

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

Form 10-Q

(Mark One)

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

For the Quarterly Period Ended June 30, 2026

OR

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

For the transition period from _____ to _____

Commission File Number: **001-40439**

NeuroOne Medical Technologies Corporation
(Exact name of Registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

27-0863354

(I.R.S. Employer
Identification Number)

**7599 Anagram Drive
Eden Prairie, MN**

(Address of Principal Executive Offices)

55344

(Zip Code)

Registrant's Telephone Number, Including Area Code: **952-426-1383**

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(s)	Name of Each Exchange on Which Registered
Common stock, \$0.001 par value	NMTC	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 (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Non-accelerated filer	☒
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 ☒

The number of outstanding shares of the registrant's common stock as of August 11, 2026 was 9,105,763.

NEUROONE MEDICAL TECHNOLOGIES CORPORATION
FORM 10-Q

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

NeuroOne Medical Technologies Corporation Condensed Balance Sheets

	As of	
	June 30, 2026 (Unaudited)	September 30, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,047,596	\$ 6,570,382
Accounts receivable	1,098,965	1,264,805
Inventory, net	2,290,254	2,226,805
Deferred offering costs	33,046	22,920
Prepaid expenses	318,940	141,372
Total current assets	5,788,801	10,226,284
Intangible assets, net	28,210	44,946
Right-of-use asset	166,751	255,195
Property and equipment, net	202,333	259,222
Total assets	<u>\$ 6,186,095</u>	<u>\$ 10,785,647</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 905,716	\$ 1,010,369
Accrued expenses and other liabilities	1,135,711	1,292,714
Total current liabilities	2,041,427	2,303,083
Warrant liability	303,805	1,266,894
Operating lease liability, long term	73,320	143,148
Total liabilities	<u>2,418,552</u>	<u>3,713,125</u>
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding.	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 8,702,982 and 8,334,336 shares issued and outstanding as of June 30, 2026 and September 30, 2025, respectively.	8,703	8,334
Additional paid-in capital	88,194,870	85,673,975
Accumulated deficit	(84,436,030)	(78,609,787)
Total stockholders' equity	3,767,543	7,072,522
Total liabilities and stockholders' equity	<u>\$ 6,186,095</u>	<u>\$ 10,785,647</u>

See accompanying notes to condensed financial statements

NeuroOne Medical Technologies Corporation
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended June 30,		For the Nine Months Ended June 30,	
	2026	2025	2026	2025
Product revenue	\$ 1,973,105	\$ 1,696,050	\$ 6,727,790	\$ 6,356,767
Cost of product revenue	790,496	781,215	2,987,089	2,743,982
Product gross profit	<u>1,182,609</u>	<u>914,835</u>	<u>3,740,701</u>	<u>3,612,785</u>
License revenue	<u>—</u>	<u>—</u>	<u>—</u>	<u>3,000,000</u>
Operating expenses:				
Selling, general and administrative	2,181,768	1,618,950	5,986,594	5,602,818
Research and development	<u>1,425,153</u>	<u>1,182,485</u>	<u>4,282,923</u>	<u>3,865,376</u>
Total operating expenses	<u>3,606,921</u>	<u>2,801,435</u>	<u>10,269,517</u>	<u>9,468,194</u>
Loss from operations	(2,424,312)	(1,886,600)	(6,528,816)	(2,855,409)
Fair value change in warrant liability	405,702	319,625	620,171	1,099,421
Financing costs	—	(9,325)	—	(334,063)
Other income	12,279	75,432	82,402	103,898
Loss before income taxes	<u>(2,006,331)</u>	<u>(1,500,868)</u>	<u>(5,826,243)</u>	<u>(1,986,153)</u>
Provision for income taxes	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Net loss	<u><u>\$ (2,006,331)</u></u>	<u><u>\$ (1,500,868)</u></u>	<u><u>\$ (5,826,243)</u></u>	<u><u>\$ (1,986,153)</u></u>
Net loss per share (Note 3):				
Basic	<u>\$ (0.23)</u>	<u>\$ (0.19)</u>	<u>\$ (0.68)</u>	<u>\$ (0.32)</u>
Diluted	<u><u>\$ (0.28)</u></u>	<u><u>\$ (0.19)</u></u>	<u><u>\$ (0.75)</u></u>	<u><u>\$ (0.32)</u></u>
Number of shares used in per share calculations (Note 3):				
Basic	<u>8,661,624</u>	<u>8,100,603</u>	<u>8,511,313</u>	<u>6,141,509</u>
Diluted	<u><u>8,739,505</u></u>	<u><u>8,100,603</u></u>	<u><u>8,621,075</u></u>	<u><u>6,141,509</u></u>

See accompanying notes to condensed financial statements

NeuroOne Medical Technologies Corporation
Condensed Statements of Changes in Stockholders' Equity
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at September 30, 2025	8,334,336	\$ 8,334	\$85,673,975	\$ (78,609,787)	\$ 7,072,522
Stock-based compensation	—	—	359,255	—	359,255
Exercise of warrants	62,500	63	411,607	—	411,670
Issuance of common stock upon vesting of restricted stock units	5,959	6	(6)	—	—
Share repurchases for the payment of employee taxes	(680)	(1)	(3,631)	—	(3,632)
Net loss	—	—	—	(1,437,890)	(1,437,890)
Balance at December 31, 2025	<u>8,402,115</u>	<u>8,402</u>	<u>86,441,200</u>	<u>(80,047,677)</u>	<u>6,401,925</u>
Issuance of common stock attributed to equity financings	166,666	167	670,233	—	670,400
Stock-based compensation	—	—	342,135	—	342,135
Exercise of warrants	14,470	15	105,607	—	105,622
Issuance of common stock upon vesting of restricted stock units	47,069	47	(47)	—	—
Share repurchases for the payment of employee taxes	(14,788)	(15)	(60,762)	—	(60,777)
Net loss	—	—	—	(2,382,022)	(2,382,022)
Balance at March 31, 2026	<u>8,615,532</u>	<u>8,616</u>	<u>87,498,366</u>	<u>(82,429,699)</u>	<u>5,077,283</u>
Issuance of common stock attributed to equity financings	80,671	81	358,905	—	358,986
Issuance costs related to equity financing	—	—	(11,996)	—	(11,996)
Stock-based compensation	—	—	352,777	—	352,777
Issuance of common stock upon vesting of restricted stock units	8,955	9	(9)	—	—
Share repurchases for the payment of employee taxes	(4,085)	(4)	(3,172)	—	(3,176)
Reverse stock split adjustment	1,909	1	(1)	—	—
Net loss	—	—	—	(2,006,331)	(2,006,331)
Balance at June 30, 2026	<u>8,702,982</u>	<u>\$ 8,703</u>	<u>\$88,194,870</u>	<u>\$ (84,436,030)</u>	<u>\$ 3,767,543</u>

See accompanying notes to condensed financial statements

NeuroOne Medical Technologies Corporation
Condensed Statements of Changes in Stockholders' Equity
(unaudited)

	Common Stock		Additional Paid-In	Accumulated	Total
	Shares	Amount	Capital	Deficit	Stockholders' Equity
Balance at September 30, 2024	5,135,861	\$ 5,136	\$75,821,290	\$ (75,004,413)	\$ 822,013
Stock-based compensation	—	—	339,224	—	339,224
Issuance of common stock upon vesting of restricted stock units	6,295	6	(6)	—	—
Share repurchases for the payment of employee taxes	(2,075)	(2)	(11,265)	—	(11,267)
Net income	—	—	—	1,785,322	1,785,322
Balance at December 31, 2024	5,140,081	5,140	76,149,243	(73,219,091)	2,935,292
Issuance of common stock attributed to equity financings	59,314	59	413,978	—	414,037
Issuance costs related to equity financings	—	—	(95,929)	—	(95,929)
Stock-based compensation	—	—	250,170	—	250,170
Issuance of common stock upon vesting of restricted stock units	47,017	47	(47)	—	—
Share repurchases for the payment of employee taxes	(15,719)	(15)	(107,090)	—	(107,105)
Net loss	—	—	—	(2,270,607)	(2,270,607)
Balance at March 31, 2025	5,230,693	5,231	76,610,325	(75,489,698)	1,125,858
Issuance of common stock attributed to equity financing	3,066,666	3,067	9,196,933	—	9,200,000
Issuance costs related to equity financing	—	—	(960,717)	—	(960,717)
Stock-based compensation	—	—	316,654	—	316,654
Issuance of common stock upon vesting of restricted stock units	7,220	7	(7)	—	—
Share repurchases for the payment of employee taxes	(680)	(1)	(3,473)	—	(3,474)
Net loss	—	—	—	(1,500,868)	(1,500,868)
Balance at June 30, 2025	8,303,899	\$ 8,304	\$85,159,715	\$ (76,990,566)	\$ 8,177,453

See accompanying notes to condensed financial statements

NeuroOne Medical Technologies Corporation
Condensed Statements of Cash Flows
(unaudited)

	For the Nine Months Ended June 30,	
	2026	2025
Operating activities		
Net loss	\$ (5,826,243)	\$ (1,986,153)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	172,554	197,355
Stock-based compensation	1,054,167	906,048
Valuation adjustments for excess or obsolete inventory	1,000	7,500
Amortization of deferred offering costs	—	192,647
Non-cash lease expense	88,444	83,187
Fair value change in warrant liability	(620,171)	(1,099,421)
Debt termination costs reclassified to financing activities	—	141,416
Change in assets and liabilities:		
Accounts receivable	165,840	176,636
Inventory	(64,449)	729,952
Prepaid expenses	(177,568)	(16,902)
Accounts payable	(93,078)	(286,960)
Accrued expenses, operating leases and other liabilities	(226,831)	(356,905)
Net cash used in operating activities	<u>(5,526,335)</u>	<u>(1,311,600)</u>
Investing activities		
Purchase of property and equipment	(98,929)	(71,135)
Net cash used in investing activities	<u>(98,929)</u>	<u>(71,135)</u>
Financing activities		
Proceeds from issuance of common stock attributed to equity financings	1,029,386	9,614,037
Issuance costs related to equity financings	(10,777)	(1,231,873)
Financing costs in connection with debt facility	—	(297,942)
Deferred issuance costs in connection with at-the-market offering program	(22,920)	—
Exercise of warrants	174,374	—
Share repurchases for the payment of employee taxes	(67,585)	(121,846)
Net cash provided by financing activities	<u>1,102,478</u>	<u>7,962,376</u>
Net (decrease) increase in cash and cash equivalents	<u>(4,522,786)</u>	<u>6,579,641</u>
Cash and cash equivalents at beginning of period	6,570,382	1,460,042
Cash and cash equivalents at end of period	<u>\$ 2,047,596</u>	<u>\$ 8,039,683</u>
<i>Supplemental non-cash financing and investing transactions:</i>		
Change in unpaid issuance costs	\$ 11,575	\$ —
Modification of right-of-use asset and associated lease liability	\$ —	\$ 111,898
Purchased property and equipment in accounts payable	\$ —	\$ 7,228
Cashless exercise of warrants	\$ 87,188	\$ —
Reclass of warrant liability to equity upon exercise	\$ 342,918	\$ —
Amortization of deferred offering costs related to equity financings	\$ 1,219	\$ —

See accompanying notes to condensed financial statements

NOTE 1 – Description of Business and Basis of Presentation

NeuroOne Medical Technologies Corporation (the “Company” or “NeuroOne”), a Delaware corporation, is a medical technology company focused on the development and commercialization of thin film electrode for continuous electroencephalogram (“cEEG”) and stereoelectroencephalography (“sEEG”) recording, monitoring, ablation and stimulation solutions to diagnose and treat patients with epilepsy, trigeminal neuralgia, Parkinson’s disease, dystonia, essential tremors, chronic back pain and other pain-related neurological disorders. The Company is also developing the capability to use its sEEG electrode technology to deliver drugs or gene therapy while being able to record activity before, during, and after delivery.

The Company has received 510(k) clearance from the United States (“U.S.”) Food and Drug Administration (“FDA”) for four of its devices: (i) its Evo cortical electrode technology for recording, monitoring, and stimulating brain tissue for up to 30 days (“Evo Cortical”), (ii) its Evo® sEEG electrode technology for temporary (less than 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain (“Evo sEEG”); (iii) its OneRF ablation system for creation of radiofrequency lesions in nervous tissue for functional neurosurgical procedures (the “OneRF Ablation System”) and (iv) our OneRF TN ablation system for use in procedures to create radiofrequency (RF) lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures (“OneRF TN Ablation System”, together with the Evo Cortical, Evo sEEG, and OneRF Ablation System, the “Commercialized Products”). The Company has a distribution agreement with Zimmer, Inc. (“Zimmer”) providing Zimmer with a license to commercialize and distribute the Evo Cortical, Evo sEEG, and OneRF Ablation System in the brain. The Company initiated a limited market release of its OneRF TN Ablation System in December 2025 and completed the limited market release in March 2026. The Company’s other products and indications are still under development.

The Company is based in Eden Prairie, Minnesota.

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the conflicts between Russia and Ukraine and in the Middle East, disruptions in the banking system and financial markets, and increased inflation. The general economic and capital market conditions both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected the Company’s access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms or at all. If economic conditions continue to decline, the Company’s future cost of equity or debt capital and access to the capital markets could be adversely affected. The Company has experienced minor price increases from our suppliers related to tariffs on imported goods and may experience additional price increases.

The Company’s operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the conflicts in Ukraine and the Middle East, disruptions in the banking system and financial markets, and steps taken by governments and central banks, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates. The Company expects to submit a request for a tariff refund for minor tariffs paid by the Company to the U.S. government under the International Emergency Economic Powers Act, but the timing and amount of cash receipt pursuant to such future submission remains uncertain. We will continue to monitor guidance issued regarding the refund process.

Basis of presentation

The accompanying unaudited condensed financial statements have been prepared by the Company, pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) have been condensed or omitted pursuant to such rules and regulations. The condensed financial statements may not include all disclosures required by U.S. GAAP; however, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended September 30, 2025 included in the Company’s Annual Report on Form 10-K. The condensed balance sheet at September 30, 2025 was derived from the audited financial statements of the Company.

In the opinion of management, all adjustments, consisting of only normal recurring adjustments that are necessary to present fairly the financial position, results of operations, and cash flows for the interim periods, have been made. The results of operations for the interim periods are not necessarily indicative of the operating results for the full fiscal year or any future periods.

Reverse Stock Split

On April 14, 2026, the Company filed an amendment to its Amended and Restated Certificate of Incorporation, as amended and/or restated from time to time, to effectuate a reverse stock split of the Company’s issued and outstanding shares of common stock, par value \$0.001 per share (the “Reverse Stock Split”). Trading of the common stock on The Nasdaq Capital Market commenced on a split-adjusted basis at market open on April 16, 2026. All share and per-share amounts, and related equity amounts as applicable in the condensed financial statements have been retroactively adjusted to reflect the Reverse Stock Split.

As a result of the Reverse Stock Split, every 6 shares of the Company’s common stock issued or outstanding was automatically reclassified into one validly issued, fully-paid and non-assessable new share of common stock, subject to the treatment of fractional shares as described below, without any action on the part of the holders. Proportional adjustments were made to the number of shares of common stock awarded and available for issuance under the Company’s equity incentive plans, as well as the exercise price and the number of shares issuable upon the exercise or conversion of the Company’s outstanding stock options and other equity securities under the Company’s equity incentive plans. All outstanding warrants were also adjusted in accordance with their terms. The shares of common stock outstanding following the Reverse Stock Split will remain fully paid and non-assessable. The Reverse Stock Split did not affect the number of authorized shares of common stock or the par value per share of the common stock.

No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise be entitled to receive fractional shares as a result of the Reverse Stock Split were automatically entitled to receive a cash payment equal to the market value of the fractional share. The Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder’s relative interest in the Company’s equity securities, except for any adjustments for fractional shares.

NOTE 2 – Going Concern

The accompanying condensed financial statements have been prepared on the basis that the Company will continue as a going concern. The Company has incurred losses since inception, negative cash flows from operations, and an accumulated deficit of \$84.4 million as of June 30, 2026. To date, the Company’s revenues have not been sufficient to cover its full operating costs, and as such, it has been dependent on funding operations through the issuance of debt and sale of equity securities which previously resulted in substantial doubt regarding the Company’s ability to continue as a going concern. As of June 30, 2026, the Company had \$2.0 million in cash and cash equivalents. The Company believes its current available cash and cash equivalents, including cash received through the ATM Program subsequent to June 30, 2026, coupled with the anticipated increase in product revenues from minimum purchases and improved gross margins under the distribution agreement with Zimmer (See “Note 7– Zimmer Distribution Agreement and Other Product Revenue”) and forecasted operating expense reductions, will be sufficient to fund the Company’s operations into January 2027. The raising of additional funds is not solely within the control of the Company. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The condensed financial statements do not include any adjustments that might result from the outcome of this condition. If the Company is unable to raise additional funds, or the Company’s anticipated operating results are not achieved, management believes planned expenditures may need to be reduced in order to extend the time period that existing resources can fund the Company’s operations.

NeuroOne Medical Technologies Corporation
Notes to Condensed Financial Statements (Unaudited)

The Company intends to fund ongoing activities by utilizing its current cash and cash equivalents on hand, from product and collaborations revenue and by raising additional capital through equity or debt financing. If management is unable to obtain the necessary capital, it may have a material adverse effect on the operations of the Company and the development of its technology, or the Company may have to cease operations altogether.

NOTE 3 – Summary of Significant Accounting Policies

Management's Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and are evaluated regularly by the Company's chief operating decision maker ("CODM") in deciding how to allocate resources and assessing performance. The Company's CODM is its Chief Executive Officer. The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment. See "Note 14 – Segment Reporting".

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original contractual maturity on date of purchase of less than or equal to three months to be classified and presented as cash equivalents on the balance sheets. Cash equivalents are stated at cost, which approximates fair value. The Company's cash and cash equivalents may include demand deposit accounts with large financial institutions, institutional money market funds, U.S. Treasury securities, and corporate notes and bonds. The Company monitors the creditworthiness of the financial institutions, institutional money market funds, and corporations in which the Company invests its surplus funds. The Company has experienced no credit losses from its cash and cash equivalent investments.

Revenue Recognition

The Company entered into a development and distribution agreement which has current and future revenue recognition implications. See "Note 7 – Zimmer Distribution Agreement and Other Product Revenue."

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Performance obligations may include license rights, development services, and services associated with regulatory submission and approval processes. Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations are either completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

NeuroOne Medical Technologies Corporation
Notes to Condensed Financial Statements (Unaudited)

Product Revenue

Revenues from product sales are recognized when control of the promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. At the inception of each customer contract, performance obligations are identified and the total transaction price is allocated to the performance obligations.

Cost of Product Revenue

Cost of product revenue consists of the manufacturing and materials costs incurred by the Company's third-party contract manufacturers in connection with OneRF Brain Ablation System and the OneRF® Trigeminal Nerve Ablation System (the "OneRF Products"), strip and grid cortical electrodes (the "Strip/Grid Products"), depth electrodes ("sEEG Products") and outside supplier materials costs in connection with the electrode cable assembly products ("Electrode Cable Assembly Products") when sold. In addition, cost of product revenue includes royalty fees incurred in connection with the Company's license agreements as well as valuation adjustments for excess or obsolete inventory.

