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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 June 30, 2025

OR

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

For the transition period from ___ to ___

Commission File Number: 001-42364

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 August 1, 2025, the registrant had 36,663,968 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 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 on Form 10-Q, 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 "may," "will," "shall," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential," "goal," "objective," "seeks," "likely," "ongoing," "assumes," "forecast," "guidance," "hope," or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans, or intentions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our ability to attract and retain customers;
- our expectations concerning orders for our products and utilization by existing customers;
- our expectations regarding the potential market size for our products;
- our ability to maintain our competitive technological advantages;
- our plans to develop and release new features for the Ceribell System;
- our plans to expand into new indications;
- our intentions to pursue adjacent and international markets;
- our ability to continue improving our product and technology, including our AI-powered algorithm;
- our commercialization and marketing capabilities and strategies;
- the implementation of our business model and strategic plans for our business and products and technology;
- our relationships with, and the capabilities of, our component manufacturers and suppliers;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products;
- our ability to effectively manage our growth;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing, and our ability to obtain additional capital; and
- our future financial performance.

We caution you that the foregoing list does not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations, estimates, forecasts, 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 contained in this Quarterly Report on Form 10-Q, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, and other factors described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties 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 on Form 10-Q. The results, events, and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events, or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking

statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to the registration statement, of which this Quarterly Report on Form 10-Q is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Quarterly Report on Form 10-Q by these cautionary statements.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 40,141	$ 194,370
Marketable securities	137,287	—
Accounts receivable, net	12,312	10,878
Inventory	6,000	6,937
Contract costs, current	2,024	1,837
Prepaid expenses and other current assets	2,022	3,250
Total current assets	**199,786**	**217,272**
Property and equipment, net	2,105	2,313
Operating lease right-of-use assets	1,652	2,132
Contract costs, long-term	1,671	1,507
Other non-current assets	2,475	2,188
Total assets	**$ 207,689**	**$ 225,412**
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,441	$ 1,143
Accrued liabilities	10,426	10,052
Contract liabilities, current	216	97
Operating lease liability, current	1,146	1,088
Other current liabilities	785	609
Total current liabilities	**15,014**	**12,989**
Long-term liabilities		
Notes payable, long-term	19,681	19,558
Contract liabilities, long-term	7	30
Other liabilities, long-term	106	356
Operating lease liability, long-term	726	1,314
Total long-term liabilities	**20,520**	**21,258**
Total liabilities	**$ 35,534**	**$ 34,247**
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, $0.001 par value;		
Authorized shares: 10,000,000 as of both June 30, 2025 and December 31, 2024		
Issued and outstanding shares: none as of both June 30, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value;		
Authorized shares: 500,000,000 as of both June 30, 2025 and December 31, 2024		
Issued and outstanding shares: 36,599,663 and 35,850,606 as of June 30, 2025 and December 31, 2024, respectively	37	36
Additional paid-in capital	365,477	358,073
Accumulated other comprehensive income	5	—
Accumulated deficit	(193,364)	(166,944)
Total stockholders' equity	**172,155**	**191,165**
Total liabilities and stockholders' equity	**$ 207,689**	**$ 225,412**

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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Revenue				
Product revenue	$ 15,923	$ 11,576	$ 31,531	$ 22,611
Subscription revenue	5,276	3,739	10,159	7,104
Total revenue	**21,199**	**15,315**	**41,690**	**29,715**
Cost of revenue				
Product cost of goods sold	2,351	2,033	4,711	3,977
Subscription cost of revenue	166	123	290	237
Total cost of revenue	**2,517**	**2,156**	**5,001**	**4,214**
Gross profit	**18,682**	**13,159**	**36,689**	**25,501**
Operating expenses				
Research and development	4,852	3,270	9,098	6,254
Sales and marketing	17,422	10,712	35,455	21,288
General and administrative	11,360	7,612	21,295	14,847
Total operating expenses	**33,634**	**21,594**	**65,848**	**42,389**
Loss from operations	**(14,952)**	**(8,435)**	**(29,159)**	**(16,888)**
Interest expense	(477)	(528)	(948)	(963)
Change in fair value of warrant liability	—	(242)	—	(244)
Other income, net	1,786	264	3,687	633
Loss, before provision for income taxes	**(13,643)**	**(8,941)**	**(26,420)**	**(17,462)**
Provision for income tax expense	—	—	—	—
Net loss	**$ (13,643)**	**$ (8,941)**	**$ (26,420)**	**$ (17,462)**
Net loss per share attributable to common stockholders:				
Basic and diluted	(0.38)	(1.61)	(0.73)	(3.17)
Weighted-average shares used in computing net loss per share attributable to common stockholders:				
Basic and diluted	36,293,559	5,559,718	36,088,433	5,506,597
Other comprehensive loss				
Unrealized gain on marketable securities	$ 11	$ —	$ 5	$ —
Comprehensive loss	**$ (13,632)**	**$ (8,941)**	**$ (26,415)**	**$ (17,462)**

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, 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**

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

CeriBell, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)
(unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in-Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Par Value			
Balance December 31, 2023	**17,817,643**	**$ 147,412**	**5,430,298**	**5**	**$ 14,232**	**$ (126,489)**	**$ (112,252)**
Issuance of common stock pursuant to stock option exercises	—	—	30,904	—	118	—	118
Stock-based compensation	—	—	—	—	757	—	757
Net loss	—	—	—	—	—	(8,521)	(8,521)
Balance March 31, 2024	**17,817,643**	**$ 147,412**	**5,461,202**	**5**	**$ 15,107**	**$ (135,010)**	**$ (119,898)**
Issuance of common stock pursuant to stock option exercises	—	—	133,763	—	488	—	488
Stock-based compensation	—	—	—	—	1,076	—	1,076
Net loss	—	—	—	—	—	(8,941)	(8,941)
Balance June 30, 2024	**17,817,643**	**$ 147,412**	**5,594,965**	**5**	**$ 16,671**	**$ (143,951)**	**$ (127,275)**

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

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

	Six months ended June 30,	
	2025	2024
Cash flows from operating activities		
Net loss	**$ (26,420)**	**$ (17,462)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	659	534
Noncash lease expense	(50)	(22)
Stock-based compensation expense	5,515	1,833
Amortization of debt discount	202	198
Accretion (amortization) of discount and premium on marketable securities	(487)	—
Change in fair value of warrant liability	—	244
Loss on disposal of property and equipment and recorders	50	96
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,434)	(1,258)
Inventory	937	111
Prepaid expenses and other current assets	1,229	460
Contract costs	(351)	(137)
Other non-current asset	(226)	(102)
Accounts payable	1,361	302
Accrued liabilities and other current liabilities	(17)	(1,422)
Contract liabilities	96	99
Net cash used in operating activities	**(18,936)**	**(16,526)**
Cash flows from investing activities		
Purchases of recorders and related components	(288)	(872)
Purchases of property and equipment	(219)	(416)
Purchases of marketable securities	(142,794)	—
Proceeds from maturities of marketable securities	6,000	—
Net cash used in investing activities	**(137,301)**	**(1,288)**
Cash flows from financing activities		
Proceeds from exercise of common stock pursuant to stock option exercises	2,158	606
Proceeds from debt issuance	—	7,905
Debt issuance cost	(150)	(304)
Payment of deferred IPO offering costs	—	(531)
Net cash provided by financing activities	**2,008**	**7,676**
Net decrease in cash and cash equivalents	**(154,229)**	**(10,138)**
Cash and cash equivalents, beginning of period	194,370	34,495
Cash and cash equivalents, end of period	**$ 40,141**	**$ 24,357**
Supplemental disclosure of cash flow information		
Cash paid for interest	**$ 950**	**$ 920**
Right-of-use asset obtained in exchange for operating lease obligation	**—**	**778**
Property and equipment included in accounts payable and accrued expenses	**152**	**73**
Unpaid deferred IPO offering costs included in accounts payable and accrued liabilities	—	**1,360**
Tax withholding related to settlement or vesting of equity awards in accruals	**268**	—

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") 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 June 30, 2025, the Company's principal sources of liquidity consisted of $177.4 million of cash and cash equivalents and marketable securities.

The Company has incurred operating losses and negative cash flows from operations since its inception. On June 30, 2025, the Company had an accumulated deficit of $193.4 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 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 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 company sales, profitability, and results of operations.

The Company utilizes contract manufacturers in China to supply key sub-assemblies for its primary products. In addition, political instability or the deterioration of trade relations between the United States and China 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 United States Securities and Exchange Commission ("SEC").

The unaudited interim 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 June 30, 2025, and the results of its operations for the three and six months ended June 30, 2025 and 2024 and cash flows for the six months ended June 30, 2025 and 2024. The condensed balance sheet at June 30, 2025, was derived from audited annual financial statements but does not contain all of the footnote disclosures from the annual financial statements.

