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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from ___ to ___

Commission File Number: 001-42364

CeriBell, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-1785452**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
360 N. Pastoria Avenue	
Sunnyvale, CA	**94085**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (800) 436-0826

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 per share	CBLL	The Nasdaq Stock Market LLC

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

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

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

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

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

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

As of October 30, 2026, the registrant had 38,835,010 shares of common stock, $0.001 par value per share, outstanding.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management, and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipates," "believes," "continue," "could," "estimates," "expects," "forecast," "guidance," "intends," "likely," "may," "ongoing," "plans," "potential," "predicts," "projects," "seeks," "should," "target," "will," or "would," or the negative of these words or other similar terms or expressions.

Forward-looking statements in this Quarterly Report include statements regarding our growth strategy and plans for new features, indications, and markets, the timing and outcome of regulatory clearances, coverage and reimbursement, and our commercialization and manufacturing capabilities. They also include statements regarding the effect of tariffs, our legal proceedings, our capital requirements and compliance with our credit facility, and the period during which we will remain an emerging growth company under the Jumpstart Our Business Startups Act (the "JOBS Act").

You should not rely upon forward-looking statements as predictions of future events. We have based these statements primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations, and prospects. Although we believe that we have a reasonable basis for each forward-looking statement, we cannot guarantee that the future results, levels of activity, performance, or events reflected in them will be achieved or occur at all. These statements are subject to risks, uncertainties, and other factors described in Part II, Item 1A. "Risk Factors" and elsewhere in this Quarterly Report, in our Annual Report on Form 10-K for the year ended December 31, 2025, and in our other filings with the Securities and Exchange Commission (the "SEC"). We operate in a very competitive and rapidly changing environment. New risks emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report. Actual results, events, or circumstances could therefore differ materially from those described in our forward-looking statements.

Our forward-looking statements speak only as of the date of this Quarterly Report, and, except as required by law, we undertake no obligation to update them to reflect later events or circumstances or new information. They do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make. We intend our forward-looking statements to be covered by the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

You should read this Quarterly Report and the documents we have filed as exhibits with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited).

CeriBell, Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 41,989	$ 40,476
Marketable securities	75,478	118,785
Accounts receivable, net	17,792	15,053
Inventory	6,955	7,288
Contract costs, current	2,232	2,210
Prepaid expenses and other current assets	2,991	2,906
Total current assets	**147,437**	**186,718**
Property and equipment, net	1,774	2,030
Operating lease right-of-use assets	1,516	2,296
Contract costs, long-term	1,503	1,847
Other non-current assets	4,140	2,912
Total assets	**$ 156,370**	**$ 195,803**
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,334	$ 2,838
Accrued liabilities	14,059	14,328
Deferred revenue	230	—
Contract liabilities, current	—	101
Operating lease liability, current	1,218	1,105
Other current liabilities	193	818
Total current liabilities	**18,034**	**19,190**
Long-term liabilities		
Notes payable, long-term	20,000	19,811
Other liabilities, long-term	367	106
Operating lease liability, long-term	432	1,360
Total long-term liabilities	**20,799**	**21,277**
Total liabilities	**$ 38,833**	**$ 40,467**
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, $0.001 par value;		
Authorized shares: 10,000,000 as of September 30, 2026 and December 31, 2025		
Issued and outstanding shares: none as of September 30, 2026 and December 31, 2025	—	—
Common stock, $0.001 par value;		
Authorized shares: 500,000,000 as of September 30, 2026 and December 31, 2025		
Issued and outstanding shares: 38,820,703 and 37,485,124 as of September 30, 2026 and December 31, 2025, respectively	39	38
Additional paid-in capital	398,353	375,495
Accumulated other comprehensive income (loss)	(143)	159
Accumulated deficit	(280,712)	(220,356)
Total stockholders' equity	**117,537**	**155,336**
Total liabilities and stockholders' equity	**$ 156,370**	**$ 195,803**

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

CeriBell, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Revenue				
Product revenue	$ 22,235	$ 17,020	$ 63,667	$ 48,551
Subscription revenue	7,106	5,569	20,266	15,728
Total revenue	**29,341**	**22,589**	**83,933**	**64,279**
Cost of revenue				
Product cost of goods sold	2,658	2,461	7,557	7,172
Subscription cost of revenue	343	186	976	476
Total cost of revenue	**3,001**	**2,647**	**8,533**	**7,648**
Gross profit	**26,340**	**19,942**	**75,400**	**56,631**
Operating expenses				
Research and development	7,403	4,983	20,311	14,081
Sales and marketing	25,032	18,569	71,837	54,024
General and administrative	14,453	11,037	44,526	32,332
Total operating expenses	**46,888**	**34,589**	**136,674**	**100,437**
Loss from operations	**(20,548)**	**(14,647)**	**(61,274)**	**(43,806)**
Interest expense	(267)	(480)	(1,139)	(1,428)
Other income (expense), net	(536)	1,662	2,056	5,349
Loss before provision for income taxes	**(21,351)**	**(13,465)**	**(60,357)**	**(39,885)**
Provision for income tax expense	—	—	—	—
Net loss	**$ (21,351)**	**$ (13,465)**	**$ (60,357)**	**$ (39,885)**
Net loss per share attributable to common stockholders:				
Basic and diluted	(0.55)	(0.37)	(1.59)	(1.10)
Weighted-average shares used in computing net loss per share attributable to common stockholders:				
Basic and diluted	38,500,027	36,806,918	38,068,145	36,326,792
Other comprehensive loss				
Net unrealized gain (loss) on marketable securities	$ (51)	$ 134	$ (302)	$ 139
Comprehensive loss	**$ (21,402)**	**$ (13,331)**	**$ (60,659)**	**$ (39,746)**

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

CeriBell, Inc.
Condensed Statements of Stockholders' Equity
(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-in-Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance December 31, 2025	**37,485,124**	**38**	**$ 375,495**	**$ 159**	**$ (220,356)**	**$ 155,336**
Issuance of restricted stock awards	96,073	—	—	—	—	—
Issuance of common stock	278,483	—	1,632	—	—	1,632
Stock-based compensation	—	—	3,723	—	—	3,723
Net loss	—	—	—	—	(19,737)	(19,737)
Other comprehensive loss	—	—	—	(141)	—	(141)
Balance March 31, 2026	**37,859,680**	**38**	**$ 380,850**	**$ 18**	**$ (240,093)**	**$ 140,813**
Issuance of restricted stock awards	204,451	—	—	—	—	—
Issuance of common stock	159,090	1	879	—	—	880
Stock-based compensation	—	—	5,998	—	—	5,998
Net loss	—	—	—	—	(19,268)	(19,268)
Other comprehensive loss	—	—	—	(110)	—	(110)
Balance June 30, 2026	**38,223,221**	**39**	**$ 387,727**	**$ (92)**	**$ (259,361)**	**$ 128,313**
Issuance of restricted stock awards	183,176	—	—	—	—	—
Issuance of common stock	414,306	—	3,527	—	—	3,527
Stock-based compensation	—	—	7,099	—	—	7,099
Net loss	—	—	—	—	(21,351)	(21,351)
Other comprehensive loss	—	—	—	(51)	—	(51)
Balance September 30, 2026	**38,820,703**	**39**	**$ 398,353**	**$ (143)**	**$ (280,712)**	**$ 117,537**

	Common Stock		Additional Paid-in-Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance December 31, 2024	**35,850,606**	**36**	**$ 358,073**	**$ —**	**$ (166,944)**	**$ 191,165**
Issuance of restricted stock awards	12,468	—	—	—	—	—
Shares withheld for taxes	(4,303)	—	(100)	—	—	(100)
Issuance of common stock pursuant to stock option exercises	38,291	—	251	—	—	251
Stock-based compensation	—	—	2,348	—	—	2,348
Net loss	—	—	—	—	(12,777)	(12,777)
Other comprehensive loss	—	—	—	(6)	—	(6)
Balance March 31, 2025	**35,897,062**	**36**	**$ 360,572**	**$ (6)**	**$ (179,721)**	**$ 180,881**
Issuance of restricted stock awards	48,215	—	—	—	—	—
Tax withholding related to settlement or vesting of equity awards	—	—	(268)	—	—	(268)
Issuance of common stock pursuant to stock option exercises	654,386	1	2,006	—	—	2,007
Stock-based compensation	—	—	3,167	—	—	3,167
Net loss	—	—	—	—	(13,643)	(13,643)
Other comprehensive income	—	—	—	11	—	11
Balance June 30, 2025	**36,599,663**	**37**	**$ 365,477**	**$ 5**	**$ (193,364)**	**$ 172,155**
Issuance of restricted stock awards	60,927	—	—	—	—	—
Tax withholding related to settlement or vesting of equity awards	(5,445)	—	(63)	—	—	(63)
Issuance of common stock	393,252	1	1,970	—	—	1,971
Stock-based compensation	—	—	3,349	—	—	3,349
Net loss	—	—	—	—	(13,465)	(13,465)
Other comprehensive income	—	—	—	134	—	134
Balance September 30, 2025	**37,048,397**	**38**	**$ 370,733**	**$ 139**	**$ (206,829)**	**$ 164,081**

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

CeriBell, Inc.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Nine months ended September 30,	
	2026	2025
Cash flows from operating activities		
Net loss	**$ (60,357)**	**$ (39,885)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	733	1,050
Noncash lease expense	(36)	(76)
Stock-based compensation expense	16,820	8,864
Amortization of debt discount and accretion of premium on term loans	341	308
Accretion (amortization) of discount and premium on marketable securities	(1,701)	(1,389)
Loss on disposal of property and equipment and recorders	115	79
Loss on debt extinguishment	1,549	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,739)	(1,356)
Inventory	333	913
Prepaid expenses and other current assets	(85)	391
Contract costs	322	(627)
Accrued interest on marketable securities	242	—
Other non-current assets	17	(221)
Accounts payable	(444)	1,156
Accrued liabilities and other current liabilities	(738)	748
Contract liabilities and deferred revenue	129	11
Other liabilities, long-term	261	—
Net cash used in operating activities	**(45,238)**	**(30,034)**
Cash flows from investing activities		
Purchases of recorder components and recorders	(1,563)	(382)
Purchases of property and equipment	(242)	(588)
Purchases of marketable securities	(88,335)	(188,775)
Proceeds from sales of marketable securities	15,299	—
Proceeds from maturities of marketable securities	117,500	45,500
Net cash provided by (used in) investing activities	**42,659**	**(144,245)**
Cash flows from financing activities		
Proceeds related to employee stock plans	6,039	3,798
Debt issuance cost	(547)	(150)
Proceeds from revolving line of credit	40,000	—
Payments on revolving line of credit	(20,000)	—
Payments on term loan debt	(20,000)	—
Payments on debt extinguishment	(1,400)	—
Net cash provided by financing activities	**4,092**	**3,648**
Net increase (decrease) in cash and cash equivalents	**1,513**	**(170,631)**
Cash and cash equivalents, beginning of period	40,476	194,370
Cash and cash equivalents, end of period	**$ 41,989**	**$ 23,739**
Supplemental disclosure of cash flow information		
Cash paid for interest	**$ 1,141**	**$ 1,430**
Property and equipment included in accounts payable and accrued expenses	**96**	**27**
Recorder components included in accounts payable and accrued expenses	**19**	**40**

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

CeriBell, Inc.
Notes to Condensed Financial Statements
(unaudited)

1. The Company

Organization and Business

CeriBell, Inc. (the "Company" or "Ceribell") was incorporated in the state of Delaware as Brain Stethoscope, Inc., on August 29, 2014, and changed its name to CeriBell, Inc. on August 11, 2015, and maintains its principal office in Sunnyvale, California. The Company is a commercial-stage medical technology company focused on transforming the diagnosis and management of patients with serious neurological conditions.

The Company has developed the Ceribell System, a novel, point-of-care electroencephalography ("EEG") platform specifically designed to address the unmet needs of patients in the acute care setting. By combining proprietary, highly portable and rapidly deployable hardware with sophisticated artificial intelligence ("AI")-powered algorithms, the Ceribell System enables rapid diagnosis and continuous monitoring of patients with neurological conditions.

Liquidity

As of September 30, 2026, the Company's principal sources of liquidity consisted of $117.5 million of cash, cash equivalents, and marketable securities.

The Company has incurred operating losses and negative cash flows from operations since its inception. On September 30, 2026, the Company had an accumulated deficit of $280.7 million. Such losses primarily resulted from the costs incurred in the development and sales and marketing of the Company's products and building the Company's organization. The Company expects to incur losses in the near term as it continues to focus on the development and promotion of new and existing products and expand its corporate infrastructure, including the costs associated with being a public company.

Based on the Company's current operating plan, the Company believes that its existing cash and cash equivalents and marketable securities will be sufficient to fund the Company's planned operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these financial statements.

However, the Company may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue, or operating expenses, and may need to raise additional capital to fund operations, further research and development activities, or acquire, invest in, or license other businesses, assets, or technologies. The Company's future capital needs will depend upon many factors, including the market acceptance of the Company's products, the cost and pace of developing new products, and the costs of supporting sales growth.

Risks and Uncertainties

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, dependence upon third-party payers to provide adequate coverage and reimbursement, dependence on key personnel, dependence on key suppliers, protection of proprietary technology, product liability, and compliance with government regulations. There can be no assurance that the Company's products or services will be accepted in the marketplace, nor can there be any assurance that any future products or services can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products or services will be successfully marketed, if at all. These factors could have a material adverse effect on the Company's future financial results, financial position, and cash flow.

In addition, inflationary and supply chain pressures may adversely impact the Company's future financial results. The Company's operating costs have increased and may continue to increase because of these pressures, and the Company may not be able to fully offset these cost increases by raising prices for products or subscription fees, which could result in downward pressure on margins.

Adverse economic conditions in the U.S., including any economic disruptions related to another or worsening global pandemic or a recession, could negatively impact the Company's revenues and results of operations. The global credit and financial markets continue to experience volatility and disruptions, including diminished liquidity and credit availability, increased concerns about inflation, and uncertainty about economic stability. Events including a potential recession have caused economic, market, and political uncertainty. Volatility and disruption of financial markets could limit the Company's customers' ability to obtain adequate financing or credit to purchase and pay for products in a timely manner or to maintain operations, which could result in a decrease in sales volume that could harm the Company's results of operations. General concerns about the fundamental soundness of the U.S. economy may also cause customers to reduce their purchases. Changes in governmental banking, monetary, and fiscal policies to address liquidity and increase credit availability may not be effective. Continuation or further deterioration of these financial and macroeconomic conditions could harm the Company's sales, profitability, and results of operations.

The Company utilizes contract manufacturers in China and Vietnam to supply key sub-assemblies for its primary products. In addition, political instability or the deterioration of trade relations between the United States and either of these countries could adversely impact the Company's business.

To minimize supply chain disruptions, the Company continues to maintain sufficient supplies of inventory of manufactured components and parts needed to meet forecast production demand.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), and pursuant to the rules and regulations of the SEC.

The unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to a fair statement of the Company's financial position as of September 30, 2026, and the results of its operations for the three and nine months ended September 30, 2026 and 2025 and cash flows for the nine months ended September 30, 2026 and 2025. The condensed balance sheet at December 31, 2025, was derived from audited annual financial statements but does not contain all of the footnote disclosures from the annual financial statements.

Accounting Policies, Significant Judgments, and Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates and assumptions, and such differences could be material to the Company's financial position and results of operations. Significant estimates and assumptions include, but are not limited to, revenue recognition and valuation of the Company's options to purchase common stock for purposes of accounting for stock-based compensation.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company's cash and cash equivalents are invested in checking accounts and money market funds. The Company has not experienced any losses to date.

The Company's accounts receivable are derived solely from product and subscription sales to customers located in the United States. The Company performs periodic evaluations of its customers' financial condition and generally requires no collateral from its customers. Credit losses historically have not been significant. No customers comprised 10% or more of the Company's revenue for the three and nine months ended September 30, 2026 and 2025. No customers comprised 10% or more of the Company's accounts receivable balance as of September 30, 2026, or December 31, 2025.

Bank failures, events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to liquidity constraints. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which the Company maintains balances, could adversely impact liquidity and financial performance. There can be no assurance that the Company's deposits in excess of the Federal Deposit Insurance Corporation ("FDIC") or other comparable insurance limits will be backstopped by the U.S. or applicable foreign governments, or that any bank or financial institution with which the Company does business will be able to obtain needed liquidity from other banks,

government institutions, or by acquisition in the event of a failure or liquidity crisis. The Company's cash and cash equivalents are primarily held in money market funds.

Information About Segment and Geographic Areas

The Company operates and manages its business as one reportable and operating segment. The Company generates revenue from two recurring sources. Product revenue is generated by the sale of the Company's disposable headbands and headcaps ("Wearables") that are intended for single patient use. Subscription revenue is generated by monthly subscription fees charged to the Company's hospital customers for use of Clarity, recorders, and its portal. The Company has one reportable segment due to the similar customer base of its products and subscriptions and similarities in: economic characteristics; nature and compatibility of products and subscriptions; and procurement, manufacturing and distribution processes.

In accordance with the "Segment Reporting" Topic of the Accounting Standards Codification ("ASC"), the Company's Chief Executive Officer is the Chief Operating Decision Maker ("CODM"). The Company's measure of segment profit or loss is loss from operations. The CODM utilizes the Company's financial information such as loss from operations derived from revenues and operating expenses included in the Company forecast, performance metrics, and budget versus actual analyses on an aggregate basis for purposes of evaluating financial performance and how to best allocate resources across functions when developing and reviewing the annual budget to achieve the Company's long-term objectives. Significant expenses regularly provided to the CODM within loss from operations include cost of revenue, research and development, sales and marketing, and general and administrative expenses, which are each separately presented on the Company's Statements of Operations and Comprehensive Loss. The measure of segment assets is reported on the Balance Sheets as total assets. Since the Company operates in one segment, all accounting policies and financial information required by "Segment Reporting" can be found in the summary of significant accounting policies, the revenue footnote, and the annual financial statements. All of the Company's revenue was in the United States for the three and nine months ended September 30, 2026 and 2025. Long-lived assets held outside of the United States were $0.9 million as of both September 30, 2026 and December 31, 2025.

License Agreement

The Company has an in-license arrangement with Stanford University whereby the Company owes low-single digit royalty percentages related to revenue that is derived pursuant to in-licensed technologies, subject to a minimum payment. Royalty obligations are expensed as cost of revenue in the statements of operations and comprehensive loss, when incurred or over the minimum royalty periods and have not been material. On June 12, 2025, the Company extended the exclusivity of the licensed patents to the date the last licensed patent expires in May 2036 for a term exercise fee of $250,000. As the in-licensed technologies are used to generate revenue, the exercise fee has been deferred in other assets and will be amortized to cost of revenue on a straight-line basis through May 2036.

International Emergency Economic Powers Act ("IEEPA") Tariffs

On February 20, 2026, a U.S. Supreme Court ruling invalidated tariffs imposed under the IEEPA. The Company estimates it has paid approximately $1.6 million under the IEEPA tariffs. On April 20, 2026, the U.S. Customs and Border Protection ("CBP") launched an online portal referred to as the Consolidated Administration and Processing of Entries ("CAPE") that can be used to submit IEEPA tariff refund requests. All requests are reviewed by the CBP to determine validity prior to the issuance of refunds.

During the three months ended June 30, 2026, the Company recognized refunds of $1.6 million under the requirements of ASC 450, Contingencies. Of this refund amount, $1.0 million was recognized as a reduction of cost of goods sold for product that had been sold and the remaining $0.6 million related to inventory on hand as of June 30, 2026.

Related Party Transactions

The Company paid Dr. Parvizi, a Director and Co-Founder of the Company, for consulting services and reimbursement of related expenses and recorded such amounts as general and administrative expenses within the statements of operations and comprehensive loss. Expenses related to Dr. Parvizi were $51,000 and $49,000 for the three months ended September 30, 2026 and 2025, respectively, and $148,000 and $146,000 for the nine months ended September 30, 2026 and 2025, respectively.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2024-03 Disaggregation of Income Statement Expenses. The amendment requires more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, amortization, and depletion) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied

either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact this ASU will have on the Company's disclosures.

3. Revenue

Disaggregation of Revenue

The following table provides information about disaggregated revenue from contracts with customers by the nature of products and services provided (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
EEG recorders and Wearables sales, point in time	$ 22,235	$ 17,020	$ 63,667	$ 48,551
EEG portal and Clarity subscriptions and recorder loans, over time	7,106	5,569	20,266	15,728
Total Revenue	**$ 29,341**	**$ 22,589**	**$ 83,933**	**$ 64,279**

Currently, the Company's customers are solely in the United States.

Contract Costs

The Company capitalizes sales commissions that are considered to be incremental to the acquisition of customer contracts and amortizes them over an estimated period of benefit. To determine the period of benefit of its deferred commissions, the Company evaluates the type of commissions, the nature of the related benefit, and the specific facts and circumstances of its arrangements. The Company determines the period of benefit for commissions paid for the acquisition of the initial subscription contract by taking into consideration its average customer life, which is generally assumed to be three years. The Company evaluates these assumptions at least annually and periodically reviews whether events or changes in circumstances have occurred that could impact the period of benefit.

The Company has elected to utilize the practical expedient to expense sales commissions with an amortization period of less than one year and capitalize sales commissions that are considered to be incremental costs of obtaining contracts with an amortization period greater than one year.

The following table provides the breakdown of capitalized contract costs (in thousands):

	For the three months ended September 30,	For the nine months ended September 30,
	2026	2026
Contract cost balance beginning of the period	$ 3,736	$ 4,057
Contract costs capitalized during the period	665	1,675
Contract costs amortized during the period	(666)	(1,997)
Contract costs as of period end	**$ 3,735**	**$ 3,735**

Contract Liabilities and Performance Obligations

Contract liabilities consist of up-front payments received from customers primarily for the Clarity subscriptions.

The following table provides the breakdown of contract liabilities (in thousands):

	For the three months ended September 30,	For the nine months ended September 30,
	2026	2026
Contract liabilities and deferred revenue balance beginning of the period	$ 11	$ 101
Additional contract liabilities and deferred revenue during the period	426	481
Contract liabilities and deferred revenue recognized during the period	(207)	(352)
Contract liabilities and deferred revenue as of period end	**$ 230**	**$ 230**

The Company has elected not to include unfulfilled performance obligations for contracts in which the amount of revenue it recognizes is equal to the amount which the Company has a right to invoice. No revenue was recognized in the reporting period from performance obligations satisfied in previous periods. The short-term remaining performance obligations are expected to be recognized within 12 months.