License Revenue

As part of the accounting for collaboration arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. The Company allocates the total transaction price to each performance obligation based on the estimated relative stand-alone selling prices of the promised goods or service underlying each performance obligation.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the value of the associated milestone (such as a regulatory submission) is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until those approvals are received. When the Company's assessment of probability of achievement changes and variable consideration becomes probable, any additional estimated consideration is allocated to each performance obligation based on the estimated relative stand-alone selling prices of the promised goods or service underlying each performance obligation and recorded in license revenues based upon when the customer obtains control of each element.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

NeuroOne Medical Technologies Corporation
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Warrant Liability

The Company issued warrants in connection with its 2024 Private Placement. See “Note 12– Stockholders’ Equity”. The Company accounts for these warrants as a liability at fair value when warrant pricing protection provisions are not available to other common stockholders. Additionally, issuance costs associated with the warrant liability are expensed as incurred and reflected as a financing cost in the accompanying condensed statements of operations. The Company adjusts the liability for changes in fair value until the earlier of the exercise or expiration of the warrants for any period when pricing protections remain in place. Any future change in the fair value of the warrant liability is recognized in the condensed statements of operations under the fair value change in warrant liability line item.

Fair Value of Financial Instruments

The Company’s accounting for fair value measurements of assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring or nonrecurring basis adheres to the Financial Accounting Standards Board (“FASB”) fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are as follows:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the Company at the measurement date.
- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

As of June 30, 2026 and September 30, 2025, the fair values of cash, cash equivalents, accounts receivable, inventory, prepaid expenses, deferred offering costs, accounts payable and accrued expenses and other liabilities approximated their carrying values because of the short-term nature of these assets or liabilities. The fair value of the warrant liability was based on Level 3 inputs as well as the Company’s underlying stock price and associated volatility, expected term of the warrants and market interest rates. There were no transfers between fair value hierarchy levels during the three and nine months ended June 30, 2026 and 2025.

The fair value of financial instruments measured on a recurring basis is as follows:

Description	As of June 30, 2026			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	\$ 303,805	\$ —	\$ —	\$ 303,805
Total liabilities at fair value	<u>\$ 303,805</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 303,805</u>

Description	As of September 30, 2025			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	\$ 1,266,894	\$ —	\$ —	\$ 1,266,894
Total liabilities at fair value	<u>\$ 1,266,894</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,266,894</u>

NeuroOne Medical Technologies Corporation
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The following table provides a roll-forward of the warrant liability measured at fair value on a recurring basis using unobservable level 3 inputs for the nine months ended June 30, 2026 and 2025, respectively.

	<u>2026</u>	<u>2025</u>
Warrant liability		
Balance as of beginning of Period	\$ 1,266,894	\$ 2,140,315
Change in fair value of warrant liability	(620,171)	(1,099,421)
Exercises	(342,918)	—
Balance as of end of period	<u>\$ 303,805</u>	<u>\$ 1,040,894</u>

Intellectual Property

The Company has entered into two licensing agreements with major research institutions, which allow for access to certain patented technology and know-how. Payments under those agreements are capitalized and amortized to selling, general and administrative expense over the expected useful life of the acquired technology.

Property and Equipment

Property and equipment is recorded at cost and reduced by accumulated depreciation. Depreciation expense is recognized over the estimated useful lives of the assets using the straight-line method. The estimated useful life for equipment and furniture ranges from three to seven years. Tangible assets acquired for research and development activities and that have alternative use are capitalized over the useful life of the acquired asset. Estimated useful lives are periodically reviewed, and, when appropriate, changes are made prospectively. When certain events or changes in operating conditions occur, asset lives may be adjusted and an impairment assessment may be performed on the recoverability of the carrying amounts. Maintenance and repairs are charged directly to expense as incurred.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist of licensed intellectual property, property and equipment and right-of-use assets for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. The Company assesses the recoverability of long-lived assets by determining whether the carrying value of such assets will be recovered through undiscounted expected future cash flows. If the asset is considered to be impaired, the amount of impairment is measured as the difference between the carrying value and the fair value of the impaired asset.

Accounts Receivable and Allowances for Credit Losses

The Company records a provision for credit losses, when appropriate, based on historical experience, current conditions and reasonably supportable forecasts. In estimating the allowance for credit losses, the Company considers, among other factors, the estimate of credit losses over the remaining expected life of the asset, primarily using historical experience and current economic conditions that could affect the collectability of the balances in the future. Account balances are charged off against the allowance when the Company believes that it is probable that the receivable will not be recovered. Actual write-offs may be in excess of the Company's estimated allowance. The Company has not incurred any bad debt expense to date and no allowance for credit losses has been recorded during the periods presented.

Inventory

Inventory is stated at the lower of cost (using the first-in, first-out "FIFO" method) or net realizable value. The Company calculates inventory valuation adjustments for excess and obsolete inventory, when appropriate, based on current inventory levels, movement, expected useful lives, and estimated future demand of the products and spare parts. The Company's inventory is currently comprised of its commercialized product components, work-in-process and finished goods. The commercialized products are produced by a third-party contract manufacturer and electrode cable assembly components are obtained from outside suppliers.

Research and Development Costs

Research and development costs are charged to expense as incurred. Research and development expenses comprise of costs incurred in performing research and development activities, including compensation and benefits for research and development employees (including stock-based compensation), overhead expenses, cost of laboratory supplies, clinical trial and related clinical manufacturing expenses, costs related to regulatory operations, fees paid to consultants and other outside expenses. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC 730, *Research and Development*.

Advertising Expense

Advertising expense is charged to selling, general and administrative expenses during the period that it is incurred. Total advertising expense amounted to \$57,207 and \$176,606 for the three and nine months ended June 30, 2026, respectively. Total advertising expense amounted to \$45,120 and \$128,663 for the three and nine months ended June 30, 2025, respectively.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel-related costs including stock-based compensation for personnel in functions not directly associated with research and development activities. Other significant costs include legal and litigation costs relating to corporate matters, intellectual property costs, professional fees for consultants assisting with financial and administrative matters, and sales and marketing in connection with the commercial sales of the Company's products.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of ASC 718, *Compensation — Stock Compensation* ("ASC 718"). Accordingly, compensation costs related to equity instruments granted are recognized at the grant-date fair value over the requisite service period. The Company records forfeitures when they occur. Stock-based compensation arrangements to non-employees are accounted for in accordance with the applicable provisions of ASC 718.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

Net Loss Per Share

For the Company, basic loss per share of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period.

Diluted earnings or loss per share of common stock is computed similarly to basic earnings or loss per share except the weighted average shares outstanding are increased to include additional shares from the assumed exercise of any common stock equivalents, if dilutive. The Company's warrants, stock options, and restricted stock units while outstanding are considered common stock equivalents for this purpose. Diluted earnings or loss per share of common stock is computed utilizing the treasury method for the warrants, stock options and restricted stock units.

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The table below presents the computation of basic and diluted loss per share:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2026	2025	2026	2025
Basic:				
Net loss available to common stockholders - basic	\$ (2,006,331)	\$ (1,500,868)	\$ (5,826,243)	\$ (1,986,153)
Weighted average common shares outstanding - basic	8,661,624	8,100,603	8,511,313	6,141,509
Loss per share - basic	\$ (0.23)	\$ (0.19)	\$ (0.68)	\$ (0.32)
Diluted:				
Net loss available to common stockholders – diluted	\$ (2,407,254)	\$ (1,500,868)	\$ (6,438,772)	\$ (1,986,153)
Weighted average common shares outstanding - diluted	8,739,505	8,100,603	8,621,075	6,141,509
Loss per share - diluted	\$ (0.28)	\$ (0.19)	\$ (0.75)	\$ (0.32)

The following table presents the computation of weighted average common shares considered in the computation of diluted net loss per share during the three and nine months ended June 30,

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2026	2025	2026	2025
Denominator (weighted average shares)				
Basic common shares outstanding	8,661,624	8,100,603	8,511,313	6,141,509
Dilutive stock options	—	—	—	—
Dilutive restricted stock units	—	—	—	—
Dilutive warrants	77,881	—	109,762	—
Diluted common shares outstanding	8,739,505	8,100,603	8,621,075	6,141,509

The following potential common shares were not considered in the computation of basic net loss per share as their effect would have been anti-dilutive for the three and nine months ended June 30, 2026 and 2025:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2026	2025	2026	2025
Warrants	283,230	1,174,322	251,349	1,174,322
Stock options	1,127,065	1,021,952	1,127,065	1,021,952
Restricted stock units	105,390	141,421	105,390	141,421

Recent Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update (ASU) 2023-09 *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This guidance also includes certain other amendments to improve the effectiveness of income tax disclosures. This ASU is effective for fiscal years beginning after December 15, 2024, including interim periods within those fiscal years and should be applied on a prospective basis, with retrospective application permitted. The Company adopted this guidance on October 1, 2025 and the newly adopted guidance will result in additional income tax disclosures in its annual financial statements.

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In November 2024, the FASB issued ASU 2024-03 *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): Disaggregation of Income Statement Expenses. This ASU is intended to improve the disclosures related to expenses and provide investors more detailed information about certain types of expenses. This ASU is effective for annual periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the potential impact that this new standard will have on its financial statements and related disclosures.

NOTE 4 – Commitments and Contingencies

WARF License Agreement

The Company has entered into an exclusive start-up company license agreement with the Wisconsin Alumni Research Foundation (“WARF”) for WARF’s neural probe array and thin film micro electrode technology. The Company entered into an Amended and Restated Exclusive Start-up Company License Agreement (the “WARF License”) with WARF on January 21, 2020, which amended and restated in full the prior license agreement between WARF and NeuroOne, LLC, a predecessor of the Company, dated October 1, 2014, as amended on February 22, 2017, March 30, 2019 and September 18, 2019.

The WARF License grants to the Company an exclusive license to make, use and sell, in the United States only, products that employ certain licensed patents for a neural probe array or thin-film micro electrode array and method. The Company agreed to pay WARF a royalty equal to a single-digit percentage of our product sales pursuant to the WARF License, with a minimum annual royalty payment of \$150,000 while the WARF License is in effect. If the Company or any of its sublicensees contest the validity of any licensed patent, the royalty rate will be doubled during the pendency of such contest and, if the contested patent is found to be valid and would be infringed by the Company if not for the WARF License, the royalty rate will be tripled for the remaining term of the WARF License.

WARF may terminate the WARF License on 30 days’ written notice if we default on the payments of amounts due to WARF or fail to timely submit development reports, actively pursue our development plan or breach any other covenant in the WARF License and fail to remedy such default in 90 days or in the event of certain bankruptcy events involving us. WARF may also terminate the WARF License if, after royalties earned on sales begin to be paid, such earned royalties cease for more than four calendar quarters. The WARF License otherwise expires by its terms on the date that no valid claims on the patents licensed thereunder remain. The Company expects the latest expiration of a licensed patent to occur in 2030. During the three months ended June 30, 2026 and 2025, \$37,500 in royalty fees were incurred related to the WARF License during each of these periods. During the nine months ended June 30, 2026 and 2025, \$112,500 in royalty fees were incurred during each of these periods related to the WARF License. The royalty fees were reflected as a component of cost of product revenue.

Mayo Agreement

The Company has an exclusive license and development agreement with the Mayo Foundation for Medical Education and Research (“Mayo”) related to certain intellectual property and development services for thin film micro electrode technology (“Mayo Agreement”). If the Company is successful in obtaining regulatory approval, the Company is to pay royalties to Mayo based on a percentage of net sales of products of the licensed technology through the term of the Mayo Agreement, set to expire October 3, 2034. During the three and nine months ended June 30, 2026 and 2025, no royalty fees were incurred related to the Mayo Agreement.

Facility Leases

Headquarters Lease

On May 20, 2024, the Company amended its non-cancellable headquarters lease (the “Lease”) with certain landlords (together, the “Landlord”) pursuant to which the Company leases office space located at 7599 Anagram Drive, Eden Prairie, Minnesota (the “Premises”). The Company took possession of the Premises on November 1, 2019, with the term of the Lease ending June 30, 2028, as amended, unless terminated earlier (the “Lease Term”). The base rent for the Premises ranges from \$6,410 per month to \$7,107 per month by the end of the Lease Term. In addition, as long as the Company is not in default under the Lease, the Company will be entitled to an abatement of its base rent for the first two months of the amended Lease Term beginning in April 2025 and for the last month of the amended Lease Term (June 2028). In addition, the Company pays its pro rata share of the Landlord’s annual operating expenses associated with the Premises.

Los Gatos Lease

In 2021, the Company entered into and commenced a non-cancellable facility lease (the “Los Gatos Lease”), pursuant to which the Company agreed to rent office space for its research and development operations located at 718 University Avenue, Suite #111, Los Gatos, California. The facility space under the Los Gatos Lease is approximately 1,162 square feet. In 2022, the Los Gatos Lease was extended for an additional two years to December 31, 2024. The rent under the extended Los Gatos Lease ranged from \$4,453 to \$4,632 per month beginning on January 1, 2023. On December 17, 2024, the Los Gatos Lease was extended again for an additional two years to December 31, 2026. The rent under the newly extended Los Gatos Lease ranges from \$4,939 to \$5,087 per month beginning on January 1, 2025.

During the three and nine months ended June 30, 2026, rent expense associated with the facility leases amounted to \$99,896 and \$240,082, respectively. During the three and nine months ended June 30, 2025, rent expense associated with the facility leases amounted to \$70,121 and \$209,364, respectively.

Supplemental cash flow information related to the operating leases was as follows:

	For the nine months ended June 30,	
	2026	2025
Cash paid for amounts included in the measurement of lease liability:		
Operating cash flows from operating leases	<u>\$ 103,700</u>	<u>\$ 92,390</u>
Right-of-use assets obtained in exchange for lease obligations:		
Modification of right-of-use asset and associated lease liability	<u>\$ —</u>	<u>\$ 111,898</u>

Supplemental balance sheet information related to the operating leases was as follows:

	As of June 30, 2026	As of September 30, 2025
Right-of-use assets	<u>\$ 166,751</u>	<u>\$ 255,195</u>
Lease liabilities	<u>\$ 175,345</u>	<u>\$ 266,806</u>
Weighted average remaining lease term (years)	<u>1.7</u>	<u>2.3</u>
Weighted average discount rate	<u>7.2%</u>	<u>7.2%</u>

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Maturity of the operating lease liabilities was as follows:

Calendar Year	As of June 30, 2026
2026	\$ 70,330
2027	81,708
2028	34,815
Total lease payments	186,853
Less imputed interest	(11,508)
Total	175,345
Short-term portion (included in accrued expenses and other liabilities)	(102,025)
Long-term portion	\$ 73,320

Other Contingencies

In the ordinary course of business, from time to time, the Company may be subject to a broad range of claims and legal proceedings that relate to contractual allegations, patent infringement and other claims. The Company establishes accruals when applicable for matters and commitments which it believes losses are probable and can be reasonably estimated. To date, no loss contingency for such matters and potential commitments have been recorded. Although it is not possible to predict with certainty the outcome of these matters or potential commitments, the Company is of the opinion that the ultimate resolution of these matters and potential commitments will not have a material adverse effect on its results of operations or financial position.

NOTE 5 – Supplemental Balance Sheet Information

Inventory

Inventory consisted of the following as of:

	June 30, 2026	September 30, 2025
Component inventory	\$ 1,107,149	\$ 871,492
Work-in-process	398,293	130,100
Finished goods	784,812	1,225,213
Total	\$ 2,290,254	\$ 2,226,805

Excess and obsolete valuation reserve adjustments reflected as a reduction of component inventory of \$11,000 and work-in-process inventory of \$10,000 as of June 30, 2026 and September 30, 2025, respectively.

Intangibles

Intangible assets rollforward is as follows:

	Useful Life
Net Intangibles, September 30, 2025	12-13 years \$ 44,946
Less: amortization	(16,736)
Net Intangibles, June 30, 2026	\$ 28,210

Amortization expense was \$5,579 and \$16,736 for the three and nine months ended June 30, 2026, respectively, and \$5,579 and \$16,737 for the three and nine months ended June 30, 2025, respectively.

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Property and Equipment

Property and equipment held for use by category are presented in the following table:

	As of June 30, 2026	As of September 30, 2025
Equipment and furniture	\$ 1,156,974	\$ 1,058,045
Total property and equipment	1,156,974	1,058,045
Less accumulated depreciation	(954,641)	(798,823)
Property and equipment, net	<u>\$ 202,333</u>	<u>\$ 259,222</u>

Depreciation expense was \$41,423 and \$155,818 for the three months and nine months ended June 30, 2026, respectively, and \$61,015 and \$180,618 for the three months and nine months ended June 30, 2025, respectively.

NOTE 6 – Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following:

	As of June 30, 2026	As of September 30, 2025
Accrued payroll	\$ 857,292	\$ 1,055,121
Operating lease liability, short term	102,025	123,658
Royalty payments	75,000	112,500
Professional fees and other	101,394	1,435
Total	<u>\$ 1,135,711</u>	<u>\$ 1,292,714</u>

NOTE 7 – Zimmer Distribution Agreement and Other Product Revenue

On October 25, 2024, the Company entered into the Zimmer Amended and Restated Distribution Agreement (the “Amendment” or “Zimmer Distribution Agreement”) with Zimmer pursuant to which the Company granted Zimmer the exclusive right and license to distribute its OneRF Ablation System for an upfront payment of \$3.0 million, with eligibility for an additional \$1.0 million payment from Zimmer upon achievement of certain specified net sales milestones.

The Company and Zimmer previously entered into an Exclusive Development and Distribution Agreement related to the sEEG and Strip/Grid Product Systems, which was subsequently amended on multiple occasions through August 2, 2022 (the “EDDA”). The EDDA executed prior to the Amendment granted Zimmer exclusive global rights to distribute the Strip/Grid Products and the Electrode Cable Assembly Products. Additionally, the Company granted Zimmer the exclusive right and license to distribute certain sEEG Products developed by the Company and together with the Strip/Grid Products and Electrode Cable Assembly Products, the “Products”. In addition, under the prior EDDAs, the Company and Zimmer agreed to collaborate with respect to development activities through a joint development committee composed of an equal number of representatives of Zimmer and the Company.

Under the Amendment, Zimmer paid the Company \$3.0 million for an exclusive RF Distribution License (the “RF Distribution License” and “License”) for commercialization of its OneRF Ablation System in the brain. Distribution and commercialization of the OneRF® Trigeminal Nerve Ablation System is not covered by the License. In addition, the Company is eligible to receive a future milestone payment of \$1.0 million upon reaching a one-time sales volume threshold, but does not anticipate achieving this milestone.

The revised term under the Amendment (the “Term”) began on the effective date of the Amendment and will remain in effect until October 31, 2034. Upon the expiration of the Term, it may be renewed upon the mutual written consent of the parties. The Amended and Restated Exclusive Development and Distribution Agreement may be terminated before the expiration of the Term in accordance with certain terms under the Amendment. In addition, the license rights granted to Zimmer under this Amendment shall be exclusive (i) until September 30, 2032 for the sEEG Products and Strip/Grid Products; and (ii) until October 31, 2034 for the OneRF Ablation System in the brain.

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License Revenue

The Amendment was accounted for under the provisions of ASC 606 as a separate contract from the prior EDDAs. In accordance with the provisions under ASC 606, the Company identified the transfer of the RF Distribution License as the sole performance obligation of the RF Distribution License. The distribution rights granted to Zimmer, inclusive of the access to the underlying intellectual property for future production of the OneRF Product if required, was found to have significant standalone functionality as no additional substantive input was required by the Company on a go forward basis. Lastly, ancillary support related to the Amendment was concluded to be a perfunctory obligation and de minimis in terms of required resources.

The transaction price associated with the Amendment was \$3.0 million, which was comprised solely of the One RF Exclusivity Fee and was allocated totally to RF Distribution License performance obligation.

Sales Volume Milestone and Payment

The sales volume milestone associated with the Amendment was determined by sales or usage-based thresholds. The sales volume milestone was accounted for under the sales milestone recognition constraint and will be accounted for as constrained variable consideration. The Company has applied the sales volume constraint to the milestone payment and will not recognize revenue until the sales volume threshold occurs.