Reverse Stock Split

On October 4, 2024, the Company amended and restated its amended and restated certificate of incorporation to effect a 1-for-2.57 reverse stock split of the Company's common stock and redeemable convertible preferred stock (the "Reverse Stock Split"). The par value and authorized shares of the common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock, preferred stock, options to purchase common stock, warrants to purchase redeemable convertible preferred stock and per share amounts contained in the financial statements have been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented.

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, valuation of warrants, valuation of the Company's common stock (prior to the Initial Public Offering, or "IPO"), 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 receivables 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% of the Company revenue for the three and six months ended June 30, 2025 and 2024. No customers comprised 10% of the Company's accounts receivable balance as of June 30, 2025, or December 31, 2024.

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 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 Account Standard 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 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 accompanying financial statements, as well as the annual financial statements. All of the Company's revenue was in the United States for the three and six months ended June 30, 2025 and 2024. Long-lived assets held outside of the United States were $1.0 million and $0.9 million as of June 30, 2025 and December 31, 2024, respectively.

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.

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 $48,000 and $52,000 for the three months ended June 30, 2025 and 2024, respectively, and $97,000 and $101,000 for the six months ended June 30, 2025 and 2024, respectively.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09 Improvements to Income Tax Disclosures. The amendments expand income tax disclosure requirements by requiring an entity to disclose (i) specific categories in the rate reconciliation, (ii) additional information for reconciling items that meet a quantitative threshold, and (iii) the amount of taxes paid disaggregated by jurisdiction. The amendments are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The adoption is not expected to have a material impact on the Company's annual financial statements and related disclosures.

In November 2024, the FASB issued 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. We are currently evaluating the impact this ASU will have on our 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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
EEG headbands, point in time	$ 15,923	$ 11,576	$ 31,531	$ 22,611
EEG portal and Clarity subscriptions, over time	5,276	3,739	10,159	7,104
Total Revenue	**$ 21,199**	**$ 15,315**	**$ 41,690**	**$ 29,715**

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):

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Contract cost balance beginning of the period	$ 3,772	$ 2,747	$ 3,344	$ 2,753
Contract costs capitalized during the period	528	622	1,554	1,063
Contract costs amortized during the period	(605)	(479)	(1,203)	(926)
Contract Costs as of period end	**$ 3,695**	**$ 2,890**	**$ 3,695**	**$ 2,890**

Contract Liabilities and Performance Obligations

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

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

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Contract Liabilities balance beginning of the period	$ 214	$ 358	$ 127	$ 250
Additional Contract Liabilities revenue during the period	95	266	274	614
Contract Liabilities balance recognized during the period	(86)	(275)	(178)	(515)
Balance as of period end	**$ 223**	**$ 349**	**$ 223**	**$ 349**

The Company has elected not to include in 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 and non-current performance obligations are expected to be recognized within 1.5 years.

4. Fair Value Measurements

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

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

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

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

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

Fair Value of 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):

June 30, 2025	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 36,220	$ —	$ —	$ 36,220
Marketable securities				
U.S. Treasury Bills	23,733	42,957	—	$ 66,690
U.S. Notes and Bonds	3,027	67,570	—	70,597
Total assets, at fair value	**$ 62,980**	**$ 110,527**	**$ —**	**$ 173,507**

December 31, 2024	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	**$ 178,925**	**$ —**	**$ —**	**$ 178,925**
Total assets, at fair value	**$ 178,925**	**$ —**	**$ —**	**$ 178,925**

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 2 cash equivalents and available-for-sale marketable securities as of June 30, 2025 are presented in the following table (in thousands):

June 30, 2025	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury bills	$ 66,704	$ 1	$ (15)	$ 66,690
U.S. Notes and Bonds	70,578	39	(20)	70,597
Total marketable securities	**$ 137,282**	**$ 40**	**$ (35)**	**$ 137,287**

The fair value of available-for-sale marketable securities by contractual maturities as of June 30, 2025 are presented in the following table (in thousands):

	June 30, 2025
Due in less than one year	$ 118,913
Due in one to two years	18,374
Total marketable securities	**$ 137,287**

Cash and cash equivalents are comprised of Level 1 financial instruments of money market fund investments. Level 2 financial instruments are comprised of 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 is derived from quoted prices in active markets for identical assets or liabilities, which is categorized as Level 1.

5. Balance Sheet Details

Inventory

Inventory consists of the following (in thousands):

	June 30, 2025	December 31, 2024
Component materials	$ 3,898	$ 4,094
Finished goods	2,102	2,843
Total	**$ 6,000**	**$ 6,937**

Property and Equipment, net

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

	June 30, 2025	December 31, 2024
Furniture and fixtures	$ 758	$ 713
Computer equipment and software	391	391
Laboratory and manufacturing equipment	2,192	1,505
Leasehold improvements	817	810
Construction in progress	119	586
Total Property and Equipment	**4,277**	**4,005**
Less: accumulated depreciation and amortization	2,172	1,692
Property and Equipment, Net	**$ 2,105**	**$ 2,313**

Depreciation and amortization expense was $235,000 and $167,000 for the three months ended June 30, 2025 and 2024, respectively, and $480,000 and $318,000 for the six months ended June 30, 2025 and 2024, respectively.

Other Non-Current Assets

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

	June 30, 2025	December 31, 2024
Recorders at customer locations	$ 1,511	$ 1,288
Less: accumulated depreciation of recorders at customer locations	(949)	(822)
Recorders at customer locations, net	**562**	**466**
Recorders and related components	1,053	1,159
Deferred debt financing cost	417	346
Other non-current assets	443	217
Total non-current assets	**$ 2,475**	**$ 2,188**

Recorder depreciation expense was $89,000 and $110,000 for the three months ended June 30, 2025 and 2024, respectively, and $179,000 and $216,000 for the six months ended June 30, 2025 and 2024, respectively.

Accrued Liabilities

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

	June 30, 2025	December 31, 2024
Accrued bonuses and payroll	$ 3,231	$ 4,391
Accrued commissions	2,567	3,419
Professional fees and other costs	3,116	2,114
Employee stock purchase plan liability	804	—
Other	708	128
Total	**$ 10,426**	**$ 10,052**

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. We contributed $0.3 million and none during the three months ended June 30, 2025 and 2024, respectively, and $0.5 million and none during the six months ended June 30, 2025 and 2024, respectively, to our 401(k) plan.

7. Commitments and Contingencies

Litigation

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. Legal fees are expensed in the period in which they are incurred. As of June 30, 2025, and December 31, 2024, there were no litigation liabilities recorded.

8. Leases

The Company's 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):

	June 30, 2025	December 31, 2024
Operating Lease		
Operating lease right-of-use asset	**$ 1,652**	**$ 2,132**
Operating lease liability, current	1,146	1,088
Operating leases liability, long-term	726	1,314
Total operating lease liabilities	**$ 1,872**	**$ 2,402**
Weighted average remaining lease term (years)	1.6	2.1
Weighted average remaining discount rate	7.07%	7.24%

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 June 30,		For The Six Months Ended June 30,	
	2025	2024	2025	2024
Operating lease expense	$ 281	$ 218	$ 562	$ 416
Variable lease expense	71	83	169	162
Total lease expense	**$ 352**	**$ 301**	**$ 731**	**$ 578**
Total cash payments for amounts included in the measurement of lease liabilities	**$ 302**	**$ 234**	**$ 604**	**$ 438**

The Company leases office space and warehouse space under non-cancelable operating leases. As of June 30, 2025, the future minimum lease payments under the non-cancelable operating lease are as follows (in thousands):

Operating Leases:	June 30, 2025
Remainder of 2025	$ 612
2026	1,255
2027	107
Total undiscounted lease payments	1,974
Imputed interest	(102)
Net lease liabilities	**$ 1,872**

9. Term Loan

2024 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"). The Company and the Lenders agreed to refinance the existing Horizon term loan facility which also modified, among other things, the repayment terms of the existing Horizon term loan and the maturity date from October 2024 to March 2029. The amounts borrowed under the VLSA are secured by all of the Company's assets, excluding intellectual property.

Upon execution of the VLSA, the Company drew down the entire first tranche of $20.0 million in principal ("Term Loan"), including $6.0 million from SVB ("SVB Loan") and $14.0 million from Horizon ("Horizon Loan") and utilized a portion of the proceeds to repay the remaining principal on the 2020 Loan. Subject to the VLSA terms, the Company is entitled to receive up to $30.0 million ("Outstanding Commitment") in three additional tranches of $10.0 million each. Each lender's obligation to lend its undisbursed portion of the Outstanding Commitment to the Company shall terminate if, in such Lender's sole good faith discretion, there has been 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 has been any material adverse deviation by the Company from the business plan of the Company presented to any Lender. No material adverse changes have been identified as of June 30, 2025. In each of the three additional tranches, $3.0 million is allocated to SVB, and $7.0 million is allocated to Horizon. Any amounts drawn under the Outstanding Commitment are subject to the same terms and conditions as the SVB Loan and Horizon Loan.