4. Fair Value Measurements

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

Fair Value of Assets and Liabilities

The following tables represent the Company's financial assets and liabilities according to the fair value hierarchy, measured at fair value (in thousands):

September 30, 2026	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 38,085	$ —	$ —	$ 38,085
Marketable securities				
U.S. Treasury Bills	3,982	40,284	—	44,266
U.S. Notes and Bonds	—	31,212	—	31,212
Total assets, at fair value	**$ 42,067**	**$ 71,496**	**$ —**	**$ 113,563**

December 31, 2025	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 34,918	$ —	$ —	$ 34,918
Marketable securities				
U.S. Treasury Bills	7,900	53,329	—	61,229
U.S. Notes and Bonds	—	57,556	—	57,556
Total assets, at fair value	**$ 42,818**	**$ 110,885**	**$ —**	**$ 153,703**

The carrying amount of the Company's notes payable is carried at amortized cost and approximates its fair value.

The fair value and amortized cost of Level 1 and 2 available-for-sale marketable securities as of September 30, 2026 and December 31, 2025 are presented in the following table (in thousands):

September 30, 2026	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury Bills	$ 44,351	$ —	$ (85)	$ 44,266
U.S. Notes and Bonds	31,270	—	(58)	31,212
Total marketable securities	**$ 75,621**	**$ —**	**$ (143)**	**$ 75,478**

December 31, 2025	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury Bills	$ 61,178	$ 51	$ —	$ 61,229
U.S. Notes and Bonds	57,448	108	—	57,556
Total marketable securities	**$ 118,626**	**$ 159**	**$ —**	**$ 118,785**

The fair value of available-for-sale marketable securities by contractual maturities as of September 30, 2026 are presented in the following table (in thousands):

	September 30, 2026
Due in less than one year	$ 75,478
Due in one to two years	—
Total marketable securities	**$ 75,478**

Cash equivalents are comprised of Level 1 financial instruments of money market fund investments. Level 1 financial instruments are comprised of cash equivalents and certain U.S. Treasury bills. Level 2 financial instruments are comprised of certain U.S. Treasury bills and U.S. Notes and Bonds. The Company's valuation technique used to measure the fair value of money market funds and Level 1 U.S. Treasury bills is derived from quoted prices in active markets for identical assets or liabilities. The fair value of Level 2 financial instruments is derived using observable inputs other than quoted prices.

5. Balance Sheet Details

Inventory

Inventory consists of the following (in thousands):

	September 30, 2026	December 31, 2025
Component materials	$ 5,021	$ 4,985
Finished goods	1,934	2,303
Total	**$ 6,955**	**$ 7,288**

Property and Equipment, net

Property and equipment are comprised of the following (in thousands):

	September 30, 2026	December 31, 2025
Furniture and fixtures	$ 927	$ 857
Computer equipment and software	391	391
Laboratory and manufacturing equipment	2,758	2,418
Leasehold improvements	855	852
Construction in progress	80	218
Total Property and Equipment	**5,011**	**4,736**
Less: accumulated depreciation and amortization	3,237	2,706
Property and Equipment, Net	**$ 1,774**	**$ 2,030**

Depreciation and amortization expense was $0.2 million and $0.3 million for the three months ended September 30, 2026 and 2025, respectively, and $0.5 million and $0.8 million for the nine months ended September 30, 2026 and 2025, respectively.

Other Non-Current Assets

Other non-current assets are comprised of the following (in thousands):

	September 30, 2026	December 31, 2025
Recorders at customer locations	$ 2,241	$ 1,838
Less: accumulated depreciation of recorders at customer locations	(1,098)	(1,033)
Recorders at customer locations, net	**1,143**	**805**
Recorders and related components	2,001	1,141
Deferred debt financing cost	381	335
Other non-current assets	615	631
Total other non-current assets	**$ 4,140**	**$ 2,912**

Recorder depreciation expense was $0.1 million for both the three months ended September 30, 2026 and 2025, and $0.2 million and $0.3 million for the nine months ended September 30, 2026 and 2025, respectively.

Accrued Liabilities

Accrued liabilities are comprised of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued bonuses and payroll	$ 5,756	$ 6,082
Accrued commissions	4,629	4,048
Professional fees and other costs	2,469	1,994
Employee stock purchase plan liability	609	1,004
Other	596	1,200
Total	**$ 14,059**	**$ 14,328**

6. Employee Benefit Plan

The Company offers its employees a tax-deferred savings plan, commonly referred to as a 401(k) plan. Employee contributions are withheld from payroll checks and are automatically withdrawn from the Company's checking account and deposited into participants' retirement accounts a few days following each payroll period. Beginning March 1, 2025, the Company provides a 50% match for employee contributions up to a certain limit. The Company contributed $0.3 million for both the three months ended September 30, 2026 and 2025, and $1.2 million and $0.8 million during the nine months ended September 30, 2026 and 2025, respectively, to its 401(k) plan.

7. Commitments and Contingencies

Litigation

On July 7, 2025, the Company filed patent infringement complaints against Natus Medical Incorporated and related subsidiaries ("Natus") with the U.S. International Trade Commission ("USITC") and the U.S. District Court for the District of Delaware (the "District Court"). On August 6, 2025, the USITC instituted an investigation of these claims pursuant to Section 337 of the Tariff Act of 1930 and on August 12, 2025, the District Court stayed the pending patent infringement action until the final determination of the USITC investigation.

Legal fees are expensed in the period in which they are incurred and are included in accrued liabilities. In addition to expenses incurred, as of September 30, 2026, the Company has a commitment to pay $2.9 million in deferred legal fees contingent upon the earlier of settlement or favorable Initial Determination by the Administrative Law Judge related to the Natus patent infringement complaints. The Company records a provision for a liability when management believes that it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. No provision or accrual has been recorded related to the deferred legal fees based on currently available information. As of September 30, 2026, and December 31, 2025, there were no litigation liabilities recorded for the contingent deferred legal fees described above.

IEEPA Tariff Refunds

The Company does not expect future IEEPA tariff refunds to be material, but will recognize the refunds when the requirements under ASC 450, Contingencies, have been met.

8. Leases

The Company's right-of-use ("ROU") asset relates to its leased corporate offices and warehouse in Sunnyvale, CA. Supplemental balance sheet information related to leases was as follows (in thousands):

	September 30, 2026	December 31, 2025
Operating Lease		
Operating lease right-of-use asset	**$ 1,516**	**$ 2,296**
Operating lease liability, current	1,218	1,105
Operating lease liability, long-term	432	1,360
Total operating lease liabilities	**$ 1,650**	**$ 2,465**
Weighted average remaining lease term (years)	1.3	2.1
Weighted average discount rate	8.00%	8.00%

A summary of total lease expense and other information for the periods relating to the Company's operating leases was as follows (in thousands):

	Three months ended September 30, 2026	Three months ended September 30, 2025	Nine months ended September 30, 2026	Nine months ended September 30, 2025
Operating lease expense	$ 305	$ 282	$ 916	$ 844
Variable lease expense	103	73	303	242
Total lease expense	**$ 408**	**$ 355**	**$ 1,219**	**$ 1,086**
Total cash payments for amounts included in the measurement of lease liabilities	**$ 313**	**$ 303**	**$ 936**	**$ 907**

The Company leases office space and warehouse space under non-cancelable operating leases. As of September 30, 2026, the future minimum lease payments under the non-cancelable operating lease are as follows (in thousands):

Operating Leases:	September 30, 2026
Remainder of 2026	$ 319
2027	1,306
2028	109
Total undiscounted lease payments	1,734
Imputed interest	(84)
Net Lease Liabilities	**$ 1,650**

9. Debt

2024 VLSA Term Loan

In consideration of the 2024 principal loan repayment schedule and future operating cash flow requirements, effective February 6, 2024, the Company executed a Venture Loan and Security Agreement ("VLSA") with Horizon Technology Finance Corporation ("Horizon") as a lender and the collateral agent and Silicon Valley Bank ("SVB") as a lender (collectively, the "Lenders").

Upon execution of the VLSA, the Company drew down the entire first tranche of $20.0 million in principal ("VLSA Term Loan"), including $6.0 million from SVB ("SVB Loan") and $14.0 million from Horizon ("Horizon Loan"). Subject to the VLSA terms, the Company was entitled to receive up to $30.0 million ("Outstanding Commitment") in three additional tranches of $10.0 million each. On June 30, 2026, the first $10.0 million tranche expired and the Company did not draw down on the first tranche. $20.0 million remained available as of June 30, 2026. Each lender's obligation to lend its undisbursed portion of the Outstanding Commitment to the Company would have terminated if, in such Lender's sole good faith discretion, there was a material adverse change in the results of operations or financial condition of the Company, whether or not arising from transactions in the ordinary course of business, or there had been any material adverse deviation by the Company from the business plan of the Company presented to any Lender. No material adverse changes were identified through the termination of the VLSA.

The VLSA Term Loan was payable to the Lenders in twelve equal monthly installments between April 1, 2028 ("Amortization Date") and March 1, 2029 ("Maturity Date") subject to certain prepayment fees in accordance with the VLSA. The SVB Loan carried a variable per annum interest rate at the Prime Rate (as published in the Wall Street Journal), subject to the floor of 6.00%. The Horizon Loan carried a variable per annum interest rate at the Prime Rate plus 2.75%, subject to the floor of 9.25%. Collateral for the VLSA consisted of a security interest in all assets of the Company, excluding intellectual property.

On August 5, 2026, the Company entered into a Credit, Security and Guaranty Agreement (the "Credit Agreement") with MidCap Funding IV Trust, as agent, MidCap Financial Trust, as term loan servicer, and the lenders party thereto (collectively, "MidCap"). Concurrently with entering into the Credit Agreement, the Company repaid in full and terminated its VLSA with the Lenders, under which $20.0 million of term loans were outstanding. The aggregate payoff of $21.4 million (excluding accrued interest) comprised of the $20.0 million principal balance, a $0.8 million end-of-term fee, and a $0.6 million prepayment fee. The Company recognized a loss on extinguishment of debt of $1.5 million in the three months ended September 30, 2026, consisting of the prepayment and end-of-term fees paid (net of amounts previously accreted) and the write-off of unamortized debt discounts and deferred financing costs associated with the VLSA. The loss is presented within Other income (expense), net, in the condensed statements of operations.

Senior Revolving Facility

In February 2024, the Company also executed a Loan and Security Agreement ("LSA") with SVB to receive a senior revolving line of credit of up to $10.0 million ("Revolving Facility"). The Revolving Facility matured on February 6, 2026. No borrowings were made under the Revolving Facility, and the Revolving Facility is no longer available for borrowing.

MidCap Credit Facility

The Credit Agreement provides for (i) a term loan facility, consisting of a $30.0 million commitment available to draw at the Company's request at any time before December 31, 2028 in minimum increments of $5.0 million ("Term Loan Tranche 1") and an additional $25.0 million of uncommitted capital that may be available at MidCap's discretion, and (ii) a revolving loan facility in an aggregate principal amount of up to $20.0 million, which may be increased to up to $30.0 million at the Company's discretion upon satisfaction of certain conditions set forth therein (the "MidCap Revolving Facility"). The $20.0 million revolving credit facility operates on a non-formula basis through December 31, 2027, (or earlier upon an event of default), after which time, availability under the facility will be subject to a borrowing base based on eligible accounts receivable and inventory. All loans under the Credit Agreement mature on August 5, 2031.

The MidCap Revolving Facility bears interest at Term SOFR (subject to a 1.00% floor) plus 3.75% per annum, and term loans bear interest at Term SOFR (subject to 1.00% floor) plus 5.00% per annum, in each case payable monthly in arrears. The Company also pays a facility fee of 0.50% per annum on the revolving loan commitment, payable monthly, and a quarterly minimum balance fee equal to the shortfall, if any, between interest actually earned by the lenders on revolving loans and interest computed on 25% of the revolving loan commitment. If the Company terminates or permanently reduces the revolving commitment, or prepays term loans, before the third anniversary of closing, exit fees of 3.0%, 2.0%, or 1.0% of the amount terminated, reduced, or prepaid apply in years one, two, and three, respectively; no such fees apply thereafter or upon repayment at maturity, and none have been accrued because early termination is not considered probable. The Company's obligations under the Credit Agreement are secured by a security interest in substantially all of the Company's assets, including its intellectual property.

The Credit Agreement contains affirmative, negative, and financial covenants. The financial covenants are tested only while outstanding term loans plus the revolving loan commitment exceed $35.0 million. Because no term loans were outstanding as of

September 30, 2026, the Company was not in a financial covenant testing period. The Company was in compliance with all covenants under the Credit Agreement as of September 30, 2026.

The Company incurred $0.5 million of costs in connection with the Credit Agreement, of which $0.2 million was allocated to the MidCap Revolving Facility to be recognized as interest expense through the maturity date, and $0.3 million was allocated to the Term Loan Tranche 1 commitment to be recognized as interest expense through the end of its availability period on December 31, 2028, subject to reclassification upon any draw. As of September 30, 2026, unamortized deferred financing costs were recorded as assets, of which $0.1 million was included in prepaid expenses and other current assets and $0.4 million in other non-current assets on the condensed balance sheets.

At closing, the Company borrowed $20.0 million under the MidCap Revolving Facility, the proceeds of which, together with cash on hand, were used to repay the VLSA. Future borrowings will be used for working capital and general corporate purposes. As of September 30, 2026, $20.0 million of revolving loans were outstanding, and no term loans had been drawn. The revolving loans are classified as long-term based on the August 2031 maturity.

On August 18, 2026, the Company repaid $20.0 million on the MidCap Revolving Facility. On September 21, 2026, $20.0 million was again drawn by the Company under the MidCap Revolving Facility. The $20.0 million was repaid on October 7, 2026.

Notes payable consists of the following (in thousands):

	September 30, 2026	December 31, 2025
Principal of notes payable	$ 20,000	$ 20,000
End of term fee accretion	—	251
Unamortized debt issuance costs	—	(440)
Carrying value of Notes Payable	**$ 20,000**	**$ 19,811**

10. Warrants

On February 6, 2024, the Company, Horizon, and SVB entered into a $60.0 million financing commitment as discussed in Note 9. Warrants representing the right to purchase 41,345 shares of Series C-1 redeemable convertible preferred stock at a price of $11.49 per share were issued upon closing. Immediately prior to the Company's initial public offering ("IPO") on October 15, 2024, all warrants exercisable for redeemable convertible preferred stock were converted into warrants exercisable for common stock and reclassified from liabilities to equity. All warrants are currently exercisable, in whole or in part, and expire in 2030, 2032, and 2034. To the extent the warrants are not previously exercised, and if the fair market value of one share is greater than the exercise price under the warrants then in effect, the warrants shall be deemed automatically exercised immediately before expiration. The warrants issued to the lenders in connection with the VLSA survive its termination and remain outstanding and remain classified within stockholders' equity.

	Common Stock	Common Stock	Total warrants
Balance December 31, 2025	**45,726**	**56,573**	**102,299**
Exercise price per warrant	$ 7.6540	$ 11.49	
Warrants issued	—	—	—
Balance September 30, 2026	**45,726**	**56,573**	**102,299**
Exercise price per warrant	$ 7.6540	$ 11.49	

The warrants are included in Additional paid-in capital as of September 30, 2026, and December 31, 2025.

11. Stockholders' Equity

Common Stock

The Company is authorized to issue 500,000,000 shares of $0.001 par value common stock as of both September 30, 2026, and December 31, 2025.

The holders of common stock are entitled to receive dividends whenever funds and assets are legally available and when declared by the Board of Directors. As of September 30, 2026, no dividends had been declared.

As of September 30, 2026, and December 31, 2025, the Company had reserved common stock for future issuance as follows:

	September 30, 2026	December 31, 2025
Conversion of outstanding warrants	102,299	102,299
Outstanding options	4,003,933	4,135,501
Outstanding RSUs	2,523,076	1,561,534
Shares reserved for future issuance under the Company's equity plans	5,383,325	5,279,680
Total	**12,012,633**	**11,079,014**

Stock Incentive Plan

Activity under the 2014 Stock Incentive Plan (the "2014 Plan"), 2024 Equity Incentive Plan (the "2024 EIP"), and 2024 Incentive Award Plan (the "2024 Plan") is as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Balance at December 31, 2025	**4,135,501**	**$ 8.70**	**7.38**	**54,842**
Options granted	768,254	19.03		
Options exercised	(706,006)	5.77		
Options forfeited	(193,816)	15.71		
Balance at September 30, 2026	**4,003,933**	**10.93**	**6.91**	**53,897**
Options vested and expected to vest as of September 30, 2026	4,003,933	10.93	6.91	53,897
Options exercisable at September 30, 2026	2,410,370	$ 7.75	6.09	40,125

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2026 and 2025 was $11.58 and $10.47 per share, respectively. The aggregate intrinsic value of options exercised during the nine months ended September 30, 2026 and 2025 was $10.8 million and $12.6 million, respectively.

Restricted Stock Unit activity under the plans is as follows:

	Number of shares	Weighted average grant date fair value
Unvested at December 31, 2025	**1,561,534**	**$ 17.94**
Granted	1,769,197	19.37
Vested	(483,700)	18.56
Cancelled	(323,955)	18.66
Unvested at September 30, 2026	**2,523,076**	**$ 18.74**

The total fair value of shares vested during the nine months ended September 30, 2026 and 2025 was $9.0 million and $2.7 million, respectively.

Stock-Based Compensation

As of September 30, 2026, the aggregate unrecognized compensation costs related to outstanding unvested options and RSUs under the 2014 Plan, 2024 EIP, and 2024 Plan was $56.8 million. The Company expects to recognize those costs over a weighted average period of 3.0 years.

The fair value of RSUs is based on the Company's closing stock price on the date of grant. The fair value of service-based stock options and RSUs are amortized on a straight-line basis over the requisite service period of the awards.

The fair value of employee stock options granted was estimated using the following weighted-average assumptions for the three and nine months ended September 30, 2026 and 2025:

	Three months ended September 30, 2026	2025	Nine months ended September 30, 2026	2025
Expected term (in years)	4.8	*	4.7	5.0
Expected volatility	71.0%	*	71.0%	61.1%
Risk-free interest rate	4.4%	*	4.0%	3.9%
Dividend yield	—	*	—	—

*There were no options granted for the three months ended September 30, 2025

The expected term is based on an average of the midpoint of the requisite service period and the contractual term, and the historical exercise behavior. The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as well as the Company's historical volatility. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history and expectation of no dividend payouts.

The Company's total stock-based compensation expense was as follows (in thousands):

	Three months ended September 30, 2026	2025	Nine months ended September 30, 2026	2025
Cost of revenue	$ 17	$ 95	$ 176	$ 222
Research and development	913	552	2,561	1,489
Sales and marketing	2,328	1,336	6,433	3,316
General and administrative	3,841	1,366	7,650	3,837
Total stock-based compensation expense	**$ 7,099**	**$ 3,349**	**$ 16,820**	**$ 8,864**

Stock-based compensation expense does not include the impact of estimated forfeitures. Forfeitures are taken as a reduction in expense in the period in which they occur. No compensation cost is recorded for awards that do not vest. Option awards included performance-based awards which are subject to the achievement of performance goals. For options subject to performance goals, the Company recognizes expense when it is probable that the performance condition will be achieved. These performance-based awards represent 27,236 and 40,854 of option awards outstanding as of September 30, 2026 and December 31, 2025, respectively and stock-based compensation related to performance-based awards was not material. Total stock-based compensation expense includes non-employee stock-based compensation of $0.3 million and $0.2 million for the three months ended September 30, 2026 and 2025, respectively, and $0.8 million and $0.9 million for the nine months ended September 30, 2026 and 2025, respectively.

Employee Stock Purchase Plan

In February 2025, the Company adopted the Employee Stock Purchase Plan (the "ESPP"). The Company allows eligible employees to purchase shares of the Company's common stock through payroll deductions at a price equal to 85% of the lesser of the fair market value of the stock as of the first date or the ending date of each offering period, which is typically six months. In January 2026, the number of shares of common stock available for issuance under the ESPP was increased by 374,848 shares as a result of the automatic increase provision in the ESPP.

As of September 30, 2026, 1,001,501 shares under the ESPP remain available for purchase. The offering period and purchase period is determined by the Board of Directors. Stock-based compensation related to the ESPP was not material and is included in the Company's total stock-based compensation expense table above.

12. Net loss attributable to common stockholders

Basic net loss per share attributable to the Company's common stockholders is computed by dividing the net loss attributable to the Company's common stockholders by the weighted-average number of shares of common stock outstanding during the period.

Diluted net loss per share is the same as basic net loss per share for all periods presented because the effects of potentially dilutive items were anti-dilutive given the Company's net loss position in each period presented.

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	Three months ended September 30, 2026	2025	Nine months ended September 30, 2026	2025
Net loss attributable to common stockholders	$ (21,351)	$ (13,465)	$ (60,357)	$ (39,885)
Weighted-average shares outstanding, basic and diluted	38,500	36,807	38,068	36,327
Net loss per share, basic and diluted	**$ (0.55)**	**$ (0.37)**	**$ (1.59)**	**$ (1.10)**

The following potentially dilutive securities outstanding have been excluded from the computations of weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares, in thousands):

	Three months ended September 30, 2026	2025	Nine months ended September 30, 2026	2025
Warrants	102	102	102	102
Equity plan stock options outstanding	4,004	4,495	4,004	4,495
Restricted stock units	2,523	1,451	2,523	1,451
Shares committed under ESPP	31	33	31	33
Total	**6,660**	**6,081**	**6,660**	**6,081**

13. Income Taxes

The Company had an effective tax rate of 0.0% for both of the three and nine months ended September 30, 2026 and 2025. The Company continues to incur operating losses.

During the three and nine months ended September 30, 2026 and 2025, the Company evaluated all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and determined that it is more likely than not that its net deferred tax assets will not be realized. Due to uncertainties surrounding the realization of the deferred tax assets, the Company continues to maintain a full valuation allowance against its net deferred tax assets.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes included elsewhere in this Quarterly Report and our audited financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the year ended December 31, 2025 included in our Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs that involve significant risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to those differences include those discussed below and elsewhere in this Quarterly Report, particularly in "Risk Factors" and "Special Note Regarding Forward-Looking Statements."