Product Revenue

Product revenue recognized during the three and nine months ended June 30, 2026 was \$1,973,105 and \$6,727,790, respectively, and was comprised of sales of OneRF Products.

Product revenue recognized during the three and nine months ended June 30, 2025 was \$1,696,050 and \$6,356,767, respectively, and was comprised solely of OneRF Product revenue.

Recognition of License Revenue

The Company determined that the RF Distribution License represented functional intellectual property given Zimmer's access to the underlying intellectual property associated with the OneRF Product. As such, the revenue related to the license was recognized at the point in time in which the license/know-how was delivered to Zimmer which occurred in October 2024. Revenue recognized under the Amendment during the nine months ended June 30, 2025 was \$3.0 million. No license revenue was recognized during the three and nine months ended June 30, 2026.

NOTE 8 – Stock-Based Compensation

During the three and nine months ended June 30, 2026 and 2025, stock-based compensation expense related to stock-based awards was included in selling, general and administrative and research and development costs as follows in the accompanying condensed statements of operations.

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2026	2025	2026	2025
Selling, general and administrative	\$ 293,214	\$ 246,709	\$ 835,073	\$ 711,896
Research and development	59,563	69,945	219,094	194,152
Total stock-based compensation expense	<u>\$ 352,777</u>	<u>\$ 316,654</u>	<u>\$ 1,054,167</u>	<u>\$ 906,048</u>

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2025 Equity Incentive Plan

On January 10, 2025, the Board of Directors of the Company adopted the NeuroOne Medical Technologies Corporation 2025 Equity Incentive Plan (the “2025 Plan”). On February 14, 2025, at the 2025 annual meeting of stockholders, the stockholders of the Company approved the 2025 Plan.

The 2025 Plan is the successor to and continuation of the Company’s 2017 Equity Incentive Plan (the “2017 Plan”) and to the Company’s 2016 Equity Incentive Plan (together, the “Prior Plans”). As of the Effective Date, (i) no additional awards may be granted under the Prior Plans; (ii) any Returning Shares will become available for issuance pursuant to Awards granted under the 2025 Plan; and (iii) all outstanding awards granted under the Prior Plans will remain subject to the terms of the Prior Plans (except to the extent such outstanding awards result in returning shares that become available for issuance pursuant to awards granted under the 2025 Plan).

Initially, the maximum number of shares of the Company’s common stock that may be issued under the 2025 Plan may not exceed (1) 500,000 and (2) any shares subject to outstanding stock awards under the 2017 Plan that are forfeited or otherwise returned to the share reserve.

On April 3, 2026, at the 2026 annual meeting of stockholders, the stockholders of the Company approved the increase in share authorization under the 2025 Plan by 250,000 shares for a revised aggregate total of 750,000 shares. In addition, an evergreen provision was approved whereby the number of shares available under the 2025 Plan will be increased automatically on January 1 each year between January 1, 2027 and January 1, 2031. The aggregate number of shares of common stock that may be issued pursuant to awards (as defined in the 2025 Plan) by an amount equal to 5% of the fully diluted shares (as defined in the 2025 Plan) as of the last day of the preceding calendar year, provided, however that the Board of Directors may act prior to the effective date of any such annual increase to provide that the increase for such year will be a lesser number of shares of common stock.

Inducement Plan

In October 2021, the Company adopted the NeuroOne Medical Technologies Corporation 2021 Inducement Plan (the “Inducement Plan”), pursuant to which the Company reserved 70,058 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual’s entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The Inducement Plan was approved by the Company’s Board of Directors without stockholder approval in accordance with such a rule. On November 9, 2023, the Company’s Board of Directors adopted the First Amendment to the Company’s Inducement Plan, increasing the aggregate number of shares of common stock that may be issued pursuant to equity incentive awards under the Inducement Plan by 25,000 shares. Additionally, on May 20, 2025, the Board of Directors adopted the Second Amendment to the Company’s Inducement Plan, increasing the aggregate number of shares of common stock that may be issued pursuant to equity incentive awards under the Inducement Plan by an additional 95,833 shares. Lastly, on February 25, 2026, the Board of Directors adopted the Third Amendment to the Company’s Inducement Plan, increasing the aggregate number of shares of common stock that may be issued pursuant to equity incentive awards under the Inducement Plan by an additional 83,333 shares for an aggregate total of 274,224 shares.

Stock Options

During the three months ended June 30, 2026 and 2025, the Company granted 29,027 and 547,593 stock options, respectively, to its board of directors, officers and employees. During the nine months ended June 30, 2026 and 2025, the Company granted 113,162 and 556,107 stock options, respectively, to its board of directors, officers and employees. Vesting generally occurs over a 12 to 48 month period based on a time of service condition. The grant date fair value of the grants issued during the three months ended June 30, 2026 and 2025 was \$3.35 and \$2.98 per share, respectively. The grant date fair value of the grants issued during the nine months ended June 30, 2026 and 2025 was \$3.38 and \$3.03 per share, respectively.

NeuroOne Medical Technologies Corporation
Notes to Condensed Financial Statements (Unaudited)

The total expense for the three months ended June 30, 2026 and 2025 related to stock options was \$253,243 and \$203,095, respectively. The total expense for the nine months ended June 30, 2026 and 2025 related to stock options was \$742,331 and \$534,426, respectively. The total number of stock options outstanding as of June 30, 2026 and September 30, 2025 was 1,127,065 and 1,013,903, respectively.

The weighted-average assumptions used in the Black-Scholes option-pricing model are as follows for the stock options:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2026	2025	2026	2025
Expected stock price volatility	107.1%	109.9%	107.1%	110.0%
Expected life of options (years)	5.6	6.0	5.9	6.0
Expected dividend yield	—%	—%	—%	—%
Risk free interest rate	4.1%	4.0%	3.7%	4.0%

During the three months ended June 30, 2026 and 2025, 177,687 and 22,762 stock options vested, respectively, and zero and 3,205 stock options were forfeited during these periods, respectively. During the nine months ended June 30, 2026 and 2025, 233,130 and 106,786 stock options vested, respectively, and zero and 3,205 stock options were forfeited during these periods, respectively. During the three and nine months ended June 30, 2026 and 2025, no options were exercised.

Restricted Stock Units

During the three and nine months ended June 30, 2026, the Company granted an aggregate of 27,956 and 29,249 restricted stock units (“RSUs”) to a non-employee directors under the 2025 Plan. The weighted average grant date fair value of the RSUs granted during the three and nine months ended June 30, 2026 was \$4.77 and \$4.75 per RSU. The RSUs granted vest over a one-year period in equal monthly installments, subject to the recipient’s continued service on such dates.

During the nine months ended June 30, 2025, the Company granted an aggregate of zero and 13,890 RSUs to non-employee directors under the 2025 Plan. The weighted average grant date fair value of the RSUs granted during the three and nine months ended June 30, 2025 was \$7.20 per RSU. The RSUs granted vest over a one-year period in equal monthly installments, subject to the recipient’s continued service on such dates.

During the three months ended June 30, 2026 and 2025, 7,311 and 5,962 RSUs vested, respectively, and zero and 417 RSUs were forfeited during these periods, respectively. During the nine months ended June 30, 2026 and 2025, 59,294 and 60,355 RSUs vested, respectively, and zero and 417 RSUs were forfeited during these periods, respectively. The total expense for the three months ended June 30, 2026 and 2025 related to these RSUs was \$99,534 and \$113,559, respectively. The total expense for the nine months ended June 30, 2026 and 2025 related to these RSUs was \$311,836 and \$371,622, respectively. The total RSUs outstanding as of June 30, 2026 and September 30, 2025 was 105,390 and 135,439, respectively.

General

As of June 30, 2026, 250,708 shares were available in the aggregate for future issuance under the 2025 Plan, 2017 Plan and Inducement Plan. Unrecognized stock-based compensation was \$2.3 million as of June 30, 2026. The unrecognized share-based expense is expected to be recognized over a weighted average period of 2.1 years.

NOTE 9 – Concentrations

Revenue

For the three months and nine months ended June 30, 2026, one customer accounted for 100% and 99.8% of the Company's product revenue, respectively.

For the three months and nine months ended June 30, 2025, one customer accounted for 100.0% and 93.9% of the Company's product revenue, respectively.

Supplier concentration

One contract manufacturer produces all of the Company's Strip/Grid Products and sEEG Products and another supplier was responsible for the development of the Company's OneRF Ablation System generator.

NOTE 10 – Income Taxes

The effective tax rate for the three and nine months ended June 30, 2026 and 2025 was zero percent. As a result of the analysis of all available evidence as of June 30, 2026 and September 30, 2025, the Company recorded a full valuation allowance on its net deferred tax assets. Consequently, the Company reported no income tax benefit during the three and nine months ended June 30, 2026 and 2025. If the Company's assumptions change and the Company believes that it will be able to realize these deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets will be recognized as a reduction of future income tax expense. If the assumptions do not change, each period the Company could record an additional valuation allowance on any increases in the deferred tax assets.

NOTE 11 – Debt Financing

On August 2, 2024, the Company entered into a loan and security agreement (the "Debt Facility Agreement") with Growth Opportunity Funding, LLC, as the lender (the "Lender"), which provided for a delayed draw term loan facility in an aggregate principal amount not to exceed \$3.0 million (the "Debt Facility"). The Company was permitted to borrow loans under the Debt Facility from time to time (collectively, the "Loans"), for general corporate purposes and subject to certain specified conditions, until the earliest of: (i) November 30, 2024, (ii) the occurrence of any Monetization Event or Change of Control (as each defined in the Debt Facility Agreement), or (iii) at the Lender's option, upon the occurrence and during the continuance of an event of default under the Debt Facility Agreement. On November 7, 2024, the Company terminated the Debt Facility Agreement, and no amounts were drawn under the Debt Facility Agreement. The Company paid a termination fee of \$125,000 to the Lender and incurred additional legal fees of \$7,091 related to the termination. The Company also incurred non-termination Debt Facility costs of \$192,647 during the nine months ended June 30, 2025.

At closing of the Debt Facility, the Company issued to the Lender a warrant exercisable for five years for 16,666 shares of common stock at an exercise price of \$3.96 per share, subject to adjustment (the "Closing Date Debt Facility Warrant"). The Closing Date Debt Facility Warrant was accounted for and classified as equity on the accompanying condensed balance sheets.

NOTE 12 – Stockholders' Equity

March 2026 Private Placement

On March 1, 2026, the Company entered into a securities purchase agreement (the "March 2026 Private Placement") with a newly appointed officer of the Company, to issue and sell 166,666 shares of the Company's common stock at a price per share equal to \$4.02242. The March 2026 Private Placement closed on March 2, 2026 upon which the Company received gross proceeds in the amount of \$670,400. Issuance costs in connection with the March 2026 Private Placement were nil.

August 2024 Private Placement

On August 1, 2024, the Company entered into a Securities Purchase Agreement with certain accredited investors (the “Purchasers”), pursuant to which the Company, in a private placement (the “2024 Private Placement”), agreed to issue and sell an aggregate of (i) 490,741 shares of the Company’s common stock and (ii) warrants to purchase an aggregate of 368,052 shares of common stock (the “PIPE Warrants”) at a purchase price of \$5.40 per unit, consisting of one share and a PIPE Warrant to purchase 0.75 shares of common stock, resulting in total gross proceeds of approximately \$2.65 million before deducting expenses. Issuance costs attributed to 2024 Private Placement amounted to approximately \$0.2 million. The 2024 Private Placement closed on August 2, 2024.

The PIPE Warrants are exercisable beginning on the date of issuance, have an initial exercise price of \$7.14 per share, subject to adjustment, and will expire on the third anniversary of the date of issuance. One of the Purchasers in the 2024 Private Placement included Paul Buckman, a director on the Company’s Board of Directors. In April 2025, the exercise price was reset to \$2.79 upon the close of the April 2025 Financing for all of the PIPE Warrants, except for the PIPE Warrants to purchase 3,472 shares of common stock issued to a director on our Board of Directors for which the exercise price was reset to \$5.26 per share.

The PIPE Warrants were accounted for and classified as liabilities on the accompanying condensed balance sheets given certain price reset provisions not used for a fair valuation under a fixed for fixed settlement scenario as required for equity balance sheet classification. A Monte Carlo simulation model was used to estimate the aggregate fair value of the PIPE Warrants. Input assumptions used were as follows on June 30, 2026 and September 30, 2025: risk-free interest rate 3.92% and 3.55%, respectively; expected volatility of 74.7% and 94.5%; respectively; expected life of 1.09 years and 1.84 years, respectively; and expected dividend yield zero percent for both dates. The underlying stock price used was the market price as quoted on Nasdaq as of June 30, 2026 and September 30, 2025. The Company recorded the fair value change of the PIPE Warrants in the amount of a \$405,702 benefit and a \$620,171 benefit associated with the fair value change in the warrant liability line item on the accompanying condensed statements of operations for the three and nine months ended June 30, 2026, respectively. The Company recorded the fair value change of the PIPE Warrants in the amount of a \$319,625 benefit and a \$1,099,421 benefit to the fair value change in warrant liability line item on the accompanying condensed statements of operations for the three and nine months ended June 30, 2025, respectively.

At-The-Market Offering

On December 21, 2022, the Company entered into a Capital on DemandTM Sales Agreement (the “Sales Agreement”) with JonesTrading Institutional Services LLC (“JonesTrading”) that created an at-the-market offering program (“ATM”) under which the Company may offer and sell common stock having an aggregate offering price of up to \$14.5 million. JonesTrading is entitled to a commission at a fixed commission rate of up to 3% of the gross proceeds.

In 2023, the Company changed the amount of common stock that can be sold pursuant to the Sales Agreement to \$4.8 million (including shares previously sold). On April 3, 2025, we decreased the amount of common stock available under the ATM to zero, and on August 15, 2025, we increased the amount of common stock that can be sold pursuant to the Sales Agreement to \$6,750,000. On June 12, 2026, we increased the amount of common stock that can be sold pursuant to the Sales Agreement to \$13,400,000.

During the three and nine months ended June 30, 2026, 80,671 shares of common stock were issued under the ATM for an aggregate offering price of \$358,986. Issuance costs incurred under the ATM during the three and nine months ended June 30, 2026 were \$11,996.

During the three and nine months ended June 30, 2025, 59,314 shares of common stock were issued under the ATM for an aggregate offering price of \$414,037. Issuance costs incurred under the ATM during the three and nine months ended June 30, 2025 were \$9,325 and \$105,254, respectively.

The total aggregate offering price and common stock issued since inception of the ATM Program through June 30, 2026 was \$8,359,586 and 1,004,752 shares, respectively. Cumulative issuance costs incurred under the ATM Program through June 30, 2026 was \$629,878, inclusive of deferred offering costs. See Note 15 – Subsequent Events.

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Notes to Condensed Financial Statements (Unaudited)

Warrant Activity and Summary

	Warrants	Exercise Price Per Warrant	Weighted Average Exercise Price	Weighted Average Term (years)
Outstanding at September 30, 2025	1,149,323	\$ 2.79-33.66	\$ 21.92	0.96
Issued	—	\$ —	\$ —	—
Exercised (1)	(93,750)	\$ 2.79	\$ 2.79	—
Expired	(694,462)	\$ 31.50	\$ 31.50	—
Outstanding at June 30, 2026	361,111	\$ 2.79-33.66	\$ 8.47	1.28
Outstanding and exercisable at June 30, 2026	361,111	\$ 2.79-33.66	\$ 8.47	1.28

(1) 16,780 of the shares exercised were withheld in connection with a cashless exercise.

The following table summarizes information about warrants outstanding as of June 30, 2026:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual life (Years)	Number Exercisable as of June 30, 2026
\$ 2.79	245,830	1.09	245,830
\$ 3.96	16,666	3.09	16,666
\$ 5.26	3,472	1.09	3,472
\$ 18.00	58,333	1.09	58,333
\$ 33.66	36,810	2.00	36,810
Total	361,111		361,111

NOTE 13 – Defined Contribution Plan

The Company has a 401(k) defined contribution plan (the “401K Plan”) for all employees age 21 and older. Employees can defer up to 100% of their compensation through payroll withholdings into the 401K Plan subject to federal law limits. The Company may match 100% of deferrals up to 3% of one’s contributions. The Company’s matching contributions to employee deferrals are discretionary. The Company may also make discretionary profit sharing contributions under the 401K Plan in the future, but it has not done so through June 30, 2026.

Employee contributions and any employer matching contributions made to satisfy certain non-discrimination tests required by the Internal Revenue Code are 100% vested upon contribution. Discretionary employer matches to employee deferrals vest over a six year period beginning on the second anniversary of an employee’s date of hire. Discretionary profit sharing contributions vest over a five year period beginning on the first anniversary of an employee’s date of hire. The Company did not make any contributions to the 401K Plan during the three and nine months ended June 30, 2026. During the three and nine months ended June 30, 2025, the Company contributed zero and \$31,105 to the 401K Plan, respectively.

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Notes to Condensed Financial Statements (Unaudited)

NOTE 14 – Segment Reporting

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the CODM in deciding how to allocate resources in assessing performance. The Company has one reportable segment, which is the business of development and commercialization of products related to comprehensive neuromodulation cEEG and sEEG recording, monitoring, ablation, and stimulation solutions (“Neuromodulation Products”). NeuroOne is a medical technology company focused on developing and commercializing Neuromodulation Products. The Company recognizes the Neuromodulation Products as one reporting segment.

The accounting policies of the Neuromodulation Products segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the Neuromodulation Products segment based on net loss, which is reported on the statements of operations as net loss. The measure of segment assets is reported on the balance sheet as total assets. The Company does not have any intra-entity sales or transfers.

The CODM uses cash forecast models in deciding how to invest into the Neuromodulation Products segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment and in establishing management’s compensation.

The statements of operations below are inclusive of the significant expense categories regularly reviewed by the CODM for the three and nine months ended June 30, 2026 and 2025:

	Three months ended June 30,		Nine months ended June 30,	
	2026	2025	2026	2025
Product revenue	\$ 1,973,105	\$ 1,696,050	\$ 6,727,790	\$ 6,356,767
Cost of product revenue	790,496	781,215	2,987,089	2,743,982
Product gross profit	<u>1,182,609</u>	<u>914,835</u>	<u>3,740,701</u>	<u>3,612,785</u>
License revenue	<u>—</u>	<u>—</u>	<u>—</u>	<u>3,000,000</u>
Operating expenses:				
General and administrative	1,693,450	1,264,808	4,651,242	4,501,069
Sales	261,079	150,009	634,372	512,361
Marketing	227,239	204,133	700,980	589,388
Development	1,172,517	1,039,733	3,727,222	3,379,700
Quality assurance	252,636	142,752	555,701	485,676
Total operating expenses	<u>3,606,921</u>	<u>2,801,435</u>	<u>10,269,517</u>	<u>9,468,194</u>
Loss from operations	(2,424,312)	(1,886,600)	(6,528,816)	(2,855,409)
Fair value change in warrant liability	405,702	319,625	620,171	1,099,421
Financing costs	—	(9,325)	—	(334,063)
Other income	12,279	75,432	82,402	103,898
Loss before income taxes	(2,006,331)	(1,500,868)	(5,826,243)	(1,986,153)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (2,006,331)</u>	<u>\$ (1,500,868)</u>	<u>\$ (5,826,243)</u>	<u>\$ (1,986,153)</u>

NOTE 15 – Subsequent Events

On July 13, 2026, we issued an additional 400,346 shares of common stock for gross proceeds in the amount of \$1,041,180 in connection with the ATM Program.