The Term Loan is 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 carries 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 carries a variable per-annum interest rate at the Prime Rate plus 2.75%, subject to the floor of 9.25%. The Company is also required to pay end-of-term fees of 4.0% per tranche drawn on the Maturity Date or upon repayment of the amounts due to the Lenders under the VLSA. The Company is required to pay additional commitment fees of $0.03 million upon funding of each additional tranche.

Upon execution of the VLSA, the Company paid to the Lenders $0.2 million and issued warrants to purchase 41,345 shares of the Company's Series C-1 Preferred Stock at a price of $11.49 per share ("Initial Warrants"). The fair value of the Initial Warrants was determined to be approximately $0.3 million. If the Company draws down any amounts of the Outstanding Commitment, it will be required to issue additional warrants exercisable for shares of the Company's most senior Preferred Stock with the aggregate exercise price of $0.2 million per tranche ("Additional Warrants"). The exercise price of the Additional Warrants will be $11.49 per share, subject to a down-round adjustment. See Note 10 for a discussion of the Initial Warrants.

The VLSA was treated as a loan syndication, and the SVB Loan was determined to be a new loan. The issuance of the Horizon Loan was accounted for as a modification of the outstanding term loan. The Company utilized the proceeds from the Horizon Loan to repay the outstanding principal of $11.3 million and end-of-term fees of $0.8 million under the existing term loan due to Horizon.

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 is secured by the Company's accounts receivable, inventory, and other property, excluding intellectual property. The Company may draw up to 85% of the eligible trade receivables and is required to remit the underlying customer proceeds to repay the Revolving Facility.

The Revolving Facility carries a variable per-annum interest rate at the Prime Rate plus 0.25%, subject to the floor of 6.00%, and includes additional fees of $0.3 million that are payable regardless of whether any amounts are drawn. The Revolving Facility matures on February 6, 2026. Any borrowings under the Revolving Facility are subordinate to the VLSA.

The Company allocated the issuance costs under the LSA and VLSA as follows: (1) $0.5 million to the Term Loan liability representing the initial lender fees and the fair value of the Initial Warrants to be recognized as interest expense through the Maturity Date, (2) $0.3 million to the deferred debt financing cost asset to be recognized as interest expense through the Maturity Date and to be reclassified to the Term Loan liability upon draws or expiration of the tranches, and (3) $0.1 million to the Revolving Facility deferred debt financing cost asset to be recognized as interest expense over the availability period of two years. The end-of-term fee is being accreted and the debt issuance costs are being amortized over the term of the notes using the effective interest method. The effective interest rate is 9.5%, inclusive of the end-of-term fee and debt issuance as of June 30, 2025.

The LSA and VLSA have interrelated provisions and financial covenants based on net indebtedness and certain revenue-based ratios. Upon an event of default, the interest on the Term Loan and Revolving facility may be increased by 5.0%. The Term Loan also includes a late payment fee of 6.0% of the amount not paid when due.

As of June 30, 2025, the Company was in compliance with debt covenants under the LSA and VLSA. No amounts were drawn under the Outstanding Commitment and Revolving Facility through June 30, 2025.

Notes payable consists of the following (in thousands):

	June 30, 2025	December 31, 2024
Principal of notes payable	$ 20,000	$ 20,000
End of term fee accretion	180	113
Unamortized debt issuance costs	(499)	(555)
Carrying value of Notes Payable	**$ 19,681**	**$ 19,558**

Collateral for the VLSA consists of a security interest in all assets of the Company, excluding intellectual property.

10. Warrants

Effective February 6, 2024, the Company, Horizon, and SVB entered into a $60.0 million financing commitment, consisting of a $50.0 million term loan commitment and a $10.0 million revolving line of credit. 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. See Note 9 for a discussion of the financing commitment. 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.

	Common Stock	Common Stock	Total warrants
Balance December 31, 2024	**45,726**	**56,573**	**102,299**
Exercise price per warrant	$ 7.6540	$ 11.49	
Warrants issued	—	—	—
Balance June 30, 2025	**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 June 30, 2025, and December 31, 2024.

Immediately prior to the closing of the Company's IPO on October 15, 2024, all warrants exercisable for redeemable convertible preferred stock converted into warrants exercisable for common stock and reclassified from long-term liabilities to equity. The warrants were subject to remeasurement at each balance sheet date, and any change in fair value was recognized as a change in fair value as a component of non-operating income or expense in the Statements of Operations and Comprehensive Loss. The change in the value of the warrant liability for the six months ended June 30, 2024, is summarized in the following table (in thousands).

Balance December 31, 2023	**$ 334**
Issuance of warrants	304
Changes in fair value of warrants	244
Balance June 30, 2024	**$ 882**

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 June 30, 2025, and December 31, 2024.

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, subject to the prior rights of holders of redeemable convertible preferred stock outstanding. As of June 30, 2025, no dividends had been declared.

As of June 30, 2025, and December 31, 2024, the Company had reserved common stock for future issuance as follows:

	June 30, 2025	*December 31, 2024*
Conversion of outstanding warrants	102,299	102,299
Outstanding options	4,907,780	5,708,070
Outstanding RSUs	1,328,240	335,511
Shares reserved for future issuance under the Company's equity plans	5,625,849	3,964,620
Total	**11,964,168**	**10,110,500**

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 (years)	Aggregate intrinsic value (thousands)
Balance at December 31, 2024	**5,708,070**	**$ 6.60**	**7.71**	**110,063**
Options granted	539,450	18.88		
Options exercised	(738,385)	3.80		
Options forfeited	(601,355)	9.24		
Balance at June 30, 2025	**4,907,780**	**8.01**	**7.49**	**52,910**
Shares outstanding, vested, and expected to vest at June 30, 2025	4,907,780	8.01	7.49	52,910
Shares exercisable at June 30, 2025	2,746,341	$ 4.93	6.44	37,912

The weighted-average grant-date fair value of options granted during the six months ended June 30, 2025 and 2024 was $10.47 and $5.92 per share, respectively. The aggregate intrinsic value of options exercised during the six months ended June 30, 2025 and 2024 was $9.5 million and $0.7 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, 2024	**335,511**	**$ 23.53**
Granted	1,202,047	18.87
Vested	(60,683)	24.55
Cancelled	(148,635)	19.41
Unvested at June 30, 2025	**1,328,240**	**19.83**

The total fair value of shares vested during the six months ended June 30, 2025 was $1.5 million. No restricted stock units were granted or vested during six months ended June 30, 2024.

Stock-Based Compensation

As of June 30, 2025, the aggregate unrecognized compensation costs related to outstanding unvested options and RSUs under the 2014 Plan, 2024 EIP, and 2024 Plan was $38.8 million. The Company expects to recognize those costs over a weighted average period of 3.2 years.

Prior to the completion of our IPO, the fair value of the common stock underlying our stock awards was determined by our Board of Directors. The valuations of our common stock prior to the completion of our IPO were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The fair value of RSUs post IPO 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 six months ended June 30, 2025 and 2024:

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Expected term (in years)	5.0	5.2	5.0	5.2
Expected volatility	61.0%	73.6%	61.1%	73.6%
Risk-free interest rate	3.9%	4.6%	3.9%	4.5%
Dividend yield	—	—	—	—

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 the Company did not have any trading history for the Company's common stock. 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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Cost of revenue	$ 102	$ —	$ 127	$ —
Research and development	564	153	937	289
Sales and marketing	1,203	235	1,980	442
General and administrative	1,298	688	2,471	1,102
Total stock-based compensation expense	**$ 3,167**	**$ 1,076**	**$ 5,515**	**$ 1,833**

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 40,854 and 118,999 of option awards outstanding as of June 30, 2025 and December 31, 2024, 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 $0.04 million for the three months ended June 30, 2025 and 2024, respectively, and $0.7 million and $0.07 million for the six months ended June 30, 2025 and 2024, 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. There were 451,689 shares of common stock initially reserved for issuance under the ESPP. In January 2025, the number of shares of common stock available for issuance under the ESPP was increased by 358,506 shares as a result of the automatic increase provision in the ESPP.

As of June 30, 2025, 810,195 shares under the ESPP remain available for purchase. The offering period and purchase period is determined by the board of directors.

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 years 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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Net loss attributable to common stockholders	$ (13,643)	$ (8,941)	$ (26,420)	$ (17,462)
Weighted-average shares outstanding, basic and diluted	36,294	5,560	36,088	5,507
Net loss per share, basic and diluted	**$ (0.38)**	**$ (1.61)**	**$ (0.73)**	**$ (3.17)**

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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Redeemable convertible preferred stock	—	17,818	—	17,818
Warrants	102	102	102	102
Equity plan stock options outstanding	4,908	5,087	4,908	5,087
Restricted stock units	1,328	—	1,328	—
Shares committed under ESPP	35	—	35	—
Total	**6,373**	**23,007**	**6,373**	**23,007**

13. Income Taxes

The Company had an effective tax rate of 0.0% for each of the three and six months ended June 30, 2025 and 2024. The Company continues to incur operating losses.

During the three and six months ended June 30, 2025 and 2024, the Company has evaluated all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and has 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.

