or that any future control deficiencies identified may not be material weaknesses that would be required to be reported in future periods.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, prospects, financial condition, contractual restrictions and capital requirements. In addition, our ability to pay cash dividends on our capital stock is limited by the terms of the Loan and Security Agreement and may be limited by the terms of any future debt or preferred securities we issue or any future credit facilities we enter into. Accordingly, you will have to, for the foreseeable future, rely on sales of your common stock after price appreciation, which may never occur, as the only way to realize any future gains on your investments.

Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of a majority of the voting power of the issued and outstanding capital stock;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Such amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, against any person in connection with any offering of the Company's securities, including, without limitation and for the avoidance of doubt, any auditor, underwriter, expert, control person, or other defendant.

These exclusive-forum provisions may increase costs for a stockholder to bring a claim and may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. We also note that stockholders cannot waive compliance (or consent to noncompliance) with the federal securities laws and the rules and regulations thereunder. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially and adversely affect our business.

Our board of directors is authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of our preferred stock, subject to limitations prescribed by applicable law, rules, and regulations and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences, and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences, and rights of these additional series of preferred stock may be senior to or on parity with our common stock, which may reduce its value.

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

As a public company, we are subject to the periodic reporting requirements of the Exchange Act. We must design 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 error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new

relationship or arrangement, causing us to fail to make a required related party transaction disclosure. 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.

General Risk Factors

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. Additionally, if we fail to maintain effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired.

In connection with the preparation of our financial statements, we identified a material weakness in our internal control over financial reporting. Specifically, we did not design and maintain effective controls over the review of the inputs in the calculation of net loss per share attributable to common stockholders. The material weakness resulted in a revision to the weighted average number of shares and net loss per share attributable to common stockholders within the statement of operations and related disclosures as of and for the year ended December 31, 2025. Additionally, this material weakness could result in misstatements to net loss per share attributable to common stockholders and related disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. We are in the process of implementing remediation measures, including the establishment of a control over the review of the calculation of weighted-average shares outstanding and net loss per share. The material weakness will not be considered remediated until management completes the design and implementation of the controls and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot accurately 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.

In addition, as a public company we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our Annual Report on Form 10-K for the year ended December 31, 2027, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for 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 to meet the detailed standards under the rules. During the course of its testing, our management may identify additional material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to remediate this material weakness and comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

Macroeconomic conditions could harm our business, financial condition and results of operations.

Macroeconomic conditions, such as high inflationary pressure, changes to monetary policy, high interest rates, volatile currency exchange rates, credit and debt concerns, decreasing consumer confidence and spending, including capital spending, concerns about the stability and liquidity of certain financial institutions, the introduction of or changes in tariffs or trade barriers, and global recessions can adversely impact demand for our products, which could negatively impact our business, financial condition and results of operations. Recent macroeconomic conditions have been adversely impacted by geopolitical instability and military hostilities in multiple geographies and monetary and financial uncertainties.

The impacts of these macroeconomic conditions, and the actions taken by governments, central banks, companies, and consumers in response, have resulted in, and may continue to result in, higher inflation in the United States and globally, which is likely, in turn, to lead to an increase in costs and may cause changes in fiscal and monetary policy, including additional increases in interest rates. Other adverse impacts of recent macroeconomic conditions have been, and may continue to be, imposition of tariffs and other trade measures, supply chain constraints, logistics challenges, liquidity concerns in the broader financial services industry and fluctuations in labor availability.

Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal information.

Issues in the use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. We may adopt and integrate generative AI tools throughout our business, including into our information systems. Our vendors may incorporate generative AI tools into their services and offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to data privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. Any integration of AI in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. If we, our vendors, or our third-party partners experience an actual or perceived breach or data privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and Confidential Information and our reputation and the public perception of the effectiveness of our security measures could be harmed. 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. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price, and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business, or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance, or our market, or if our results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our ability to use our net operating loss carryforwards or certain other tax attributes to offset future taxable income or income taxes, as applicable, may be subject to certain limitations.

As of December 31, 2025, and 2024, the Company had U.S. federal net operating loss (NOL) carryforwards of approximately $127.4 million and $88.4 million, respectively. For U.S. federal income tax purposes, NOLs generated in tax years beginning before January 1, 2018, can be carried forward for up to 20 years, and NOLs generated in tax years beginning after December 31, 2017, can be carried forward indefinitely but can only offset up to 80% of taxable income in any given tax year beginning after December 31, 2020. Of the total U.S. federal NOL carryforward as of December 31, 2025, $22.1 million will begin to expire in 2027 and $105.3 million will not expire but will be subject to the 80% utilization limit.