Following this issuance, the exercise price of existing PIPE Warrants was reset to \$2.5227, except for the PIPE Warrants to purchase 3,472 shares of common stock issued to a director on our Board of Directors for which the exercise price remains \$5.26 per share.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and notes included in Part I "Financial Information", Item I "Financial Statements" of this Quarterly Report on Form 10-Q (the "Report") and the audited financial statements and related footnotes included in our Annual Report on Form 10-K for the year ended September 30, 2025.

Forward-Looking Statements

This Report contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "target," "seek," "contemplate," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- our ability to maintain regulatory clearance of our commercial products;
- the results of our development and distribution relationship with Zimmer, Inc. ("Zimmer"), and Zimmer's ability to commercialize our technology in the United States;
- our ability to achieve or sustain profitability;
- our ability to raise additional capital and to fund our operations;
- the availability of additional capital on acceptable terms or at all as or when needed;
- we have been the victim of a cyber-related crime, and our controls may not be successful in avoiding future cyber-related crimes;
- the performance, productivity, reliability and regulatory compliance of our third-party manufacturers of our products;
- our ability to develop our products in development;
- our future development priorities;

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- our expectations about the willingness of healthcare providers to recommend our technology to people with epilepsy, Parkinson's disease, dystonia, essential tremors, facial pain, chronic back pain and other related neurological disorders;
- our future commercialization, marketing and manufacturing capabilities and strategy;
- our ability to comply with applicable regulatory requirements;
- our ability to maintain our intellectual property position;
- our expectations regarding international opportunities for commercializing our products;
- our estimates regarding the size of, and future growth in, the market for our technology, including technology under development; and
- our estimates regarding our future expenses and needs for additional financing.

Forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. You should refer to the "Risk Factors" section of our Annual Report on Form 10-K for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

These forward-looking statements speak only as of the date of this Report. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the Securities and Exchange Commission (the "SEC") after the date of this Report.

Overview

We are a medical technology company focused on (i) diagnostic, ablation and deep brain stimulation technology for brain related conditions such as epilepsy and Parkinson's disease; (ii) ablation and stimulation for pain management throughout the body; and (iii) drug delivery to the brain including diagnostic and stimulation capabilities.

We are developing and commercializing thin film electrode technology for continuous electroencephalogram ("cEEG") and stereoelectroencephalography ("sEEG"), spinal cord stimulation, brain stimulation, drug delivery and ablation solutions for patients suffering from epilepsy, trigeminal neuralgia, Parkinson's disease, dystonia, essential tremors, chronic back pain and other pain-related neurological disorders. The Company is also developing the capability to use its sEEG electrode technology to deliver drugs, stem cells or gene therapy while being able to record activity before, during, and after delivery.

We have received 510(k) clearance for four of our devices from the Food and Drug Administration ("FDA"), including: (i) our Evo cortical electrode technology for recording, monitoring, and stimulating brain tissue for up to 30 days ("Evo Cortical"), (ii) our Evo sEEG electrode technology for temporary (less than 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain ("Evo sEEG"), (iii) our OneRF ablation system for creation of radiofrequency lesions in nervous tissue for functional neurosurgical procedures ("OneRF Ablation System"), (iv) our OneRF TN ablation system for use in procedures to create radiofrequency (RF) lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures ("OneRF TN Ablation System"). We have a distribution agreement with Zimmer, Inc. ("Zimmer") providing Zimmer with a license to commercialize and distribute the Evo Cortical, Evo sEEG, and OneRF Ablation System in the brain. We initiated a limited market release of the OneRF TN Ablation System in December 2025 and completed the limited market release in March 2026. The Company's other products and indications are still under development.

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We have largely incurred losses since inception. As of June 30, 2026, we had an accumulated deficit of \$84.4 million, primarily as a result of expenses incurred in connection with our research and development, selling, general and administrative expenses associated with our operations and interest expense, fair value adjustments and loss on extinguishments related to our debt, offset in part by license and product revenues.

Prior to FDA clearance of certain of our products, our main sources of cash, cash equivalents and short-term investments were proceeds from the issuances of notes, common stock, warrants and unsecured loans. See “*Liquidity and Capital Resources—Capital Resources*” below. While we have begun to generate revenue from the sale of our Evo Cortical, Evo sEEG, OneRF Ablation System, and OneRF TN Ablation System, and through milestone and other payments from our current collaboration and distribution arrangement with Zimmer, we expect to continue to incur significant expenses and may incur increasing operating and net losses for the foreseeable future until we generate a higher level of revenue from commercial sales.

We may be unable to raise additional funds when needed on favorable terms or at all. Our failure to raise such capital as and when needed would have a negative impact on our financial condition and our ability to develop and commercialize our cortical strip, grid electrode and depth electrode technology and future products and our ability to pursue our business strategy. See “*Liquidity and Capital Resources—Liquidity Outlook*” below.

Recent Developments

Corporate Updates

Reverse Stock Split

On April 14, 2026, we filed an amendment to our Amended and Restated Certificate of Incorporation, as amended and/or restated from time to time, to effectuate a reverse stock split of our issued and outstanding shares of common stock, par value \$0.001 per share, which became effective on April 15, 2026 at 5:00 p.m. Eastern Time (the “Reverse Stock Split”). Trading of the common stock on The Nasdaq Capital Market commenced on a split-adjusted basis at market open on April 16, 2026. All amounts in the condensed financial statements have been retroactively adjusted to reflect the Reverse Stock Split.

As a result of the Reverse Stock Split, every 6 shares of our common stock issued or outstanding was automatically reclassified into one validly issued, fully-paid and non-assessable new share of common stock, subject to the treatment of fractional shares as described below, without any action on the part of the holders. Proportional adjustments were made to the number of shares of common stock awarded and available for issuance under our equity incentive plans, as well as the exercise price and the number of shares issuable upon the exercise or conversion of our outstanding stock options and other equity securities under our equity incentive plans. All outstanding warrants were also adjusted in accordance with their terms. The shares of common stock outstanding following the Reverse Stock Split remain fully paid and non-assessable. The Reverse Stock Split did not affect the number of authorized shares of common stock or the par value per share of the common stock.

No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise be entitled to receive fractional shares as a result of the Reverse Stock Split were automatically entitled to receive a cash payment equal to the market value of the fractional share. The Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder’s relative interest in our equity securities, except for any adjustments for fractional shares.

2025 Equity Incentive Plan

On April 3, 2026, at the 2026 annual meeting of stockholders, our stockholders approved the increase in share authorization under the 2025 Equity Incentive Plan (the “2025 Plan”) by 250,000 shares. In addition, an evergreen provision was approved whereby the number of shares available under the 2025 Plan will be increased automatically on January 1 each year between January 1, 2027 and January 1, 2031. The aggregate number of shares of common stock that may be issued pursuant to awards (as defined in the 2025 Plan) by an amount equal to 5% of the fully diluted shares (as defined in the 2025 Plan) as of the last day of the preceding calendar year, provided, however that our Board of Directors may act prior to the effective date of any such annual increase to provide that the increase for such year will be a lesser number of shares of common stock.

March 2026 Private Placement

On March 1, 2026, we entered into a securities purchase agreement (the “March 2026 Private Placement”) with a newly appointed officer of the Company, to issue and sell 166,666 shares of our common stock at a price per share equal to \$4.02242. The March 2026 Private Placement closed on March 2, 2026 upon which we received gross proceeds in the amount of \$670,400.

Trigeminal Limited Market Release

We initiated a limited market release of the OneRF TN Ablation System in December 2025 and completed the limited market release in March 2026. The Company is currently evaluating the distribution options for the OneRF TN Ablation System.

Nasdaq Minimum Bid Price Notification

On May 6, 2025, we received a letter from the Listing Qualifications Department of Nasdaq Stock Market (“Nasdaq”) notifying us that because the closing bid price of our common stock was below \$1.00 per share for the prior 30 consecutive business days, we are not in compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2) (the “Minimum Bid Price Requirement”). In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we had a period of 180 calendar days, or until November 3, 2025, to regain compliance with the Minimum Bid Price Requirement.

On November 4, 2025, we received a letter from Nasdaq notifying us that we have been granted a 180-day extension, until May 4, 2026, to regain compliance with the Minimum Bid Price Requirement.

On April 30, 2026, we received a letter from Nasdaq notifying us that we have regained compliance with the Minimum Bid Price Requirement as a result of the closing bid price of the Company’s common stock being at \$1.00 per share or greater for the prior 10 consecutive business days. Accordingly, the letter indicated we are in compliance with the Minimum Bid Price Requirement and the matter is closed.

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the conflicts between Russia and Ukraine and in the Middle East, disruptions in the banking system and financial markets, and increased inflation. The general economic and capital market conditions both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms or at all. If economic conditions continue to decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected. We have experienced minor price increases from our suppliers related to tariffs on imported goods, and may experience additional price increases. We expect to submit a request for a tariff refund for minor tariffs paid by the Company to the U.S. government under the International Emergency Economic Powers Act, but the timing and amount of cash receipt pursuant to such future submission remains uncertain. We will continue to monitor guidance issued regarding the refund process.

Our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, increased inflation, the conflicts in Ukraine and the Middle East, disruptions in the banking system and financial markets, and steps taken by governments and central banks, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates.

Financial Overview

Product Revenue

Our product revenue was derived from the sale of our Evo Cortical, Evo sEEG, and OneRF Ablation Systems when they occur, which have each received FDA 510(k) clearance.

Product Gross Profit

Product gross profit represents our product revenue less our cost of product revenue. Our cost of product revenue consists of the manufacturing and materials costs incurred by our third-party contract manufacturers in connection with our Evo Cortical, Evo sEEG, and OneRF Ablation Systems, and outside supplier costs of producing our electrode cable assembly products. In addition, the cost of product revenue includes royalty fees incurred in connection with our license agreements as well as valuation adjustments for excess or obsolete inventory.

License Revenue

The Company determined that the RF Distribution License granted under the Zimmer Amended and Restated Distribution Agreement represented functional intellectual property given Zimmer's access to the underlying intellectual property associated with the OneRF Ablation System in the brain. As such, the revenue related to the license was recognized at the point in time in which the license/know-how was delivered to Zimmer which occurred in October 2024. Revenue recognized under the Amendment during the three months ended December 31, 2024 was \$3.0 million. For further discussion about the determination of license revenue, product revenue and cost of product revenue, and for a discussion of milestones and royalty payments under the Zimmer Amended and Restated Distribution Agreement, see "—Liquidity and Capital Resources—Liquidity Outlook" below and see "Note 7 — Zimmer Distribution Agreement and Other Product Revenue" to our condensed financial statements included in "Part 1, Item 1 – Financial Statements" of this Report.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel-related costs including stock-based compensation for personnel in functions not directly associated with research and development activities. Other significant costs include legal and litigation costs relating to corporate matters, intellectual property costs, professional fees for consultants assisting with financial and administrative matters, and sales and marketing in connection with the commercial sale of our Evo Cortical, Evo sEEG, and OneRF Ablation Systems. We anticipate that our selling, general and administrative expenses will increase in the future to support our continued research and development activities, further commercialization of our technology, and the increased costs of operating as a public company.

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities in developing our technology. Research and development expenses include compensation and benefits for research and development employees including stock-based compensation, overhead expenses, laboratory supplies, clinical trial and related clinical manufacturing expenses, costs related to regulatory operations, fees paid to consultants and other outside expenses. Research and development costs are expensed as incurred and costs incurred by third parties are expensed as the contracted work is performed.

Fair Value Change in Warrant Liability

The net change in the fair value line item is attributed to the warrant liability while outstanding.

Financing Costs

Financing costs consists of the amortization of the deferred issuance costs and other lending and issuance costs in connection with the debt facility described further below.

Other Income

Other income primarily consists of interest income related to our cash and cash equivalents,

Results of Operations

Comparison of the Three Months Ended June 30, 2026 and 2025

The following table sets forth the results of operations for the three months ended June 30, 2026 and 2025, respectively.

	For the Three Months Ended June 30, (unaudited)		
	2026	2025	Period to Period Change
Product revenue	\$ 1,973,105	\$ 1,696,050	\$ 277,055
Cost of product revenue	790,496	781,215	9,281
Product gross profit	<u>1,182,609</u>	<u>914,835</u>	<u>267,774</u>
Operating expenses:			
Selling, general and administrative	2,181,768	1,618,950	562,818
Research and development	<u>1,425,153</u>	<u>1,182,485</u>	<u>242,668</u>
Total operating expenses	<u>3,606,921</u>	<u>2,801,435</u>	<u>805,486</u>
Loss from operations	(2,424,312)	(1,886,600)	(537,712)
Fair value change in warrant liability	405,702	319,625	86,077
Financing costs	—	(9,325)	9,325
Other income	12,279	75,432	(63,153)
Loss before income taxes	<u>(2,006,331)</u>	<u>(1,500,868)</u>	<u>(505,463)</u>
Provision for income taxes	—	—	—
Net loss	<u><u>\$ (2,006,331)</u></u>	<u><u>\$ (1,500,868)</u></u>	<u><u>\$ (505,463)</u></u>

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Product Revenue and Product Gross Profit

Product revenue was \$2.0 million during the three months ended June 30, 2026 with a gross profit and gross profit percentage of \$1.2 million and 59.9%, respectively. Product revenue was \$1.7 million during the three months ended June 30, 2025 with a gross profit and gross profit percentage of \$0.9 million and 53.9%, respectively. The increase in gross profit percentage during the current period was largely due to a change in sales mix and sales of higher margin products. Product revenue consisted of OneRF Products related sales during the periods presented. The cost of product revenue consisted of the manufacturing and materials costs incurred by our third-party contract manufacturers in connection with our OneRF Products and outside supplier materials costs. In addition, cost of product revenue included royalty fees incurred of approximately \$38,000 in connection with our license agreements during each of the three months ended June 30, 2026 and 2025.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$2.2 million during the three months ended June 30, 2026 compared to \$1.6 million during the three months ended June 30, 2025. The increase of \$0.6 million in the current quarter over the comparable prior year quarter was largely attributed to higher payroll costs, including stock-based compensation, of \$0.3 million, sales and marketing costs of \$0.1 million, professional fees of \$0.1 million and higher operating costs of \$0.1 million on a net basis. Selling, general and administrative expenses included \$0.3 million and \$0.2 million of stock-based compensation during the three months ended June 30, 2026 and 2025, respectively.

Research and Development Expenses

Research and development expenses were \$1.4 million during the three months ended June 30, 2026 compared to \$1.2 million during the three months ended June 30, 2025. The increase of \$0.2 million in the current period over the prior year period was attributed largely to the timing of product development activities in the current quarter when compared to the comparable prior year quarter. Research and development expenses primarily included salary-related expenses and costs related to consulting services, materials and supplies associated with the development of additional applications of our thin-film electrode technology, including the delivery of drugs or gene therapy to the brain, and basivertebral nerve ablation (BVNA) and spinal cord stimulation for treatment of chronic lower back pain. Research and development expenses included \$0.1 million of stock-based compensation during each of the three months ended June 30, 2026 and 2025.

Fair Value Change in Warrant Liability

The net change in fair value of the warrant liability during the three months ended June 30, 2026 was a \$0.4 million benefit compared to a \$0.3 million benefit during the three months ended June 30, 2025. The change was due primarily to fluctuations in our common stock fair value.

Financing costs

We did not incur any financing costs during the three months ended June 30, 2026. Financing costs during the three months ended June 30, 2025 consisted of the costs associated with the at-the market offering facility (described further below) in the amount of \$9,000.

Other Income

Other income during the three months ended June 30, 2026 and 2025 related to interest income on our cash, cash equivalents and short-term investments in the amount of \$12,000 and \$75,000, respectively.

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

The following table sets forth the results of operations for the nine months ended June 30, 2026 and 2025, respectively.

	For the Nine Months Ended June 30, (unaudited)		
	2026	2025	Period to Period Change
Product revenue	\$ 6,727,790	\$ 6,356,767	\$ 371,023
Cost of product revenue	2,987,089	2,743,982	243,107
Product gross profit	3,740,701	3,612,785	127,916
License revenue	—	3,000,000	(3,000,000)
Operating expenses:			
Selling, general and administrative	5,986,594	5,602,818	383,776
Research and development	4,282,923	3,865,376	417,547
Total operating expenses	10,269,517	9,468,194	801,323
Loss from operations	(6,528,816)	(2,855,409)	(3,673,407)
Fair value change in warrant liability	620,171	1,099,421	(479,250)
Financing costs	—	(334,063)	334,063
Other income	82,402	103,898	(21,496)
Loss before income taxes	(5,826,243)	(1,986,153)	(3,840,090)
Provision for income taxes	—	—	—
Net loss	\$ (5,826,243)	\$ (1,986,153)	\$ (3,840,090)

Product Revenue and Product Gross Profit

Product revenue was \$6.7 million during the nine months ended June 30, 2026 with a gross profit and gross profit percentage of \$3.7 million and 55.6%, respectively. Product revenue was \$6.4 million during the nine months ended June 30, 2025 with a gross profit and gross profit percentage of \$3.6 million and 56.8%, respectively. The decrease in gross profit percentage during the current period was largely due to the sales mix and sales of higher margin products in the prior year period. Product revenue consisted of OneRF Products during the period presented. The cost of product revenue consisted of the manufacturing and materials costs incurred by our third-party contract manufacturers in connection with our OneRF Products and outside supplier materials costs. In addition, cost of product revenue included royalty fees incurred of approximately \$0.1 million in connection with our license agreements during each of the nine months ended June 30, 2026 and 2025.

License Revenue

No license revenue was generated from the Amended and Restated Zimmer Development Agreement during the nine months ended June 30, 2026. License revenue was \$3.0 million for the nine months ended June 30, 2025 related to the distribution license granted to Zimmer for the OneRF Product in the brain in October 2024.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$6.0 million for the nine months ended June 30, 2026, compared to \$5.6 million for the nine months ended June 30, 2025. The \$0.4 million increase in the current nine-month period compared to the comparable prior year period was primarily due to higher payroll related costs of \$0.5 million inclusive of stock-based compensation, sales and marketing costs of \$0.3 million and other operating expenses of \$0.1 million on a net basis, offset in part by lower legal costs of \$0.3 million and lower professional fees of \$0.2 million. Selling, general and administrative expenses included \$0.8 million and \$0.7 million of stock-based compensation during the nine months ended June 30, 2026 and 2025, respectively.

Research and Development Expenses

Research and development expenses were \$4.3 million for the nine months ended June 30, 2026, compared to \$3.9 million for the nine months ended June 30, 2025. The \$0.4 million increase period over period was attributed to the timing of development activities during the current nine-month period when compared to the comparable prior year period. Research and development primarily included salary-related expenses and costs related to consulting services, materials and supplies associated with the development of additional applications of our thin-film electrode technology, including the delivery of drugs or gene therapy to the brain, and basivertebral nerve ablation (BVNA) and spinal cord stimulation for treatment of chronic lower back pain. Research and development expenses included \$0.2 million of stock-based compensation during each of the nine months ended June 30, 2026 and 2025.

Fair Value Change in Warrant Liability

The net change in fair value of the warrant liability during the nine months ended June 30, 2026 was a \$0.6 million benefit compared to a \$1.1 million benefit for the nine months ended June 30, 2025. The change was due primarily to fluctuations in our common stock fair value.

Financing Costs

We did not incur any financing costs during the nine months ended June 30, 2026. Financing costs during the nine months ended June 30, 2025 consisted of the amortization of the deferred issuance costs associated with the debt facility (described further below) in the amount of \$0.2 million and additional legal and loan facility termination costs of \$0.1 million upon the termination of the Debt Facility in November 2024.

Other Income

Other income during each of the nine month periods ended June 30, 2026 and 2025 consisted of \$0.1 million related to interest income attributed to our cash and cash equivalents.