On July 4, 2025, the One Big Beautiful Bill Act (the “OBBB Act”) was enacted, introducing amendments to U.S. tax laws with various effective dates from 2025 to 2027. The Company is currently assessing the implications of these tax law changes and an estimate of the financial impact cannot be made at this time. Since the OBBB Act was enacted subsequent to the Company’s balance sheet date, the Company’s tax provision for the three and six months ended June 30, 2025, does not incorporate the effects of these tax law changes.

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 on Form 10-Q 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, 2024 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 on Form 10-Q, 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 AI-powered algorithms, the Ceribell System enables rapid diagnosis and continuous monitoring of patients with neurological conditions.

We are 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 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 in the acute care setting, resulting in improved patient outcomes and hospital and payer economics. As of June 30, 2025, the Ceribell System has been adopted by more than 550 active accounts, ranging from top academic centers to small community hospitals, and has been used to care for over 200,000 patients. For information regarding how patient care and clinical outcomes are measured, see "Business—Market Overview—Challenges of Managing Seizures in the Acute Care Setting" in our Annual Report on Form 10-K.

We specifically designed the Ceribell System to address the limitations of conventional EEG in the acute care setting and 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 a disposable, flexible headband and a pocket-sized, 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 algorithm, Clarity™, which continuously monitors the patient's EEG signal and can support the clinician's real-time assessment of seizure activity.

We are currently focused on becoming the standard of care for the detection and management of seizures in the acute care setting. There are approximately 6,000 acute care facilities in the United States that we believe could benefit from our 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. We also plan to engage in market access initiatives in attractive international regions in which we see significant opportunity.

We manage all aspects of manufacturing, supply chain, and distribution of the headband and recorder from our facilities in Sunnyvale, California. Contract manufacturers in China assemble the Ceribell headband, with final inspection and labeling completed at our California facilities. We have dual sources for major components of the headband. 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 June 30, 2025, we had an accumulated deficit of $193.4 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 proceeds, and cash generated from the sale of headbands and subscriptions. As of June 30, 2025, we had $177.4 million in cash and cash equivalents and marketable securities. Based on our current operating plan, we believe that the net proceeds from our IPO, together with the expected cash generated from revenue transactions with customers and our existing cash and cash equivalents, 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 in new accounts.*** As of June 30, 2025, we had over 550 active accounts. We define active accounts as those with an active subscription or recent headband usage, which is typically considered to have occurred during the previous six months. When determining the number of active accounts, we do not count a care facility (such as a hospital) as more than one account, even though the facility may have both an ED and an ICU using the Ceribell System. The headbands used as part of the Ceribell System are designed to be used only once by a single patient, so an active account is expected to purchase multiple headbands to be used as part of the Ceribell System. There are approximately 6,000 acute care facilities in the United States that we believe could benefit from our system. We believe that any facility with either an ICU or ED, or both, has patients who could benefit from the Ceribell System, because the patients arriving at such facilities may experience seizures triggered by the conditions leading them to seek acute medical care. We have initially targeted a subset of these acute care facilities through our commercial organization, prioritizing certain facilities based on factors such as geographic characteristics and sales potential. Over time, we expect to target additional acute care facilities as we grow our sales. To penetrate these hospitals, we continue to increase the size of our commercial organization. This team comprises TMs and CAMs, who are responsible for new account acquisition by engaging with key decision makers to educate them about the value proposition of the Ceribell System. As we seek to increase our account base, we expect that our revenue will increase due to increased utilization of the headbands and therefore increased product revenue, as well as new Clarity subscribers and increased subscription revenue. The rate at which we grow our commercial organization and the speed at which newly hired personnel become effective can impact our revenue growth and our costs incurred in anticipation of such growth.
- ***Utilization of the Ceribell System within our existing customer base.*** Our revenue is impacted by the utilization of the headband component of the Ceribell System within hospitals. Because the headbands used as part of the Ceribell System are designed to be used only once by a single patient, utilization has a direct relationship with our product revenue. Within each hospital, we are initially focused on site onboarding and launch. Currently, many 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 raise awareness of our technology as well as, non-convulsive seizures generally, 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. Once a launch is complete, our CAMs drive greater utilization of the Ceribell System within the hospital by reinforcing our value proposition, increasing disease state awareness, and supporting the integration of standard protocols or workflows for monitoring at-risk patients. CAMs also are focused on expanding the use of our system into additional departments within the hospital. As hospitals and physicians gain exposure to our system, we expect to leverage their experiences to increase usage and establish rapid EEG as the standard of care for the detection and management of seizures in the acute care setting.
- ***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 our system for diagnosing and monitoring seizures in the acute care setting. We believe the platform nature of our system will enable us to efficiently deploy it for use in other serious neurological conditions beyond seizures, and we have begun the technical validation process for several 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 headbands 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 headbands 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 system is made available to a customer. Our revenue fluctuates primarily based on the number of active accounts and the volume of headband 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 our 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 headbands 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 headbands 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. We expect our product inventory, currently located within the United States, to enable sufficient supply of finished goods through at least the end of 2025. We do not expect any material impact to our financial results from incremental tariffs until at least the fourth quarter of 2025. 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 on Form 10-Q.

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 our existing 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 our 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 algorithm, 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 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, seek to 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.

Interest and Other Income (Expense), net

Interest and other income (expense), net is primarily interest income on our cash and cash equivalents and marketable securities and interest expense on our term loans. Interest expense primarily consists of interest on our term loans and a non-cash interest charge related to amortization of debt issuance costs. Gains and losses related to the change in fair value of the redeemable convertible preferred stock warrant liability issued as a part of our term loans were recognized in the income statement each quarter until the warrants were converted to common stock warrants immediately prior to the IPO.

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 Six Months Ended June 30, 2025 and 2024

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

	Three Months Ended June 30,			
	2025	2024	$ Change	% Change
Revenue				
Product revenue	$ 15,923	$ 11,576	$ 4,347	38%
Subscription revenue	5,276	3,739	1,537	41%
Total revenue	**21,199**	**15,315**	**5,884**	**38%**
Cost of revenue				
Product cost of goods sold	2,351	2,033	318	16%
Subscription cost of revenue	166	123	43	35%
Total cost of revenue	**2,517**	**2,156**	**361**	**17%**
Gross profit	**18,682**	**13,159**	**5,523**	**42%**
Operating expenses:				
Research and development	4,852	3,270	1,582	48%
Sales and marketing	17,422	10,712	6,710	63%
General and administrative	11,360	7,612	3,748	49%
Total operating expenses	**33,634**	**21,594**	**12,040**	**56%**
Loss from operations	**(14,952)**	**(8,435)**	**(6,517)**	**77%**
Interest and other income (expense), net	1,309	(506)	1,815	NM*
Loss before provision for income taxes	**(13,643)**	**(8,941)**	**(4,702)**	**53%**
Provision for income taxes	—	—	—	—
Net loss	**$ (13,643)**	**$ (8,941)**	**$ (4,702)**	**53%**

	Six Months Ended June 30,			
	2025	2024	$ Change	% Change
Revenue				
Product revenue	$ 31,531	$ 22,611	$ 8,920	39%
Subscription revenue	10,159	7,104	3,055	43%
Total revenue	**41,690**	**29,715**	11,975	40%
Cost of revenue				
Product cost of goods sold	4,711	3,977	734	18%
Subscription cost of revenue	290	237	53	22%
Total cost of revenue	**5,001**	**4,214**	787	19%
Gross profit	**36,689**	**25,501**	11,188	44%
Operating expenses:				
Research and development	9,098	6,254	2,844	45%
Sales and marketing	35,455	21,288	14,167	67%
General and administrative	21,295	14,847	6,448	43%
Total operating expenses	**65,848**	**42,389**	**23,459**	**55%**
Loss from operations	**(29,159)**	**(16,888)**	**(12,271)**	**73%**
Interest and other income (expense), net	2,739	(574)	3,313	NM*
Loss before provision for income taxes	**(26,420)**	**(17,462)**	**(8,958)**	**51%**
Provision for income taxes	—	—	—	0%
Net loss	**$ (26,420)**	**$ (17,462)**	**$ (8,958)**	**51%**

** Not Meaningful*

Comparison of the Three and Six Months Ended June 30, 2025 and 2024

Revenue

Product revenue for the three and six months ended June 30, 2025, increased $4.3 million and $8.9 million, or 38% and 39%, respectively, compared to the same periods of fiscal year 2024. Product revenue growth is primarily driven by the addition of new customers and an increase in utilization of headbands and resulting headband sales, driven by continued customer education that resulted in increased awareness and adoption of our products.

Subscription revenue for the three and six months ended June 30, 2025, increased $1.5 million and $3.1 million, or 41% and 43%, respectively, compared to the same periods of fiscal year 2024. Subscription revenue growth is primarily driven by an increase in adoption of subscriptions.

Cost of Revenue

Product cost of revenue for the three and six months ended June 30, 2025, increased $0.3 million and $0.7 million, or 16% and 18%, respectively, compared to the same periods of fiscal year 2024. The increase in cost of goods sold for products was primarily due to an increase in headband sales to new and existing active accounts, partially offset by a decrease in the cost of goods sold per unit, as non-variable costs are allocated among a larger number of units.