Overview

We are a medical technology company focused on transforming the diagnosis and management of patients with serious neurological conditions. We have developed the Ceribell System, a novel, point-of-care EEG platform specifically designed to address the unmet needs of patients in the acute care setting. By combining proprietary, highly portable, and rapidly deployable hardware with sophisticated artificial intelligence ("AI")-powered algorithms, the Ceribell System enables rapid diagnosis and continuous monitoring of patients with neurological conditions. We initially focused on becoming the standard of care for the detection and management of seizures in the acute care setting, where the technological and operational limitations of conventional EEG systems have contributed to significant delays in seizure and delirium diagnosis and suboptimal patient care and clinical outcomes, as well as a high economic burden for hospitals and the healthcare system. By making EEG more accessible and enabling continuous monitoring through the power of AI, the Ceribell System enables clinicians to more rapidly and accurately diagnose and manage patients at risk of seizure and delirium in the acute care setting, resulting in improved patient outcomes and hospital and payer economics. As of September 30, 2026, the Ceribell System has been adopted by more than 700 hospitals, ranging from top academic centers to small community hospitals. For information regarding how patient care and clinical outcomes are measured, see "Business—Market Overview—Challenges of Managing Seizures in the Acute Care Setting" included in our Annual Report on Form 10-K filed with the SEC on February 24, 2026.

We specifically designed the Ceribell System to address the limitations of conventional EEG in the acute care setting and dramatically improve clinical outcomes of critically ill patients at high risk of seizures. The Ceribell System integrates proprietary, highly portable hardware with AI-powered algorithms to aid in the detection and management of seizures. Our hardware is composed of disposable, flexible headbands and headcaps ("Wearables") and a pocket-sized, rechargeable battery-operated recorder used to capture and wirelessly transmit EEG signals. The hardware is simple to use and, after approximately one hour of training, can be applied within minutes by any non-specialized healthcare professional. The recorder is integrated with a proprietary web-based portal that allows neurologists to remotely access EEG data in real time from any web-enabled device. EEG data captured by the recorder is interpreted by our proprietary AI-powered seizure detection algorithms, which continuously monitor the patient's EEG signal and can support the clinician's real-time assessment of seizure activity and delirium.

We are currently focused on becoming the standard of care for the detection and management of seizures in the acute care setting. In May 2023, Clarity® became the first device to receive 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for diagnosing electrographic status epilepticus. In December 2025, the FDA granted 510(k) clearance for Ceribell's proprietary Delirium Monitor System, the first and only FDA-cleared delirium screening and monitoring device. In June 2026, we received FDA 510(k) clearance that encompasses two separate neurology focused algorithms, EEG Artifact Reduction and Epileptiform Abnormality Detection. We also received FDA clearance on the full next-generation hardware platform that we anticipate will support our expansion into new indications and new application areas. In September 2026, we received FDA 510(k) clearance for Quantitative EEG Trending and Amplitude-Integrated EEG Analysis software that is designed to make it easier and faster for clinicians to interpret longitudinal brain activity and make appropriate clinical decisions.

There are approximately 6,000 acute care facilities in the United States that we believe could benefit from the Ceribell System. We intend to expand the size of our direct sales organization in the United States to support our efforts to drive further adoption and utilization of the Ceribell System. While our current commercial focus is on the United States, we have received a CE Mark for the Ceribell System in Europe and we intend to pursue additional regulatory clearances in Europe and elsewhere outside of the United States in the future.

We manage all aspects of manufacturing, supply chain, and distribution of the Wearables and recorder from our facilities in Sunnyvale, California. Contract manufacturers in China and Vietnam assemble the headbands, with final inspection and labeling completed at our California facilities. We have dual sources for major components of the Wearables. The components for our recorder are procured from various suppliers and shipped to our facilities for final testing and assembly.

Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, research and development activities, obtaining FDA clearances and other regulatory milestones, business planning, raising capital, establishing and maintaining our intellectual property portfolio, conducting direct sales efforts and marketing initiatives, conducting clinical studies, and providing general and administrative support for these operations.

As of September 30, 2026, we had an accumulated deficit of $280.7 million. To date, we have funded our operations primarily through proceeds from the sale of shares of our stock, including common stock and redeemable convertible preferred stock, term loan and revolver proceeds, and cash generated from the sale of Wearables and subscriptions. As of September 30, 2026, we had $117.5 million in cash, cash equivalents, and marketable securities. Based on our current operating plan, we believe that our existing cash and cash equivalents and marketable securities, together with the expected cash generated from revenue transactions with customers, will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. We may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue, or operating expenses, and may need to raise additional capital to fund operations, further research and development activities, or acquire, invest in, or in-license other businesses, assets, or technologies.

We have incurred operating losses since the commencement of our operations and we expect to continue to incur losses as we grow and continue the transition to operating as a public company.

Our Business Model

Key Factors Affecting Our Results of Operations and Performance

We believe there are several important factors that have impacted and that we expect will impact our operating performance and results of operations for the foreseeable future. These factors include:

- ***Adoption of the Ceribell System by new accounts.*** There are approximately 6,000 acute care facilities with an Intensive Care Unit ("ICU") or Emergency Department ("ED") or both in the United States that we believe could benefit from the Ceribell System because the patients arriving at such facilities may experience seizures or delirium triggered by the conditions leading them to seek acute medical care. As of September 30, 2026, we have successfully deployed the Ceribell System to more than 700 hospitals, ranging from top academic centers to small community hospitals. We believe that all acute care facilities in the United States can benefit from the Ceribell System, and our goal is to establish the Ceribell System as the standard of care for the detection and management of seizures in critically ill patients. To drive further adoption of the Ceribell System, we leverage our commercial infrastructure including Territory Managers ("TMs"), who focus on new account acquisition and onboarding, and Clinical Account Managers ("CAMs"), who focus on ongoing account coverage to increase utilization and further support hospital onboarding. Our commercial team engages with customers to communicate the value proposition of the Ceribell System, leveraging our large base of clinical evidence.
- ***Utilization of the Ceribell System within our existing customer base.*** We believe there are over three million acute care patients in the United States who should be monitored with EEG each year due to high risk of seizures. Currently, many of these patients are not promptly monitored by EEG, as a physician may not be aware of the risk of seizures in a given patient population. Our CAMs work to educate our customers to raise awareness of our technology, non-convulsive seizures, and the risks of delayed treatment. Even at facilities with access to the Ceribell System, clinicians may not use Ceribell on all eligible patients if they are not fully aware of the risks of seizures and the benefits of our solution. We aim to support hospitals in their efforts to integrate Ceribell into protocols for different patient populations, based on established guidelines. We are also continuing our efforts to expand to new hospital departments and provide training to more providers.
- ***Investment in research and development to drive innovation and expand our addressable market.*** Our research and development initiatives are focused on introducing enhancements, features, and improvements aimed at increasing the value provided by the Ceribell System for diagnosing and monitoring seizures and delirium in the acute care setting. We believe the platform nature of the Ceribell System will enable us to efficiently deploy it for use in other serious neurological conditions beyond seizures and delirium to additional indications.

Components of our Results of Operations

Revenue

We generate revenue from two recurring sources. Product revenue is generated by the sale of our disposable Wearables that are intended for single patient use. Subscription revenue is generated by monthly subscription fees charged to our hospital customers for use of Clarity, recorders, and our portal. Revenue from sales of Wearables is recognized at a point in time upon transfer of control of the product. We generally recognize subscription revenue ratably over the related contractual term beginning on the date that the Ceribell System is made available to a customer. Our revenue fluctuates primarily based on the number of active accounts and the volume of Wearable usage.

We expect that our revenue will continue to fluctuate quarter-to-quarter due to a variety of factors, including the potential success of our sales force in extending adoption of the Ceribell System to new accounts and expanding the utilization of the Ceribell System in existing accounts. For purposes of managing our business, we do not separately track increases in revenue solely attributable to new accounts. We may experience fluctuations in the number of Wearables used by our customers based on seasonal factors that impact the number of patients in the acute care setting. For example, the number of patients in the intensive care unit is typically lower during the summer months.

Cost of Revenue

Cost of revenue consists primarily of the cost of materials and labor to manufacture Wearables and depreciation of the manufacturing cost of recorders, as well as third-party hosting fees and personnel-related expenses for our subscription cost of revenue. Cost of revenue also includes expenses related to manufacturing overhead comprising compensation for personnel, manufacturing supervision, facilities, utilities, quality assurance, property tax, and certain direct costs such as tariffs and shipping costs. As we acquire new customers and existing customers increase their use of our product and software, we expect that our cost of revenue will continue to increase.

Gross Profit and Gross Margin

Gross profit, or revenue less cost of revenue, and gross margin, or gross profit as a percentage of revenue, have been and will continue to be affected by various factors that may cause gross margins to fluctuate. These include the product mix between product and subscription revenues, potential changes to sales prices, the timing of our acquisition of new customers, renewals of and follow-on sales to existing customers, costs associated with third-party hosting fees, costs associated with third-party manufacturing and supply chain purchases of inventory, and other direct costs such as tariffs and shipping. Our gross margin may fluctuate from period to period, based upon the factors described above and in the section titled “Risk Factors” included elsewhere in this Quarterly Report.

Operating Expenses

Research and Development

Research and development expenses are incurred in connection with the advancement of the Ceribell System with the goal to improve and expand on the existing Ceribell System and indications. Research and development expenses consist primarily of engineering, product development, regulatory activities, consulting services, materials, depreciation, and other costs associated with products and technologies being developed. These expenses include employee and non-employee compensation, including benefits, stock-based compensation, supplies, materials, consulting, related travel expenses, and facilities expenses. Our research and development team includes clinical study experts as well as hardware and software engineers with deep expertise in mechanical and electrical engineering, data science, AI, embedded software design, and cloud-based data and security architecture. We invest in research and development efforts with the goal of driving continuous improvements in our current system and solutions and expanding the clinical application of the Ceribell System and AI algorithms, in the acute care setting and beyond. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized and are recognized as expense as the goods are delivered or as related services are performed.

We record research and development expenses in the periods in which they are incurred. Costs for certain activities, such as clinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and collaborators.

We expect our research and development expenses to increase as we continue to improve and optimize our products, leverage our platform to expand indications, and develop products for use beyond the acute care setting.

Sales and Marketing

Sales and marketing expenses consist primarily of employee-related costs, including salaries, commissions, bonuses, benefits, travel, and stock-based compensation as well as investments in marketing initiatives to increase market awareness of our technology and the prevalence of seizures and delirium in critically ill patient populations, including expenses related to travel, conferences, trade shows, and consulting services.

We expect our sales and marketing expenses to increase for the foreseeable future as we continue to increase the size of our sales organization and market penetration in the United States, expand indications, and potentially establish an international presence by pursuing marketing authorizations and engaging in other market access initiatives in international regions in which we see significant potential opportunity.

General and Administrative

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits, and stock-based compensation expense for personnel in executive, finance, accounting, commercial operations, legal, human resource, IT, and administrative functions. General and administrative expenses also include direct or allocated expenses for rent and maintenance of facilities and insurance, not otherwise included in research and development expenses, sales and marketing expenses, or cost of revenue, as well as professional fees for legal, patent, and consulting services.

We expect that our general and administrative expenses will increase in the foreseeable future as we increase our headcount to support the continued growth of our business. We also anticipate incurring additional expenses associated with operating as a public company, including increased expenses related to audit, legal, regulatory, compliance, director and officer insurance, investor and public relations, and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange and intellectual property enforcement activities.

Interest and Other Income (Expense), net

Interest and other income (expense), net is primarily interest income on our cash, cash equivalents, and marketable securities. Interest expense primarily consists of interest on our term loans and revolver and a non-cash interest charge related to amortization of debt issuance costs.

Provision for Income Taxes

To date, we have not recorded any U.S. federal or state income tax expense. We have recorded deferred tax assets for U.S. federal income taxes for which we provide a full valuation allowance. These deferred tax assets primarily include net operating loss carryforwards and we expect to maintain this full valuation allowance for the foreseeable future as it is not more likely than not the deferred tax assets will be realized based on our history of losses.

Results of Operations for the three and nine months ended September 30, 2026 and 2025

The following tables set forth our results of operations for the periods presented (in thousands). The period-to-period comparison of financial results is not necessarily indicative of financial results to be achieved in future periods.

	Three months ended September 30, 2026	2025	$ Change	% Change
Revenue				
Product revenue	$ 22,235	$ 17,020	$ 5,215	31%
Subscription revenue	7,106	5,569	1,537	28%
Total revenue	**29,341**	**22,589**	**6,752**	**30%**
Cost of revenue				
Product cost of goods sold	2,658	2,461	197	8%
Subscription cost of revenue	343	186	157	84%
Total cost of revenue	**3,001**	**2,647**	**354**	**13%**
Gross profit	**26,340**	**19,942**	**6,398**	**32%**
Operating expenses:				
Research and development	7,403	4,983	2,420	49%
Sales and marketing	25,032	18,569	6,463	35%
General and administrative	14,453	11,037	3,416	31%
Total operating expenses	**46,888**	**34,589**	**12,299**	**36%**
Loss from operations	**(20,548)**	**(14,647)**	**(5,901)**	**40%**
Interest and other income (expense), net	(803)	1,182	(1,985)	-168%
Loss before provision for income taxes	**(21,351)**	**(13,465)**	**(7,886)**	**59%**
Provision for income taxes	—	—	—	—
Net loss	**$ (21,351)**	**$ (13,465)**	**$ (7,886)**	**59%**

	Nine months ended September 30, 2026	2025	$ Change	% Change
Revenue				
Product revenue	$ 63,667	$ 48,551	$ 15,116	31%
Subscription revenue	20,266	15,728	4,538	29%
Total revenue	**83,933**	**64,279**	**19,654**	**31%**
Cost of revenue				
Product cost of goods sold	7,557	7,172	385	5%
Subscription cost of revenue	976	476	500	105%
Total cost of revenue	**8,533**	**7,648**	**885**	**12%**
Gross profit	**75,400**	**56,631**	**18,769**	**33%**
Operating expenses:				
Research and development	20,311	14,081	6,230	44%
Sales and marketing	71,837	54,024	17,813	33%
General and administrative	44,526	32,332	12,194	38%
Total operating expenses	**136,674**	**100,437**	**36,237**	**36%**
Loss from operations	**(61,274)**	**(43,806)**	**(17,468)**	**40%**
Interest and other income (expense), net	917	3,921	(3,004)	-77%
Loss before provision for income taxes	**(60,357)**	**(39,885)**	**(20,472)**	**51%**
Provision for income taxes	—	—	—	—
Net loss	**$ (60,357)**	**$ (39,885)**	**$ (20,472)**	**51%**

Comparison of the three and nine months ended September 30, 2026 and 2025

Revenue

Product revenue for the three and nine months ended September 30, 2026, increased $5.2 million and $15.1 million, or 31% and 31%, respectively, compared to the same period of fiscal year 2025. Product revenue growth was primarily driven by the addition of new customers and an increase in utilization of Wearables and resulting sales of Wearables, driven by continued customer education that resulted in increased awareness and adoption of our products.

Subscription revenue for the three and nine months ended September 30, 2026, increased $1.5 million and $4.5 million, respectively, or 28% and 29%, respectively, compared to the same period of fiscal year 2025. Subscription revenue growth was primarily driven by the addition of new customers.

Cost of Revenue

Product cost of revenue for the three months ended September 30, 2026, increased $0.2 million, or 8% compared to the same period of fiscal year 2025. Product cost of revenue for the nine months ended September 30, 2026 increased $0.4 million, or 5%, compared to the same period of fiscal year 2025. The increase in cost of goods sold for products for the three and nine months ended September 30, 2026 was primarily due to an increase in Wearables sales to new and existing active accounts. The increase in cost of goods sold for products was partially offset by tariff refunds for the nine months ended September 30, 2026.

Subscription cost of revenue for three and nine months ended September 30, 2026, increased $0.2 million and $0.5 million, or 84% and 105%, respectively, compared to the same period of fiscal year 2025. The increase in subscription cost of revenue was primarily due to increased hosting costs for new and existing active accounts for subscriptions and incremental recorder depreciation associated with new subscriptions.

Gross Profit (in thousands) and Gross Margin

	Three months ended September 30,			
	2026	2025	$ Change	% Change
Gross profit	$ 26,340	$ 19,942	$ 6,398	32%
Gross margin	90%	88%		2%
Product gross profit	19,577	14,559	5,018	34%
Product gross margin	88%	86%		2%
Subscription gross profit	6,763	5,383	1,380	26%
Subscription gross margin	95%	97%		-2%

	Nine months ended September 30,			
	2026	2025	$ Change	% Change
Gross profit	$ 75,400	$ 56,631	$ 18,769	33%
Gross margin	90%	88%		2%
Product gross profit	56,110	41,379	14,731	36%
Product gross margin	88%	85%		3%
Subscription gross profit	19,290	15,252	4,038	26%
Subscription gross margin	95%	97%		-2%

Gross profit for the three and nine months ended September 30, 2026 increased $6.4 million and $18.8 million, or 32% and 33%, respectively, compared to the same period of fiscal year 2025. The increase is primarily due to increased revenue and decreased cost of sales per unit due to cost reduction strategies.

Operating Expenses

Research and Development Expenses

Research and development expenses increased $2.4 million, or 49%, for the three months ended September 30, 2026, compared to the same period of fiscal year 2025. The increase was primarily due to an increase of $1.4 million in personnel and related expenses directly associated with an increase in headcount as well as an increase of $0.7 million for consultants and materials driven by increased research activity.

Research and development expenses increased $6.2 million, or 44%, for the nine months ended September 30, 2026, compared to the same period of fiscal year 2025. The increase was primarily due to an increase of $4.6 million in personnel and related expenses directly associated with an increase in headcount as well as an increase of $1.3 million for consultants and materials driven by increased research activity.

Sales and Marketing Expenses

Sales and marketing expenses increased $6.5 million, or 35%, for the three months ended September 30, 2026, compared to the same period of fiscal year 2025. The increase was primarily due to an increase in personnel and related expenses directly associated with an increase in headcount.

Sales and marketing expenses increased $17.8 million, or 33%, for the nine months ended September 30, 2026, compared to the same period of fiscal year 2025. The increase was primarily due to an increase in personnel and related expenses directly associated with an increase in headcount.

General and Administrative Expenses

General and administrative expenses increased $3.4 million, or 31%, for the three months ended September 30, 2026, compared to the same period of fiscal year 2025. The increase was primarily due to an increase in personnel and related expenses directly associated with an increase in headcount and stock modification.

General and administrative expenses increased $12.2 million, or 38%, for the nine months ended September 30, 2026, compared to the same period of fiscal year 2025. The increase was primarily due to an increase of $5.6 million in personnel and related expenses directly associated with an increase in headcount and stock modification, as well as an increase in professional services of $6.7 million driven by legal costs associated with intellectual property enforcement activities, including a patent infringement suit initiated in July 2025.

Interest and Other Income (Expense), net

Interest and other income (expense), net decreased $2.0 million, or 168% for the three months ended September 30, 2026, compared to the same period for fiscal year 2025. The decrease in interest and other income, net was primarily due to a $1.5 million loss on debt extinguishment and lower balances of cash equivalents and marketable securities, compared to the same period of the prior year. This was partially offset by lower interest expense compared to the prior year, as interest on the MidCap Revolving Facility is less than that of the VLSA, which terminated on August 5, 2026.

Interest and other income, net decreased $3.0 million, or 77% for the nine months ended September 30, 2026, compared to the same period for fiscal year 2025. The decrease in interest and other income, net was primarily due to lower balances of cash equivalents and marketable securities, compared to the same period of the prior year, as well as a $1.5 million loss on debt extinguishment.

Cash Flows

The following table shows a summary of our cash flows for each of the periods presented (in thousands):

	Nine months ended September 30,	
	2026	2025
	(in thousands)	
Net cash used in operating activities	$ (45,238)	$ (30,034)
Net cash provided by (used in) investing activities	$ 42,659	$ (144,245)
Net cash provided by financing activities	$ 4,092	$ 3,648

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2026, consisted primarily of our net loss of $60.4 million and net amortization premiums on marketable securities of $1.7 million, offset by non-cash charges of stock-based compensation of $16.8 million and depreciation and amortization of $0.7 million. Additionally, we had a $1.5 million loss on debt extinguishment and a net increase in operating assets of $1.9 million and a net decrease in operating liabilities of $0.8 million. Net operating assets increased and net operating liabilities decreased primarily due to timing of payments.

Net cash used in operating activities during the nine months ended September 30, 2025, consisted primarily of our net loss of $39.9 million, offset by non-cash charges of stock-based compensation of $8.9 million, and depreciation and amortization of $1.1 million. Additionally, we had a net increase in operating assets of $0.9 million and a net increase in operating liabilities of $1.9 million.

Net operating assets increased due to increases in accounts receivable and inventory due to higher inventory purchases in the nine months ended September 30, 2025. Net operating liabilities increased primarily due to timing of payments.

Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2026 was $42.7 million, and consisted of maturities and sales of marketable securities, offset by purchases of marketable securities, equipment, and recorders provided to customers.

Net cash used in investing activities during the nine months ended September 30, 2025 was $144.2 million, and consisted of purchases of marketable securities and equipment and recorders provided to customers.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2026, consisted of proceeds from the exercise of options and purchase of shares in accordance with our ESPP and proceeds from the MidCap Revolving Facility, offset by payments made for the debt extinguishment, payments made on the VLSA, and payments made on the MidCap Revolving Facility.

Net cash provided by financing activities during the nine months ended September 30, 2025, consisted of proceeds from the exercise of options, offset by debt issuance costs.

IEEPA Tariffs

In April 2025, the U.S. government announced new tariffs on goods imported into the U.S. from dozens of countries, including China and the European Union member states. In response, governments have threatened or imposed reciprocal tariffs or taken other measures, and the United States is in the process of negotiating trade agreements with certain governments. In February 2026, the U.S. Supreme Court ruled to invalidate the U.S. administration's tariff program implemented under IEEPA. In the three months ended June 30, 2026, we recognized refunds of $1.6 million. Of this refund amount, $1.0 million was recognized as a reduction of cost of goods sold for product that had been sold and the remaining $0.6 million related to inventory on hand and remains capitalized in inventory as of June 30, 2026.