Our U.S. federal NOL carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future taxable income because of their limited duration or because of restrictions under U.S. federal law.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points (by value) over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards or certain other pre-change tax attributes to offset its post-change taxable income or income taxes, as applicable, may be limited. Similar rules may apply under state tax laws. We believe (but have not undertaken any formal analysis or other assessment to determine) that no such ownership changes have occurred to date. Our ability to utilize our NOL carryforwards or other tax attributes to offset future taxable income or income taxes, as applicable, may be limited if such ownership changes have occurred. Furthermore, we may experience ownership changes as a result of our initial public offering or in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control, which could limit (or further limit) our ability to use our NOL carryforwards and other tax attributes. We have not conducted any studies to determine future annual limitations, if any, that could result from such changes in our stock ownership. Any such limitations on our ability to utilize our NOL carryforwards and certain other tax attributes could have a material adverse effect on our business, financial condition and results of operations.

Changes in tax laws could have a material adverse effect on our business, financial condition, and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us. The likelihood of any such changes being enacted or implemented is uncertain. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, our customers or our suppliers, including as a result of related uncertainty, these changes could have a material adverse effect on our business, financial condition and results of operations.

Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, value added or similar taxes, and we could be subject to liability with respect to past or future sales, which could materially and adversely affect our results of operations.

We may not collect sales and use, value added, and similar taxes in all jurisdictions in which we have sales, based on our belief that such taxes are not applicable. Sales and use, value added, and similar tax laws and rates vary greatly by jurisdiction. Any jurisdictions in which we do not collect such taxes may assert that such taxes are applicable, which could result in tax assessments, penalties, and interest, and we may be required to collect such taxes in the future. Such tax assessments, penalties and interest or future requirements may materially and adversely affect the results of our operations.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because medical device and healthcare companies have experienced significant stock price volatility in recent years. If we face such litigation, even if ultimately decided in our favor, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

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

Unregistered Sales of Equity Securities

None of the transactions described below were issued in a registered offering under the Securities Act and these transactions did not involve any underwriters, underwriting discounts or commissions. The offers, sales, and issuances of the securities described in such sections were deemed to be exempt from registration under Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering or under Rule 701 promulgated under the Securities Act, as transactions under compensatory benefits plans and contracts relating to compensation. The recipients of the securities in each of these transactions in such sections represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the securities issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

From January 1, 2026 through March 31, 2026, we issued and sold the following unregistered securities:

1. We granted stock options and stock awards to employees, directors and consultants under our 2022 Equity Incentive Plan covering an aggregate of 524,180 shares of common stock, at a weighted average exercise price of $7.91 per share. Of these, no options were cancelled without being exercised.

2. We issued and sold an aggregate of 119,226 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of $0.4 million upon the exercise of stock options.

3. We issued convertible promissory notes in an aggregate principal amount of $40.0 million to accredited investors, which converted into 3,333,324 shares of the common stock in connection with the completion of our IPO in May 2026.

Use of Proceeds from our Public Offering of Common Stock

On May 11, 2026, we completed our IPO of common stock, pursuant to which we issued and sold 10,000,000 shares of our common stock at a public offering price of $15.00 per share.

All shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-295160), as amended (the "Registration Statement"), declared effective by the SEC on May 7, 2026.

We received net proceeds of approximately $134.5 million after deducting underwriting discounts and commissions of $10.5 million and offering expenses of $5.0 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. BofA Securities, Inc., J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC, BTIG, LLC, Nomura Securities International, Inc. and WR Securities, LLC acted as managing underwriters for the offering.

The net proceeds from our IPO have been invested primarily in savings and money market accounts. There has been no material change in the expected use of the net proceeds from our IPO as described in our Prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on May 8, 2026.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) None.

(b) None.

(c) During the three months ended March 31, 2026, none of our officers or directors (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as those terms are defined in Item 408 of Regulation S-K).