Subscription cost of revenue for three and six months ended June 30, 2025, increased $0.04 million and $0.05 million, or 35% and 22%, respectively, compared to the same periods of fiscal year 2024. The increase in subscription cost of revenue was primarily due to increased hosting costs for new active accounts for subscriptions and incremental recorder depreciation associated with new subscriptions.

Gross Profit (in thousands) and Gross Margin

	Three Months Ended June 30,			
	2025	2024	$ Change	% Change
Gross profit	$ 18,682	$ 13,159	$ 5,523	42%
Gross margin	88%	86%		2%
Product gross profit	13,572	9,543	4,029	42%
Product gross margin	85%	82%		3%
Subscription gross profit	5,110	3,616	1,494	41%
Subscription gross margin	97%	97%		—

	Six Months Ended June 30,			
	2025	2024	$ Change	% Change
Gross profit	$ 36,689	$ 25,501	$ 11,188	44%
Gross margin	88%	86%		2%
Product gross profit	26,820	18,634	8,186	44%
Product gross margin	85%	82%		3%
Subscription gross profit	9,869	6,867	3,002	44%
Subscription gross margin	97%	97%		—

Gross profit for the three and six months ended June 30, 2025 increased $5.5 million and $11.2 million, or 42% and 44%, respectively, compared to the same period of fiscal year 2024. The increase is primarily due to increased revenue and decreased cost of goods sold per unit, as non-variable costs are allocated among a larger number of units.

Operating Expenses

Research and Development Expenses

Research and development expenses for the increased $1.6 million, or 48%, for the three months ended June 30, 2025, compared to the same period of fiscal year 2024. The increase was primarily due to an increase of $1.1 million in personnel and related expenses directly associated with an increase in headcount, as well as an increase of $0.6 million in clinical study and professional expenses.

Research and development expenses for the increased $2.8 million, or 45%, for the six months ended June 30, 2025, compared to the same period of fiscal year 2024. The increase was primarily due to an increase of $1.7 million in personnel and related expenses directly associated with an increase in headcount, as well as an increase of $1.1 million in clinical study and professional expenses.

Sales and Marketing Expenses

Sales and marketing expenses increased $6.7 million, or 63%, for the three months ended June 30, 2025, compared to the same period of fiscal year 2024. 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 $14.2 million, or 67%, for the six months ended June 30, 2025, compared to the same period of fiscal year 2024. 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 $3.7 million, or 49%, for the three months ended June 30, 2025, compared to the same period of fiscal year 2024. The increase was primarily due to an increase of $1.7 million in personnel and related expenses directly associated with an increase in headcount, as well as an increase of $1.8 million in legal, accounting, and professional service fees related to our transition to a public company and costs associated with intellectual property enforcement activities, including a new patent infringement claim initiated during the quarter.

General and administrative expenses increased $6.4 million, or 43%, for the six months ended June 30, 2025, compared to the same period of fiscal year 2024. The increase was primarily due to an increase of $3.6 million in personnel and related expenses directly associated with an increase in headcount, as well as an increase of $2.4 million in legal, accounting, and professional service fees related to our transition to a public company and costs associated with intellectual property enforcement activities, including a new patent infringement claim initiated during the quarter.

Interest and Other Income (Expense), net

Interest and other income (expense), net increased $1.8 million for the three months ended June 30, 2025, compared to the same period for fiscal year 2024. The increase in interest income was primarily due to higher balances of cash equivalents and marketable securities, resulting from the investment of IPO proceeds.

Interest and other income (expense), net increased $3.3 million for the six months ended June 30, 2025, compared to the same period for fiscal year 2024. The increase in interest income was primarily due to higher balances of cash equivalents and marketable securities, resulting from the investment of IPO proceeds.

Cash Flows

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

	Six Months Ended June 30,	
	2025	2024
Net cash used in operating activities	$ (18,936)	$ (16,526)
Net cash used in investing activities	$ (137,301)	$ (1,288)
Net cash provided by financing activities	$ 2,008	$ 7,676

Operating Activities

Net cash used in operating activities during the six months ended June 30, 2025, consisted primarily of our net loss of $26.4 million, offset by non-cash charges of stock-based compensation of $5.5 million, and depreciation and amortization of $0.7 million. Additionally we had a net decrease in operating assets of $0.2 million and a net increase in operating liabilities of $1.4 million. Net operating assets decreased due to decreases in prepaid expenses and inventory due to lower inventory purchases in the six months ended June 30, 2025. Net operating liabilities decreased primarily due to timing of payments.

Net cash used in operating activities during the six months ended June 30, 2024, consisted primarily of our net loss of $17.5 million, non-cash charges of stock-based compensation of $1.8 million, and a net decrease in operating liabilities of $1.0 million. Net operating liabilities decreased primarily due to timing of payments.

Investing Activities

Net cash used in investing activities during the six months ended June 30, 2025 and 2024 was $137.3 million and $1.3 million, respectively, and consisted of purchases of marketable securities during the six months ended June 30, 2025, and purchases of equipment and recorders provided to customers for both periods.

Financing Activities

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

Net cash provided in financing activities during the six months ended June 30, 2024, consisted primarily of $0.6 million in proceeds from the exercise of options, $0.5 million in payments of deferred initial public offering costs, and $7.6 million in net proceeds from debt issuance.

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 cash generated from the sale of headbands 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 June 30, 2025, our principal sources of liquidity consisted of $177.4 million of cash and cash equivalents and marketable securities and $20.0 million of term loans.

On February 6, 2024, we entered into the VLSA with SVB and Horizon. The VLSA provides a term loan commitment of $50.0 million. We drew $20.0 million of the $50.0 million term loan commitment at closing, (consisting of $6.0 million from SVB and $14.0 million from Horizon), which was used to retire our existing debt with Horizon, pay transaction fees, and for general corporate purposes. The remaining $30.0 million term loan commitment consists of three tranches of $10.0 million commitments. The maturity date of VLSA is March 1, 2029.

Concurrent with the VLSA, we also entered into the Revolving Facility for a line of credit of up to $10.0 million. The Revolving Facility matures on February 6, 2026.

Funding Requirements

Based on our current operating plan, we believe that the net proceeds from our IPO together with the expected cash generated from revenue transactions with customers and our existing cash and cash equivalents, 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 June 30, 2025 include:

Debt — Principal payments required on long-term debt outstanding at June 30, 2025, was $20.0 million. Please refer to the section titled "Liquidity" in Note 1 for a discussion of changes in commitments.

Operating leases — As of June 30, 2025, estimated contractual obligations for operating lease payments were $2.0 million due within 19 months.

Critical Accounting 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 25, 2025. There have been no material changes to our significant accounting policies and estimates during the six months ended June 30, 2025.

Recently Issued Accounting Pronouncements

See Note 2 to our financial statements included elsewhere in this Quarterly Report on Form 10-Q 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

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 defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this Quarterly Report on Form 10-Q. 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 June 30, 2025.

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 Rule 13a-15(d) and 15d-15(d) of the Exchange Act during the quarter ended June 30, 2025 by this Quarterly Report on Form 10-Q 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, 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 an award of damages in the District Court sufficient to compensate us for the alleged infringement, as well as other costs and expenses in this action.

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 periods of significant business changes in a short time, making it difficult for you to evaluate our business and future prospects. If we are unable to manage our business and any fluctuations in our business effectively, our business and growth prospects 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, growing to over 280 employees in 2025. Accordingly, we have a limited operating history, which makes evaluation of our future prospects difficult. In that time, we have had periods of significant growth in revenue and employees, which have required us to scale the size of our organization as our business has rapidly changed. 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. While our quarterly revenues have generally increased each quarter 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 the 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 place significant demands on our management and other resources and will require us to continue developing and improving our operational, financial and other internal controls, reporting systems, and procedures. In particular, continued growth increases the challenges involved in a number of areas, including recruiting and retaining sufficient skilled personnel, providing adequate training and supervision to maintain our 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 any changes in scale, related 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 and changes to 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. In addition, our business is affected by general macroeconomic and business conditions around the world, including the impacts of inflation, increased interest rates, market instability, geopolitical conditions and conflicts, health crises, and natural disasters. If we do not effectively manage our business through 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 fiscal quarter ended June 30, 2025, we incurred a net loss of $13.6 million. As of June 30, 2025, we had an accumulated deficit of $193.4 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 produces by the Ceribell System. In addition, 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 our algorithm and overall 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 (if any) 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.

Adapting our manufacturing and production capacities to evolving patterns of demand is expensive, time-consuming, and subject to significant uncertainties. We may not be able to adequately predict existing customer trends and may be unable to adjust our production and inventory levels in a timely manner.