Non-GAAP Financial Measures

In addition to our financial results determined in accordance with GAAP, we believe the following EBITDA and Adjusted EBITDA non-GAAP measures are useful in evaluating our operating performance. We use EBITDA and Adjusted EBITDA to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that these non-GAAP financial measures, when taken together with the corresponding GAAP financial measures, provide meaningful supplemental information regarding our performance by excluding certain items that may not be indicative of our business, results of operations, or outlook. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool, and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to its most directly comparable GAAP financial measure set forth below, and not to rely on any single financial measure to evaluate our business.

EBITDA and Adjusted EBITDA are key performance measures that we use to assess our operating performance. Because EBITDA and Adjusted EBITDA facilitate internal comparisons of our historical operating performance on a more consistent basis, we use these measures for business planning purposes.

We calculate EBITDA as net loss adjusted to exclude (i) provision for income taxes (zero for each of the periods presented), (ii) depreciation and amortization expense, and (iii) interest income and interest expense, net (which consists primarily of interest income on our cash equivalents and marketable securities and interest expense on our term loans and revolver and non-cash interest charges related to amortization of debt issuance costs). We then adjust EBITDA to exclude (iv) stock-based compensation expense, (v) legal fees and related professional services costs incurred in connection with the patent infringement action we filed against Natus in July 2025, as further described in Part II, Item 1 — Legal Proceedings of this Quarterly Report (the "Natus IP Matter"), and (vi) the loss on debt extinguishment, to arrive at Adjusted EBITDA.

We are involved from time to time in routine intellectual property activities in the ordinary course of business, including patent prosecution and portfolio maintenance, and the costs of those activities are not excluded from Adjusted EBITDA. The expenses excluded as the "Natus IP Matter" relate solely to that specific, discrete enforcement action, which we believe is outside the ordinary course of our business and materially larger in magnitude than our historical intellectual property enforcement spending. Management excludes these expenses from Adjusted EBITDA because they are not representative of our underlying operating performance and because excluding them facilitates more meaningful period-over-period comparison of our results. We periodically reassess whether the costs associated with this matter continue to be appropriately excluded from Adjusted EBITDA.

Our use of EBITDA and Adjusted EBITDA has limitations as an analytical tool and should not be considered in isolation or as a substitute for analysis of our results as reported under GAAP. Some of these limitations are:

- EBITDA and Adjusted EBITDA do not reflect changes in, or cash requirements for, our working capital needs;
- although depreciation and amortization are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future, and EBITDA and Adjusted EBITDA do not reflect capital expenditure requirements for such replacements;
- EBITDA and Adjusted EBITDA do not reflect interest expense on our outstanding indebtedness or interest income earned on our cash equivalents and marketable securities;
- EBITDA and Adjusted EBITDA do not reflect any provision for, or cash requirements associated with, income taxes that we may be required to pay in future periods;
- other companies, including companies in our industry, may calculate EBITDA and Adjusted EBITDA measures differently, which reduces their usefulness as a comparative measure.

In evaluating EBITDA and Adjusted EBITDA, we anticipate that we will continue to incur expenses similar to those reflected in the adjustments above. Accordingly, our presentation of EBITDA and Adjusted EBITDA should not be construed as suggesting that our future results will be unaffected by these expenses. When evaluating our financial results, EBITDA and Adjusted EBITDA should be considered alongside other financial performance measures, including our net loss and other GAAP results.

The following table presents a reconciliation of EBITDA and Adjusted EBITDA to our net loss, the most directly comparable U.S. GAAP financial measure, for each of the periods indicated (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Net Loss (GAAP)	**$ (21,351)**	**$ (13,465)**	**$ (60,357)**	**$ (39,885)**
Non-GAAP Adjustments:				
Interest (income) and expense, net	(759)	(1,208)	(2,460)	(3,948)
Depreciation and amortization	249	391	733	1,050
EBITDA (Non-GAAP)	**(21,861)**	**(14,282)**	**(62,084)**	**(42,783)**
Stock-based compensation	7,099	3,349	16,820	8,864
IP litigation matter	1,073	1,703	10,580	3,756
Loss on debt extinguishment	1,549	—	1,549	—
Adjusted EBITDA (Non-GAAP)	**$ (12,140)**	**$ (9,230)**	**$ (33,135)**	**$ (30,163)**

Liquidity and Capital Resources

Since inception, we have financed operations primarily through the net proceeds we have received from the sales of our preferred stock and common stock as well as net proceeds from our term loans and revolver and cash generated from the sale of Wearables and Clarity subscriptions. On October 15, 2024, we completed our IPO and received net proceeds of $187.8 million after deducting underwriting discounts, commissions and offering expenses.

Our losses primarily resulted from the costs incurred in the development and sales and marketing of our products and providing general and administrative support for our operations. We expect to continue to incur losses in the foreseeable future and to expend significant amounts of cash in the foreseeable future as we continue to scale our business, invest in research and development activities, increase sales and marketing expenses to support commercial expansion, and increase general and administrative expenses to support our transition into being a publicly-traded company.

Sources of Liquidity

As of September 30, 2026, our principal sources of liquidity consisted of $117.5 million of cash, cash equivalents, and marketable securities.

On August 5, 2026, we entered into a Credit, Security and Guaranty Agreement (the "Credit Agreement") with MidCap Funding IV Trust, as agent, MidCap Financial Trust, as term loan servicer, and the lenders party thereto, providing for (i) a term loan facility, consisting of a $30.0 million commitment and an additional $25.0 million of uncommitted capital that may be available at the Lender's discretion, and (ii) a revolving loan facility in an aggregate principal amount of up to $20.0 million, which may be increased to up to $30.0 million in up to two tranches of at least $5.0 million each at the Company's discretion upon satisfaction of certain conditions set forth therein. This extended our debt maturity from March 2029 to August 2031.

The $20.0 million revolving credit facility operates on a non-formula basis through December 31, 2027, after which time, availability under the facility will be subject to a borrowing base based on eligible accounts receivable and inventory. After that date (or earlier upon an event of default), availability will be determined by the calculated borrowing base, 85% of eligible accounts receivable, plus 40% of eligible inventory (with availability capped at 25% of the revolving loan limit), less reserves the agent may establish, and could be less than the $20.0 million commitment depending on the level and aging of our receivables at the time.

The term loan may be drawn at the Company's request at any time before December 31, 2028. Term Loan Tranche 1 may be drawn only in minimum increments of $5.0 million and only through December 31, 2028, after which any undrawn commitment expires; amounts repaid may not be reborrowed. In addition, because our financial covenants are tested only while outstanding term loans plus the revolving commitment exceed $35.0 million, any term loan draw that takes us above that threshold would require us to first demonstrate either pro forma compliance with the $70.0 million minimum trailing net revenue covenant or unrestricted cash at least $65.0 million before the draw is funded, and commences quarterly covenant testing thereafter. At closing, the Company borrowed $20.0 million under the revolving facility and has no balance drawn under the term loan. The proceeds of borrowings under the Credit Agreement were used to repay in full the Company's outstanding obligations under the VLSA described in Note 9. The VLSA was terminated on August 5, 2026. Future borrowings will be used for working capital and general corporate purposes.

We believe the refinancing meaningfully increases our committed access to capital while deferring any contractual principal repayment until 2031. The refinancing resulted in a one-time loss on extinguishment of debt of $1.5 million in the three months ended September 30, 2026, of which $1.4 million was paid in cash. The terms of the Credit Agreement, our covenant compliance, and the components of the extinguishment loss are described in Note 9 to our condensed financial statements. We manage borrowings under the MidCap Revolving Facility to minimize interest expense while maintaining continuous access to committed capital. Because the MidCap Revolving Facility permits repayment and reborrowing of revolving loans at any time without a prepayment fee (with two business days' notice for each draw), our practice is to draw on the facility shortly before the end of each fiscal quarter, hold the borrowings through the beginning of the following quarter, and repay them early in that quarter from cash on hand. Exit fees apply only if we terminate or permanently reduce the revolving commitment, as described in Note 9. Interest accrues only while borrowings are outstanding, so this practice limits contractual interest largely to the days surrounding each quarter end; during the remainder of the quarter, our recurring costs of the facility are limited to the 0.50% per annum facility fee on the committed amount and any quarterly minimum balance fee, which together are substantially less than the cost of keeping the facility fully drawn.

As a result of this practice, our balance sheet at each quarter end reflects both the $20.0 million of revolving borrowings and a corresponding amount of cash. During the three months ended September 30, 2026, the maximum amount outstanding at any time was $20.0 million. On October 7, 2026, we repaid the $20.0 million outstanding at September 30, 2026 from cash on hand.

Funding Requirements

Based on our current operating plan, we believe that the expected cash generated from revenue transactions with customers and our existing cash, cash equivalents, and marketable securities, will be sufficient to fund our planned operating expenses and capital

expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. We may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue, or operating expenses, and may need to raise additional capital to fund operations, further research and development activities, or acquire, invest in, or in-license other businesses, assets, or technologies.

In order to generate and obtain adequate amounts of cash to meet requirements beyond the next 12 months, we may continue to seek funds through equity or debt financings, or through other sources of financing. Our future capital needs will depend upon many factors, including:

- the market acceptance of our products;
- the cost and pace of developing new products and our research and development activities;
- the scope, timing and costs of supporting sales growth and expansion of our commercial organization;
- the costs associated with any product recall that may occur;
- the costs associated with the manufacturing of our products at increased production levels or in different countries;
- the costs of attaining, defending, and enforcing our intellectual property rights;
- whether we acquire third-party products or technologies;
- the terms and timing of any other collaborative, licensing, and other arrangements that we may establish;
- the emergence of competing technologies or other adverse market developments;
- our ability to raise additional funds to finance our operations should they be needed in the future;
- debt service requirements; and
- the costs associated with being a public company.

Contractual Obligations and Commitments

Our contractual obligations at September 30, 2026 include:

Debt — Principal payments required on long-term debt outstanding at September 30, 2026, was $20.0 million. On August 5, 2026, we entered into the Credit Agreement, which provides for (i) a term loan facility, consisting of a $30.0 million commitment and an additional $25.0 million of uncommitted capital that may be available at the Lender's discretion, and (ii) a revolving loan facility in an aggregate principal amount of up to $20.0 million, which may be increased to up to $30.0 million at the Company's discretion upon satisfaction of certain conditions set forth therein, and materially increased our borrowing capacity and secured indebtedness; see Note 9.

Operating leases — As of September 30, 2026, estimated contractual obligations for operating lease payments were $1.7 million due within 16 months.

Litigation — As of September 30, 2026, we have a commitment to pay $2.9 million in deferred legal fees contingent upon the earlier of settlement or favorable Initial Determination by the Administrative Law Judge related to the Natus patent infringement complaints. The Company records a provision for a liability when management believes that it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. No provision or accrual has been recorded related to the deferred legal fees based on currently available information; see Note 7, “Commitments and Contingencies.”

Critical Accounting Policies, Significant Judgments, and Use of Estimates

Our management’s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and the disclosure of our contingent liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Information about our significant accounting policies and how estimates are involved in the preparation of our financial statements are described in our Annual Report on Form 10-K filed with the SEC on February 24, 2026. There have been no material changes to our significant accounting policies and estimates during the nine months ended September 30, 2026.

Recently Issued Accounting Pronouncements

See Note 2 to our financial statements included elsewhere in this Quarterly Report for a description of recent accounting pronouncements applicable to our financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as of the end of the period covered by this Quarterly Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2026.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act during the quarter ended September 30, 2026 covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

Our management team, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal controls over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, the effectiveness of any internal control over financial reporting is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to completely eliminate all potential for misconduct. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in any cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On July 7, 2025, we filed patent infringement complaints against Natus Medical Incorporated and related subsidiaries ("Natus") with the U.S. International Trade Commission ("USITC") and the U.S. District Court for the District of Delaware (the "District Court"), alleging that Natus is infringing on six patents owned by us related to important features of the Ceribell EEG headband and electrode design through Natus's making, using, selling, offering for sale in the United States, and/or importing into the United States, of rapid point-of-care EEG monitoring products (the "Natus Products"), and that Natus is engaging in unfair competition. We have requested that the USITC investigate these claims and issue an exclusion order to bar the importation of any infringing Natus Products into the United States. We have also requested in the District Court a permanent injunction against the Natus Products and an award of damages sufficient to compensate us for the alleged infringement, as well as other costs and expenses in this action. On August 6, 2025, the USITC instituted an investigation of these claims pursuant to Section 337 of the Tariff Act of 1930 and on August 12, 2025, the District Court granted a stay of the pending patent infringement action until the final determination of the USITC investigation. Trial proceedings in the USITC investigation concluded as of June 12, 2026, and the parties are now in the process of post-trial briefing. An initial determination is expected by November 19, 2026, and a final determination by March 2027.

We may become involved in other various legal proceedings arising from the normal course of business activities. We are not presently a party to any litigation the outcome of which, we believe, if determined adversely to us, would individually or taken together, materially and adversely affect our business, financial condition, or results of operations. Involvement in legal proceedings is costly and can impose a significant burden on management and employees. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of legal expenses and settlement costs, diversion of management attention and resources, and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could have a material adverse effect on our business, financial condition, results of operations, and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently believe are not material may also impair our business, financial condition, results of operations, and prospects.

Business and Industry Risk Factors

We have a limited operating history and have experienced rapid growth, which may strain our resources and make it difficult to evaluate our business and future prospects. If we are unable to manage our expansion effectively, our business could be materially and adversely affected.

We were founded in 2014 and began selling Ceribell headbands, recorder, and portal in 2018. Since our formation in 2014, we have achieved several key operational milestones that we believe position us for continued growth and success, including our receipt of 510(k) clearance from the FDA for our recorder and headband in 2017, our first commercial sales in 2018, our receipt of 510(k) clearance from the FDA for an early version of Clarity in 2019, and our growth to over 380 employees as of September 30, 2026. Accordingly, we have a limited operating history, which makes evaluation of our future prospects difficult. In that time, we have experienced periods of significant growth in revenue and employees and rapid changes in our business, which have required us to scale the size of our organization and infrastructure.

Any growth that we experience in the future will require us to further expand our sales and marketing and research and development personnel (including those with software and hardware expertise), our manufacturing operations, and our general and administrative infrastructure. In addition to the need to scale our operational capacity, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could impact our capacity to manufacture, market, sell, and support our products, which could result in inefficiencies, unanticipated costs, and disruptions to our operations, and could also pose challenges to retaining our existing employees, including through increased reliance on overtime that could result in greater attrition and reduced productivity. While our quarterly revenues have generally increased since our commercial launch, our results of operations have fluctuated in the past, and our future quarterly and annual results of operations may fluctuate as we focus on increasing demand for our products. We may need to make business decisions that could adversely affect our results of operations and prospects, such as modifications to our pricing and reimbursement strategy, business structure, or operations.

The challenges we face in managing our business, including the changing reimbursement and regulatory landscapes, place significant demands on our management, financial, operational, manufacturing, technological, and other resources, and we expect that managing our business will continue to require us to develop and improve our operational, financial and other internal controls, reporting systems, and procedures at a pace consistent with our growth. Continued growth increases challenges in areas such as recruiting and retaining sufficient skilled personnel, providing adequate training and supervision to maintain high-quality product standards and regulatory compliance, and preserving our culture and values. We have also had, and may in the future experience, delays with onboarding new accounts due to scheduling and other logistical issues. We may not be able to address these challenges in a cost-effective manner, or at all. As we grow, we may also need to invest significant resources to improve and expand our manufacturing capabilities and technology, and we may not be able to do so in a cost-effective manner or at all. We cannot assure you that changes in scale, quality, or compliance assurance, including those related to any future additional indications for the Ceribell System, will be successfully implemented or that appropriate personnel will be available to facilitate the management of our business. Failure to implement necessary quality and compliance procedures, transition to new manufacturing processes or supply chains, or hire or maintain necessary personnel could result in higher costs or an inability to meet demand. If we do not effectively manage our growth and the various challenges we face, we may not be able to execute on our business plan, respond to competitive pressures, take advantage of market opportunities, satisfy customer requirements, or maintain high-quality products, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We have a history of net losses, and we expect to incur additional substantial losses in the foreseeable future.

We have incurred net losses since inception, and we expect to incur additional substantial losses in the foreseeable future. For the nine months ended September 30, 2026, we incurred a net loss of $60.4 million. As of September 30, 2026, we had an accumulated deficit of $280.7 million. We also expect our operating expenses to increase in future periods, and if our revenue growth does not increase to more than offset these anticipated increases in our operating expenses, we may not be able to achieve or maintain profitability, and our business, financial condition, results of operations, and prospects will be harmed. Since inception, we have spent significant

amounts to develop the Ceribell System and related algorithms, to fund clinical studies, to develop and build our manufacturing capacities, to scale our commercial operations, and to recruit and retain key talent.

We have encountered and will continue to encounter risks and difficulties frequently experienced by growing companies, including increasing expenses as we continue to grow our business. We expect our operating expenses to increase significantly over the next several years as we continue to expand our operations and infrastructure and continue to develop the Ceribell System and related algorithms, including for any future additional indications. In addition to the anticipated costs of growing our business, we also expect to incur additional legal, accounting, and other expert expenses as we grow. These investments may be more costly than we expect, and if we do not achieve the benefits anticipated from these investments, or if the realization of these benefits is delayed, they may not result in increased revenue or growth in our business. If our growth rate were to decline significantly or become negative, it could adversely affect our business, financial condition, results of operations, and prospects.

We cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will be able to sustain or increase profitability. Our prior losses, combined with potential future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We depend on sales from the use of the Ceribell System for our revenue. If we are unable to successfully achieve substantial market acceptance and adoption of the Ceribell System, or any of our future products, or if confidence in our products is diminished, our business, financial condition, results of operations, and prospects would be harmed.

We expect that revenue from sales of the Ceribell System will continue to account for almost all of our revenue for the foreseeable future. Continued and widespread market acceptance of alternatives to conventional EEG systems, particularly in the acute care setting, is critical to our future success. The size of our customer base and our ability to acquire new customers is critical to our success as well. Thus, our commercial success will depend in large part on further adoption of the Ceribell System by hospital customers and healthcare professionals and an increase in the number of patients evaluated with it in the acute care setting, as well as on our ability to retain existing customers. Existing customers may choose to terminate or not renew their subscription typically on 30 days' notice to us without payment of a penalty or termination fee, and we may not be able to replace any customers that elect to terminate or not renew their subscriptions with us.

Various factors can contribute to our ability to effectively engage and retain customers and their use of our products. For example, hospitals and healthcare professionals may be reluctant to purchase or use the Ceribell System due to familiarity with conventional EEG systems that are well-established and known to them, and because they must continue to use conventional EEG systems outside of the acute care setting. Our ability to grow sales of the Ceribell System and drive market acceptance will depend on successfully educating hospitals and healthcare professionals of the relative benefits of the Ceribell System compared to the standard of care, which includes conventional EEG systems in the acute care setting, as well as educating such hospitals or healthcare professionals regarding the uses and limitations of the Ceribell System.

If healthcare professionals do not perceive our products to be useful, effective, reliable, and trustworthy, or if we are unable to provide sufficient training to healthcare professionals or harmonize our products with hospital information technology systems, we may not be able to attract or retain customers. Healthcare professionals may perceive the Ceribell System to be less useful if they do not subscribe for access to the Clarity algorithm as part of their use of the Ceribell System, whether because of incremental cost, lack of familiarity or trust in the algorithm's diagnostic accuracy, or if, for similar reasons, they do not rely on the Clarity algorithm (including automated alerts) to interpret the EEG results produced by the Ceribell System. In addition, building a strong brand is critical to our success, but negative clinical research results or publicity or an adverse change to published or unpublished guidelines or recommendations from third parties (including, without limitation, medical societies) relating to the use, clinical benefit, or risk profile of the Ceribell System or AI-enabled devices, or reduced montage EEGs or rapid EEGs in general could result in negative perception by healthcare professionals and affect our brand and reputation. For example, Villamar et al. (2023), a study that retrospectively reviewed EEG recordings for 21 patients who were admitted to a medical intensive care unit after cardiac arrest, found that the Clarity algorithm that was in use at the time of the study did not detect seizures in the four patients who were experiencing them. While we constantly work to improve the Ceribell algorithm and overall Ceribell System, the technologies we work with are novel and complex, and we cannot assure you that there will not be additional negative reports on the Ceribell System in the future. Further, customers who are dissatisfied with their experiences with the Ceribell System may post negative reviews, and we have been, and may in the future become, the subject of blog, forum, or other social media postings that contain negative statements about us, which are outside of our control and may be inaccurate. Any negative publicity, whether real or perceived, disseminated by word-of-mouth, the general media, electronic or social networking platforms, competitor materials, or other methods, could harm our reputation and brand and could severely diminish consumer confidence in our products. Further, a shortage of neurologists or other clinicians available to read the results of the Ceribell System could negatively affect the timely assessment of data from the Ceribell System. Lack of support for our products from healthcare professionals can affect how receptive physicians will be to use our products for their patients and could result in decreased demand for our products. Negative healthcare professional perception could also render us less attractive to future hospital customers, which could

result in decreased sales of our products. A number of other factors, including the impacts of economic conditions and regulatory changes on hospital budgets and spending patterns, could potentially negatively affect new customer acquisitions and demand for our products.

We operate in a highly competitive industry, and competitive pressures could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The market for EEG alternatives is competitive in terms of development, availability, pricing, product quality, and time-to-market. Our primary competition is from conventional EEG systems, which are used in the majority of hospitals in the United States that have resources to purchase and support EEG systems. These competitors have greater name and brand recognition, greater market share, greater resources, stronger financial profiles, and may have larger sales forces than we do, as well as legacy status among hospitals. For example, the two primary conventional EEG providers in the United States are Natus and Nihon Kohden, both of which have much longer operating histories than we do. We also face competition from companies that provide or are developing rapid EEG systems, including Nihon Kohden, Natus, and other companies, that can be used in the acute care and other settings (e.g., home and ambulance), or EEG systems specifically for use in the acute care setting, and conventional EEG providers may also seek to develop additional EEG systems. Our competitors may be able to offer products similar or superior to ours at a more attractive price than we can. Our competitors could also be better positioned to serve certain segments of our market, which could create additional price pressure. In light of these factors, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards, or customer requirements. As a result, even if the Ceribell System is more effective than our competitors' products, current or potential customers may accept competitive products, including conventional EEG systems and rapid EEG systems that can be used in multiple settings, in lieu of purchasing and using our products. In addition, because the Ceribell System is supplemental to, and not a replacement for, conventional EEG systems for rapid acute care diagnosis, customers may view our products as an additional expense and choose to purchase and maintain only conventional EEG systems. If we are unable to successfully compete, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

Changes in trade policy, tariffs, and our reliance on international manufacturing and supply chain operations expose us to foreign operational and trade risks that may adversely affect our business, results of operations, and financial condition.