Liquidity and Capital Resources

Overview

As of June 30, 2026, our principal source of liquidity consisted of cash and cash equivalents in the aggregate of approximately \$2.0 million. While we began to generate revenue in fiscal year 2021 from commercial sales and through milestone and other payments under our agreement with Zimmer, we expect to continue to incur significant expenses and increasing operating and net losses for the foreseeable future until and unless we generate an adequate level of revenue from commercial sales to cover expenses. Our most significant cash requirements relate to the funding of our ongoing product development and commercialization operations. Our additional material cash needs include commitments under operating leases, royalty obligations under our intellectual property licenses with the Wisconsin Alumni Research Foundation and the Mayo Foundation for Medical Education and Research as well as other administrative services. See “Funding Requirements” below for more information. We anticipate that our expenses will increase substantially as we continue to develop and commercialize our electrode technology and pursue pre-clinical and clinical trials, seek regulatory approvals, manufacture products, market and distribute our OneRF Products, hire additional staff, add operational, financial and management systems and continue to operate as a public company.

Capital Resources

Our sources of cash and cash equivalents to date have been limited to license, collaboration and product revenues, along with proceeds from the issuances of notes with warrants, common stock with and without warrants and unsecured loans with the terms of our more recent financings described below.

March 2026 Private Placement

On March 1, 2026, we entered into the March 2026 Private Placement with a newly appointed officer of the Company, to issue and sell 166,666 shares of our common stock at a price per share equal to \$4.02242. The March 2026 Private Placement closed on March 2, 2026 upon which we received gross proceeds in the amount of \$670,400. Issuance costs in connection with the March 2026 Private Placement were nil.

April 2025 Financing

On April 4, 2025, we entered into an underwriting agreement with Ladenburg, relating to the issuance and sale of 2,666,666 shares of our common stock, at a price to the public of \$3.00. In addition, under the terms of the underwriting agreement, we granted Ladenburg an option, exercisable for 45 days, to purchase up to an additional 400,000 shares of common stock on the same terms as the offering, which was exercised in full. Issuance costs in connection with the April 2025 Financing amounted to approximately \$1.0 million which included a 7.0% commission to the Underwriter and legal and other expenses in the amount of \$0.3 million. The Company received approximately \$8.2 million in net proceeds.

August 2024 Private Placement

On August 1, 2024, we entered into a Securities Purchase Agreement with certain purchasers, pursuant to which we, in a private placement, agreed to issue and sell an aggregate of (i) 490,741 shares of our Company's common stock (the "Shares"), and (ii) warrants to purchase an aggregate of 368,052 shares of common stock (the "PIPE Warrants") at a purchase price of \$5.40 per unit, consisting of one share and a PIPE Warrant to purchase 0.75 shares of common stock, resulting in total gross proceeds of approximately \$2.65 million before deducting expenses. The 2024 Private Placement closed on August 2, 2024. Issuance costs attributed to the 2024 Private Placement amounted to \$0.2 million.

The PIPE Warrants are exercisable beginning on the date of issuance and had an initial exercise price of \$7.14 per share, subject to adjustment. In April 2025, the exercise price was reset to \$2.79 upon the close of the April 2025 Financing for all of the PIPE Warrants, except for the PIPE Warrants to purchase 3,472 shares of common stock issued to a director on our Board of Directors for which the exercise price was reset to \$5.26 per share. The PIPE Warrants will expire on the third anniversary of the date of issuance.

In connection with the 2024 Private Placement, we agreed to file a registration statement with the SEC covering the resale of the Shares and the shares of common stock issuable upon exercise of the PIPE Warrants which became effective on September 13, 2024.

At-The-Market Offering

On December 21, 2022, we entered into a Capital on DemandTM Sales Agreement ("Sales Agreement") with JonesTrading Institutional Services LLC ("JonesTrading") to create an at-the-market offering program ("ATM Program") under which we may offer and sell shares having an aggregate offering price of up to \$14.5 million. JonesTrading is entitled to a commission at a fixed commission rate of up to 3% of the gross proceeds. On April 3, 2025, we decreased the amount of common stock that can be sold pursuant to the Sales Agreement to zero, and on August 15, 2025, we increased the amount of common stock that can be sold pursuant to the Sales Agreement to \$6,750,000. On June 12, 2026, we increased the amount of common stock that can be sold pursuant to the Sales Agreement to \$13,400,000. Through June 30, 2026, we have issued 1,004,752 shares of common stock under the ATM Program for gross proceeds in the amount of \$8.4 million. We incurred issuance costs in connection with the ATM Program in the amount of \$0.6 million through June 30, 2026.

Debt Facility Financing

On August 2, 2024, we entered into the Debt Facility Agreement with Growth Opportunity Funding, LLC, as the Lender, which provided for a delayed draw term loan facility in an aggregate principal amount not to exceed \$3.0 million. We were permitted to borrow loans under the Debt Facility Agreement from time to time, for general corporate purposes and subject to certain specified conditions, until the earliest of: (i) November 30, 2024, (ii) the occurrence of any Monetization Event or a Change of Control, as each defined in the Debt Facility Agreement, or (iii) at the Lender's option, upon the occurrence and during the continuance of an event of default under the Debt Facility Agreement. On November 7, 2024, the Company terminated the Debt Facility Agreement, and no amounts were drawn under the Debt Facility Agreement. Total costs incurred under the debt facility financing was \$0.4 million.

Funding Requirements

As noted above, certain of our cash requirements relate to the funding of our ongoing product development and commercialization operations and our milestone and royalty obligations under our intellectual property licenses with WARF and Mayo. See “Item 1—Business—Clinical Development and Regulatory Pathway—Clinical Experience, Future Development and Clinical Trial Plans” in our Annual Report on Form 10-K for the year ended September 30, 2025 for a discussion of design, development, pre-clinical and clinical activities that we may conduct in the future, including expected cash expenditures required for some of those activities, to the extent we are able to estimate such costs.

Under the Amended and Restated License and Development Agreement with Mayo (the “Mayo Development Agreement”), we have agreed to pay Mayo a royalty equal to a single-digit percentage of certain of our product sales pursuant to the Mayo Development Agreement. See “Note 4 – Commitments and Contingencies” to our condensed financial statements included in “Part 1, Item 1 – Financial Statements” of this Report for more information about the WARF License and the Mayo Development Agreement.

Our other cash requirements within the next twelve months include accounts payable, accrued expenses, purchase commitments and other current liabilities. Our other cash requirements greater than twelve months from various contractual obligations and commitments include operating leases and contracted services. Refer to “Note 4 – Commitments and Contingencies” to our condensed financial statements included in “Part 1, Item 1 – Financial Statements” of this Report for further detail of our lease obligations and the timing of expected future payments. Contracted services include agreements with third-party service providers for clinical research, product development, manufacturing, supplies, payroll services, equipment maintenance services, and audits for periods up to fiscal year 2028.

We expect to satisfy our short-term and long-term obligations through cash on hand and revenue from commercial sales to cover expenses.

Liquidity Outlook

For a discussion of potential fee payments under the Amended and Restated Zimmer Development Agreement, see “Note 7 — Zimmer Distribution Agreement and Other Product Revenue” to our condensed financial statements included in “Part 1, Item 1 – Financial Statements” of this Report. Even though we have received regulatory clearance to expand the use of our Evo sEEG electrode technology for up to 30 days, commercial sales of the sEEG electrodes and OneRF Ablation System are expected to take some time to be a significant source of liquidity. Zimmer has exclusive global rights to distribute our strip and grid cortical electrodes, depth electrodes and electrode cable assembly products. Zimmer’s failure to timely commercialize these products would have a material adverse effect on our business and operating results. In October 2024, we entered into an Amended and Restated Distribution Agreement with Zimmer (“Zimmer Distribution Agreement”) to provide Zimmer with the exclusive right and license to distribute our OneRF Ablation System in the brain for an upfront payment of \$3.0 million, with eligibility for an additional \$1.0 million payment from Zimmer upon achievement of certain specified net sales milestones.

As of June 30, 2026, we had cash and cash equivalents in the aggregate of approximately \$2.0 million. Management has noted the existence of substantial doubt about our ability to continue as a going concern. Additionally, our independent registered public accounting firm included an explanatory paragraph in the report on our financial statements as of and for the years ended September 30, 2025 and 2024, respectively, noting the existence of substantial doubt about our ability to continue as a going concern. Our existing cash and cash equivalents may not be sufficient to fund our operating expenses through at least twelve months from the date of this filing. To continue to fund operations, we will need to secure additional funding through public or private equity or debt financing, through collaborations or partnerships with other companies, or other sources.

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We may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise capital when needed could compromise our ability to execute on our business plan. If we are unable to raise additional funds, or if our anticipated operating results are not achieved, we believe planned expenditures may need to be reduced in order to extend the time period that existing resources can fund our operations. If we are unable to obtain the necessary capital in the future from operating results or future financing, it may have a material adverse effect on our operations and the development of our technology, or we may have to cease operations altogether.

The development and commercialization of our cortical strip, grid electrode, depth electrode, ablation system technology and future products and technology is subject to numerous uncertainties, and we could use our cash and cash equivalent resources sooner than we expect. Additionally, the process of developing medical devices is costly, and the timing of progress in pre-clinical tests and clinical trials is uncertain. Our ability to successfully transition to profitability will be dependent upon achieving further regulatory approvals and achieving a level of product sales adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Our other cash requirements within the next twelve months include accounts payable, accrued expenses, purchase commitments and other current liabilities. Our other cash requirements greater than twelve months from various contractual obligations and commitments include operating leases and contracted services.

We expect to satisfy our short term and long term obligations through cash on hand and, until we generate an adequate level of revenue from commercial sales to cover expenses, if ever, from future equity and debt financings.

Cash Flows

The following is a summary of cash flows for each of the periods set forth below.

	For the Nine Months Ended June 30,	
	2026	2025
Net cash used in operating activities	\$ (5,526,335)	\$ (1,311,600)
Net cash used in investing activities	(98,929)	(71,135)
Net cash provided by financing activities	1,102,478	7,962,376
Net (decrease) increase in cash and cash equivalents	<u>\$ (4,522,786)</u>	<u>\$ 6,579,641</u>

Net cash used in operating activities

Net cash used in operating activities was \$5.5 million for the nine months ended June 30, 2026, which consisted of a net loss of \$5.8 million partially offset by non-cash stock-based compensation, depreciation, amortization related to intangible assets, a fair value change in warrant liability and operating lease expense, totaling approximately \$0.7 million in the aggregate. The net change in our net operating assets and liabilities associated with fluctuations in our operating activities resulted in a cash use of approximately \$0.4 million. The change in operating assets and liabilities consisted primarily of a decrease in our accounts payable and accrued expenses attributed to the timing of payments and by an increase in both our prepaid expenses and inventory purchases; a decrease in our accounts receivable given the timing of collections served to partially offset the net cash use impact during the period.

Net cash used in operating activities was \$1.3 million for the nine months ended June 30, 2025, which consisted of a net loss of \$2.0 million partially offset by non-cash stock-based compensation, depreciation, amortization related to intangible assets, a fair value change in warrant liability and operating lease expense, totaling approximately \$0.3 million in the aggregate. Our net loss was further adjusted to account for the reclassification of debt and equity facility termination costs to financing activities in the amount of \$0.1 million. The net change in our net operating assets and liabilities associated with fluctuations in our operating activities resulted in a cash source of approximately \$0.3 million. The net cash source stemming from the change in operating assets and liabilities was primarily attributable to both a decrease in accounts receivable and inventory, partially offset by a net decrease in our aggregate accrued expense and accounts payable as well as by a slight increase in our prepaid expenses associated with the timing of payments.

Net cash used in investing activities

Net cash used in investing activities was \$99,000 for the nine months ended June 30, 2026 and consisted of outlays for purchases of property and equipment.

Net cash used in investing activities was \$71,000 for the nine months ended June 30, 2025 and consisted of outlays for purchases of property and equipment.

Net cash provided by financing activities

Net cash provided by financing activities was \$1.1 million for the nine months ended June 30, 2026, which consisted of net proceeds from the March 2026 private placement in the amount of \$0.7 million, the ATM Program in the amount of \$0.3 million and from the exercise of warrants in the amount of \$0.2 million. The proceeds were offset in part by issuance costs and by repurchases of common stock for the payment of employee taxes in the amount of \$0.1 million in the aggregate.

Net cash provided by financing activities was \$8.0 million for the nine months ended June 30, 2025, which consisted of net proceeds from the April 2025 Financing of \$8.2 million and from the ATM Program in the amount of \$0.3 million, offset by debt facility issuance costs of \$0.3 million, issuance costs paid in connection with a prior year private placement of approximately \$0.1 million and repurchases of common stock for the payment of employee taxes in the amount of \$0.1 million.

Critical Accounting Estimates

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles. These accounting principles require us to make estimates and judgments that can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenue and expense during the periods presented. We believe that the estimates and judgments upon which we rely are reasonably based upon information available to us at the time that we make these estimates and judgments. To the extent that there are material differences between these estimates and actual results, our financial results will be affected. The accounting policies that reflect our more significant estimates and judgments and which we believe are the most critical to aid in fully understanding and evaluating our reported financial results are described in Note 3 — “Summary of Significant Accounting Policies” to our condensed financial statements in “Part 1, Item 1 – Financial Statements” of this Report.

Of these policies, the following are considered critical to an understanding of our condensed financial statements included in “Part 1, Item 1 – Financial Statements” of this Report as they require the application of the most subjective and the most complex judgments:

Revenues:

For discussion about the determination of license revenue and product revenue, see “Note 7 — Zimmer Distribution Agreement and Other Product Revenue” to our condensed financial statements included in “Part 1, Item 1 – Financial Statements” of this Report. To date, we have not had, nor expect to have in the future, significant variable consideration adjustments related to product revenue, such as chargebacks, sales allowances and sales returns.

Fair Value of Warrant liability

We issued warrants in connection with our August 2024 Private Placement. The warrants were classified as a liability on our balance sheet and were recorded at fair value as certain provisions precluded equity accounting treatment for these instruments. We will continue to adjust the liabilities for changes in fair value until the earlier of the exercise, expiration, or until such time that cash settlement or indexation provisions are no longer in effect for the warrants. For discussions about the application of fair value associated with the warrants, see “Note 12 – Stockholders’ Equity” to our condensed financial statements included in “Part 1, Item 1 – Financial Statements” of this Report.

Recent Accounting Pronouncements

Refer to “Note 3— Summary of Significant Accounting Policies” to our condensed financial statements included in “Part 1, Item 1 – Financial Statements” of this Report for a discussion of recently issued accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the direction of the Chief Executive Officer and the Chief Financial Officer, we have evaluated our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of June 30, 2026 due to the material weaknesses in our internal controls over financial reporting as discussed further below that were identified in both the Company’s Annual Report on Form 10-K for the year ended September 30, 2025 and in the Company’s Quarterly Report on the Form 10-Q for the three and six months ended March 31, 2026. Notwithstanding this material weakness, our management has concluded that the condensed financial statements included elsewhere in this Quarterly Report present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles.

The Company identified a material weakness related to insufficient segregation of duties within its accounting and financial reporting functions. Specifically, due to the Company’s limited accounting personnel and organizational structure, certain individuals had the ability to initiate, process, record, and review financial transactions, as well as prepare and post journal entries, without adequate independent review.

This material weakness resulted in an increased risk that errors or misstatements in the Company’s financial statements may not be prevented or detected on a timely basis.

In addition, the restatement of our condensed financial statements for the three and six months ended March 31, 2026 identified a further material weakness related to ineffective controls over revenue recognition, specifically with respect to: (i) the review of customer purchase order modifications and related shipping documentation, and (ii) the reconciliation of shipments.

Remediation Plans

Management has been implementing and continues to implement measures designed to ensure that control deficiencies contributing to the material weaknesses are remediated, such that these controls are designed, implemented, and operating effectively. The remediation actions include:

- Enhancing reconciliation procedures between shipping records, billing, and recorded revenue to confirm completeness and accuracy of revenue recognized;
- Enhancing policies and procedures to retain adequate documented evidence for certain management review controls over certain business processes including precision of review and evidence of review procedures performed to demonstrate effective operation of such controls;
- Segregating key functions within our financial processes supporting our internal controls over financial reporting; and
- Continuing to enhance and formalize our accounting, business operations, procedures, and controls to achieve complete, accurate, and timely financial accounting, reporting and disclosures.

As of the end of the reporting period, these material weaknesses had not been remediated. Accordingly, management concluded that our internal control over financial reporting was not effective.

Changes in Internal Control over Financial Reporting

There has not been any material change in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2026 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Quarterly Report and our Annual Report on Form 10-K for the fiscal year ended September 30, 2025. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

Risks Related to Our Business

We have incurred significant operating losses since inception and cannot assure you that we will ever achieve or sustain profitability.

We have incurred losses since inception, and as of June 30, 2026, we had an accumulated deficit of \$84.4 million primarily as a result of expenses incurred in connection with our operations and from our research and development programs. We expect to continue to incur significant expenses and increasing operating costs resulting in net losses for the foreseeable future, and management has raised substantial doubt about our ability to continue as a going concern. Substantial doubt about the Company's ability to continue as a going concern existed as of and for the fiscal year ended September 30, 2025, and, based on management's assessment, substantial doubt continued to exist as of June 30, 2026. To date, we have financed our operations primarily through debt and equity financings, and our primary activities have been limited to, and our limited resources have been dedicated to, performing business and financial planning, raising capital, recruiting personnel, negotiating with business partners and the licensors of our intellectual property, securing regulatory clearances for our products, managing third party supplier and distributor relationships, and conducting research and development activities.

We have never been profitable and do not expect to be profitable in the foreseeable future. We expect our expenses to continue to increase as we pursue our objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, and we expect to continue incurring significant expenses and operating losses over the next several years. Our prior losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Any additional operating losses may have an adverse effect on our stockholders' equity, and we cannot assure you that we will ever be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our Company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain regulatory approvals or continue our operations.

We have a limited operating history, making it difficult for you to evaluate our business and your investment.

We are an early-stage medical technology company which continues to develop and commercialize comprehensive neuromodulation sEEG monitoring, ablation, and stimulation solutions to diagnose and treat patients with epilepsy, Parkinson's disease, dystonia, essential tremors, facial pain, chronic back pain and other related neurological disorders. Our operations are subject to all of the risks inherent in the establishment of a new business enterprise, including but not limited to the absence of an operating history, limited sales of commercialized products, insufficient capital, expected substantial and continual losses for the foreseeable future, limited experience in dealing with regulatory issues, lack of manufacturing and marketing experience, need to rely on third parties for the development and commercialization of our proposed products, a competitive environment characterized by well-established and well-capitalized competitors and reliance on key personnel.

From our inception through June 30, 2026, we have generated limited revenue from the commercial sales of our products. Because we have generated limited revenues from commercialization, our operations to date have been principally financed through public and private offerings of our Common Stock and convertible debt and exercises of options and warrants.

Investors are subject to all the risks incident to the creation and development of a new business and each investor should be prepared to withstand a complete loss of his, her or its investment. Furthermore, the accompanying financial statements have been prepared assuming that we will continue as a going concern. However, the factors included above raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our Company has limited experience in medical device development and may not be able to successfully develop any device or therapy. Our ability to become profitable depends primarily on: our ability to further develop our technology, our successful completion of all necessary pre-clinical testing and clinical trials on such technology, our ability to obtain clearance or approval for such technology and successfully commercialize such technology, our ongoing research and development efforts, the timing and cost of clinical trials, our ability to identify personnel with the necessary skill sets or enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, regulatory affairs, sales, marketing and distribution and our ability to obtain and maintain necessary intellectual property rights to such technology. Our limited experience in medical device development may make it more difficult for us to complete these tasks.