We market the Ceribell System directly to potential customers in the United States, where we face the risk of significant changes in the demand for our products, including demand for our disposable headbands based on usage rates. If demand decreases, we will need to implement capacity and cost reduction measures involving restructuring costs. If demand increases, we will be required to make capital expenditures related to increased production and expenditures to hire and train production, sales and marketing, and product support personnel. This would put pressure on our internal and third-party manufacturing capabilities. For example, a sudden increase in demand could require increased production of components, such as our disposable headbands that are intended for single patient use, so that our customers can timely deliver care to their patients. Adapting to changes in demand inherently lags behind the actual changes because it takes time to identify the change the market is undergoing and to implement any measures to take as a result. Finally, capacity adjustments are inherently risky because there is imperfect information, and sales trends may rapidly intensify, ebb, or even reverse. We may be unable to accurately or timely predict trends in demand and customer behavior or to take appropriate measures to mitigate risks and react to opportunities resulting from such trends. Any inability in the future to identify or to adequately and effectively react to changes in demand could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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, or actual demand could be stronger than our forecast, which may result in a reduction to previously recorded reserves and write-downs in the future and increase the volatility of our operating results.

We are dependent on international manufacturers and suppliers, which exposes us to foreign operational risks and trade risks that may harm our business.

We rely on manufacturers and third-party suppliers that are based outside of the United States, including in China, who complete the primary assembly and initial inspection of all of our headbands and supply a significant portion of the components used in the manufacturing of our products.

Our reliance on an international supply chain and operations exposes us to risks and uncertainties, including:

- product or material delays or disruption, including logistics challenges such as delays or disruptions in shipping;
- higher prices for components used in the manufacturing of our products;
- controlling quality of supplies and finished product;
- trade protection measures, tariffs, and other duties, especially in light of trade disputes between the United States and several foreign countries, including China;
- political, social, and economic instability;
- the outbreak of contagious diseases;
- laws and business practices that favor local companies;
- interruptions and limitations in telecommunication services;
- import and export license requirements and restrictions;
- difficulties in the protection of intellectual property;
- inflation and/or deflation;
- the threat of nationalization and expropriation;
- exchange controls, currency restrictions, and fluctuations in currency values;
- potential adverse tax consequences;
- supplies being purchased through purchase orders without long-term guaranteed commitments from our suppliers;
- suppliers ceasing to do business with us; and
- labor disputes, terrorism, vandalism, natural disasters, or work stoppages.

The U.S. has recently signaled its intention to change U.S. trade policy, including potentially renegotiating or terminating existing trade agreements and leveraging tariffs. From February 2025 to April 2025, the U.S. imposed additional tariffs on imports from China and announced and subsequently paused implementation of tariffs on imports from Canada and Mexico. These additional tariffs, as well as a government's adoption of "buy national" policies or retaliation by another government against such tariffs or policies have introduced significant uncertainty into the market and may affect the prices of and demand for the Company's products, which could have a negative impact on the Company's results of operations.

If any of these risks were to materialize, it could have a material adverse effect on our business, financial condition, results of operations, and prospects, including the potential costs of identifying new suppliers and/or new manufacturing partners and relocating operations.

We source and manufacture a substantial number of our products from third-party suppliers and manufacturers in China, which exposes us to risks inherent in doing business in China.

We currently source and manufacture a substantial number of our products from third-party suppliers and manufacturers in China. We rely on two primary contract manufacturers in China to complete the manufacturing, primary assembly, and inspection of our headband. In addition, we have a team of contractors who are employed by an agency in China and perform monitoring and quality inspection services at the facilities of our manufacturers in China.

Our third-party suppliers and manufacturers in China expose us to political, legal, and economic risks. Our operations and the operations of our third-party suppliers and manufacturers in China may be adversely affected by deterioration of the U.S.-China relationship, adverse changes in U.S. economic and political policies relating to China (and vice versa), such as policies favoring domestically manufactured products, and changes in the United States and Chinese laws and regulations such as those related to, among

other things, sanctions, taxation, import and export restrictions, tariffs, environmental protection, land use rights, intellectual property, currency controls, network security, labor and human rights practices, privacy, public health, and other matters. For example, the tariffs imposed by the United States on products imported from China could have a material adverse effect on the businesses of our third-party suppliers and manufacturers in China, potentially causing them to go out of business, in which case we would be forced to transition to alternative suppliers and manufacturers. See the risk factor titled, "*We depend on a limited 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.*"

In addition, in December 2021, the U.S. Congress enacted the Uyghur Forced Labor Prevention Act in an effort to prevent what it viewed as forced labor and human rights abuses in the Xinjiang Uyghur Autonomous Region ("XUAR"). If it is determined that our third-party suppliers and manufacturers produce or manufacture our components or products wholly or in part from the XUAR, then we could be prohibited from importing such components or products into the United States. In addition, the political, legal, and economic climate in China, both nationally and regionally, is fluid and unpredictable. Chinese trade regulations are in a state of flux, and we or our third-party suppliers and manufacturers in China may become subject to additional taxation, tariffs, and duties, including retaliatory trade restrictions. Sustained uncertainty about or worsening of tensions between the United States and China could also result in a global economic slowdown and long-term changes to global trade. Furthermore, the third parties we rely on in China may disclose our confidential information or intellectual property to competitors or third parties, which could result in the illegal distribution and sale of counterfeit versions of our products. If any of these events occur, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

Furthermore, with the rapid development of the Chinese economy, the cost of labor has increased and may continue to increase in the future. Our results of operations will be materially and adversely affected if the labor costs of our suppliers and manufacturers increase significantly and are passed on to us. In addition, our manufacturers and suppliers may not be able to find a sufficient number of qualified workers due to the intensely competitive and fluid market for skilled labor in China, which would negatively affect our manufacturers' and suppliers' ability to meet our needs. Any of these events may materially and adversely affect our business, financial condition, results of operations, and prospects.

Changes in trade policy and regulations in the United States and other countries, including changes in trade agreements and the imposition of tariffs, as well as retaliatory responses, may have adverse impacts on our business, results of operations and financial condition.

The U.S. government has implemented or proposed changes to international trade policy through the renegotiation, and potential termination, of certain existing bilateral or multilateral trade agreements and treaties, along with the imposition of tariffs on a wide range of products and other goods from China, countries in EMEA, and other regions. In response, China and other countries have imposed or proposed additional tariffs and additional trade restrictions on certain imports from the U.S. The current trade relations between the U.S. and China, in particular, remain volatile and uncertain.

We rely significantly on manufacturing facilities in China. In addition, we and our manufacturers rely on the availability of raw materials and components to produce a significant amount of our products. The imposition of increased tariffs and any countermeasures could increase the cost of our products, limit the availability of the materials or components we use, disrupt the global supply chain, increase market volatility, and create additional challenges to our operations. This could have a material adverse effect on the sales, cost, or gross margin of our products, and the demand from our customers may be diminished. In addition, uncertainty surrounding international trade policy and regulations as well as disputes and protectionist measures could also have an adverse effect on consumer confidence and spending.

Moreover, our ongoing efforts to address these risks may not be effective and may have long-term adverse effects on our operations and operating results that we may not be able to reverse. Such efforts may also take time to implement or to have an effect and may result in adverse financial results or fluctuations in our financial results. In addition, these tariffs and retaliatory actions could affect our long-term strategies. If we deem it necessary to alter all or a portion of our activities or operations in response to such policies, agreements or tariffs, our capital and operating costs may increase. As a result, changes in trade policy and regulations in the United States and other countries could adversely affect our business, results of operations and financial condition.

If we cannot innovate at the pace of our competitors, we may not be able to develop or exploit new technologies in time to remain competitive.

For us to remain competitive, it is essential to be at the forefront of new technologies, including in the rapidly evolving area of AI. If we are unable to meet customer demands for new technology, or if the technologies we introduce are viewed less favorably than our competitors' products, our results of operations and future prospects may be negatively affected. To meet our customers' needs in these areas, we must continuously work on our product design, develop our algorithms, and invest in and develop new technologies. We

will also need to anticipate customer demand with respect to these technologies and which technological advances are most desirable in the EEG monitoring products and any future additional products we market. This need will result in requiring our employees to continue learning and adapting to new technologies, and us competing for highly skilled talent in a competitive market. Our operating results depend to a significant extent on our ability to anticipate and adapt to technological changes in the EEG monitoring market, maintain innovation, maintain a strong product pipeline, and reduce or maintain low costs for producing high-quality EEG monitoring products. Any inability to do so could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 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 fail to maintain our culture, our business may be negatively affected.

Maintaining a positive company culture is necessary to enable us to retain and hire key talent and have a cohesive, aligned employee base. Our ability to maintain this culture will directly affect the continued growth and success of our company. Our culture could face sustainability challenges as we continue to grow. Potential obstacles include reduced adoption of our culture by new employees, limited ability to maintain consistency of culture within business teams, and failure to attract and retain leaders who are mission-minded and support our culture.

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.

We spend significant amounts on marketing and brand-building initiatives to acquire and retain customers, which may not be successful or cost effective.