The U.S. government has implemented or proposed changes to international trade policy through the renegotiation or potential termination of existing trade agreements and the imposition of tariffs on a wide range of products from China, Vietnam, countries in Europe, the Middle East, and Africa, and other regions. In response, China and other countries have imposed or proposed additional tariffs and trade restrictions on imports from the United States. Trade relations between the United States and China remain volatile and uncertain. In 2025, the U.S. imposed additional tariffs on imports from China, Vietnam, and other regions and announced and subsequently paused implementation of certain tariffs. In February 2026, the U.S. Supreme Court invalidated the tariff program implemented under IEEPA, and in the three months ended June 30, 2026, we recognized refunds of $1.6 million for previously paid IEEPA tariffs. We do not expect future IEEPA tariff refunds to be material. The U.S. government may impose tariffs or other trade restrictions under other legal authorities, and the scope, timing, and duration of any such measures remain uncertain. These actions and related retaliation have created significant market uncertainty and may affect the prices of and demand for our products, negatively impacting our results of operations.

We rely on manufacturing facilities and third-party suppliers outside the United States, including in China and Vietnam, for the primary assembly and inspection of our Wearables and for a significant portion of our components. We rely on two primary contract manufacturers in China and maintain contractors in China who perform monitoring and quality inspection services. Our operations also depend on the availability of raw materials and components.

Our suppliers and manufacturers in China expose us to political, legal, and economic risks, including deterioration of U.S.–China relations and changes in U.S. and Chinese laws and regulations relating to sanctions, taxation, import and export restrictions, tariffs, environmental protection, intellectual property, currency controls, cybersecurity, labor and human rights practices, privacy, and public health. Tariffs on products imported from China could adversely affect our suppliers' operations, potentially causing disruptions or requiring us to transition to alternative manufacturers.

In addition, the Uyghur Forced Labor Prevention Act could prohibit the importation of products or components if any portion of our supply chain is determined to involve forced labor in the Xinjiang Uyghur Autonomous Region. Trade regulations in China remain fluid, and sustained geopolitical tensions could result in additional tariffs, trade restrictions, or a global economic slowdown.

Increased tariffs and countermeasures could raise costs, limit material availability, disrupt global supply chains, increase market volatility, and create operational challenges, materially adversely affecting our sales, gross margins, and customer demand.

Although we have engaged vendors and a contract manufacturer in Vietnam to mitigate certain supply chain risks, these efforts may not be effective, may increase capital and operating costs, and could adversely affect our operating results. Labor costs in China have increased and may continue to rise, and shortages of qualified workers could further constrain production and increase costs passed on to us.

Our international operations also expose us to risks including logistics disruptions, higher component costs, quality control issues, political and economic instability, geopolitical conflicts, outbreaks of contagious diseases, regulatory restrictions, intellectual property protection challenges, currency fluctuations, adverse tax consequences, lack of long-term supplier commitments, supplier failures, and labor disputes or natural disasters.

Geopolitical conflicts may increase our costs and disrupt our supply chain.

Ongoing geopolitical tensions and military conflict in the Middle East, including the conflict involving Iran, have disrupted, and may continue to disrupt, global energy and transportation markets, including shipping through the Strait of Hormuz, a critical corridor for international trade. These developments may result in increased fuel and logistics costs, reduced shipping availability, and broader supply chain constraints.

We rely on third-party manufacturers and suppliers, including in China and Vietnam, for the production and assembly of our products and components. As a result, supply chain and transportation disruptions, as well as increases in supplier and logistics costs, may delay our ability to obtain components and deliver finished products and increase our operating costs. In addition, increased costs incurred by our suppliers or contract manufacturers may be passed through to us, which could adversely affect our gross margins.

Geopolitical instability may also contribute to broader macroeconomic impacts, including inflationary pressures and financial market volatility. The duration and severity of these developments are uncertain, and any escalation could exacerbate these risks. If we are unable to effectively manage these impacts, our business, financial condition, results of operations, and prospects could be adversely affected.

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

Issues in the development and use of AI, including the algorithms used in the Clarity platform and other AI-enabled features of the Ceribell System, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. We may adopt and integrate AI tools, including generative AI tools, for specific use cases reviewed by legal and information security. Our vendors may incorporate generative AI tools into their offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience.

If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and have a material adverse effect on our business, financial condition and results of operations.

Any future sales in international markets will subject us to additional costs and risks that may have a material adverse effect on our business, financial condition, results of operations, and prospects.

To date, all of our sales have been to customers in the United States. We have received a CE Mark for the Ceribell System in Europe and intend to enter into international markets in the future, and there are significant costs and risks inherent in conducting business in international markets. Upon our expansion into foreign markets, we will be subject to new business risks, in addition to regulatory risks. See the risk factor titled, "*We face risks related to obtaining necessary foreign regulatory clearance or approvals.*" In addition, expansion into foreign markets will impose additional burdens on our executive and administrative personnel, finance and legal teams, sales and marketing teams, and general managerial resources.

We have limited experience with international regulatory regimes and market practices, and we may not be able to penetrate or successfully generate sales in new markets. We may also encounter difficulty expanding into international markets because of limited brand recognition in certain parts of the world, leading to delayed acceptance of our products by potential customers in these international markets. In addition, international markets may have different reimbursement pathways that present additional challenges and make those markets less commercially viable. If we are unable to expand internationally and manage the complexity of international sales operations successfully, it could have a material adverse effect on our business, financial condition, results of operations, and prospects. If our efforts to introduce our products into foreign markets are not successful, we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion.

If we fail to attract and retain senior management and other key personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain, and motivate highly qualified management, sales and marketing, and research and development personnel, including those with hardware expertise and software expertise, in particular in the area of AI. We are highly dependent upon our senior management team as well as our senior technology personnel. We have experienced, and may in the future experience, planned or unplanned departures of members of our senior management team or senior technology personnel. Any loss of services, whether planned or unplanned, of any of the members of our senior management team could adversely affect our business until a suitable replacement can be found.

Competition for qualified personnel in the medical device field in general and the EEG field specifically is intense, due to the limited number of individuals who possess the training, skills, and experience required by our industry. We intend to continue to review and, where necessary, strengthen our senior management as the needs of our business develop, including through internal promotion and external hires. However, there may be a limited number of people with the requisite competencies to serve in these positions, and we cannot assure you that we will be able to locate or employ such qualified personnel on terms acceptable to us or at all. We also face significant competition for personnel where our main office is located in the San Francisco Bay Area. To attract and maintain key personnel, we need to remain competitive in our "total rewards" offers to employees, including attractive cash compensation, equity, and benefits packages. While we regularly assess market trends for any changes in compensation across all functions, we need to remain diligent in our compensation benchmarking, especially for key personnel, to ensure we are providing attractive offers to new employees and compensating existing employees well. Therefore, the loss of one or more of our key personnel, whether planned or unplanned, or our failure to attract and retain additional key personnel, could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, to the extent we hire personnel from competitors, we have been, and may in the future be, subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

If we are unable to successfully develop new products and effectively manage their introduction or improve our existing products, our business may be adversely affected.

We must successfully manage introductions of new or enhanced products or new or enhanced features of the Ceribell System and Clarity, including those related to any future indications in addition to seizure. Introductions of new products or features of the Ceribell System and Clarity could also adversely impact the sales of our existing products to customers. For instance, the introduction or announcement of a new or advanced Ceribell System could shorten the life cycle of our existing devices or reduce demand for them, potentially reducing any benefits of successful new product or enhancement introductions and leading to challenges in managing the inventory of existing products. In addition, new or enhanced products may have higher manufacturing, marketing, information technology, or other costs than our existing products, or lower market acceptance, which could negatively impact our gross margins and operating results. As the technological complexity of our products increases, the infrastructure to support our products, such as our design and manufacturing processes and technical support for our products, may also become more complex. Accordingly, if we fail to effectively manage introductions of new or advanced products, our business may be adversely affected.

Our expansion into new indications and application areas subjects us to additional clinical, regulatory, commercial, and reimbursement risks, and we may not realize the anticipated benefits of these efforts.

We are expanding our product portfolio beyond seizure detection. In December 2025, the FDA granted 510(k) clearance for our Delirium Monitor System, and in 2026 we received additional 510(k) clearances for neurology-focused algorithms, EEG analysis tools, and a next-generation hardware platform. In January 2026, we received Breakthrough Device Designation for the Ceribell large vessel occlusion ("LVO") System, which remains in development. Our ability to generate revenue from these products and any future indications will depend on, among other things, adoption by hospitals and clinicians of applications that are new to the acute care setting, our ability to generate supporting clinical evidence, our ability to obtain and maintain required marketing authorizations, and the availability of adequate coverage and reimbursement.

Delirium screening and monitoring with EEG is a new application for many hospitals, and hospitals and clinicians may not adopt or continue to use the Delirium Monitor System or our other new offerings at the levels we expect. These offerings may require additional training, workflow changes, or integration with hospital information technology systems, and clinicians may not perceive sufficient clinical or economic benefit. Although the Centers for Medicare & Medicaid Services ("CMS") granted a new technology add-on payment ("NTAP") for eligible Medicare inpatient cases using the Delirium Monitor System, effective October 1, 2026, the NTAP is temporary, does not assure adoption, and may not offset hospitals' costs, and other payers may not provide coverage or reimbursement. See the risk factor titled, "*If adequate reimbursement becomes unavailable for the diagnostic tests using our products, it could diminish our sales or affect our ability to sell the Ceribell System profitably.*"

Our new products and any future indications may require significant additional investment in research and development, clinical studies, manufacturing, and sales and marketing before generating meaningful revenue, if at all. The Ceribell LVO System is in development and is intended to notify clinicians of suspected stroke events that must be confirmed by other imaging; we may be unable to demonstrate the clinical performance needed to obtain marketing authorization, and the potential benefits of Breakthrough Device Designation may

not materialize. In addition, transitioning customers and our supply chain to our next-generation hardware platform may result in higher costs, supply disruptions, excess or obsolete inventory of existing products, or customer dissatisfaction. Any failure to successfully develop, obtain authorization for, and commercialize these products could materially adversely affect our business, financial condition, results of operations, and prospects.

Our products are complex to design and manufacture and can contain defects. The production and sale of defective products could adversely affect our business, financial condition, results of operations, and prospects. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit sales of our products.

The Ceribell System contains highly complex electronic components, which are sourced from external third parties, and there is an inherent risk that defects may occur in the production of any of our products. Although we rely on the suppliers' internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we or our suppliers will be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition to the risk of product returns by our customers due to product defects, we face exposure to product liability claims in the event that any of our devices are alleged to have resulted in personal injury, over- or under-reporting of seizures resulting in inappropriate diagnosis or treatment, damage to property, or otherwise to have caused harm. We may be sued if any of our devices allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing, sale, or use. For example, Clarity is not designed to detect all short seizures, and users of the Ceribell System may allege the failure to detect all short seizures is a defect. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers or limitations inherent in the product, negligence, strict liability, and a breach of warranty. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit sales of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in decreased demand for our current or future products, injury to our reputation, loss of revenue, and the inability to sell our current or any future products. They may also result in litigation costs, a diversion of management's time and our resources, substantial monetary awards to customers and patients, and regulatory investigations, product recalls, withdrawals, or labeling, marketing, or promotional restrictions.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the sale of our current or any future products we develop. Although we currently carry product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. The production and sale of defective products in the future could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The size and expected growth of our addressable market has not been established with precision, and may be smaller than we estimate.

Our estimates of the addressable market for our current products and any future products are based on a number of internal and third-party estimates and assumptions, including the prevalence of seizures in the acute care setting and additional indications we intend to expand into, and the level of underutilization of EEG in the acute care setting. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct. As a result, our estimates of the addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products and services, the price at which we can sell future products or services or the addressable market for our products or services is smaller than we estimate, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Alternative technologies or therapies addressing seizure, non-convulsive status epilepticus or other indications we intend to expand into could materially adversely affect our business, financial condition, results of operations, and prospects.

If medical research were to lead to the discovery of alternative therapies or technologies that address seizure, status epilepticus or other indications we intend to expand into in a way that is or is perceived to be more accurate, reliable, cost-effective, or otherwise improved relative to the Ceribell System, for example through alternative monitoring or testing technologies, medication, or therapies, the demand for our products could decrease significantly, leading to a material adverse effect on our business, financial condition, results of operations, and prospects.

Macroeconomic conditions could materially adversely affect our business, financial condition, results of operations, and prospects.

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

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

In a higher inflationary environment, we may be unable to raise the prices of our products sufficiently to keep up with the rate of inflation. A higher inflationary environment can also negatively impact raw material, component, and logistics costs that, in turn, may increase the costs of producing and distributing our products.

Hospitals, in particular, are experiencing and may continue to experience financial and operational pressures as a result of staffing shortages, the supply chain environment, and high inflation, which could impact their ability to access capital markets and other funding sources, increase the cost of funding, or impede their ability to comply with debt covenants, all of which could impede their ability to provide patient care and impact their profitability. To the extent that hospitals face financial pressures, delayed access, or loss of access to uninsured deposits, reductions in government spending or higher interest rates, hospitals' ability or willingness to spend on equipment may be adversely impacted, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Shutdowns of the U.S. federal government could materially adversely affect our business, financial condition, results of operations, and prospects.

The U.S. federal government has shut down multiple times in the past, including during 2025 and 2026, and certain regulatory agencies, including the FDA, CMS, the USITC, the U.S. Patent and Trademark Office ("USPTO"), the U.S. Department of Defense, and the U.S. Department of Veterans Affairs, have had to furlough employees and suspend some of their activities. Future government shutdowns, including following the expiration of temporary government funding measures, could similarly disrupt the operations of these and other federal agencies. A prolonged shutdown, in addition to any reductions in FDA program funding or changes in personnel, could delay regulatory reviews and approvals, reimbursement-related activities, litigation proceedings, or government program implementations and could ultimately disrupt or delay our research and development, manufacturing, commercialization, or intellectual property enforcement activities. Any such delays or disruptions could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Regulatory Matters

If adequate reimbursement becomes unavailable for the diagnostic tests using our products, it could diminish our sales or affect our ability to sell the Ceribell System profitably.

Diagnostic tests performed with the Ceribell System are generally reimbursed under existing physician and hospital codes. Our ability to increase sales of the Ceribell System depends, in significant part, on the availability of adequate coverage and reimbursement from third-party payers, including governmental payers (such as the Medicare and Medicaid programs in the United States), managed care organizations, and private health insurers. Third-party payers decide which diagnostic tests they will cover and establish reimbursement rates for those tests. We do not bill any third-party payers for the Ceribell System. Instead, we invoice healthcare providers and the cost is bundled into the reimbursement received by healthcare providers for the tests using the Ceribell System.

We expect the Ceribell System will continue to be purchased by hospitals who will then seek reimbursement from third-party payers. Reimbursement for the hospital services during an inpatient stay generally is made under a prospective payment system that is determined by a classification system known as diagnosis-related groups, which are assigned using a number of factors including the principal diagnosis, major procedures, discharge status, patient age, and complicating secondary diagnoses, among other things. In August 2023, CMS approved an NTAP under the Medicare inpatient prospective payment system for our electrographic status epilepticus Clarity algorithm, effective October 1, 2023. The Clarity electrographic status epilepticus NTAP expired on September 30, 2026, and, as a result, hospitals no longer receive additional Medicare payment for eligible inpatient cases utilizing the electrographic status epilepticus Clarity algorithm, which could have an adverse effect on hospitals' economics and, in turn, on the adoption and use of Clarity and on our pricing. In August 2026, CMS granted an NTAP under the Medicare inpatient prospective payment system for eligible Medicare patient cases utilizing our Delirium Monitor System, effective October 1, 2026. The NTAP designation for a product

lasts for no more than three years for a specific indication. Once an applicable NTAP expires or our products are otherwise no longer eligible for such NTAP, our customers may no longer receive additional reimbursement to offset the costs associated with the use of our products, which could adversely affect their profit margins. In light of the potential unreimbursed costs, some of our target customers may be unwilling to adopt our products and some of our existing customers may terminate their contracts with us.

While third-party payers currently cover and provide reimbursement for tests using the Ceribell System, we can give no assurance that these third-party payers will continue to provide coverage and adequate reimbursement, or that current reimbursement levels for the tests will continue. Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, no uniform policy of coverage and reimbursement for tests using our products exists among third-party payers. Therefore, coverage and reimbursement for tests using our products can differ significantly from payer to payer. Other competitive products may be more widely covered or subject to different reimbursement policies and requirements, which could impact demand for our products.

Furthermore, the overall amount of reimbursement available for EEG monitoring and seizure diagnosis could decrease in the future. We cannot be sure that the reimbursement amounts available for hospital services and tests using the Ceribell System will not reduce or otherwise negatively impact the demand for our products. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Failure by users of the Ceribell System to obtain adequate reimbursement for these tests would have a material adverse effect on our business, financial condition, results of operations, and prospects.

The continued commercialization of our products depends in part on the extent to which governmental authorities and health insurers provide coverage and adequate reimbursement levels. Failure to obtain and maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

While third-party payers generally currently cover and provide reimbursement for diagnostic tests using the Ceribell System, there is significant uncertainty related to the insurance coverage and reimbursement of newly approved and launched products. In the United States, third-party payers, including private and governmental payers, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new devices will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payers and other governmental payers develop their coverage and reimbursement policies for medical devices. Some third-party payers may require pre-approval of coverage for new or innovative devices before they will reimburse healthcare providers who use such devices.

In addition, customers that use our products may be subject to reimbursement claim denials upon submission of their claims. Customers may also be subject to recovery of overpayments if a payer makes payment for the claim and subsequently determines that the payer's coding, billing, or coverage policies were not followed. These events, or any other decline in the amount payers are willing to reimburse our customers, could make it difficult for existing customers to continue using or to adopt our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Obtaining coverage and reimbursement can be a time-consuming process that could require us to provide supporting scientific, clinical, and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to satisfy governmental and other third-party payers that diagnostic tests using our products should be covered and reimbursed. In addition, payers continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and tests. There can also be no assurance that third-party payer policies will provide coverage for tests using our products.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in international markets, which may impact utilization of our products. Third-party coverage and reimbursement for our products or any of our products in development for which we may receive regulatory clearance, certification, or approval may not be available or adequate in either the United States or international markets. If demand for our products is adversely affected by third-party reimbursement policies and decisions, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We are subject to certain federal and state fraud and abuse laws and transparency laws, and any failure to comply could subject us to substantial penalties or other adverse consequences. In addition, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, and transparency laws regarding payments and other transfers of value made to physicians and other healthcare professionals. Our business practices and relationships with providers are subject to scrutiny under these laws. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of medical device manufacturers. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- The federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. In addition, certain marketing practices that, for example, induce providers to upcode to a higher reimbursement service or site of service, may also violate false claims laws. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement;
- The federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder (collectively, "HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- The federal Physician Payments Sunshine Act, which requires certain applicable manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under certain federal healthcare programs, to monitor and report to CMS, certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, and certified nurse midwives), and teaching hospitals, and to report annually ownership and investment interests held by physicians and their immediate family members;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers; and
- Analogous state law equivalents of each of the above federal laws, state anti-kickback, and false claims laws; state laws requiring device companies to comply with specific compliance standards, restrict payments made to healthcare providers and other potential referral sources, and report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional and research activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians, or other potential purchasers of our products. In particular, these laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements, as well as interactions with healthcare professionals through consultant arrangements, product training, sponsorships, or other activities. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare and other laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including arrangements with teleneurology

providers and customers for the provision of remote EEG interpretation services or agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. We may be subject to private qui tam actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act including mandatory treble damages and significant per-claim penalties. In addition, as a result of these investigations and qui tam actions, we may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have a material adverse effect on our business, financial condition, results of operations, and prospects. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

We cannot always identify and deter misconduct by our employees, consultants, and commercial partners, and the precautions we take may not protect us from governmental investigations or actions arising from a failure to comply with these laws. If any such actions are instituted against us or our operations are otherwise found to be in violation of any of the federal and state laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputation harm, oversight if we become subject to a consent decree or corporate integrity agreement, or disgorgement, and we could be required to curtail, restructure or cease our operations. Any of the foregoing consequences will have an adverse effect on our business, financial condition, results of operations, and prospects.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In the United States, there have been and continue to be a number of legislative and regulatory initiatives to contain healthcare costs. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the diagnostic tests associated with the use of our products. The cost containment measures that payers and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

By way of example, in the United States, the Affordable Care Act (the "ACA") made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models; and expanded the eligibility criteria for Medicaid programs.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, among other things, reduced Medicare payments to providers, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken.

More recently, the One Big Beautiful Bill Act (the "OBBB Act") was signed into law on July 4, 2025, which included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our products could adversely affect our revenue and commercial prospects.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our products or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or whether any future legislation or regulation in the United States may negatively affect our business, financial condition, results of operations, and prospects. The continuing efforts of the government, insurance companies, managed care organizations, and other payers of healthcare services to contain or reduce costs of

healthcare may adversely affect our ability to set a price that we believe is fair for our products, our ability to generate revenue and achieve or maintain profitability, and the availability of capital.

Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

The regulations to which we are subject are complex, burdensome to understand and apply and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces its regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we or any of our contract manufacturers will be found compliant in connection with any future FDA or foreign inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; import alerts; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

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

In the United States, before we can market a new medical device, or a new use of, or other significant modification to an existing, marketed medical device, we must first receive either clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act (the "FDCA"), approval of a premarket approval application ("PMA"), or grant of a *de novo* classification request from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices. In the *de novo* classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the *de novo* classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

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

authorizations for any of our future products, if granted, may include significant limitations on the indicated uses for the device, which may limit the potential commercial market for the device.