Item 6. Exhibits

Exhibit Number	Description of Document	Incorporated by Reference				Filed / Furnished Herewith
		Form	Date	Number	Exhibit	
3.1	Amended and Restated Certificate of Incorporation.	8-K	5/11/2026	333-295160	3.1	
3.2	Amended and Restated Bylaws.	8-K	5/11/2026	333-295160	3.2	
4.1	Specimen Common Stock Certificate of the Registrant.	S-1	4/17/2026	333-295160	4.3	

Exhibit Number	Description of Document	Incorporated by Reference				Filed / Furnished Herewith
		Form	Date	Number	Exhibit	
4.2	Warrant (Loan A) issued December 29, 2023 to lender.	S-1	4/17/2026	333-295160	4.4	
4.3	Warrant (Loan B) issued December 29, 2023 to lender.	S-1	4/17/2026	333-295160	4.5	
10.1#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	4/17/2026	333-295160	10.1	
10.2#	2007 Stock Option Plan, as amended.	S-1	4/17/2026	333-295160	10.2	
10.2.1#	Form of Stock Option Agreement under the 2007 Stock Option Plan, as amended.	S-1	4/17/2026	333-295160	10.2.1	
10.3#	2022 Equity Incentive Plan, as amended.	S-1	4/17/2026	333-295160	10.3	
10.3.1#	Form of Stock Option Agreement under the 2022 Equity Incentive Plan, as amended.	S-1	4/17/2026	333-295160	10.3.1	
10.3.2#	Form of Restricted Stock Purchase Agreement under the 2022 Equity Incentive Plan, as amended.	S-1	4/17/2026	333-295160	10.3.2	
10.4#	2026 Incentive Award Plan.	S-8	5/8/2026	333-295709	10.3	
10.4.1#	Form of Option Award Agreement under the 2026 Incentive Award Plan.	S-8	5/8/2026	333-295709	10.3.1	
10.4.2#	Form of Restricted Stock Unit Award Agreement under the 2026 Incentive Award Plan.	S-8	5/8/2026	333-295709	10.3.2	
10.5#	2026 Employee Stock Purchase Plan.	S-8	5/8/2026	333-295709	10.4	
10.6#	Non-Employee Director Compensation Program.	S-1	4/17/2026	333-295160	10.6	
10.7#	Restated Employment Agreement between the Registrant and Richard Foust, dated April 3, 2026.	S-1	4/17/2026	333-295160	10.12	
10.8#	Restated Employment Agreement between the Registrant and Nelson Bunker Curnes, dated April 3, 2026.	S-1	4/17/2026	333-295160	10.13	
10.9#	Restated Employment Agreement between the Registrant and Thomas Jordan Curnes II, dated April 3, 2026.	S-1	4/17/2026	333-295160	10.14	
10.10#	Restated Employment Agreement between the Registrant and Douglas (Doug) Ellison, dated April 3, 2026.	S-1	4/17/2026	333-295160	10.15	
10.11#	Restated Employment Agreement between the Registrant and Prashant Rawat, dated April 3, 2026.	S-1	4/17/2026	333-295160	10.16	
10.12#	Restated Employment Agreement between the Registrant and Chase Leavitt, dated April 3, 2026.	S-1	4/17/2026	333-295160	10.17	
10.13#	Executive and Key Employee Severance and Change in Control Plan.	S-1	4/17/2026	333-295160	10.18	
10.14^	Amended and Restated Registration Rights Agreement among the Registrant and certain of its stockholders, dated March 5, 2025.	S-1	4/17/2026	333-295160	4.1	

Exhibit Number	Description of Document	Incorporated by Reference				Filed / Furnished Herewith
		Form	Date	Number	Exhibit	
10.15^	Amended and Restated Shareholders' Agreement among the Registrant and certain of its stockholders, dated March 5, 2025.	S-1	4/17/2026	333-295160	4.2	
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to 302 of the Sarbanes Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to 302 of the Sarbanes Oxley Act of 2002.					*
32.1	Certification 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.					**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					

# Indicates management contract or compensatory plan.

^ Pursuant to Item 601(a)(5) of Regulation S-K, the registrant has omitted certain of the schedules (or similar attachments) to this exhibit.

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

MOBIA MEDICAL, INC.
(Registrant)

Date: June 4, 2026

/s/ RICHARD FOUST
Richard Foust
Chief Executive Officer
(Principal Executive Officer)

Date: June 4, 2026

/s/ BUNKER CURNES
Bunker Curnes
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard Foust, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Mobia 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)) 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) [Omitted];

   (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: June 4, 2026

By: /s/ RICHARD FOUST
Richard Foust
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Bunker Curnes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Mobia 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)) 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) [Omitted];

   (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: June 4, 2026

By: /s/ BUNKER CURNES
Bunker Curnes
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Mobia Medical, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Richard Foust, Chief Executive Officer of the Company, and Bunker Curnes, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report 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 result of operations of the Company.

Date: June 4, 2026

/s/ RICHARD FOUST
Richard Foust
Chief Executive Officer
(Principal Executive Officer)

/s/ BUNKER CURNES
Bunker Curnes
Chief Financial Officer
(Principal Financial Officer)