Even if we successfully develop and market such technology, we may not generate sufficient or sustainable revenue to achieve or sustain profitability, which could cause us to cease operations and cause you to lose all of your investment.

Zimmer has exclusive global rights to distribute our Evo Cortical, Evo sEEG, and OneRF Ablation System in the brain. We are reliant on Zimmer to drive the commercialization and sales of these products. Zimmer's failure to timely commercialize these products, or to achieve certain milestones, would have a material adverse effect on our business and operating results.

The Company granted Zimmer an exclusive global right to distribute our Evo Cortical, Evo sEEG, and OneRF Ablation System in the brain. We are reliant on Zimmer to drive the commercialization and sales of these products until 2034 under the Zimmer Amended and Restated Distribution Agreement for the exclusive distribution, marketing and sales license provided to Zimmer. The collaboration with Zimmer may not be successful due to several factors, including the following:

- Zimmer may not perform its obligations under the Zimmer Amended and Restated Distribution Agreement, including meeting minimum revenue purchase requirements;
- Zimmer has, and may in the future, submitted delayed or modified purchase orders, with insufficient lead time for our supply chain to deliver product on a timely basis;
- Zimmer may fail to achieve certain net sales milestones;

- Zimmer may fail to effectively commercialize our products; or
- contractual disputes or other disagreements between us and Zimmer, including those regarding the development, manufacture, and commercialization of our products, interpretation of the Zimmer Amended and Restated Distribution Agreement, and ownership of proprietary rights.

Any of the foregoing could adversely impact the likelihood and timing of any payments or product revenue we are eligible to receive under the Zimmer Amended and Restated Distribution Agreement. If Zimmer does not perform its obligations under the Zimmer Amended and Restated Distribution Agreement, sales would be substantially delayed and could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

Our business and operating results are subject to the inventory management decisions of our distributor

We are subject to risks relating to the inventory management decisions and operational and sourcing practices of Zimmer, as the distributor of our Evo Cortical, Evo sEEG, and OneRF Ablation System in the brain. Zimmer carries inventories of our products as part of their ongoing operations and currently they are purchasing inventory of our OneRF Ablation System based on contractual minimum purchase requirements in the Zimmer Agreement, which may not reflect their assessments of end-customer demand. This may result in higher than needed inventory levels. We are currently working on shelf-life extension of our OneRF Ablation System, which could also create higher inventory levels at Zimmer. If Zimmer's inventory levels are higher than it desires, Zimmer may postpone product purchases from us, which could cause our sales to be lower than planned and have a materially negative impact on our working capital goals as well as our operating results.

An inability to obtain adequate supply of components and raw material products has had and could continue to have a material adverse effect on our business, financial condition and results of operations.

We have recently experienced delays in the availability of certain components and raw materials, which have not been available to us on a timely basis. These delays have resulted in backorders of certain of our products, which have delayed or prevented us from fulfilling customer orders on a timely basis. We are dependent on third-party manufacturers for the medical products that we develop, and we have limited control over the ability of our suppliers and manufacturers to deliver components and raw materials on schedule. If these supply delays continue, we may continue to experience backorders, delayed sales, and increased costs, any of which could have a material adverse impact on our business, financial condition and results of operations.

Our ability to continue our operations requires that we raise additional capital and our operations could be curtailed if we are unable to obtain the additional funding as or when needed.

Our independent registered public accounting firm included an explanatory paragraph in the report on our financial statements as of and for the years ended September 30, 2025 and 2024, respectively, noting the existence of substantial doubt about our ability to continue as a going concern. The Company has incurred losses since inception, negative cash flows from operations, and an accumulated deficit of \$84.4 million as of June 30, 2026. To date, the Company's revenues have not been sufficient to cover its full operating costs, and as such, it has been dependent on funding operations through the issuance of debt and sale of equity securities. At June 30, 2026, we had cash and cash equivalents in the aggregate of approximately \$2.0 million. Our existing cash, cash equivalents and short-term investments will not be sufficient to fund our operating expenses. To continue to fund operations, we will need to secure additional funding. We may obtain additional financing in the future through the issuance of our Common Stock, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our business, results of operations, financial position and liquidity by increasing our overall cost structure, particularly if we are unable to achieve commensurate increases in the prices we charge our customers. The existence of inflation in the economy has the potential to result in higher interest rates and capital costs, supply shortages, increased costs of labor and other similar effects. As a result of inflation, we may experience increases in the costs of labor, materials, and other inputs, such as engineering consultants. Although we may take measures to mitigate the impact of this inflation, if these measures are not effective our business, results of operations, financial position and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost inflation is incurred.

We will need to raise substantial additional funds in the future, and these funds may not be available on acceptable terms or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, scale back or cease some or all operations.

The continued growth of our business, including the development, regulatory approval and commercialization of our technology, will significantly increase our expenses going forward. As a result, we will be required to seek substantial additional funds in the future. Our future capital requirements will depend on many factors, including:

- the cost of further developing our technology;
- obtaining and maintaining regulatory clearance or approval for our technology;
- the costs associated with commercializing our technology;
- any change in our development priorities;
- the revenue generated by sales of our technology;
- the costs associated with expanding our sales and marketing infrastructure for commercialization of our technology;
- any change in our plans regarding the manner in which we choose to commercialize any approved product in the United States;
- the cost of ongoing compliance with regulatory requirements;
- expenses we incur in connection with potential litigation or governmental investigations;
- expenses and costs we incur in connection with changes in the economy and regulatory process;
- the costs to develop additional intellectual property;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

As a result of these and other factors, we do not know whether and the extent to which we may be required to raise additional capital. We may in the future seek additional capital from public or private offerings of our capital stock, borrowings under credit lines or other sources.

We may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise additional capital could compromise our ability to execute on our business plan, and we may be forced to liquidate our assets. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

If we issue additional equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies or grant licenses on terms that are not favorable to us.

We depend on a limited number of third-party suppliers for the components of our technology, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of materials, could harm our business.

We use a limited number of third-party suppliers of components for our products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. We may not have long term supply agreements with our suppliers and, in many cases, we may make our purchases on a purchase order basis. Our ability to purchase adequate quantities of components or our products may be limited and we may not be able to convince suppliers to make components and products available to us. Additionally, our suppliers may encounter problems that limit their ability to supply components or manufacture products for us, including financial difficulties, damage to their manufacturing equipment or facilities, product discontinuations, or complications due to worldwide economic and social instability. As a result, there is a risk that certain components could be discontinued and no longer available to us. We may be required to make significant “last time” purchases of component inventory that is being discontinued by the supplier to ensure supply continuity. If we fail to obtain sufficient quantities

of high quality components to meet demand for our products in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and regulatory requirements, we may not be able to quickly engage additional or replacement suppliers for some of our critical components. Failure of any supplier to deliver components at the level our business requires could disrupt the manufacturing of our products and, if approved, limit our ability to meet our sales commitments, which could harm our reputation and adversely affect our business.

We may not procure volumes sufficient to receive favorable pricing, which could impact our gross margins if we are unable to pass along price differences to our customers. Recent global economic cost inflation trends could unfavorably impact pricing from our suppliers.

Furthermore, vandalism, terrorism or a natural or other disaster, such as an earthquake, fire or flood, could damage or destroy equipment, our inventory of component supplies or finished products, cause substantial delays in development or our operations, result in the loss of key information, and cause us to incur additional expenses. We maintain liability insurance and property casualty insurance, but it may not be adequate to fully cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our or our suppliers' facilities could harm our business, financial condition and operating results.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other regulatory agencies, and the failure of any supplier to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, and termination of distribution, product seizures or civil penalties. It could also require us to cease using the components, seek alternative components or technologies and modify our products to incorporate alternative components or technologies, which could result in a requirement to seek additional regulatory approvals. Any disruption of this nature or increased expenses could harm our development, approval or commercialization efforts and adversely affect our operating results.

We have four products which have each received 510(k) clearance from the FDA. If we are unable to successfully develop and receive regulatory clearance/approval for our other products under development, or if we experience significant delays in doing so, our business will be harmed.

Four of our products have received 510(k) clearance from the FDA: our Evo® Cortical, Evo® sEEG Electrode, OneRF® Ablation System, and OneRF® TN Ablation System. None of our other products have received clearance or approval for commercial sale. Our ability to generate revenue from our developed products, if any, will depend heavily on their successful development and regulatory approval for commercialization.

For our current products under development clinical studies in humans may be required, which is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Further, the outcomes of completed clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain marketing clearance or approval. We have limited resources to complete the expensive process of medical device development, pre-clinical testing and clinical trials, putting us at a disadvantage, particularly compared to some of our larger and established competitors, and we may not have sufficient resources to commercialize our products under development in a timely fashion, if ever.

We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our products, including:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the failure to successfully complete pre-clinical testing requirements required by the FDA;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts with third parties or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;

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- clinical trials of our technology under development may not meet the primary endpoints of the clinical trial protocol, may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our development programs;
- the number of people with brain or central nervous system related disorders required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or people may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our products may have unanticipated adverse events, undesirable side effects or other unexpected characteristics adjudicated by the trial Data Safety Monitoring Board, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors conducting the clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our products may be greater than we anticipate;
- the supply or quality of our products or other materials necessary to conduct clinical trials of our products may be insufficient or inadequate; and
- delays from our suppliers and manufacturers could impact clinical trial completion and impact revenue.

If we are required to conduct additional clinical trials or other testing of our technology under development beyond those that we contemplate, if we are unable to successfully complete clinical trials, if the results of these trials or tests are not favorable or if there are safety concerns, we may:

- not obtain marketing approval at all;
- be delayed in obtaining marketing approval for our technology under development in a jurisdiction;
- be subject to additional post-marketing testing requirements; or
- have our technology removed from the market after obtaining marketing clearance/approval.

Our development costs will also increase if we experience delays in testing or marketing clearance/approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could allow our competitors to bring innovative products to market before we do and impair our ability to successfully commercialize our products.

Even if we obtain regulatory clearance and/or approval for all of our products, we will remain subject to extensive regulatory scrutiny and compliance obligations.

Both before and after a product is commercially released, we will have ongoing responsibilities under FDA regulations. We will also be subject to periodic inspections by the FDA and comparable foreign authorities to determine compliance with regulatory requirements, such as the QSR, of the FDA, medical device reporting regulations and regulations regarding notification, corrections, and recalls. These inspections can result in observations or reports, warning letters or other similar notices or forms of enforcement action. If the FDA concludes that we are not in compliance with applicable laws or regulations, or that any of our products are ineffective or pose an unreasonable health risk, it could ban these products, suspend or cancel our marketing authorizations, impose “stop-sale” and “stop-import” orders, detain or seize adulterated or misbranded products, order a recall, repair, replacement, correction or refund of such products, or require us to notify health providers and others that the products present unreasonable risks of substantial harm to the public health. Discovery of previously unknown problems with our product’s design or manufacture may result in restrictions on use, restrictions placed on us or our suppliers, or withdrawal of an existing regulatory clearance. The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, assess civil or criminal penalties against our officers, employees or us, or recommend criminal prosecution of our Company. Adverse regulatory action may restrict us from effectively marketing and selling our products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our business, financial condition, and operating results.

In addition, even though we have obtained FDA clearance to market four of our products, and even if we obtain the proper regulatory approval or clearance to market any additional products under development, the FDA has the power to require us to conduct post-market surveillance studies. These studies are designed to identify adverse events, device malfunctions or complaints from patients implanted with the device during a specified period after the commencement of commercial use in the U.S. The FDA may also require us to conduct post-approval studies to further monitor the safety and/or effectiveness of our products under development if approved. Failure to conduct required surveillance or studies in a timely manner could result in the revocation of the approved PMA product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

Potential complications from our technologies that are currently unknown may come to light.

Based on our industry experience and the experience of the physicians that use products similar to our products may result in the following complications:

- *from use of our OneRF® Ablation System:* temporary motor deficit, post-operative pain, skin burns hemorrhage, infection.
- *for OneRF® TN Ablation System:* masseter weakness, paresthesias, diplopia, keratitis, corneal reflex impairment, anesthesia dolorosa, and vasomotor rhinorrhea.
- *from use of our Evo® Cortical, Evo® sEEG Electrode:* post-operative hemorrhage, infection, brain inflammation, brain tissue necrosis, inability to accurately localize the epileptogenic focus (the area of the cerebral cortex responsible for causing epileptic seizures), neurologic deficit (abnormal function of a body area due to weaker function of the brain, spinal cord, muscles or nerves, such as abnormal reflexes, inability to speak and decreased sensation) and extra axial fluid collections (fluid that occurs in the brain after surgery).

If these or unanticipated complications or side-effects result from the use of our products, our product development may be delayed, we may not be able to obtain regulatory clearance or approval for new products, we could be subject to liability and, even for cleared/approved products, our technology would not be widely adopted. We cannot assure you that use, even for a limited time, would not result in unanticipated complications, even after the device is removed.

Undetected errors or defects in our technologies under development or future versions thereof could harm our reputation, decrease the market acceptance of our technology or expose us to product liability claims adversely affecting our financial condition and results of operations or liquidity.

Our cortical strip/grid electrode system, depth electrode system, RF probes and RF generator ablation system technologies may contain undetected errors or defects. As a result, we may be subject to warranty and liability claims for damages related to errors or defects in such products. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our cortical strip/grid electrode and depth electrode technology could harm our business and operating results. This risk exists even if a device is cleared or approved for commercial sale and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products are designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our cortical strip/grid electrode system, depth electrode system, RF probes and RF generator ablation system technology or future versions thereof could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability lawsuits. Our clinical and commercial product liability insurance coverage may not be sufficient to cover claims that may be made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost, or in sufficient amounts or scope, to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management team and other resources, and adversely impact or eliminate the prospects for commercialization of the product candidate, or sale of the product, which is the subject of any such claim.

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The sale and use of our cortical strip/grid electrode system, depth electrode system, RF probes and RF generator ablation system technology or future versions thereof could lead to the filing of product liability claims if someone were to allege that our cortical strip/grid electrode system, depth electrode system, RF probes and RF generator ablation system technology or one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our cortical strip/grid electrode system, depth electrode system, RF probes and/or RF generator ablation system technology;
- decreased demand;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards or settlements to patients or other claimants; or
- loss of revenue.

Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, could cause us to incur substantial costs, delay our product development efforts, place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation, increase our product liability insurance rates, once we obtain such insurance, or prevent us from securing such insurance coverage in the future and adversely affect our ability to attract and retain customers, if approved, any of which could harm our business, financial condition and operating results.

We currently maintain commercial product liability insurance with an aggregate limit of \$5,000,000. We cannot be assured that such insurance would adequately protect our assets from the financial impact of defending a product liability claim because these policies typically have substantial deductibles. Product liability claims in excess of applicable insurance coverage would negatively impact our business, financial condition and operating results. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all.

We may not be successful in commercializing our technology.

We anticipate that we will derive nearly all of our revenue from the sales of our cortical strip, grid electrode and depth electrode technology or future versions thereof.

Moreover, we expect the revenue opportunity for additional uses of our technology to be greater than the technology and uses that have currently been cleared by the FDA, and so we believe our ability to generate significant revenue in the future will be dependent upon the receipt of additional FDA clearances.

Our future revenue will be dependent, in part, upon the size of the markets in which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of people we target is not as significant as we estimate or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

The success of any products that we develop will depend on several factors, including:

- receipt of timely commercialization approvals from applicable regulatory authorities;

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- our ability to procure and maintain suppliers and manufacturers of the components of our current cortical strip, grid electrode and depth electrode technology and future versions;
- market acceptance of our cortical strip, grid electrode and depth electrode technology by people with epilepsy, Parkinson's disease, dystonia, essential tremors, facial pain, chronic back pain and other related neurological disorders, the medical community and third-party payors;
- our success in educating healthcare providers and people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic back pain and other related neurological disorders about the benefits, administration and use of our cortical strip, grid electrode and depth electrode technology and future versions;
- the perceived advantages, cost, safety, convenience and accuracy of alternative therapies;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our cortical strip, grid electrode and depth electrode technology and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including current good manufacturing practices; and
- obtaining and maintaining a continued acceptable performance and safety profile of our cortical strip, grid electrode and depth electrode technology.

The continuing development and commercialization of our products depends upon us maintaining strong relationships with academic and healthcare institutions and professionals.

If we fail to maintain our strong working relationships with healthcare and academic institutions and their professionals, many of our products may not be developed and marketed in line with the needs and expectations of the professionals who use and support our products, which could cause a decline in our earnings and profitability. The development, marketing and sales of many of our products depends on our maintaining working relationships with healthcare institutions and professionals. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. If we are unable to maintain strong relationships with these institutions and professionals, the development and marketing of our products could suffer, which could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

Our success depends on our ability to continue to develop, commercialize and gain market acceptance for our products and technology.

Our current business strategy is highly dependent on developing and commercially launching our products and technology and achieving and maintaining market acceptance. In order for us to sell cortical strip, grid electrode and depth electrode technology to people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic back pain and other related neurological disorders, we must convince them, their caregivers and healthcare providers that our technology offers meaningful advantages over existing solutions for neuromodulation, cEEG and sEEG recording, ablation, and stimulation. Key challenges include overcoming physician preference for established competitive products and demonstrating superior clinical outcomes. Several factors could negatively impact market acceptance, including: failure to gain support from key opinion leaders, insufficient clinical evidence supporting our technology's benefits, perceived risks associated with the technology, introduction of competitive products, adverse clinical trial results, loss of regulatory approvals, or adverse publicity. Healthcare providers typically adopt new technologies slowly due to liability concerns and reimbursement uncertainties. Additionally, hospital purchases of our RF Generator require capital expenditure approvals, typically involving value analysis committees, budget cycles, and multiple administrative and clinical stakeholders. These processes commonly take six to eighteen months or longer and may be delayed or abandoned due to hospital budget constraints, competing capital priorities, staffing shortages, or macroeconomic conditions.

In addition, people with such medical conditions, their caregivers or healthcare providers may perceive our products and technology to be more complicated or less effective than current technology, and people may be unwilling to change their current regimens. Moreover, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement. Accordingly, healthcare providers may not recommend our cortical strip, grid electrode and depth electrode technology until, if ever, there is sufficient evidence to convince them to alter the treatment methods they typically recommend, such as receiving recommendations from prominent healthcare providers or other key opinion leaders in the community.

If we fail to convince patients, caregivers, and healthcare providers of our technology's benefits or cannot achieve widespread market acceptance, our sales potential and strategic objectives would be compromised, adversely affecting our business, financial condition, and operating results.

Failure to secure or retain coverage or adequate reimbursement for our cortical strip, grid electrode and depth electrode technology or future versions thereof, including the implantation procedures, by third-party payors could adversely affect our business, financial condition and operating results.

We plan to derive nearly all of our revenue from sales of our cortical strip, grid electrode and depth electrode technology, in the United States and expect to do so for the next several years. We anticipate a substantial portion of the purchase price of our cortical strip, grid electrode and depth electrode technology will be paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Patients who receive treatment for their medical conditions and their healthcare providers generally rely on third-party payors to reimburse all or part of the costs associated with their medical treatment, including healthcare providers' services. Coverage and adequate reimbursement from third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, and commercial payors, is critical to new product acceptance. Future sales of our cortical strip, grid electrode and depth electrode technology will be limited unless people with epilepsy, Parkinson's disease, dystonia, essential tremors, facial pain, chronic back pain and other related neurological disorders can rely on third-party payors to pay for all or part of the cost to purchase our cortical strip, grid electrode and depth electrode technology. Access to adequate coverage and reimbursement for our cortical strip, grid electrode and depth electrode technology by third-party payors is essential to the acceptance of our products by people with epilepsy, Parkinson's disease, dystonia, essential tremors, facial pain, chronic back pain and other related neurological disorders.