In the United States, any modification to a medical device for which we have obtained marketing authorization may require us to submit a new 510(k) premarket notification and obtain clearance, to submit a PMA and obtain FDA approval, or to submit a *de novo* request prior to implementing the change. For example, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, generally requires a new 510(k) clearance or other marketing authorization. The FDA requires every manufacturer to make such determinations in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with a manufacturer's decisions regarding whether new clearances or approvals are necessary. We may make modifications or add additional features in the future to our medical devices that we believe do not require a new 510(k) clearance, *de novo* request, or approval of a PMA. If the FDA disagrees with our determination and requires us to seek new marketing authorizations for the modifications for which we have concluded that new marketing authorizations are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain such marketing authorization, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business.

The FDA can delay, limit, or deny marketing authorization of a device for many reasons, including our inability to demonstrate substantial equivalence to a predicate device, or that our products are safe and effective and that their benefits outweigh their risks, for their intended uses. The FDA may also disagree with the design or implementation of our clinical trials or our interpretation of the data, find our preclinical or clinical data insufficient to support clearance, de novo classification, or approval, or identify deficiencies in our manufacturing processes or facilities. Serious and unexpected adverse device effects in our clinical trials, or significant changes to FDA regulations or policies that render our clinical data or regulatory filings insufficient, could also delay or prevent authorization.

In addition, in January 2026, we received Breakthrough Device Designation from the FDA for our Ceribell LVO System, a portable EEG-based stroke detection and monitoring system in development intended for use in hospital settings to monitor adult patients for whom a reliable neurological exam for LVO stroke are often challenging and to notify medical professionals of suspected LVO stroke, which notifications are intended to be confirmed by CT or MR angiography prior to initiation of treatment. Breakthrough Device Designation provides certain benefits, including more interactive and timely communications with FDA staff, potential use of post-market data collection to facilitate expedited development and review, opportunities for more efficient and flexible clinical study design, and prioritized review of premarket submissions. However, there can be no guarantee that these benefits will materialize or significantly impact our development and regulatory approval process. Even where our product candidates have received Breakthrough Device Designation, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. Breakthrough Device Designation does not alter the regulatory standards for marketing authorization or guarantee that we will ultimately obtain FDA clearance or approval for the designated indication. Furthermore, the FDA may rescind Breakthrough Device Designation if it believes that the designation is no longer supported by data from our clinical development program. As with all FDA marketing authorizations, we will need to continue to comply with applicable regulations and standards, which may change over time.

Even if we successfully apply for marketing authorization for future products, there is no guarantee that we will obtain the marketing authorizations within the expected timeline, or at all. Staff reductions in the FDA office charged with regulating devices may cause delay.

Our clinical testing process is complex, lengthy, can be expensive, and carries uncertain outcomes. Future trials and studies by us or others may fail to replicate positive results observed to date.

We conduct our own clinical studies and provide support for trials initiated by third parties that evaluate different aspects of the Ceribell System. Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned, or future products may not be predictive of the results of later clinical trials or real-world performance, and interim results of a clinical trial do not necessarily predict final results. The data and results from our clinical studies do not ensure that we will achieve similar results in future clinical trials, are not head to head studies and not directly comparable with each other, as they have different sample sizes, designs, limitations, assumptions, and objectives, and are conducted on different patient populations at different sites by different researchers. In addition, as some of these studies are prospective studies, they may not reflect real-world performance. Some of our studies have not been peer reviewed or published, and peer reviewers may disagree with the methodologies or conclusions of such studies and may not deem them worthy of publication. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in

preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials, or have viewed such data in different ways than regulators.

The risk that future trials and studies of the Ceribell System fail to replicate positive results observed to date is increased because most of our studies and trials are conducted on small samples, not powered for statistical significance, controlled for other clinical variables, or have other design limitations and almost all such studies were conducted or sponsored by us. Independent studies with larger samples or different designs may not replicate results observed to date. In addition, the performance of the Clarity algorithm is typically evaluated by comparing the algorithm results to a retrospective review of the EEG by a panel of neurologists. There is a high degree of inter-rater variability in the interpretation of EEGs by clinicians, such that Ceribell System study results may vary from study to study depending on the size and composition of the neurologist panel. Clinical studies or investigations on the Ceribell System have produced, and may in the future produce, negative or inconclusive results. Furthermore, others, including healthcare professionals and regulators, may perceive a conflict of interest with studies supported, sponsored, or funded by us or conducted by our employees or consultants, and may not find results of such studies to be compelling or credible. As a result of the foregoing, we may decide, or regulators may require us, to conduct additional clinical and nonclinical testing in addition to those we have planned. The initiation and completion of clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in our clinical trials for a number of reasons, including disagreements with regulators or institutional review boards ("IRBs") regarding trial design, insufficient or slower than anticipated patient enrollment, failures by clinical sites or third-party contractors to meet their obligations, changes in regulatory requirements, and higher than anticipated costs, any of which could adversely affect the costs, timing, or successful completion of our clinical trials.

Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing authorization of any medical device.

Patient enrollment in clinical trials, and completion of patient follow-up, if applicable, depend on many factors, including the size of the patient population, the nature of the trial protocol, the eligibility criteria for the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the product being studied. Patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to an investigational device. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations, or guidelines, and are subject to oversight by these governmental agencies and IRBs, or other bodies at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under current good manufacturing practice ("cGMP") or similar foreign requirements, and other regulations applicable to the location where the clinical trial is conducted. We rely on third-party researchers and clinical trial sites, and may in the future rely on CROs, to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on these third parties to conduct our clinical trials in compliance with good clinical practice ("GCP") requirements. To the extent they fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, trial delays or both. In addition, if we conduct clinical trials in other countries in the future, we may be subject to further delays and expenses as a result of increased shipment costs and additional regulatory requirements, and the engagement of non-U.S. third-party contractors may expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening, and medical care. See the risk factor titled, "*We rely on third parties to conduct and support our preclinical studies and clinical trials. These third parties may not properly and successfully carry out their contractual duties or meet expected deadlines, which could harm our ability to obtain marketing authorization of or commercialize future products we develop.*"

Interim, "top-line," and preliminary data that we announce or publish may change as more patient data become available and are subject to audit and verification procedures.

From time to time, we may publicly announce interim or preliminary data from our clinical studies, including studies supporting our new indications. These data are based on a preliminary analysis, remain subject to audit and verification, and may change materially as additional patient data become available. Regulators, clinicians, and others may also interpret the data differently than we do. Adverse differences between interim and final results could harm our reputation, our ability to obtain marketing authorization or drive adoption, and the price of our common stock.

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

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

We have ongoing responsibilities under FDA regulations, and the FDA and state regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state regulatory authorities, which may include the sanctions described above under the risk factor titled "*Our products and operations are subject to extensive government regulation and oversight in the United States, and our failure to comply with applicable requirements could harm our business*," as well as customer notifications or repair, replacement, or refunds, and the FDA's refusal to issue certificates to foreign governments needed to export our products.

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

In addition, the FDA may change its marketing authorization policies affecting future products, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of any products under development or impact our ability to modify any products authorized for market on a timely basis. Such changes may also occur in foreign jurisdictions where we may market our products in the future. Such changes could impose additional requirements upon us that could delay our ability to obtain future marketing authorizations, increase the costs of compliance, or restrict our ability to maintain any marketing authorizations we have obtained. See the risk factor titled, "*Legislative or regulatory reforms in the United States may make it more difficult and costly for us to manufacture, market, or distribute our products, or to obtain marketing authorizations for any future products.*"

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

In the United States, the methods used in, and the facilities used for, the manufacture of medical devices must comply with the FDA's cGMPs for medical devices, known as the Quality Management System Regulation ("QMSR"), which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures, and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QMSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations governing manufacturing.

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

Our products may cause or contribute to adverse medical events which we may be required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition, results of operations, and prospects. In addition, the discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA, could have a negative impact on us.

It is possible that there may be side effects and adverse events associated with the use of our medical devices or any future devices we develop. For example, the Ceribell System has in certain instances issued false alarms, i.e., reported seizure activity when there is

no seizure, and in other instances has failed to report or under-reported seizure activity when there is seizure, and may continue to do so, all of which may lead to patients being misdiagnosed, receiving unnecessary medical procedures or treatments, or experiencing delays in receiving necessary medical procedures or treatments. Additionally, the Wearables used as part of the Ceribell System may cause skin irritation to patients or break down sooner than expected. Use of the Ceribell System, including both the Wearables and EEG recorder, may present infection control hazards to both patients and healthcare staff. The EEG recorder may also present additional hazards to patients and healthcare staff, including mechanical hazards, electrical hazards, and thermal hazards relating to the device's integrated lithium-ion battery. Failure of the EEG recorder to transmit data to our portal due to software or hardware problems, incorrect setup or configuration, network incompatibility, or user error may lead to patients experiencing delays in receiving necessary medical procedures or treatments. The FDA's medical device reporting regulations require us to assess reportability of adverse events that come to our attention and report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the event as well as the nature of the event. We may fail to report events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. The FDA may also disagree with our determinations that an event was not reportable. To date, we have not filed any adverse event-related medical device reports with the FDA. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our marketing authorizations, seizure of our products, or delay in obtaining marketing authorizations for our future products.

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

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

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

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

Our commercial products, and any marketing authorization we may receive for future products, are, and will be, limited to specified indications for use. Our sales and marketing personnel, as well as our direct sales force, are trained to not promote our devices for uses outside of the FDA-authorized indications for use, known as "off-label uses." We cannot, however, prevent a healthcare professional from using our devices off-label, when in the healthcare professional's independent professional judgment he or she deems it appropriate. There may be increased risk of injury to patients if healthcare professionals attempt to use our devices off-label, which could harm our reputation in the marketplace among healthcare professionals and patients.

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

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

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

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its policies, adopt additional regulations, or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of any future products under development or impact our ability to modify any products for which we have already obtained marketing authorizations on a timely basis. For example, on February 2, 2026, the FDA's final rule implementing the FDA's QMSR became effective. The QMSR, which replaced the FDA's former Quality System Regulation ("QSR"), sets forth the FDA's cGMP requirements for medical devices, and among other things, incorporates by reference certain elements of the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, and although our quality management system is designed to comply with ISO 13485, the FDA has indicated that ISO 13485 certification alone will not ensure compliance under the QMSR, nor will ISO certification exempt manufacturers from FDA inspection. The QMSR also includes certain compliance obligations, such as those relating to unique device identification, product traceability, and maintenance of complaint and service records, that align more closely with the FDA's existing medical device requirements than with ISO standards. Accordingly, it remains unclear the extent to which the QMSR may impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business.

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

The FDA has also established requirements and issued guidance applicable to connected and AI-enabled medical devices, including our products. For example, Section 524B of the FDCA imposes cybersecurity requirements on certain medical devices, including requirements relating to premarket submissions and post-market cybersecurity monitoring and vulnerability management. The FDA has also issued guidance regarding AI-enabled device software functions, including the use of predetermined change control plans for certain software modifications. Compliance with these cybersecurity requirements, changes in FDA policies or guidance, or limitations on our ability to implement modifications to our AI-enabled software without additional regulatory submissions could increase our compliance costs, delay product enhancements or adversely affect our ability to develop and commercialize our products.

We face risks related to obtaining necessary foreign regulatory clearance or approvals.

We intend to pursue additional regulatory clearances in Europe and elsewhere outside the United States. Upon our expansion into foreign markets, we will be subject to foreign regulatory requirements that we have limited experience with and vary widely from country to country and from the United States. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals and may also incur significant costs in attempting to obtain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products in new jurisdictions, or if we fail to receive these approvals, we may be unable to market our products in international markets in a timely manner, if at all, which could materially impact our international expansion and adversely affect our business as a whole. If any of these risks were to materialize, they could limit our expected international growth and profitability, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Failure to comply with the Foreign Corrupt Practices Act (the "FCPA"), economic and trade sanctions regulations, and similar laws could subject us to penalties and other adverse consequences.

We are subject to the FCPA and other laws in the United States and elsewhere that prohibit improper payments or offers of payments to foreign governments and their officials and political parties for the purpose of obtaining or retaining business. Certain

suppliers and manufacturers of our devices and components of our devices are located in countries known to experience corruption. Business activities in these countries create the risk of unauthorized payments or offers of payments by one of our employees, contractors, or agents that could be in violation of various laws, including the FCPA and anti-bribery laws in these countries, even though these parties are not always subject to our control. While we have implemented policies and procedures designed to discourage these practices by our employees, consultants, and agents and to identify and address potentially impermissible transactions under such laws and regulations, we cannot assure you that none of our employees, consultants, and agents will take actions in violation of our policies, for which we may be ultimately responsible.

We are also subject to certain economic and trade sanctions programs that are administered by the U.S. Department of the Treasury's Office of Foreign Assets Control which prohibit or restrict transactions to or from or dealings with specified countries, their governments, and in certain circumstances, their nationals, and with individuals and entities that are specially-designated nationals of those countries, narcotics traffickers and terrorists or terrorist organizations.

Failure to comply with any of these laws and regulations or changes in this regulatory environment, including changing interpretations and the implementation of new or varying regulatory requirements by the government, may result in significant financial penalties or reputational harm, which could adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Our Reliance on Third Parties

Various factors outside our direct control may negatively impact our manufacturing of the Ceribell System, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We manufacture the Ceribell System at our manufacturing facilities in Sunnyvale, California, using Wearables supplied by third-party manufacturers located in China and Vietnam and components for our recorder procured from various suppliers and shipped to our facility for final assembly. While we believe that we currently have adequate manufacturing capacity and supplies to meet our demand forecasts, increases in demand, disruptions involving our third-party manufacturers or suppliers, including as a result of trade restrictions related to China, or expansion into additional geographies or indications may require us to expand our manufacturing capabilities, qualify new suppliers or engage additional manufacturers. Any inability to do so in a timely or cost-effective manner could adversely affect our ability to meet customer demand.

Our manufacturing operations and those of our third-party manufacturers and suppliers are subject to various risks, including production delays, equipment malfunctions, quality control issues, component shortages, personnel shortages, natural disasters, international conflicts, labor disputes, financial difficulties and other supply chain disruptions. Our manufacturing facility in Sunnyvale, California may be particularly susceptible to earthquakes and wildfires. Manufacturing difficulties, including contamination, human error or failure to follow established procedures, could reduce production yields, increase costs, delay product deliveries or require us to suspend manufacturing operations. In addition, changes in demand may require us to adjust our manufacturing operations, potentially resulting in additional costs, delays or quality issues. In addition, we may experience challenges managing the inventory of components of the Ceribell System, which can lead to excess inventory. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which could impact our gross margins. Reserves and write-downs for discounts, promotions, and excess inventory are recorded based on our strategic plans and forecast of future demand. Actual future demand could be less than our forecast, which may result in additional reserves and write-downs in the future.

Our dependence on third-party manufacturers and suppliers, including single-source suppliers, exposes us to additional risks, including interruptions or discontinuation of supply, price fluctuations, defects or reliability issues, and difficulties identifying and qualifying alternative suppliers. Changes in suppliers, components or manufacturing processes may also require additional testing, validation or regulatory approvals, which could delay production or commercialization. Furthermore, our manufacturing operations and those of our third-party manufacturers and suppliers must comply with applicable regulatory requirements, including the QMSR. Failure to comply with these requirements could result in production delays, regulatory enforcement actions, product recalls or other adverse consequences. See the risk factor titled, "*Our products must be manufactured in accordance with applicable laws and regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.*"

Any of these events could impair our ability to manufacture and deliver products in sufficient quantities, maintain required quality standards or meet customer demand, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We depend on a number of manufacturers and suppliers in connection with the manufacture of the Ceribell System, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We source and rely upon components and sub-assemblies of the Ceribell System, as well as manufacturing services from approved manufacturers and suppliers, some of which are single-source suppliers.

These components, sub-assemblies and services are critical to us, and there are relatively few alternative sources of supply. Our suppliers generally are not under long-term contracts with us, and may experience delays or issues, stop producing our components or sub-assemblies, increase the prices they charge us, or elect to terminate their relationships with us. In any of these cases, we could face a delay of several months to identify, perform appropriate testing and qualify alternative manufacturers and suppliers with regulatory authorities, as we currently have transition plans for some but not all of our manufacturers and suppliers. In addition, the failure of our third-party manufacturers and suppliers to maintain acceptable quality requirements could result in quality issues, including recalls of our products. If one of our manufacturers or suppliers fails to maintain acceptable quality requirements, we may have to identify and qualify a new manufacturer or supplier. Although we require our third-party manufacturers and suppliers to supply us with materials, components, and services that meet our specifications and comply with applicable provisions of the QMSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing, or other acceptance activities to ensure the materials and components meet our requirements, there is a risk that they may not supply components that meet our requirements or supply components in a timely manner.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on our manufacturing partners for compliance with cGMP regulations applicable to certain components of our products. Third-party manufacturers may not be able, or fail, to comply with cGMP regulations. If our third-party manufacturers cannot successfully manufacture our products that conform to our specifications and the strict regulatory requirements of the FDA, they will not be able to secure and/or maintain registration for their manufacturing facilities. In addition, we do not have complete control over the ability of our third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. The failure of our manufacturing partners to maintain acceptable quality requirements could result in quality issues, including recalls of our products. If one of our manufacturing partners fails to maintain acceptable quality requirements or perform as agreed, we may have to identify and qualify a new supplier or develop in-house manufacturing capabilities, which could require significant capital investments.

The number of third-party manufacturers and suppliers with the necessary manufacturing and regulatory expertise and facilities to produce our device components is limited and certification of a new manufacturer or supplier may be complex and time consuming. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new manufacturer or supplier with the appropriate regulatory authorities, including the FDA. The added time and cost to arrange for alternative manufacturers or suppliers could harm our business. New manufacturers of any planned product would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the planned product. Obtaining the necessary FDA or international approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property or other proprietary rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

We rely on third parties to conduct and support our preclinical studies and clinical trials. These third parties may not properly and successfully carry out their contractual duties or meet expected deadlines, which could harm our ability to obtain marketing authorization of or commercialize future products we develop.

We utilize and depend upon independent investigators and collaborators, such as third-party researchers, medical institutions, and strategic partners, to conduct and support portions of our preclinical studies and clinical trials under agreements with us, and may in the future rely on CROs. For some clinical research projects, we provide funding and for others, such as those supported by grants, we only provide access to our data or supply the Ceribell System at a discount. The terms of these agreements generally include joint publication rights and sole ownership of background intellectual property, as well as indemnification and insurance terms so that risk of injury or damages claims is appropriately allocated, guidelines for dispute resolution to address conflicts, and grounds for contract termination by each party.

We negotiate budgets and contracts with these third parties and may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We have relied heavily on these third parties for our preclinical studies and expect to continue to do so, and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing, and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required

to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for medical devices in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites.

If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or other bodies may require us to perform additional clinical trials. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our investigational devices must be produced in accordance with cGMP, which are now set forth in the QMSR (and were previously set forth in the QSR). Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the marketing authorization process. Moreover, our business may be implicated if any of these third parties violates federal, state or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Third parties conducting or supporting portions of our clinical trials are not our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our investigational products. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other product development activities, which could affect their performance on our behalf. These third parties may not successfully carry out their contractual duties or obligations or meet expected deadlines. They may need to be replaced or the quality or accuracy of the clinical data they obtain may be compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons. Accordingly, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain marketing authorizations for or successfully commercialize our future devices.

Switching or adding third parties to conduct or support portions of our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which could have an adverse impact on our product development, results of operations, and prospects.

Data Privacy Risk Factors

Actual or perceived failures to comply with applicable data privacy and security laws, regulations, standards and other requirements could adversely affect our business, financial condition, results of operations, and prospects.

The global data protection landscape is rapidly evolving, and we, and the third-party service providers on which we rely, are or may become subject to numerous state, federal, and foreign laws, requirements, and regulations, as well as contractual obligations and research protocols governing the collection, use, disclosure, retention, processing, maintenance, transfer, and security of personal information, such as information that we and our third-party service providers collect in connection with the use and development of the Ceribell System and the Clarity algorithm and in clinical trials or studies, including patient EEG data. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business; affect us or our service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer, use, process, and share personal information; necessitate the acceptance of more onerous obligations in our contracts; result in liability; impose additional costs on us; necessitate changes to our information technologies, systems and practices and those of third parties that process personal information on our behalf; and may require us to change our business model.

In the United States, numerous state and federal laws, regulations, standards, and other legal obligations, including consumer protection laws and regulations, which govern the collection, dissemination, use, access to, confidentiality, security, transfer, disclosure, and processing of personal information, including health-related information, could apply to our operations or the operations of our customers. For example, HIPAA imposes privacy, security, and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining, or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. Among other requirements, HIPAA requires business associates to develop and maintain policies with respect to the protection of, use and disclosure of protected health information ("PHI"), including the adoption of administrative, physical, and technical safeguards to protect such information, certain notification requirements in the event of a breach of unsecured PHI, and requirements to report breaches of unsecured PHI to covered entities within 60 days of discovery of the breach by the business associate or its agents. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if found to be in violation of HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, collection, use, processing, disclosure, and protection of health-related and other personal information. Such laws and regulations will be subject to

interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our customers. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA") requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have been passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. For example, Washington State enacted the Washington My Health My Data Act, which broadly defines consumer health data, creates a private right of action to allow individuals to sue for violations of the law, imposes stringent consent requirements, and grants consumers certain rights with respect to their health data, including to request deletion of their information. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

We may in the future become subject to foreign data protection laws, including the European Union and United Kingdom General Data Protection Regulations (together, the "GDPR"), which impose stringent requirements on the processing and cross-border transfer of personal data, including health information, and authorize fines of up to €20 million or 4% of annual global revenues, whichever is greater. As we expand into foreign countries and jurisdictions, we will become subject to additional laws and regulations that will affect how we conduct business, and legal uncertainty regarding international transfers of personal data may continue, which could increase our costs or affect how we operate our business.