We spend significant amounts in marketing initiatives to increase market awareness of the Ceribell System and the prevalence of seizures in critically ill patient populations. Through our marketing and educational efforts, we reinforce the prevalence and severity of non-convulsive status epilepticus, the importance of prompt diagnosis and treatment, and the limitations of conventional EEG systems in the acute care setting. We believe our marketing programs are essential to increasing adoption of our system and expanding the use of EEG monitoring to a greater number of at-risk patients.

While we have developed robust marketing initiatives, we may fail to identify marketing opportunities that satisfy our anticipated return on marketing spend or accurately predict customer acquisition or product-related concerns. If any of our marketing efforts prove less successful than anticipated in attracting new or retaining existing customers, we may not be able to recover our marketing spend, and our rates of customer acquisition and/or customer retention may fail to meet market expectations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our marketing efforts may not result in increased sales of our products, and we may be unable to compete effectively in the long term.

In addition, we believe that building a strong brand and developing and achieving broad awareness of the Ceribell System is critical to achieving market success. If any of our brand-building activities prove less successful than anticipated, or such activities are inhibited by the negative perceptions of healthcare professionals, including with respect to AI-enabled devices or reduced montage EEG in general, or the safety, reliability and efficacy of the Ceribell System, it could materially adversely impact our ability to attract new and retain existing customers and the rate of use of our products by existing customers. If this were to occur, we may not be able to recover our brand-building spend, and our rates of customer acquisition and retention and product usage may fail to meet market expectations, any of which could have a material adverse effect on 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;
- costs to defend the related litigation;
- a diversion of management's time and our resources;

- substantial monetary awards to customers and patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to sell our current or any future products.

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.

We may in the future be deemed to manufacture or contract to manufacture products that contain conflict minerals.

We may in the future be deemed to manufacture or contract to manufacture products that contain certain minerals that have been designated as "conflict minerals" under the Dodd-Frank Wall Street Reform and Consumer Protection Act. As a result, in future periods, we may be required to diligence the origin of such minerals and disclose and report whether or not such minerals originated in the Democratic Republic of the Congo or adjoining countries. The implementation of these new requirements could adversely affect the sourcing, availability, and pricing of materials used in the manufacture of our products. In addition, we may incur additional costs to comply with the disclosure requirements, including costs related to determining the source of any relevant minerals and metals used in our products.

Our continued rapid growth could strain our personnel resources and infrastructure, and if we are unable to manage the anticipated growth of our business, our business, financial condition, results of operations, and prospects could be materially adversely effected.

We have experienced rapid growth in business. Any growth that we experience in the future will pose challenges to our organization, requiring us to expand our sales personnel, manufacturing, and 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 and unanticipated costs and disruptions to our operations. Additionally, rapid expansion could pose challenges to retaining our existing employees, for example, by requiring us to rely on overtime to increase capacity that could, in turn, result in greater employee attrition and/or a loss in productivity during the process of recruiting and training additional resources and add to our operating expenses. In addition, rapid and significant growth may strain our

administrative and operational infrastructure, financial and management controls, and reporting systems and procedures. Our ability to manage our business and growth will depend on our ability to continue to improve our infrastructure, controls, systems, and procedures at a pace consistent with our growth. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business, financial condition, results of operations, and prospects may be materially adversely affected.

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 and monetary and financial uncertainties.

The impacts of these macroeconomic conditions, and the actions taken by governments, central banks, companies, and consumers in response, have resulted in, and may continue to result in, higher inflation in the United States and globally, which is likely, in turn, to lead to an increase in costs and may cause changes in fiscal and monetary policy, including additional increases in interest rates. Other adverse impacts of recent macroeconomic conditions have been, and may continue to be, 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.

Also, we have experienced, and may continue to experience, supply chain constraints, including difficulties obtaining a sufficient supply or increased prices of component materials used in our products. Increased interest rates may make access to credit more difficult, which may result in the insolvency of key suppliers, which would exacerbate supply chain challenges. Such supply chain constraints could cause us to fail to meet product demand or maintain our margins.

Risk 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, discharged 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 newest Clarity algorithm, effective October 1, 2023. The NTAP designation for a product lasts for no more than three years for a specific indication. Once our new Clarity algorithm is no longer eligible for NTAP, the additional cost associated with the use of our products could affect our

customers' profit margin. In light of the potential additional associated cost, 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 and have a material adverse effect on our business, financial condition, results of operations, and prospects. In Europe, reimbursement is entirely regulated at member state level, varies significantly between countries, and member states are facing increased pressure to limit public healthcare spending. 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, anesthesiologist assistants, 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.

If our operations are 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.

Our employees, consultants and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless, or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other regulators (both domestic and foreign), including those laws requiring the reporting of true, complete, and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws, and regulations in the United States and internationally or laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing, and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. It is not always possible to identify and deter misconduct by our employees, consultants, and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, oversight if we become subject to a consent decree or corporate integrity agreement, and curtailment of operations, any of which could adversely affect our business, financial condition, results of operations, and prospects. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations.

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. There have been executive, judicial, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

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. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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 the effect of 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 relationships with contracted physicians to provide remote EEG interpretation services to certain customers must be structured in compliance with state laws prohibiting the corporate practice of medicine or fee splitting and could be found to violate such laws.

Our relationships with physicians providing remote EEG interpretation services to certain customers may implicate certain state laws that generally prohibit non-professional entities from providing licensed medical services or exercising control over licensed physicians or other healthcare professionals (such activities generally referred to as the "corporate practice of medicine") or engaging in certain practices such as fee-splitting with such licensed professionals. The interpretation and enforcement of these laws vary significantly from state to state. There can be no assurance that these laws will be interpreted in a manner consistent with our practices or that other laws or regulations will not be enacted in the future that could have a material adverse effect on our business, financial condition, results of operations, and prospects. Regulatory authorities, state boards of medicine, state attorneys general, and other parties may assert that, despite the agreements through which we operate, we are nonetheless engaged in the provision of medical services and/or that our arrangements with the physicians constitute the unlawful practice of medicine and/or fee-splitting. If a jurisdiction's prohibition on the corporate practice of medicine or fee-splitting is interpreted in a manner that is inconsistent with our practices, we would be required to restructure or terminate our arrangements with our employed and contracted physicians to bring our activities into compliance with such laws. A determination of non-compliance, or the termination of or failure to successfully restructure these relationships, could result in disciplinary action, penalties, damages, fines, and/or a loss of revenue, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. State corporate practice and fee-splitting prohibitions also often impose penalties on healthcare professionals for aiding in the improper rendering of professional services, which could discourage physicians from providing reading services to our customers with whom we contract.

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, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices. In the *de novo* classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the *de novo* classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

The PMA approval, 510(k) clearance and *de novo* classification processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Clinical data may also be required in connection with an application for 510(k) clearance or a *de novo* 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 to the satisfaction of the FDA that our products are substantially equivalent to a predicate device or are safe and effective for their intended uses;
- the disagreement of the FDA with the design or implementation of our clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our preclinical studies and clinical trials may be insufficient to support clearance, *de novo* classification, or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for marketing authorization regulations of the FDA to change significantly in a manner rendering our clinical data or regulatory filings insufficient for marketing authorization.

In September 2022, we received Breakthrough Device Designation from the FDA for the detection and monitoring of delirium using our Ceribell System. 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. 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 detection and monitoring of delirium using our Ceribell System. 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 third party–initiated trials 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, which could adversely affect the costs, timing, or successful completion of our clinical trials, including related to the following:

- regulators may disagree as to the design or implementation of our clinical trials;
- regulators and/or institutional review boards ("IRBs"), or other bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with third-party researchers, clinical trial sites, or prospective contract research organizations ("CROs"), the terms of which can be subject to extensive negotiation and may vary significantly among different researchers, trial sites, and CROs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- we might have to suspend or terminate clinical trials for various reasons, including occurrence of adverse events or other findings that the subjects in our clinical trials are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB, or other bodies and/or regulatory authorities for re-examination;
- regulators, IRBs, other bodies, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- marketing authorization or regulations of FDA may change in a manner rendering our clinical data insufficient for marketing authorization;
- we may be required to submit an investigational device exemption ("IDE") application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials, or place restrictions on the conduct of such trials; similar requirements may apply in foreign jurisdictions; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

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

From time to time, we may publicly disclose interim, top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial or additional data collected at a later time. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line, or preliminary results that we report may differ from future results of the same trial, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, top-line, or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top-line, or preliminary data we previously announced. As a result, interim, top-line, and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in our share price.

Further, others, including regulatory agencies or other bodies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular trial, or the approvability or potential for commercialization of the particular medical device. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. The interim, top-line, or preliminary data that we report may differ from final results, and regulatory authorities and other bodies may disagree with the conclusions reached, which may harm our ability to obtain marketing authorization for, and commercialize, our future products, which could harm our business, financial condition, results of operations, and prospects.