In the United States, a third-party payor's decision to provide coverage for our products does not imply that an adequate reimbursement rate will be obtained. Further, one third-party payor's decision to cover our products does not assure that other payors will also provide coverage for the products or will provide coverage at an adequate reimbursement rate. Healthcare providers may choose not to order a product unless third-party payors pay a substantial portion of the product. Within and outside the United States, reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans. These third-party payors determine whether to provide coverage and reimbursement for specific products and procedures. Coverage determinations and reimbursement levels of both our products and the healthcare provider's performance of the insertion and removal procedures are critical to the commercial success of our product, and if we are not able to secure positive coverage determinations and reimbursement levels for our products or the insertion and removal procedures, our business would be materially adversely affected.

In addition, there may be significant delays in obtaining reimbursement, and coverage may be more limited than the purposes for which the product is cleared by the FDA or other foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States.

Because there is generally no separate reimbursement for medical devices and other supplies used in such procedures, including our cortical strip, grid electrode and depth electrode technology, and because we believe that our cortical strip, grid electrode and depth electrode technology, if approved, would be adequately described by existing DRG and ICD-9 codes for epilepsy surgery, some of our target customers may be unwilling to adopt our cortical strip, grid electrode and depth electrode technology over more established or lower cost therapeutic alternatives already available or subsequently become available. Further, any decline in the amount payors are willing to reimburse our customers for procedures using our cortical strip, grid electrode and depth electrode technology could make it difficult for new customers to adopt our cortical strip, grid electrode and depth electrode technology and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business.

Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained.

If sufficient coverage and reimbursement is not available for any product we develop, in the United States, the demand for our products and our revenues will be adversely affected.

Reimbursement by Medicare is highly regulated and subject to change.

The Medicare program is administered by CMS, which imposes extensive and detailed requirements on medical services providers, including, but not limited to, rules that govern how we structure our relationships with physicians, and how and where we provide our solutions. Our failure to comply with applicable Medicare rules could result in discontinuing the ability for physicians to receive reimbursement as they will likely utilize our cortical strip, grid electrode and depth electrode technology under the Medicare payment program, civil monetary penalties, and/or criminal penalties, any of which could have a material adverse effect on our business and revenues.

Changes in the configuration of our technology under development may result in additional costs or delay.

As new products are developed, it is common that various aspects of the development program, such as manufacturing methods and configuration, are altered along the way in an effort to optimize processes and results. Any changes we make carry the risk that they will not achieve the intended objectives. Any of these changes could cause our products to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered device. Such changes may also require additional testing, regulatory notification or regulatory approval. This could delay completion of pre-clinical testing or clinical trials, increase costs, delay approval of our future products and jeopardize our ability to commence sales and generate revenue.

If our competitors are better able to develop and market products for the diagnosis and treatment of epilepsy, Parkinson's disease, dystonia, essential tremors, facial pain, chronic back pain and other related neurological disorders that are safer, more effective, less costly, easier to use or otherwise more attractive than our cortical strip, grid electrode and depth electrode technology, our business will be adversely impacted.

The medical device industry is highly competitive and subject to technological change. Our success depends, in part, upon our ability to establish a competitive position in the market for the diagnosis and treatment of epilepsy, Parkinson's disease, dystonia, essential tremors, facial pain, chronic back pain and other related neurological disorders by securing broad market acceptance of our cortical strip, grid electrode and depth electrode technology. Any product we develop that achieves regulatory clearance or approval will have to compete for market acceptance and market share. We believe that the primary competitive factors of our cortical strip, grid electrode and depth electrode technology will be: reduced infections, ability to record additional brain activity, minimally invasive surgical procedure, ease of use and cost effectiveness. We face significant competition in the United States and internationally, which we believe will intensify. For example, our major competitors are: (i) in the market for diagnosis, Ad-Tech Medical Instrument Corporation, PMT Corporation and Dixi Medical, (ii) in the market for neuro-ablation, Medtronic and Monteris Medical and (iii) in the market for trigeminal neuralgia, Boston Scientific and Avanos RF ablation systems. Each of the foregoing competitors has systems approved in the United States and certain foreign jurisdictions and has been established for several years. We face a particular challenge overcoming the long-standing practices by some physicians of using the existing technology of our larger, more established competitors. Physicians may be reluctant to try new products from a source with which they are less familiar. If these physicians do not try to subsequently adopt our product, then we may never achieve profitability and such failure to adopt our product could have a material adverse effect on our business, financial condition and operating results.

In addition to facing competition from major competitors and potentially our development partner, we may also face competition from other emerging competitors or smaller companies with active development programs that may emerge in the future.

Many of the companies developing or marketing competing products enjoy several advantages over us, including:

- more experienced sales forces;
- greater name recognition;
- more established sales and marketing programs and distribution networks;
- earlier regulatory clearance or approval in the United States or foreign jurisdictions;

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- long established relationships with physicians and hospitals;
- significant patent portfolios, including issued U.S. and foreign patents and pending patent applications, as well as the resources to enforce patents against us or any of our third-party suppliers and distributors;
- the ability to acquire and integrate our competitors and/or their technology;
- demonstrated ability to develop product enhancements and new product offerings;
- established history of product reliability, safety and durability;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives;
- greater financial and human resources for product development, sales, and marketing; and
- greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing approved products.

Our competitors may develop and patent processes or products earlier than us, obtain patents that may apply to us at any time, obtain regulatory clearance or approvals for competing products more rapidly than us or develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. Furthermore, the frequent introduction by competitors of products that are, or claim to be, superior to our products may create market confusion that may make it difficult to differentiate the benefits of our products over competitive products. In addition, the entry of multiple new products may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of any product we may develop and commercialize. We also face fierce competition in recruiting and retaining qualified sales, scientific, and management personnel, establishing clinical trial sites and enrolling patients in clinical studies. If our competitors are more successful than us in these matters, our business may be harmed.

The size and future growth in the market for our cortical strip, grid electrode and depth electrode technology and for other future products and technology under development have not been established with precision and may be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of these markets, our sales growth may be adversely affected.

The size and future growth potential of the market for our cortical strip, grid electrode and depth electrode technology and other future products and technology under development may be materially smaller than our estimates. Our market projections are based on internal and third-party studies, current treatment patterns, and our belief that the incidence of targeted neurological disorders (including epilepsy, Parkinson's disease, dystonia, essential tremors, and chronic back pain) is increasing in the United States and worldwide.

While we believe these factors provide reliable tools for market estimation, the underlying assumptions and conditions may change, affecting their predictive accuracy. If our assumptions about disease incidence rates or potential market demand prove incorrect, the actual market size and growth potential could be materially different from our projections. Any overestimation of the market opportunity could adversely impact our projected sales growth and overall business performance.

We depend on our partnership with Mayo to license certain know how for the development and commercialization of our technology. Termination of this partnership would harm our business, and even if this partnership continues, it may not be successful.

We have entered into the Mayo Development Agreement to (i) exclusively license worldwide certain Mayo improvements for the development and commercialization of products, methods and processes related to flexible circuit technology for the recording and stimulation of tissue and (ii) license, on a non-exclusive basis, worldwide Mayo thin film electrode technology know-how for the development and commercialization of products, methods and processes related to flexible circuit technology for the recording and stimulation of tissue. Mayo has agreed to assist the Company by providing access to the Mayo Principal Investigators in developing a minimally invasive device/delivery system and procedure for a minimally invasive approach for the implantation of any flexible circuit technology developed by the Company, including prototype development, animal testing, protocol development for human and animal use, abstract development and presentation and access to and license of any intellectual property that the Mayo Principal Investigators develop relating to the procedure. See "Business-Mayo Foundation for Medical Education and Research License and Development Agreement" for additional information regarding our agreement with Mayo.

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The Mayo Development Agreement generally will expire in October 2034, unless the Mayo know-how and improvements under the Mayo Development Agreement remain in use, and the Mayo Development Agreement may be terminated by Mayo for cause or under certain circumstances. Mayo and the Company may not be successful in their efforts to develop any product, method, process, device, delivery system or minimally invasive approach by such expiration date or termination, if at all. If no such minimally invasive device or delivery system and procedure for minimally invasive approach is developed, the Company may never receive regulatory approval of its cortical strip, grid electrode and depth electrode technology under development or the market may never accept such technology, if approved.

Disputes may arise between us and Mayo regarding intellectual property subject to the Mayo Development Agreement or other matters, including with respect to: the scope of rights granted under the agreement and other interpretation-related issues; the amount and timing of payments; the rights and obligations of Mayo under the license agreement; and the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by Mayo and us.

Any disputes with Mayo may prevent or impair our ability to maintain our current arrangement. We depend on the intellectual property licensed from and development assistance from Mayo to develop our cortical strip, grid electrode and depth electrode technology. We cannot assure you that we will be able to continue to comply with the Mayo Development Agreement. In fact, the original license and development agreement entered into with Mayo in 2014 required that, upon the Merger with the LLC, we make certain payments and issue shares of Common Stock to Mayo, which we failed to do at such time.

We contract with third parties for the manufacture of our cortical strip, grid electrode and depth electrode technology and for our future products and technology under development, and expect to continue to do so for clinical trials and commercialization. Risks associated with the manufacturing of our products could reduce our gross margins and negatively affect our operating results.

We currently rely, and expect to continue to rely, on third parties for the manufacture of our cortical strip, grid electrode and depth electrode technology. Therefore, our business strategy depends on our third-party manufacturers' ability to manufacture our cortical strip, grid electrode and depth electrode technology and future generations thereof in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. To date, we have only manufactured small quantities of our cortical electrodes. As a result, we currently have limited data and experience regarding the quality, reliability and timeliness of our third-party manufacturers.

We are subject to numerous risks relating to the manufacturing capabilities of our third-party manufacturers, including:

- quality or reliability defects;
- inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- failure to increase production to meet demand;
- inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;
- difficulty identifying and qualifying alternative manufacturers in a timely manner;
- inability to manufacture product components cost-effectively;
- inability to establish agreements with future third-party manufacturers or to do so on acceptable terms;
- potential damage to or destruction of our manufacturers' equipment or facilities;
- failure to complete sterilization on time or in compliance with the required regulatory standards;
- transportation and import and export risk;
- delays in analytical results or failure of analytical techniques that we will depend on for quality control and release of products;
- natural disasters, labor disputes, financial distress, raw material availability, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturers or suppliers; or
- latent defects that may become apparent after products have been released and that may result in a recall of such products.

These risks are likely to be exacerbated by our limited experience with our cortical strip, grid electrode and depth electrode technology and its manufacturing process. As demand for our products increases, our third-party suppliers will need to invest additional resources to purchase components, hire and train employees, and enhance their manufacturing processes. If our manufacturers fail to increase production capacity efficiently, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, manufacturing any future versions of our cortical strip, grid electrode and depth electrode technology may require the modification of production lines, the identification of new manufacturers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make any future versions of our cortical strip, grid electrode and depth electrode technology commercially viable.

We depend on sophisticated information technology systems, and any breach or disruption affecting these systems could adversely affect our business, financial condition and operating results.

The efficient operation of our business depends on our information technology systems, which we use to manage product development tasks, research and development data and accounting and financial functions. In the future, we may rely on our information technology systems for inventory management and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods, other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures.

In addition, our data management application and a variety of our software systems are hosted by third-party service providers whose security and information technology systems are subject to similar risks. If our, or our third-party service provider's, security systems are breached or fail, unauthorized persons may be able to obtain access to sensitive data.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability. The failure of our or our service providers' information technology systems or our transmitter's software to perform as we anticipate or our failure to effectively implement new information technology systems could disrupt our entire operation, adversely affect our products, or result in delays in our product development, clinical trial or commercialization efforts, increased overhead costs and damage our reputation. Any of these results could negatively affect our business, financial condition and operating results.

We have entered into, and may enter into additional collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop products and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

We have been the victim of a cyber-related crime and our controls may not be successful in avoiding further cyber-related crimes in the future.

In January 2023, we were the victim of a business email compromise fraud which resulted in our incurring a loss of approximately \$0.1 million. We have worked with law enforcement authorities and the banks involved in the wire transfer to pursue recovery of the \$0.1 million, but at this time we do not expect that we will be able to recover such funds. Enhancements have been made to our controls relating to electronic payments by or for us that we believe will reduce our risk of becoming a victim of future frauds related to our payments, including by wire transfers. However, cyber-related criminal activities continue to evolve and increase in sophistication, frequency and severity. As a result, the control enhancements that have been made, and any additional enhancements that may be made in the future, to our controls may not be successful in avoiding our becoming a victim to further cyber-related crimes.

Risks Related to our Intellectual Property

Our ability to protect our intellectual property and proprietary technology is uncertain.

The medical device market in which we operate is largely technology driven. We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our intellectual property and proprietary technologies. We continue to review new technological developments in order to make decisions about what additional filings would be the most appropriate for us. We also plan to seek patent protection for our proprietary technology in select countries internationally. If we fail to timely file a patent application in any jurisdiction, we may be precluded from doing so at a later date. Furthermore, we cannot assure you that any patent application will be approved in a timely manner or at all. The rights granted to us under our patents, and the rights we are seeking to have granted in our pending patent applications, may not be meaningful or provide us with any commercial advantage. In addition, those rights could be opposed, contested or circumvented by our competitors, or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Even if we are successful in receiving patent protection for certain products and processes, our competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available.

We rely on our trademarks and trade names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. For example, we have a registered U.S. trademark for the “EVO” trademark. We cannot assure you that any future trademark applications will be approved in a timely manner or at all. Third parties also may oppose our trademark applications, or otherwise challenge our use of the trademarks. 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 additional resources to marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We also rely on trade secrets, know-how and technology, which are not protectable by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in the related or resulting know-how and inventions. If any of our trade secrets, know-how or other technologies not protected by a patent were to be disclosed to or independently developed by a competitor, our business, financial condition and results of operations could be materially adversely affected.

If a competitor infringes upon one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult and time-consuming. Patent law relating to the scope of claims in the industry in which we operate is subject to rapid change and constant evolution and, consequently, patent positions in our industry can be uncertain. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may harm our business, financial condition and operating results.

There is limited market awareness of our technology, and we may not be able to establish or strengthen our brand.

There is currently limited market awareness of our technology. We believe that establishing and strengthening our brand is critical to achieving widespread acceptance of our cortical strip, grid electrode and depth electrode technology. Promoting and positioning our brand, and increasing market awareness of our technology, will depend largely on the success of our marketing efforts and our ability to provide physicians with a reliable product for successful treatment of brain-related disorders. Additionally, we believe the quality and reliability of our product is critical to building physician support in the United States. We initially received early feedback requesting improvements around the reliability of our Evo SEEG, and while we believe we have largely addressed these requests, any negative publicity regarding the quality or reliability of our cortical strip, grid electrode and depth electrode technology could significantly damage our reputation in the market. Further, given the established nature of our competitors, it is likely that our future marketing efforts will require us to incur significant additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our cortical strip, grid electrode and depth electrode technology may not be accepted by physicians, which would adversely affect our business, results of operations and financial condition.

We could become subject to patent litigation that could be costly, result in the diversion of management's time and efforts, stop our development and commercialization measures or require us to pay damages.

Our success will depend in part on not infringing the patents or violating the other proprietary rights of third-parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

In the future, we could receive communications from various industry participants alleging our infringement of their intellectual property rights. Any potential intellectual property litigation could force us to do one or more of the following:

- stop selling our products or using technology that contains the allegedly infringing intellectual property;
- incur significant legal expenses;

- pay substantial damages to the party whose intellectual property rights we are allegedly infringing;
- redesign those products that contain the allegedly infringing intellectual property; or
- attempt to obtain a license to the relevant intellectual property from third-parties, which may not be available on reasonable terms or at all, and if available, may be non-exclusive, thereby giving our competitors access to the same technology.

Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the neurostimulation market increases, the possibility of intellectual property infringement claims against us increases.

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Some of our current or future employees may have previously been employed at other medical device companies, including those that are our direct competitors or could potentially be our direct competitors. We may be subject to claims that we, or our employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we may in the future be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims.

There can be no assurance that this type of litigation will not occur, and any future litigation or the threat thereof may adversely affect our ability to hire additional employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our cortical strip, grid electrode and depth electrode technology or future versions thereof, which could have an adverse effect on our business, financial condition and operating results.

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 devices that are the same as or similar to our various electrode technologies but that are not covered by the claims of the patents that we own;
- we or any collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we 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;
- we might enforce our patent rights or defend a challenge to our issued patents or pending application, putting the patents and patent applications at risk of being invalidated or interpreted narrowly;
- 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; and
- we may not develop additional proprietary technologies that are patentable.

Risks Related to our Legal and Regulatory Environment

Our products and operations are subject to extensive governmental regulation, and any adverse regulatory action may materially adversely affect our financial condition and business operations.

Our medical devices and technologies and business activities, including marketing, clinical, manufacturing, sales and development processes, are subject to regulation by the FDA, U.S. Department of Justice (“DOJ”), Health and Human Services - Office of Inspector General, and other federal and state, governmental authorities. These governmental authorities enforce laws and regulations that are meant to assure product safety and effectiveness, including the regulation of, among other things:

- product design and development;
- pre-clinical studies, post-market studies (e.g., registries) and clinical trials;
- product safety;
- establishment registration and product listing;
- maintaining Gudid database;
- labeling, content and language of instructions for use and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance or approval;
- servicing and post-market surveillance;
- record-keeping procedures;
- product import and export;
- advertising and promotion; and
- recalls and field safety corrective actions.

The regulations to which we are subject are complex 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 revenues.

Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the regulatory agency or other regulators to grant future clearances or approvals, and the suspension or withdrawal of existing approvals by such regulatory agencies. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and operating results.

A recall of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us.

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Our third-party suppliers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to produce our products in a cost-effective and timely manner.

Further, under the FDA’s medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

We are subject to additional federal, state and foreign laws and regulations relating to our healthcare business; our failure to comply with those laws could have an adverse impact on our business.

Although we do not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from government health insurance programs or other third-party payors for our Evo® Cortical, Evo® sEEG Electrode, OneRF® Ablation System, and OneRF® TN Ablation System, we are subject to healthcare fraud and abuse regulation and enforcement by federal, state and foreign governments, which could adversely impact our business. Healthcare fraud and abuse and health information privacy and security laws potentially applicable to our operations include, but are not limited to:

- the Anti-Kickback Statute, which may apply to our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare or Medicaid programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;
- HIPAA is a U.S. federal law that protects the privacy and security of patient health information while standardizing healthcare data practices. It is enforced by the Office for Civil Rights through investigations, audits, and penalties for noncompliance;
- federal “sunshine” requirements imposed by the ACA on device manufacturers regarding any “transfer of value” made or distributed to physicians and teaching hospitals. Failure to submit required information may result in civil monetary penalties, for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. Manufacturers must submit reports by the 90th day of each subsequent calendar year;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; 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 or otherwise restrict payments that may be made to healthcare providers; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Navigating these laws and regulations can be complex due to their evolving scope, varying and changing interpretations by regulatory authorities and courts, and differences across jurisdictions. We are unable to predict what additional federal, state or foreign legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal, state or foreign governments may (i) impose additional restrictions or adopt interpretations of existing laws that could have a material adverse effect on us or (ii) challenge our current or future activities under these laws. Any of these challenges could impact our reputation, business, financial condition and operating results.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement of profits, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

For example, we inadvertently failed to timely submit certain required information to CMS under these regulations. Though we have subsequently submitted such information, we cannot fully predict whether the untimely submissions will result in adverse consequences or regulatory scrutiny. Any federal, state or foreign regulatory review to which we may become subject, regardless of the outcome, could be costly and time-consuming.