The Federal Trade Commission (the "FTC") also has authority to initiate enforcement actions against entities that mislead customers about HIPAA compliance, make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of health information, fail to implement policies to protect health information, or engage in other unfair practices that harm customers or that may violate Section 5 of the FTC Act. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce under the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Additionally, federal and state consumer protection laws are increasingly being applied by FTC and states' attorneys general to regulate the collection, use, storage, and disclosure of health-related and other personal information, through websites or otherwise, and to regulate the presentation of website content.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations, research protocols, and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any actual or perceived failure by us or our employees, representatives, contractors, consultants, or other third parties to comply with such requirements or adequately address data privacy and security concerns, even if unfounded, could result in, among other adverse impacts, significant regulatory penalties and fines, our compliance with contracts entered into with our partners, collaborators, and other third-party payers, damage to our reputation, loss of customer confidence in our security measures, withdrawal or withholding of customer consent for using patient data, government investigations, and enforcement actions and litigation and claims by third parties, any of which could have a material adverse effect on our reputation, business, financial condition, results of operations, and prospects.

We may face risks associated with our use and development of AI and machine learning models.

We use and develop AI, machine learning and automated decision-making technologies, including proprietary AI and machine learning algorithms and models (collectively, "AI Technologies"), throughout our business, and are making significant investments in this area. For example, we use AI Technologies to power our Clarity algorithm and drive continuous improvements in the performance of the Ceribell System. New products that we develop, including expansion into new indications, are also likely to incorporate AI Technologies.

We expect that increased investment will be required in the future to continuously improve our use and development of AI Technologies. As with many technological innovations, there are significant risks involved in developing, maintaining, and deploying these technologies and there can be no assurance that the usage of or our investments in such technologies will always enhance our products or be beneficial to our business, including our efficiency or results of operations.

In particular, if the models underlying our AI Technologies are: incorrectly designed or implemented; trained or reliant on incomplete, inadequate, inaccurate, biased, or otherwise poor quality data, or on data to which we do not have sufficient rights or in relation to which we and/or the providers of such data have not implemented sufficient legal compliance measures; used without sufficient oversight and governance to ensure their responsible use; misused or used outside of scope of applicable regulatory authorizations; and/or adversely impacted by unforeseen defects, technical challenges, cybersecurity threats, or material performance

issues, the performance of our products and business, as well as our reputation and the reputations of our customers, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party, regulatory enforcement actions, or civil claims.

For the Clarity algorithm, as well as for any potential future AI Technology driven products, performance of the algorithm is generally assessed by comparing the output of the algorithm against a clinically derived reference standard ("ground truth") for a specified dataset. This applies to internal evaluation of an algorithm's performance, supporting external presentations and publications, and testing to support regulatory submissions. The Clarity algorithm output will not always agree with the opinion of a qualified neurologist, and in some cases multiple qualified neurologists will not agree with each other. While we constantly work to improve our product and algorithm, the AI Technologies we work with are novel and complex, and we cannot assure you that our AI Technologies will be able to perform as intended under all circumstances.

For example, an earlier version of the Clarity algorithm was found to be unable to detect seizure or status epilepticus in certain ICU patients who had cardiac arrest. Further, the data that we use to train our AI Technologies includes data collected from EEGs performed on patients by our customers, and we are dependent upon our ability to obtain the right to use such patient data to continue to develop our products, including within appropriate time frames and on commercially reasonable terms. If we are unable to obtain sufficient rights to use such data under applicable regulatory frameworks or our agreements with our customers, or our customers were to withdraw or withhold their data from us, our ability to continue to develop our products and services to our customers, and our revenue prospects, could be materially adversely impacted.

The regulatory framework for AI Technologies is rapidly evolving as many federal, state and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. The FDA has issued guidance documents relating to the incorporation of AI Technologies into medical devices. In addition, existing laws and regulations may be interpreted in ways that would affect the operation of our AI Technologies or could be rescinded or amended as new administrations take differing approaches to evolving AI Technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations.

In the United States, the federal executive branch has rescinded and modified executive orders and administrative policies relating to AI Technologies, and may continue to do so or implement new executive orders or rulemaking relating to AI Technologies in the future. Any such changes at the federal level could require us to expend significant resources to modify our products, services, or operations to ensure compliance or remain competitive. U.S. legislation related to AI Technologies has also been introduced at the federal level and is advancing at the state level. Such additional regulations may impact our ability to develop, use, and commercialize AI Technologies in the future.

It is possible that further new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of the Ceribell System and business and the way in which we use AI Technologies. We may need to expend resources to adjust the Ceribell System in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations, and prospects.

Our business and operations may suffer in the event of information technology system failures, cyber attacks, or deficiencies in our cybersecurity.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, transmit, and process large amounts of confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data, and personal information of clinical trial participants, patients of our customers, and our employees and contractors (collectively, "Confidential Information"). We may also share Confidential Information with our partners or other third parties in conjunction with our business. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

Our information technology systems and those of our customers, third-party service providers, manufacturers, and other contractors or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e.g., ransomware), misconfigurations, "bugs" or other vulnerabilities, malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyber attacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error,

unauthorized access, fraud, denial or degradation of service attacks, and sophisticated nation-state and nation-state-supported actors. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. The risk of a security breach or disruption, particularly through cyber attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and evolved. If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. There can also be no assurance that our and our customers', third-party service providers', contractors', and consultants' cybersecurity risk management programs and processes, including policies, controls, or procedures, will be fully implemented, complied with or effective in protecting our systems, networks, and Confidential Information.

Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, information technology systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques – including AI – that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our customers and service providers may be subject to cyber attacks and security incidents from time to time. While we do not believe that we have experienced any significant information technology system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure or misappropriation of our trade secrets, personal information, patient data collected from our customers or other Confidential Information or other similar disruptions. It could also expose us to risks, including an inability to provide our services and fulfill contractual demands, and could cause management distraction and the obligation to devote significant financial and other resources to mitigate such problems, which would increase our future information security costs, including through organizational changes, deploying additional personnel, reinforcing administrative, physical and technical safeguards, further training of employees, changing third-party vendor control practices, and engaging third-party subject matter experts and consultants and reduce the demand for our technology and services. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release, or other processing of personal information, including the patient data of our customers, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws and the costs associated with the investigation, remediation, and potential notification of the breach to third-parties and data subjects could be material.

Any security compromise affecting us, our service providers, strategic partners, other contractors, consultants, or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our products and services could be delayed. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business. Furthermore, federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. Any adverse impact to the availability, integrity, or confidentiality of our or third-party information technology systems or Confidential Information, whether actual or perceived, could result in liability, legal claims, or proceedings (such as class actions), regulatory investigations and enforcement actions, fines, and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation, and future compliance costs, any of which could materially and adversely affect our business, financial condition, results of operations, and prospects.

Our existing general liability and cyber liability insurance policies may not cover, or may cover only a portion of, any potential claims related to security breaches to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim. Accordingly, if our cybersecurity measures, and those of our customers and service providers, fail to protect against unauthorized access, attacks (which may include sophisticated cyber attacks), and the mishandling of data, then our reputation, business, financial condition, results of operations, and prospects could be materially and adversely affected.

Risks Related to Our Intellectual Property

Our success will depend on our and our licensors' ability to obtain, maintain, enforce, and protect our intellectual property rights.

Our success and ability to compete depends in part on our and our licensors' ability to obtain, maintain, enforce, and protect issued patents, trademarks, trade secrets, and other intellectual property rights and proprietary technology in the United States and elsewhere. If we cannot adequately obtain, maintain, and enforce our intellectual property rights and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have and our ability to compete, which could harm our business and ability to achieve profitability and/or cause us to incur significant expenses. We generally seek to protect our proprietary position by filing patent applications that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications or other intellectual property or proprietary rights from third parties. If we are unable to obtain or maintain patent protection with respect to any proprietary technology, our business, financial condition, results of operations, and prospects could be materially harmed.

We rely on a combination of contractual provisions, confidentiality procedures, and patent, trademark, copyright, trade secret and other intellectual property laws to protect the proprietary aspects of the Ceribell System, brand, technologies, trade secrets, know-how, and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property rights and proprietary information. In addition, patents have a limited lifespan. In the United States, for example, the natural expiration of a utility patent is generally 20 years from the earliest effective non-provisional filing date. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how, and obtaining, maintaining, and enforcing other intellectual property rights. We may not be able to obtain, maintain, and/or enforce our intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend, or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner, or in all jurisdictions. Moreover, pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover relevant product, service, or the technology. There can be no assurance that our current or future patent applications will result in patents being issued or that our issued patents will afford sufficient protection against competitors or other third parties with similar products, services or technologies competitive with ours, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our licensors' intellectual property or other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property or other proprietary rights relating to our products, services and technologies could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our licensors, will be considered patentable by the USPTO or courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged. Our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Additionally, regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our products, services, technologies, or activities.

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

The degree of future protection for our intellectual property rights is uncertain, and we cannot ensure that:

- others will not develop, manufacture and/or commercialize similar or alternative products, services, or technologies that do not infringe, misappropriate, or violate any patents or other intellectual property rights that we own or have rights to;
- any patents issued to us will provide a basis for an exclusive market for our products, services, or technologies, will provide us with any competitive advantages or will not be challenged, invalidated, modified, revoked, or circumvented by third parties;

- any of our challenged patents will be found to ultimately be valid and enforceable;
- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products, services, or technologies;
- any of our pending patent applications will issue as patents, or even if issued, will include claims with a scope sufficient to protect our products, services, or technologies;
- we will be able to successfully develop, manufacture, and commercialize our products, services, or technologies on a substantial scale before relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications or we were the first to file patent applications for such inventions;
- we will develop additional proprietary inventions, products, services, or technologies that are separately patentable; or
- our commercial activities, products, services, or technologies will not infringe upon the patents of others.

If we fail to identify our patentable inventions or adequately protect our patent rights, the commercial value of our products, services or technologies may be adversely affected and our competitive position may be harmed.

We rely in part on our portfolio of issued patents and pending patent applications in the United States and other countries to protect our intellectual property and competitive position. However, it is also possible that we may fail to identify patentable aspects of inventions made in the course of the development, manufacture, and commercial activities conducted by or on behalf of us before it is too late to obtain patent protection on such inventions. If we fail to timely file for patent protection in any jurisdiction, we may be precluded from doing so at a later date. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, suppliers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Moreover, as a licensee of third parties' patents or patent applications, depending on the terms of our existing and any future in-licenses, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain or enforce the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted, maintained, and/or enforced in a manner consistent with the best interests of our business. While we generally apply for patents in those countries where we intend to make, have made, use, import, offer for sale, or sell our products or services or otherwise practice our technology, we may not accurately predict all of the countries where patent protection will ultimately be desirable. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from importing, using, manufacturing, and/or commercializing our own products or services, or otherwise practicing our own technology. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of companies, including our patent position, may involve complex legal and factual questions that have been the subject of much litigation in recent years, and, therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances about which of our patent applications will issue, the breadth of any resulting patent, whether any of the issued patents will be found to be infringed, invalid, or unenforceable or will be threatened or challenged by third parties, that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our products, services, or technology. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We cannot offer any assurances that the breadth of our issued patents will be sufficient to stop a competitor from developing, manufacturing, and commercializing one or more products, services, or technologies in a non-infringing manner that would be competitive with one or more of our products, services, or technologies, or otherwise provide us with any competitive advantage. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for our commercial success. Further, there can be no assurance that we will have adequate resources to enforce our patents.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products or services. Patents, if issued, may be challenged, deemed unenforceable, invalidated, narrowed, or circumvented. Proceedings challenging our patents or patent applications could result in either loss of the patent, or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Any successful challenge to our patents and patent applications could deprive us of exclusive rights necessary for our commercial success. In addition, defending such challenges in such proceedings

may be costly. Thus, any patents that we own or in-license may not provide the anticipated level of, or any, protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to develop, manufacture, commercialize, import, or otherwise use our products, services, or technologies.

Some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products, services, or technologies. In addition, we may need the cooperation of any such co-owners of our patents to enforce such patents against third parties, and such cooperation may not be provided to us.

Changes in U.S. or foreign patent laws or their interpretations could diminish the value of our patents in general, thereby impairing our ability to protect our current and future products, services, or technologies, and could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our current or future patents.

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

Patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain or license in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business, financial condition, results of operations, and prospects.

Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patent and intellectual property laws. We may encounter significant problems in enforcing and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in other countries, our ability to protect our intellectual property rights in those countries may be limited. We cannot predict future changes in the interpretation of patent laws in the United States and other countries or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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

Filing, prosecuting, and defending patents on our products, services, and technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third-parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, services, or technologies and, further, may export otherwise infringing products, services, or technologies to territories where we have patent protection, but

enforcement is not as strong as that in the United States. These products, services, or technologies may compete with our products, services, or technologies, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

Various companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries may not favor the enforcement of patents and other intellectual property protection, particularly those relating to medical devices and related services and technologies, which could make it difficult for us to stop the infringement of our patents or marketing of competing products, services, and technologies in violation of our intellectual property and proprietary rights. In addition, some jurisdictions, such as Europe, Japan, and China, may have a higher standard for patentability than in the United States, including, for example, imposing a high standard for making claim amendments and for the submission of supplemental experimental data during patent examination. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent rights at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing and could 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 meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied predictably. As such, we do not know the degree of world-wide uniform protection that we will have on our technologies and products in the future.

If we cannot successfully enforce our intellectual property rights, the commercial value of our products, services, or technologies may be adversely affected and our competitive position may be harmed.

The medical device industry is highly competitive and litigious with respect to patents, trademarks, trade secrets, and other intellectual property rights. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Third parties, including our competitors, may currently, or in the future, infringe, misappropriate, or otherwise violate our issued patents or other intellectual property rights, and we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time-consuming, and unsuccessful. We regularly monitor for unauthorized use of our intellectual property rights and, from time to time, analyze whether to seek to enforce our rights against potential infringement, misappropriation, or violation of our intellectual property rights. However, the steps we have taken, and are taking, to protect our proprietary rights may not be adequate to enforce our rights as against such infringement, misappropriation, or violation of our intellectual property rights. In certain circumstances it may not be practicable or cost-effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity. Our ability to enforce our patent or other intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products, services, or technologies. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product, services, or technologies. Thus, we may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our products, services, and technologies. We are currently involved in litigation against Natus, which is more fully described in "Part II, Item 1. Legal Proceedings" of this report, to protect or enforce our intellectual property rights, and we may initiate or become subject to additional litigation in the future. Litigation is inherently uncertain, may result in counterclaims or challenges to the validity of our patents, and can be costly and time-consuming. An adverse result in any litigation proceeding could harm our business. In any lawsuit we bring to enforce our intellectual property rights, a court may refuse to stop the other party from manufacturing, commercializing, using or importing the product, service, offering or technology at issue on grounds that our intellectual property rights do not cover, and the other party is not infringing, violating or otherwise misappropriating our intellectual property, through the manufacture, commercialization, use or importation of the product, service, offering or technology in question. Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate, or otherwise violate their intellectual property rights. If we initiate legal proceedings against a third party to enforce a patent covering a product, service, offering or technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from USPTO, or made a misleading statement, during prosecution. Mechanisms for such challenges

include reexamination, post-grant review, *inter partes* review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In a patent or other intellectual property proceeding, a court may decide that a patent or other intellectual property right of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from manufacturing, commercializing, using or importing the product, service, offering, or technology at issue on the grounds that our patents or other intellectual property do not cover the manufacture, commercialization, use, or importation of the product, service, offering, or technology in question. Furthermore, even if our patents or other intellectual property rights are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or administrative proceeding could put one or more of our patents or other intellectual property rights at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business, financial condition, results of operations and prospects. Moreover, even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings. A legal proceeding, regardless of the outcome, could drain our financial resources and divert the time and effort of our management. Protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our products in any jurisdiction. Patent applications in the United States, the European Union and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or the use of our products. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the European Union or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products, if approved.

Although our agreements with third-party manufacturing partners generally seek to prevent them from misusing our intellectual property and trade secrets, or using our designs to manufacture products for our competitors, we may be unsuccessful in monitoring and enforcing our intellectual property rights against these manufacturing partners and may find counterfeit goods in the market being sold as our products or future products similar to ours produced for our competitors using our intellectual property. Although we take steps to stop counterfeits, we may not be successful and customers who purchase these counterfeit goods may experience product defects or failures, harming our reputation and brand and causing us to lose future sales. Any of the foregoing could harm our business, financial condition and results of operations.

We may become a party to intellectual property litigation or administrative proceedings that could be expensive, time-consuming, and unsuccessful, and could interfere with our ability to develop, manufacture, commercialize, import, or otherwise use our products, services, or technologies.

Our commercial success depends, in part, on our ability to develop, manufacture, commercialize, import, or use our products, services, and technologies without infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. Our industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. While we take steps to ensure that we do not infringe upon, misappropriate, or otherwise violate the intellectual property rights of others, there may be other more pertinent rights of which we are presently unaware.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights. The outcomes of such proceedings are uncertain and could have a negative impact on the success of our business. It is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products, services, and technologies, or that we may be accused of misappropriating third parties' trade secrets or infringing third parties' trademarks. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products, services, or technologies, including post grant review and *inter partes* review before the USPTO or equivalent foreign regulatory authority. Furthermore, we may also become involved in other proceedings, such as reexamination, derivation, or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents, which our current or future products, services, or technologies infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid and enforceable, and infringed by the use of our products, services, or technologies, which could have a negative impact on the commercial success of our current and any future products, services, or technologies. If we were to challenge the validity of any such third-party U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. We will have similar burdens to overcome in foreign courts in order to successfully challenge a third-party claim of patent infringement.

Our defense of any litigation or administrative proceedings may fail and, even if successful, defending such claims brought against us would cause us to incur substantial expenses and distract our management and other employees. If such claims are successfully asserted against us, we could be forced to pay substantial damages. Further, if a patent infringement or other intellectual property rights-related lawsuit were brought against us, we could be forced, including by court order, to cease developing, manufacturing, commercializing, importing, or using the infringing product, service, or technology. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Although patent, trademark, trade secret, and other intellectual property disputes have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may not be able to obtain licenses on commercially reasonable terms or at all, in which event our business would be materially and adversely affected. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors and other third parties gaining access to the same intellectual property. Ultimately, if we are unable to obtain such licenses or make any necessary changes to our products, services, or technologies, we could be forced to cease some aspect of our business operations, which could harm our business significantly.

A finding of infringement or an unfavorable outcome in an administrative proceeding could prevent us from developing, manufacturing, commercializing, importing, or using our products, services, or technologies, or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations, and prospects. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. We could encounter delays in product introductions while we attempt to develop alternative products or technologies.

If third parties assert infringement, misappropriation, or other claims against our customers, these claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products, services, or technologies they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, services, or technologies.

Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit, or otherwise interfere with our ability to make, use, sell, import, and/or export our products, services, or technologies. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us may increase. Moreover, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," purchase patents, and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products, services, or technologies and business operations infringe, misappropriate, or otherwise

violate the intellectual property rights of others. These matters can be time-consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand, and cause us to incur significant expenses or make substantial payments. In addition, we purchase product components, including hardware and software, from suppliers, and the design of these components may be outside of our direct control. These suppliers may not indemnify us in the event that a third party alleges the use of such components infringes its intellectual property rights.

Any lawsuits relating to intellectual property rights could subject us to significant liability for damages and invalidate our intellectual property. Any potential intellectual property litigation also could force us to stop developing, making, selling, importing, or using affected products, services, or technologies, or to redesign them, which could be costly, disruptive, and infeasible. We could also be required to pay substantial damages, royalties, or the other party's attorneys' fees and costs, to seek a license that may not be available on commercially reasonable terms or at all, or to forgo opportunities to license our own intellectual property rights and collect royalties, and we would incur significant legal expenses.

Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post-grant review, *inter partes* review, and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our products, services, or technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our products, services, or technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, even if resolved in our favor, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business. Any of the foregoing 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.

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

We may also be subject to claims that our current or former employees, contractors, or other third parties have an ownership interest in our current or future patents, patent applications, or other intellectual property rights, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of employees, consultants, or others who were or are involved in developing our products, services, or technologies. Although it is our policy to require our employees and contractors who may be involved in the conception or development of inventions to execute agreements assigning such inventions and intellectual property rights therein to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops inventions that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of inventions may not be self-executing, or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership of inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or the right to use, valuable intellectual property rights, and other owners may be able to license their interest in such intellectual property rights to other third parties, including our competitors. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, we may be subject to claims from third parties challenging inventorship or ownership of intellectual property rights we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign their inventions and intellectual property rights therein to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions and intellectual property rights therein to another employer, to a former employer, or to another person or entity. Many of our current and former employees and consultants were previously employed at or engaged by other medical device companies, including our competitors or potential competitors. Some of these employees and consultants have executed with such previous employment or engagements confidential information non-disclosure and non-use agreements and inventions assignment agreements, which may have included non-competition provisions. Although we try to ensure that such employees and consultants do not use or otherwise disclose

confidential information or intellectual property rights of others in their work for us without such other person's consent, we may be subject to claims that we or our current or former employees or consultants have, inadvertently or otherwise, infringed, violated, or otherwise misappropriated the confidential information or the intellectual property rights of these former employers, clients, or other third parties. To the extent that our current or former employees or consultants disclose or use confidential information or intellectual property rights owned by others in their work for us, disputes may arise as to the rights in any related or resulting inventions and litigation may be necessary to defend against these claims. It may also be necessary or we may desire to obtain a license to such third party's intellectual property rights to settle any such claim; however, there can be no assurance that we would be able to obtain such license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages or a settlement payment, a court could prohibit us from manufacturing, commercializing, using or importing the product, service, or technology features or practicing other intellectual property rights that are essential to our business, which could have a material adverse effect on our competitive position as well as our business, financial condition, results of operations, and prospects. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management and our employees. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with collaborators, partners, service providers, or contractors. A loss of key personnel or their work product could hamper or prevent our ability to develop, manufacture, commercialize, import, or use our products, services, or technologies, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

We depend on certain intellectual property rights that are licensed to us. We may be unsuccessful in licensing or acquiring intellectual property rights from third parties that may be necessary to develop, manufacture, commercialize, import, or use our current and/or future products, services, or technologies.

The "brain stethoscope" EEG sonification technology, which processes data and turns it into sound, that is used in the Ceribell System is protected by intellectual property rights that we in-license from Stanford University. See the section titled "Business—Stanford Agreement" in our Annual Report on Form 10-K. We exercised our option to extend exclusivity under certain licensed patent rights owned or controlled by Stanford University through the expiration date of the last-to-expire licensed patent. However, there can be no assurance that such exclusivity will be effective in all jurisdictions or that the underlying patents will not be challenged. Our rights to use such intellectual property rights in our business are also subject to the continuation of and our compliance with the terms of the license agreements between us and each of our licensors. In addition, the agreements under which we in-license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement. Moreover, if disputes over intellectual property that we have in-licensed, or in-license in the future, prevent, or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Despite our best efforts, our current or future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, this could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development, manufacture, commercialization, import or use of our current and/or future products, services, or technologies, in which case we would need to acquire or obtain a license to such intellectual property rights from such third party. A third party that perceives us to be a competitor may be unwilling to license or assign its intellectual property rights to us. In addition, the licensing or acquisition of third-party intellectual property rights is a competitive area, and other companies may also pursue similar strategies to license or acquire such third party's intellectual property rights. Some of these companies may have a competitive advantage over us due to their size, capital resources and greater development, manufacturing, and commercialization capabilities. We also may be unable to license or acquire third party intellectual property rights on commercially reasonable terms that would allow us to make an appropriate return on our investment, or we may be unable to obtain any such license or acquisition at all. If we are unable to successfully license or acquire necessary third-party intellectual property rights, we may not be able to develop, manufacture, commercialize, import, or use our current and/or future products, services, or technologies, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to protect the disclosure and use of our confidential information and trade secrets, the value of our products, services, and technologies and our business and competitive position could be harmed.

In addition to patent protection, we also rely on other intellectual property rights, including trade secrets, know-how, and/or other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some

courts are less willing or unwilling to protect trade secrets. To protect and maintain the confidentiality of our trade secrets and other proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators, and other third parties. We generally enter into confidentiality and inventions assignment agreements with our employees, consultants, and applicable third parties upon their commencement of a relationship with us. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes, and we may not enter into such agreements with all employees, consultants, and third parties who have been involved in the development of our inventions. Although we generally require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. We may also need to share our proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad.

In addition, despite the protections we place on our intellectual property and our other proprietary rights, monitoring unauthorized use and disclosure by employees, consultants, and other third parties who have access to such intellectual property or other proprietary rights is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. Therefore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such employees, consultants, advisors, or third parties, despite the existence of our protections, including non-disclosure and use restrictions. These agreements may not provide meaningful protection against the unauthorized disclosure or use of our trade secrets, know-how, or other proprietary information in the event the unwanted use is outside the scope of the provisions of the contracts or in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how or other proprietary information that we fail to detect. There can be no assurances that such employees, consultants, advisors, or third parties will not intentionally or unintentionally breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by third parties, including our competitors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that information to compete with us. In addition to contractual measures, we try to protect the confidential nature of our proprietary information by maintaining physical security of our premises and electronic security of our information technology systems. Such security measures may not, for example, in the case of misappropriation of a trade secret by an employee, consultant or other third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee, consultant, or other third party from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully.

If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. The exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our business, financial condition, results of operations, and prospects. In particular, a failure to protect our proprietary rights may allow competitors to copy our products, services, or technologies, which could adversely affect our pricing and market share. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products, services, or technologies that we consider proprietary. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality, non-disclosure, and non-use provisions, and outcomes of such litigation are unpredictable. Enforcing a claim that a party illegally disclosed, used or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. While we use commonly accepted security measures, trade secret violations are often a combination of federal and state law in the United States, and the criteria for protection of trade secrets can vary among different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases. Finally, even if we were to be successful on the enforcement of our claims, we may not be able to obtain adequate remedies.

It is also possible that others may independently develop information or technologies that are the same as or similar to our trade secrets or other proprietary technologies and develop products, services, or technologies without obtaining access to our trade secrets or other proprietary information in which case we could not assert any intellectual property rights, including trade secret rights, against such parties in a manner that could prevent legal recourse by us. If we fail to obtain or maintain trade secret protection, or if any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or used by others without our consent or otherwise misappropriated, or if any such information was independently developed by a competitor, or if our competitors obtain our trade secrets or independently develop products, services, or technologies that are the same as or similar to ours, our competitive market position could be materially and adversely harmed.

If our trademarks and trade names are not adequately protected, we may not be able to build brand name recognition in our markets of interest and our competitive position may be harmed.

Our trademarks could be challenged, opposed, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or descriptive, or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our company, products, services, or technologies, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Further, there can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long-term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Our products contain third-party open source software components and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell our products, affect our ability to protect our proprietary information, and subject us to possible litigation.

Our products contain software tools licensed by third parties under open source software licenses. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source software licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open source software licenses contain requirements that the licensee make its source code publicly available if the licensee creates modifications or derivative works using such open source software, depending on the type of open source software the licensee uses and how the licensee uses it. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source software licenses, be required to make available the source code of certain of our proprietary software to the public for free. This could allow our competitors to create similar products with less development effort and time and ultimately could result in a loss of product sales and revenue. In addition, some companies that use third-party open source software have faced claims challenging their use of such open source software and their compliance with the terms of the applicable open source license. We may be subject to suits by third parties claiming ownership of what we believe to be open source software or claiming noncompliance with the applicable open source licensing terms. Use of open source software may also present additional security risks because the public availability of such software may make it easier for hackers and other third parties to compromise or attempt to compromise our technology platform and systems.

We are subject to certain manufacturing restrictions related to licensed intellectual property rights that were developed with the financial assistance of United States government grants.

Under the Bayh-Dole Act, the federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" in inventions produced with its financial assistance ("Government Funded Inventions") for its own benefit. The Bayh-Dole Act provides federal agencies with march-in rights ("March-In Rights"), which allows a government agency, in specified circumstances, to require the patent owner or successors in title to the patent directed to such Government Funded Inventions ("Patent Owner") to grant a "nonexclusive, partially exclusive or exclusive license" to a "responsible applicant or applicants," which if exercised, would allow such government agency to require such Patent Owner to grant a non-exclusive, partially exclusive, or exclusive license in any field of use to a third party designated by such agency. The Bayh-Dole Act also provides that the Patent Owner manufacture products embodying the respective Government Funded Inventions domestically in accordance with certain requirements. If this domestic manufacturing requirement is not met, the government agency that funded the relevant grant is entitled to exercise March-In Rights. We are subject to the Bayh-Dole Act with respect to licensed technology that was developed with United States government grants. Such licensed technology is used in our recorders. Further, we cannot be sure that if we acquire intellectual property rights in the future they will be free from government rights or regulations pursuant to the Bayh-Dole Act.

If we own, co-own, or in-license Government Funded Inventions that are critical to our business, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected. Further, the exercise of March-In Rights, the requirement that we grant additional licenses to third parties, or the termination of our license of the relevant technologies could materially adversely affect our business, financial condition, results of operations and prospects. The restrictions of the Bayh-Dole Act may also limit our ability to manufacture our products in locations where it may be otherwise more favorable for us to do so, which could limit our ability to respond to competitive developments or otherwise adversely affect our results of operations. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Financial and Accounting Matters

Our ability to use our net operating loss carryforwards and other tax attributes may be limited due to certain provisions of the Internal Revenue Code or state tax law.

We have incurred substantial losses during our history and may never achieve profitability. U.S. federal net operating loss carryforwards ("NOLs") we generated in tax years through December 31, 2017, may be carried forward for 20 years and may fully offset taxable income in the year utilized, and federal NOLs we generated in tax years beginning after December 31, 2017, may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually for tax years beginning after December 31, 2020. As of December 31, 2025, we had NOLs of approximately $165.6 million for federal income tax purposes and $157.6 million for state income tax purposes.

Realization of these NOLs depends on future taxable income, and there is a risk that our existing NOLs could expire unused and be unavailable to offset future taxable income, which could adversely affect our results of operations.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change federal NOLs and other tax attributes (such as tax credits) to offset its post-change taxable income and taxes may be limited. In general, an "ownership change" occurs if there is a greater than 50 percentage point change (by value) in a corporation's equity ownership by certain stockholders over a rolling three-year period. Transactions that have occurred since our formation may result in an ownership change. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, our ability to use pre-change federal NOLs and other tax attributes to offset future taxable income and taxes could be subject to limitations. Similar provisions of state tax law may also apply. For these reasons, even if we achieve profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

Changes in tax laws or tax rulings could adversely affect our effective tax rates, results of operations and financial condition.

The tax regimes we are subject to or operate under are unsettled and may be subject to significant change. This challenge will continue to increase as we expand our operations globally. Changes in tax laws, issuance of new tax rulings or changes in interpretations of existing laws could cause us to be subject to additional income-based taxes and non-income-based taxes, including payroll, sales, use, value-added, digital, net worth, property and goods and services taxes, which in turn could adversely affect our results of operations and financial condition. In particular, the U.S. government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income, significant changes to the taxation of income derived from international operations, and it may enact further limitations on the deductibility of business interest. For example, on July 4, 2025, the OBBB Act was enacted, introducing amendments to U.S. tax laws with various effective dates from 2025 to 2027, including changes to the treatment of research and development expenses under Section 174 of the Internal Revenue Code of 1986, as amended, modifications to the global intangible low-taxed income regime, new minimum or book-based taxes, and limitations on interest deductibility.

We are unable to predict what changes to the tax laws of the U.S. and other jurisdictions may be proposed or enacted in the future or what effect such changes would have on our business. Any of these or similar developments or changes to tax laws or rulings (which changes may have retroactive application) could adversely affect our effective tax rate and our results of operations and financial condition.

Our Credit Agreement contains financial covenants and other restrictions that limit our flexibility in operating our business.

On August 5, 2026, we entered into the Credit Agreement, which provides for term loan and revolving loan facilities. At closing, we borrowed $20.0 million under the revolving loan facility and no term loans and used the proceeds to repay in full all amounts outstanding under the VLSA, which was terminated in connection with the repayment. Our obligations under the Credit Agreement are secured by a security interest in substantially all of our assets, including our intellectual property, subject to customary exclusions. The Credit Agreement contains customary affirmative and negative covenants that limit our ability to engage in specified types of

transactions. The Credit Agreement also contains financial covenants that are tested quarterly, but only while the sum of our outstanding term loans and the revolving loan commitment exceeds $35.0 million. When tested, we must maintain minimum net revenue of $70.0 million. If we fail to satisfy that covenant, we must also maintain minimum unrestricted cash of $65.0 million on a continuous basis. In addition, if our liquidity falls below $50.0 million, the lenders may require that cash we collect be swept daily to repay the revolving loans. The covenants limit our ability to, among other things:

- sell, transfer, lease, license or otherwise dispose of assets, other than permitted asset dispositions;
- create, incur, assume, guarantee or otherwise become liable with respect to additional indebtedness or contingent obligations, other than permitted indebtedness and contingent obligations;
- create or permit liens on our assets, other than permitted liens;
- make distributions, including paying dividends on, repurchasing or making other payments with respect to our capital stock, other than permitted distributions;
- consolidate, merge or amalgamate with another person, other than specified permitted transactions;
- make investments or acquisitions, including acquisitions of businesses, assets, products, product lines or intellectual property, other than permitted investments;
- enter into joint ventures or partnerships; and
- enter into certain transactions with our affiliates.

After December 31, 2027, availability under the revolving loan facility will be subject to a borrowing base based on eligible accounts receivable and inventory, which could reduce the amount available to us under the facility.

See also “Management’s Discussion and Analysis of Financial Condition and Results of Operations”—“Liquidity and Capital Resources” for more information regarding the covenants under the Credit Agreement. The covenants in the Credit Agreement limit our ability to take certain actions and could adversely affect our ability to finance our operations, make needed capital expenditures, engage in business combinations or otherwise pursue our business strategies. In addition, if we fail to comply with a covenant or other obligation under the Credit Agreement and an event of default occurs and continues, the lenders may suspend or terminate their lending commitments, accelerate all or a portion of the amounts outstanding under the Credit Agreement, together with accrued interest, and exercise remedies against the collateral securing such indebtedness, including substantially all of our assets and intellectual property. Any such acceleration or exercise of remedies could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Ownership of Our Common Stock

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

We are an “emerging growth company” as defined in the JOBS Act. We will remain an “emerging growth company” until the earliest to occur of:

- the last day of the fiscal year during which our total annual revenue equals or exceeds $1.235 billion (subject to adjustment for inflation);
- the last day of the fiscal year following the fifth anniversary of the completion of our IPO;
- the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt; or
- the date on which we are deemed to be a “large accelerated filer” under the Exchange Act.

As a result of our “emerging growth company” status, we may take advantage of exemptions from various reporting requirements that would otherwise be applicable to public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We also are a “smaller reporting company” as defined in the Exchange Act. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal

years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Investors may 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 the market price of our common stock may be adversely affected and more volatile.

We incur significant costs as a result of operating as a public company. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would seriously harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the SEC require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. The reporting requirements, rules and regulations have and will likely continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404") and the related rules of the SEC, which generally require our management to report on the effectiveness of our internal control over financial reporting. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm our business.

We do not intend to pay dividends in the foreseeable future. As a result, your ability to achieve a return on your investment will depend on appreciation in the market price of our common stock.

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our Board of Directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, prospects, financial condition, contractual restrictions and capital requirements. In addition, our ability to pay cash dividends on our capital stock is limited by the terms of the Credit Agreement, and may be limited by the terms of any future debt or preferred securities we issue or any future credit facilities we enter into. Accordingly, investors must for the foreseeable future rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

If our operating and financial performance in any given period does not meet the guidance provided to the public or the expectations of investment analysts, the market price of our common stock may decline.

We have provided, and may in the future provide, public guidance on our expected operating and financial results for future periods. Any such guidance will be consisted of forward-looking statements subject to the risks and uncertainties described in this Quarterly Report and in our other public filings and public statements. The ability to provide this public guidance, and the ability to accurately forecast our results of operations, will be impacted by a number of factors, many of which are out of our control. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic or regulatory uncertainty. If, in the future, our operating or financial results for a particular period do not meet any guidance provided or the expectations of investment analysts or investors generally, or if we reduce our guidance for future periods, the market price of our common stock may decline. Even if we do issue public guidance, there can be no assurance that we will continue to do so in the future.

We may require additional capital to support business growth, and this capital might not be available on terms favorable to us, or at all, and may dilute existing stockholders' ownership of our common stock.

We intend to continue to make investments to support our business growth and may require additional funds to respond to business challenges and opportunities, including the need to develop new products, enhance our existing products, enhance our operating infrastructure, potentially expand internationally, and potentially acquire complementary businesses and technologies. In order to achieve these objectives, we may make future commitments of capital resources. Accordingly, we may need to engage in equity or debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. In addition, the incurrence of indebtedness would increase our fixed obligations and include covenants or other restrictions that would impede our ability to manage our operations. Further, if additional financing is needed, we may not be able to obtain additional financing on terms favorable to us or at all. Our inability to obtain adequate financing or financing on terms satisfactory to us, when we require it, could significantly limit our ability to continue supporting our business growth and responding to business challenges and opportunities. Furthermore, future issuances of our common stock, the exercise of outstanding options, the vesting of restricted stock units and other equity awards, or the perception that such issuances or sales may occur, could depress the market price of our common stock and result in additional dilution to our stockholders.

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

As of September 30, 2026, our executive officers, directors, owners of more than 5% of our capital stock and their respective affiliates beneficially owned approximately 42% of our common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our Board of Directors. These provisions include the following:

- a classified Board of Directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board of Directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our Board of Directors to elect a director to fill a vacancy created by the expansion of the Board of Directors or the resignation, death, or removal of a director, which prevents stockholders from being able to fill vacancies on our Board of Directors;
- the ability of our Board of Directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our Board of Directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or to repeal certain provisions of our amended and restated certificate of incorporation;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by our Board of Directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our Board of Directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the General Corporation Law of the State of Delaware (the "Delaware General Corporation Law"). Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the Board of Directors has approved the transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, or stockholders to us or to our stockholders, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws (as either may be amended from time to time), or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America are the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees, or agents and arising under the Securities Act. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware (a "Foreign Action"), in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder. Although our amended and restated certificate of incorporation contains the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums, and protection against the burdens of multi-forum litigation. However, this choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees, or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition, results of operations, and prospects.

The market price of our common stock may be volatile, which could cause the value of your investment to decline.

The market price of our common stock may be highly volatile and could fluctuate or decline significantly in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated fluctuations in our financial condition or results of operations;
- variance in our financial performance from expectations of securities analysts;
- sales of shares of our common stock by us or our stockholders, or the anticipation of such sales;
- hedging activities by market participants;

- announcements by us or our competitors of significant products or features, technical innovations, acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in operating performance and stock market valuations of companies in our industry, including our competitors;
- changes in third-party payer reimbursement policies;
- an inability to obtain additional funding;
- general economic, industry and market conditions, including price and volume fluctuations in the overall stock market;
- lawsuits threatened or filed against us;
- developments in new legislation and pending lawsuits or regulatory actions, including interim or final rulings by judicial or regulatory bodies; and
- other events or factors, including those resulting from political conditions, election cycles, geopolitical actions, including unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements, war or incidents of terrorism, or responses to these events, many of which are outside of our control.

In addition, extreme price and volume fluctuations in the stock markets have affected and continue to affect many medical device and technology companies' stock prices. Stock prices often fluctuate in ways unrelated or disproportionate to the companies' operating performance. In the past, stockholders have filed securities class action litigation following periods of market volatility. This risk is especially relevant for us because medical technology companies have experienced significant stock price volatility in recent years. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and seriously harm our business.

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenues or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings forecasts that we may provide.

General Risk Factors

We or the third parties we depend on may be adversely affected by natural disasters and other catastrophic events, and our business continuity and disaster recovery plans may not adequately protect us from a serious natural disaster or other catastrophic event. Any interruption in our operations or the operations of third parties who supply components or other materials for our products may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Severe weather, natural disasters and other catastrophic events, including pandemics or other public health crises (such as the COVID-19 pandemic), earthquakes, tsunamis, hurricanes, floods, fires, explosions, accidents, power outages, cyber attacks, telecommunications failures, mechanical failures, unscheduled downtimes, civil unrest, strikes, transportation interruptions, unpermitted discharges or releases of toxic or hazardous substances, other environmental risks, wars or other conflicts (including wars in Ukraine and the Middle East), sabotage, terrorist attacks, or other intentional acts of vandalism or misconduct could severely disrupt our operations, or the operations of third parties who manufacture or supply components or other materials for our products, and have a material adverse effect on our business, financial condition, results of operations, and prospects.

If a natural disaster or other catastrophic event occurs that prevents us or third-party suppliers or manufacturers from using all or a significant portion of our or their headquarters or other facilities, that damages critical infrastructure or that otherwise disrupts operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar catastrophic event. The potential impact of any disruption would depend on the nature and extent of the damage caused by a disaster. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, our corporate headquarters and manufacturing facilities are located in Sunnyvale, California, near major earthquake faults and fire zones. We do not carry earthquake insurance. Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen, and severe adverse events.

We are subject to risks from legal and arbitration proceedings that may prevent us from pursuing our business activities or require us to incur additional costs in defending against claims or paying damages.

We may become subject to legal disputes and regulatory proceedings in connection with our business activities involving, among other things, product liability, product defects, intellectual property infringement, employment matters, and/or alleged violations of other applicable laws in various jurisdictions. We may not be insured against all potential damages that may arise out of any claims to which we may be party in the ordinary course of our business. A negative outcome of these proceedings may prevent us from pursuing certain activities and/or require us to incur additional costs in order to do so and pay damages. In addition, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition, results of operations and prospects. Additionally, the significant increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

The outcome of pending or potential future legal and arbitration proceedings is difficult to predict with certainty. In the event of a negative outcome of any material legal or arbitration proceeding, whether based on a judgment or a settlement agreement, we could be obligated to make substantial payments, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, the costs related to litigation and arbitration proceedings may be significant.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

On October 15, 2024, we completed our IPO, in which we issued and sold 12,196,969 shares of our common stock, which includes an additional 1,590,909 shares of common stock purchased by the underwriters pursuant to their option to purchase additional shares, at a price to the public of $17.00 per share. The proceeds to the Company from the IPO were approximately $188.2 million, net of underwriting discounts and commissions and estimated offering costs. There has been no material change in the intended use of proceeds from our IPO as described in our final prospectus pursuant to Rule 424(b), filed with the SEC on October 11, 2024.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

Name	Action	Date	Trading Arrangement		Total Shares to be Sold	Expiration Date
			Rule 10b5-1*	Non-Rule 10b5-1**		
Josef Parvizi, M.D., Ph.D. *Director, Chief Medical Advisor, and Co-Founder*	Adopt	August 12, 2026	X		250,000	July 26, 2027
William W. Burke *Director*	Adopt	August 12, 2026	X		19,960	July 7, 2027
Xingjuan (Jane) Chao *President, Chief Executive Officer, Director, and Co-Founder*	Adopt	August 12, 2026	X		472,500	September 30, 2027

* Intended to satisfy the affirmative defense of Rule 10b5-1(c).

** Not intended to satisfy the affirmative defense of Rule 10b5-1(c).

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by reference			Provided Herewith
		Form	Dated	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	10/15/2024	3.1	
3.2	Amended and Restated Bylaws.	8-K	10/15/2024	3.2	
4.1	Form of Common Stock Certificate.	S-1/A	9/19/2024	4.01	
10.1	Credit, Security and Guaranty Agreement, dated as of August 5, 2026, by and among CeriBell, Inc., as Borrower, MidCap Funding IV Trust, as Agent, and MidCap Financial Trust, as Term Loan Servicer and the Lenders from time to time party thereto.	10-Q	8/10/2026	10.1	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase.				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).				X

* The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, are not deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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.

CERIBELL, INC.

Date: November 3, 2026

By: /s/ Xingjuan (Jane) Chao, Ph.D.
Xingjuan (Jane) Chao, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 3, 2026

By: /s/ Scott Blumberg
Scott Blumberg
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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

I, Xingjuan (Jane) Chao, Ph.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2026

By: /s/ Xingjuan (Jane) Chao, Ph.D.
Xingjuan (Jane) Chao, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Scott Blumberg, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2026

By: /s/ Scott Blumberg
Scott Blumberg
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of CeriBell, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 3, 2026

By: /s/ Xingjuan (Jane) Chao, Ph.D.
Xingjuan (Jane) Chao, Ph.D.
President and Chief Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report of CeriBell, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 3, 2026

By: /s/ Scott Blumberg
Scott Blumberg
Chief Financial Officer