To enforce compliance with the federal laws, the DOJ, has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time and resource consuming and can divert management's attention from our core business. Additionally, if we settle an investigation with law enforcement or other regulatory agencies, we may be forced to agree to additional onerous 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.

We may be liable if the FDA or another regulatory agency concludes that we have engaged in the off-label promotion of our products or have disseminated false or misleading labeling or promotional materials.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off-label use of our products. Healthcare providers may use our products, if approved, off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine.

If the FDA determines that future promotional materials or training promote an off-label use or make false or misleading claims about our commercial device(s), if any, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they determine that our promotional or training materials promote an unapproved use or make false or misleading claims, which could result in significant fines or penalties.

Although we intend to train our marketing and direct sales force to not promote our products for uses outside of their cleared uses and our policy will be to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

Legislative or regulatory healthcare reforms may have a material adverse effect on our business, financial condition, results or operations and cash flows.

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

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 regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our products would harm our business, financial condition and operating results.

While one often stated goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. For example, the ACA and Health Care and Education Affordability Reconciliation Act of 2010 were enacted into law in the U.S. in March 2010. Certain provisions of this law, including comparative effectiveness research, pilot programs to evaluate alternative payment methodologies and other changes to the payment systems, have started changing the way healthcare is delivered, reimbursed and funded. While the extent to which it has affected our business is not clear, these changes, over the long term, may adversely affect our business and results of operations. The current U.S. administration may attempt to reverse some of the previous administration's changes to the ACA, particularly related to healthcare coverage for the uninsured, and is further expected to introduce more ambitious healthcare legislation, which could include what is commonly referred to as a "public option" or changes to Medicare age requirements. If passed, this legislation would lead to increased coverage levels and utilization of services; however, at this point, the impact of any such changes is unclear because specific changes have not been enacted or implemented.

We cannot predict whether any additional healthcare reform proposals will be adopted or how such proposals may impact our business and operations. However, any changes that lower reimbursements for either our products or procedures using our products, reduce medical procedure volumes, increase cost containment pressures on us or others in the healthcare sector, or impose additional or heightened regulatory requirements could adversely affect our business and results of operations.

Risks Related to our Common Stock

Our management has identified certain internal control deficiencies, which management believes constitute material weaknesses. Our failure to establish and maintain an effective system of internal controls has caused, and could continue to cause material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our common stock.

We review and update our internal controls, disclosure controls and procedures, and corporate governance policies as our Company continues to evolve. In addition, we are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("SOX") and management is required to report annually on our internal control over financial reporting. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of SOX until the date we are no longer a "smaller reporting company" as defined by applicable SEC rules.

Our management's evaluation of the effectiveness of our internal controls over financial reporting as of September 30, 2025 concluded that our controls were not effective, due to a material weakness resulting from an ineffective overall control environment. The material weakness stems primarily from our small size and includes the inability to maintain appropriate segregation of duties. In addition, the restatement of our unaudited condensed financial statements for the three months ended March 31, 2026 identified a further material weakness related to ineffective controls over revenue recognition, specifically with respect to the review of customer purchase order modifications and related shipping documentation.

Such shortcomings could have an adverse effect on our business and financial results. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulations concerning controls and procedures could have a material effect on our business, results of operations and financial condition. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively affect the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The effect of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board and as executive officers.

Subject to limitations on liquidity, the Company is planning to take steps to remediate these material weaknesses. However, we cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies.

The price of our Common Stock might fluctuate.

Volatility in the market price of our Common Stock may prevent you from being able to sell your shares of our Common Stock at or above the price you paid for your shares. The trading price of our Common Stock may be volatile and subject to wide price fluctuations in response to various factors, including:

- actual or anticipated fluctuations in our quarterly financial and operating results;
- our progress toward developing our cortical strip and sheet electrode technology;
- the commencement, enrollment and results of our future clinical trials;
- adverse results from, delays in or termination of our clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts, if any;
- perceptions about the market acceptance of our products and the recognition of our brand;
- adverse publicity about our products or industry in general;
- overall performance of the equity markets;
- introduction of products, or announcements of significant contracts, licenses or acquisitions, by us or our competitors;
- legislative, political or regulatory developments;
- additions or departures of key personnel;
- threatened or actual litigation and government investigations;
- third-party promotional activities, which are subject to ongoing regulatory obligations;
- sale of shares of our Common Stock by us or members of our management; and
- general economic conditions.

These and other factors might cause the market price of our Common Stock to fluctuate substantially, which may negatively affect the liquidity of our Common Stock. In addition, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. The changes frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our Common Stock could fluctuate based upon factors that have little or nothing to do with our Company, and these fluctuations could materially reduce our share price.

Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in substantial costs, divert our management's attention and resources, and harm our business, operating results and financial condition.

If we fail to comply with the continued listing standards of the Nasdaq Capital Market, our Common Stock could be delisted. If it is delisted, our Common Stock and the liquidity of our Common Stock would be impacted.

The continued listing of our Common Stock on Nasdaq is contingent on our continued compliance with a number of listing standards. There is no assurance that we will remain in compliance with these standards. Delisting from Nasdaq would adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our securities and negatively affect the value and liquidity of our Common Stock. Delisting also could limit our strategic alternatives and attractiveness to potential counterparties and have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities. Moreover, we have committed in connection with the sale of securities to use commercially reasonable efforts to maintain the listing of its Common Stock during such time that certain warrants are outstanding.

On July 22, 2026, the SEC approved a new Nasdaq continued listing requirement (the “MVLS Rule”) that required each Nasdaq listed issuer to maintain a minimum market value of listed securities of at least \$5 million. Under the MVLS Rule, if the value of an issuer’s listed securities, as measured by each applicable trading day’s closing price, continues to be less than \$5 million for a period of 30 consecutive trading days, the issuer’s securities would immediately be delisted, with no compliance or cure period. The MVLS Rule would also preclude an issuer’s ability to seek stay of delisting during any appeals process, and would preclude Nasdaq hearings panels from reversing the delisting determination to situations where there was an error and the company never actually failed to satisfy the requirement. The panel would also not be able to consider any facts indicating that an issuer subsequently regained compliance with the requirement or grant an issuer any additional time to regain compliance.

On July 29, 2026, the SEC notified Nasdaq that the order granting approval of the MVLS Rule had been stayed pending further review. It is unknown whether the SEC will affirm its order to approve the MVLS Rule following such review. If approved by the SEC, the MVLS Rule could become effective on an immediate basis. Our Common Stock currently trades above the \$5 million aggregate market value threshold proposed by Nasdaq, but if it declines below \$5 million, and if the MVLS Rule is approved by the SEC, our Common Stock could be imminently delisted by Nasdaq on this basis.

If the MVLS Rule is approved, we may be required to monitor our market value of listed securities closely and, if necessary, take actions such as issuing additional securities, raising additional capital or undertaking other corporate actions to seek to maintain compliance, any of which could dilute our existing shareholders, increase our costs, or divert management’s attention. The risk of a rapid loss of Nasdaq listing, or an actual delisting, could adversely affect investor confidence, the liquidity and trading price of our Common Stock, and our ability to access the capital markets, and could have a material adverse effect on our business, financial condition and results of operations.

We identified a material weakness in our internal control over financial reporting, which resulted in the restatement of our previously issued unaudited interim financial statements. Failure to remediate this material weakness, or to otherwise maintain an effective system of internal control over our financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002, has resulted, and could in the future result, in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud, in which case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our stock.

We are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (“SOX”) and management is required to report annually on our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Although we prepare our financial statements in accordance with accounting principles generally accepted in the United States, our internal accounting controls may not meet all standards applicable to companies with publicly traded securities.

As previously disclosed, in connection with the preparation of our financial statements, management identified a material weakness in our internal control over financial reporting related to ineffective controls over revenue recognition, specifically with respect to: (i) the review of customer purchase order modifications and related shipping documentation, and (ii) the reconciliation of shipments. As a result of this material weakness, we restated our unaudited condensed financial statements as of and for the three and six months ended March 31, 2026. As of the date of this Form 10-Q, this material weakness, and the material weakness related to insufficient segregation of duties within our accounting and financial reporting functions, remain unremediated. As a result, our management has concluded that our disclosure controls and procedures and our internal control over financial reporting were not effective as of June 30, 2026.

If we fail to remediate the material weaknesses, or if we fail to otherwise maintain effective internal controls and procedures for financial reporting, it could result in additional material misstatements in the annual or interim financial statements that would not be prevented or detected in a timely manner. In that case, we could become subject to litigation, regulatory sanction or investigation, and could incur substantial additional costs. Further, these outcomes could damage investor confidence in the accuracy and reliability of our financial statements. We cannot assure you that material weaknesses or significant deficiencies will not occur in the future and that we will be able to remediate such weaknesses or deficiencies in a timely manner, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

We intend to issue more shares to raise capital, which will result in substantial dilution.

Our certificate of incorporation authorizes the issuance of a maximum of 100,000,000 shares of Common Stock and 10,000,000 shares of preferred stock. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources. Any additional financings effected by us may result in the issuance of additional securities without stockholder approval and the substantial dilution in the percentage of Common Stock held by our then existing stockholders. Moreover, the Common Stock issued in any such transaction may be valued on an arbitrary or non-arm's-length basis by our management, resulting in an additional reduction in the percentage of Common Stock held by our current stockholders. Our Board has the power to issue any or all of such authorized but unissued shares without stockholder approval. To the extent that additional shares of Common Stock are issued, dilution to the interests of our stockholders will occur and the rights of the holder of Common Stock might be materially and adversely affected.

As of June 30, 2026, we had outstanding warrants to purchase an aggregate of 361,111 shares of Common Stock, and options to purchase an aggregate of 1,127,065 shares of Common Stock. For a description of our outstanding warrants and information about the number of shares of Common Stock for which they are exercisable, see "Management's Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources-Capital Resources." To the extent these outstanding options or warrants are exercised, there will be further dilution to holders of our Common Stock.

Anti-takeover provisions in the Company's certificate of incorporation and bylaws may prevent or frustrate attempts by stockholders to change the Board or current management and could make a third-party acquisition of the Company difficult.

The Company's certificate of incorporation and bylaws contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. For example, our certificate of incorporation permits the Board without stockholder approval to issue up to 10,000,000 shares of preferred stock and to fix the designation, power, preferences, and rights of those shares. Furthermore, our Board has the ability to increase the size of the Board and fill the newly created vacancies without stockholder approval. These provisions could limit the price that investors might be willing to pay in the future for shares of the Common Stock.

Our warrant liabilities may cause significant fluctuations in our reported earnings.

The fair value of our outstanding warrant liabilities is remeasured at each reporting date, with changes in fair value recognized in earnings. Increases or decreases in our stock price, expected volatility, interest rates, or other valuation inputs may result in material non-cash gains or losses that could significantly affect our reported results of operations and cause volatility in our earnings from period to period, even though such adjustments do not affect our cash flows or business operations.

We are a smaller reporting company, and the reduced reporting requirements applicable to smaller reporting companies may make our Common Stock less attractive to investors.

We are a "smaller reporting company" as defined in Section 12 of the Exchange Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies such as, reduced disclosure obligations regarding executive compensation in our annual and periodic reports and proxy statements and stockholder approval of any golden parachute payments not previously approved. We will remain a "smaller reporting company" as long as (i) our public float remains less than \$250 million or (ii) our annual revenues are less than \$100 million and we either have no public float, or our public float is less than \$700 million. Public float is measured as of the last business day of our most recently-completed second fiscal quarter, and annual revenues are as of the most recently completed fiscal year for which audited financial statements are available. 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.

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We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Accordingly, you may have to sell some or all of your shares of our Common Stock in order to generate cash flow from your investment. You may not receive a gain on your investment when you sell shares and you may lose the entire amount of the investment.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports, about 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 and our business. Securities or industry analysts may elect not to provide coverage of our Common Stock, and such lack of coverage may adversely affect the market price of our Common Stock. In the event we do not secure additional securities or industry analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more securities or industry analysts downgrade our stock or issue other unfavorable commentary or research. If one or more securities or industry analysts ceases coverage of our Company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Our Common Stock has been, and may in the future be subject to the “penny stock” rules of the SEC, which makes transactions in our stock cumbersome and may reduce the value of an investment in our stock.

The SEC has adopted regulations which generally define a “penny stock” as an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. The SEC’s penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer’s account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s agreement to the transaction. If our Common Stock is subject to the “penny stock” rules, these rules may restrict the ability of brokers-dealers to sell our Common Stock and may affect the ability of investors to sell their shares, until our Common Stock no longer is considered a penny stock.

General Risk Factors

Adverse global economic conditions could have a negative effect on our business, results of operations and financial condition and liquidity.

A general slowdown in the global economy, including a recession, or in a particular region or industry, an increase in trade tensions with U.S. trading partners, inflation or a tightening of the credit markets could negatively impact our business, financial condition and liquidity. Adverse global economic conditions have from time to time caused or exacerbated significant slowdowns in the industries and markets in which we operate, which have adversely affected our business and results of operations. Macroeconomic weakness and uncertainty also make it more difficult for us to accurately forecast revenue, gross margin and expenses, and may make it more difficult to raise or refinance debt.

Worldwide economic and social instability could adversely affect our revenue, financial condition, or results of operations.

Generally, worldwide economic conditions remain uncertain, particularly due to the effects of the war, terrorism, military conflicts on global markets, the conflict and instability such as between Russia and Ukraine and potentially Eastern Europe, Israel, Lebanon, Iran, the Gaza Strip and the Middle East and Asia, disruptions in the banking system and financial markets, new and ongoing challenges relating to current supply chain constraints, the impact of natural disasters or global pandemics, increased inflation and rising interest rates. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected the Company’s access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, the Company’s future cost of equity or debt capital and access to the capital markets could be adversely affected. Our vendors and development partners may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all. In addition, adverse economic conditions, such as recent supply chain disruptions and labor shortages and persistent inflation, have affected, and may continue to adversely affect our suppliers’ ability to provide our manufacturers with materials and components, which may negatively impact our business. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities.

Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our business, results of operations, financial condition and cash flows.

We are subject to income and other non-income-based taxes and tariffs in the U.S., and our operations, plans and results are affected by tax and other initiatives. The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, the U.S. Treasury Department, and state/local taxing authorities. The tax laws in the U.S. could change on a prospective or retroactive basis, and any such changes could materially adversely affect our business, our results of operations, our effective tax rate, and holders of our Common Stock. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders', tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, results of operations, tax provision, cash tax liability, and effective tax rate. For example, in August 2022, the Inflation Reduction Act of 2022 ("IRA") was enacted into law. The IRA includes a 15% corporate alternative minimum tax and a 1% excise tax on share repurchases.

We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our Common Stock.

We are also subject to regular reviews, examinations, and audits by the Internal Revenue Service and other taxing authorities with respect to our taxes. Although we believe our tax estimates are reasonable, if a taxing authority disagrees with the positions we have taken, we could face additional tax liability, including interest and penalties. There can be no assurance that payment of such additional amounts upon final adjudication of any disputes will not have a material impact on our results of operations and financial position.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to complete acquisitions, or the failure to integrate them with our existing business, could harm our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. The success of our strategy relating to future acquisitions, investments or alliances will depend on a number of factors, including our ability to:

- identify suitable opportunities for acquisition, investment or alliance, if at all;
- manage acquisition, investment or alliance opportunities within our capital capacity and prioritize those investments to execute on our strategy;
- manage our due diligence process to uncover potential issues and liabilities with targets;
- finance any future acquisition, investment or alliance on terms acceptable to us, if at all;
- complete acquisitions, investments or alliances in a timely manner on terms that are satisfactory to us, if at all;
- successfully integrate and operate acquired businesses;
- successfully identify and retain key target employees;
- comply with applicable laws and regulations;
- protect intellectual property and to prevail in litigation related to newly acquired technologies;
- assimilate the acquired products or technologies;

- maintain uniform standards, procedures, controls and policies;
- anticipate costs associated with acquisitions;
- avoid the diversion of management's attention from our existing business;
- manage risks associated with entering new markets in which we have limited or no experience; and
- manage legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our officers and advisory board members. Although we have an employment agreement with our Chief Executive Officer, David Rosa, he (and each of our other key employees) may terminate his employment with us at any time and will continue to be able to do so. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous medical device companies for similar personnel, many of which have greater financial and other resources dedicated to attracting and retaining personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our business may be adversely affected by changes in our executive leadership, including the recent appointment of our Chief Financial Officer.

The success of our business depends in part on the continued contributions of our senior management team. We recently appointed a new Chief Financial Officer, and while we believe this individual is well qualified, leadership transitions can create uncertainties, disrupt operational processes, and require significant management attention. The new Chief Financial Officer may require time to become fully integrated into our business, financial reporting systems, internal controls, and strategic planning processes.

During the transition period, we may experience challenges related to maintaining effective financial oversight, executing strategic initiatives, complying with regulatory requirements, and retaining key finance personnel. If the transition is not successfully managed, or if we are unable to effectively integrate the new Chief Financial Officer into our operations, our financial performance, internal control environment, investor confidence, and stock price could be adversely affected.

In addition, the loss of institutional knowledge associated with the departure of the former Chief Financial Officer could negatively impact our operations, financial reporting processes, and relationships with investors, lenders, customers, and other stakeholders.

Prolonged negative economic conditions could adversely affect us, our customers and third-party partners, manufacturers or suppliers, if any, which could harm our financial condition.

We are subject to the risks arising from adverse changes in general economic and market conditions. Uncertainty about future economic conditions could negatively impact our existing and potential customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, and cause delays or other problems with key suppliers.

Healthcare spending in the United States has been, and is expected to continue to be, under significant pressure and there are many initiatives to reduce healthcare costs. As a result, we believe that some insurers are scrutinizing insurance claims more rigorously and delaying or denying coverage and reimbursement more often. Because the sale, if approved, of our cortical strip, grid electrode and depth electrode technology under development will generally depend on the availability of third-party coverage and reimbursement, any delay or decline in coverage and reimbursement will adversely affect our sales.

We have incurred, and may continue to incur increased costs and demands upon management as a result of being a public company.

As a public company in the United States, we incur significant legal, accounting and other costs. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the stock exchange on which we may list our Common Stock, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board, on committees of our Board or as members of senior management.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable to our Company.

Item 5. Other Information

Rule 10b5-1 Trading Plans – Directors and Section 16 Officers

During the three months ended June 30, 2026, none of the Company's directors or Section 16 officers adopted or terminated any contract, instruction or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any "non-Rule 10b5-1 trading arrangement".

NeuroOne Medical Technologies Corporation
Form 10-Q

Item 6. Exhibits

Exhibit

No.	Document
3.1	<u>Certificate of Incorporation of NeuroOne Medical Technologies Corporation (incorporated by reference to Exhibit 3.4 on the Registrant's Current Report on Form 8-K filed on June 29, 2017).</u>
3.2	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of NeuroOne Medical Technologies Corporation (incorporated by reference to Exhibit 3.1 on the Registrant's Current Report on Form 8-K, filed on March 31, 2021).</u>
3.3	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of NeuroOne Medical Technologies Corporation (incorporated by reference to Exhibit 3.1 on the Registrant's Current Report on Form 8-K filed on April 14, 2026).</u>
3.4	<u>Amended and Restated Bylaws of NeuroOne Medical Technologies Corporation (incorporated by reference to Exhibit 3.1 on the Registrant's Current Report on Form 8-K, filed on June 21, 2024).</u>
31.1*	<u>Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1**	<u>Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2**	<u>Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Documents are furnished and not filed.

NeuroOne Medical Technologies Corporation
Form 10-Q

SIGNATURES

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

Dated: August 13, 2026

NeuroOne Medical Technologies Corporation

By: /s/ David Rosa
David Rosa
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Chris Volker
Chris Volker
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)