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

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

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

- untitled letters or warning letters;

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

Any of these sanctions could result in negative publicity, higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition, 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 System Regulation ("QSR"), which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures, and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR 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., report 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 headband 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 headband 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 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 headbands 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 sizeable damage awards against us that may not

be covered by insurance, all of which would have a material adverse effect on our business, financial condition, 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 January 31, 2024, the FDA issued a final rule to amend the QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization standards. This new final rule, referred to as the Quality Management System Regulation, will take effect on February 2, 2026. Accordingly, it is unclear the extent to which any other legislative or regulatory proposal, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may 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.

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

We intend to enter into international markets in the future. 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. For example, in December 2021, the U.S. Congress enacted the Uyghur Forced Labor Prevention Act in an effort to prevent what it views as forced labor and human rights abuses in the XUAR. If it is determined that our third-party suppliers and manufacturers produce or manufacture our components or products wholly or in part from the XUAR, then we could be prohibited from importing such components or products into the United States.

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 headbands supplied by third-party manufacturers located in China 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 for our products sufficient to meet our demand forecasts, if demand for the Ceribell System increases more rapidly than we anticipate, if we encounter problems with one or more of our manufacturers, including as a result of trade restrictions related to China, or if we secure regulatory approval to commercialize our products in additional geographies or indications, we may need to either expand our manufacturing capabilities, qualify new suppliers, or outsource to other manufacturers.

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. The methods used in, and the facilities used for, the manufacture of medical devices sold in the United States must comply with the QSR. 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*." Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA requirements, other federal and state regulatory requirements and foreign regulations, to the extent applicable. If we fail to manufacture our products in compliance with the QSR, or if our or our third-party suppliers' manufacturing facilities suffer disruptions, supply chain issues, machine failures, slowdowns, or disrepair, we may not be able to fulfill customer demand and our business would be harmed.

Any contamination of the controlled environment, equipment malfunction, supply issues, natural disasters (including wildfires or earthquakes, to which our manufacturing facility in Sunnyvale, California may be especially susceptible), public health emergencies, personnel issues, including human error, or failure to strictly follow procedures can significantly reduce our yield. A drop in yield can increase our cost to manufacture our products or, in more severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources. In addition, if demand for our products shifts such that our manufacturing facilities are operated below our forecasts for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

The manufacturing and distribution of our products are technically challenging. Changes that our suppliers may make, or additional requirements from regulatory agencies, outside of our direct control can have an impact on our processes, on quality and on the successful or timely delivery of our products to our customers. Mistakes and mishandling may occur, which can affect supply and delivery. As a result, our dependence on third-party, including single-source suppliers, subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, financial condition, and results of operations, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's failure to produce components that consistently meet our quality specifications;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of our products;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key component or other supply chain constraints;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of suppliers to comply with applicable provisions of the QSR or other applicable laws or regulations enforced by the FDA and other regulatory authorities;
- delays in regulatory approvals of any changes to manufacturing, including the use of new suppliers;
- latent defects that may become apparent after our products have been released and that may result in an adverse event or a recall of such products;
- inclusion of vendors of raw materials not in compliance with regulatory requirements;

- natural or other disasters, global pandemics, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment, international conflict or war, or other forms of disruption to business operations affecting our manufacturing operations and those of our third-party manufacturers and suppliers;
- production delays related to the evaluation and testing of our products or the use of components from alternative suppliers; and
- delays in delivery by our suppliers of components, materials or services due to changes in demand from us or their other customers.

The occurrence of any of these issues could significantly harm our ability to manufacture our products and maintain sufficient quality standards, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

We depend on a limited 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 QSR 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.

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 requirements known as 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.

We rely on relationships with contracted physicians to provide remote EEG reading services to certain customers.

We contract directly or indirectly with physicians to provide remote EEG reading services to certain customers. If these physicians terminate their contracts, we or our partners may not be able to contract with alternative physicians to provide such services in a timely manner, or at all, which would impact our ability to provide services to certain customers and could adversely affect our business, financial condition, 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. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging.

We may in the future become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions, many of which have developed privacy and data protection requirements that impose requirements that differ substantially from those that apply within the United States. For example, in Europe, the European Union General Data Protection Regulation (the "EU GDPR") went into effect in May 2018 and governs the collection, use, disclosure, transfer, and other processing of personal data of individuals within the European Economic Area (the "EEA") and imposes stringent requirements for data processors and controllers of such personal data or in the context of their activities within the EEA. Companies that must comply with the EU GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant undertaking, whichever is greater. In addition to fines, a breach of the EU GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit), and/or civil claims (including class actions). The processing of "special category personal data" (such as personal data related to health and genetic information), which could become relevant to our operations in the context of our conduct of clinical trials, may also impose heightened compliance burdens under European data protection laws and is of interest to relevant regulators. Among other requirements, the EU GDPR regulates transfers of personal data subject to the EU GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. In addition, since early 2021, after the end of the transition period following the United Kingdom's departure from the European Union, the EU GDPR continues to apply in substantially equivalent form in the context of the United Kingdom under the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (the "UK GDPR"), which imposes separate but similar obligations to those under the EU GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. 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 we expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

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 personal health information, fail to implement policies to protect personal 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.

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 payors, 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 Trump administration has rescinded an executive order relating to AI Technologies that was previously implemented by the Biden administration. The Trump administration may continue to rescind other existing federal orders and/or administrative policies relating to AI Technologies, or may implement new executive orders and/or other rule-making 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 our system and business and the way in which we use AI Technologies. We may need to expend resources to adjust our 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 (confidentially, "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, 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 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 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 secret, 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 U.S. Patent and Trademark Office (the "USPTO") 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. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or in-licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

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. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, should we become a licensee of a third party's patents or patent applications, depending on the terms of any future in-licenses to which we may become a party, 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.

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

The USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent and/or applications and any patent rights we may obtain in the future. While an unintentional lapse of a patent or patent application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or our patent licensors fail to maintain the patents and patent applications that we in-license, we may not be able to stop a competitor from marketing products, services, or technologies that are the same as or similar to our products, services, or technologies, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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.

In June 2023, the European Unitary Patent system and the European Unified Patent Court (“UPC”) were launched. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system began and granted thereafter, are subject to the jurisdiction of the UPC, unless actively opted out. This was a significant change in European patent practice, and deciding

whether to opt-in or opt-out of Unitary Patent practice entail strategic and cost considerations. The UPC provides third parties with a new forum to centrally revoke our European patents and makes it possible for a third party to obtain pan-European injunctions against us. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court's existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.

The legal systems in certain countries may also favor state-sponsored or companies headquartered in particular jurisdictions over our first-in-time patents and other intellectual property protection. We are aware of incidents where such entities have stolen the intellectual property of domestic companies in order to create competing products and we believe we may face such circumstances ourselves in the future. For example, through its "Annual Special 301 Report on Intellectual Property," the Office of the United States Trade Representative has been reporting on the adequacy and effectiveness of intellectual property protection in a number of foreign countries that are U.S. trading partners and their protection and enforcement of intellectual property rights. Placement of a country on the Priority Watch List indicates that particular problems exist in that country with respect to intellectual property protection, enforcement, or market access for persons relying on intellectual property rights. Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the specific problem areas. It is possible that we will not be able to enforce our intellectual property rights against third parties that misappropriate our proprietary technology in those countries.

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. Various countries outside the United States, including certain countries in Europe, India, and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner in such countries may have limited remedies in certain circumstances, which could materially diminish the value of such patent. Accordingly, our efforts to enforce our intellectual property 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.

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 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 re-examination, post-grant review, *inter partes* review, interference proceedings, 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.

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 interference proceedings, 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 interference 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 interference or derivation proceedings outcome 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 do one or more of the following:

- stop developing, making, selling, importing, or using products, services, or technologies that allegedly infringe, misappropriate, or otherwise violate the asserted intellectual property right;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, misappropriating, or otherwise violating;
- redesign those products, services, or technologies that contain the allegedly infringing intellectual property, which could be costly, disruptive, and infeasible; and attempt to obtain a license to the relevant intellectual property rights from third parties, which may not be available on commercially reasonable terms or at all, or from third parties who may attempt to license rights that they do not have;
- lose the opportunity to license our intellectual property rights to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses; or
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing, misappropriating, or otherwise violating.

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 re-examination, 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, services provides, 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. During the quarter ended June 30, 2025, 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. While we believe this extension strengthens our intellectual property position, 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, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. 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.

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 or 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.

We rely on our trademarks, trade names, and brand names, such as our Clarity mark, to distinguish our products, services, and technologies from the products, services, and technologies of our competitors, and have registered or applied to register many of these trademarks in the United States and certain countries outside the United States; however, we have not yet registered all of our trademarks in all of our current and potential markets. There can be no assurance that all of our trademark applications will be approved for registration. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties have opposed and may oppose in the future further our trademark applications and may seek to cancel trademark registrations or otherwise challenge our use of the trademarks. Opposition or cancellation proceedings may be filed against our trademark filings in these agencies, and such filings may not survive such proceedings. While we may be able to continue the use of our trademarks in the event registration is not available, particularly in the United States, where trademark rights are acquired based on use and not registration, third parties may be able to enjoin the continued use of our trademarks if such parties are able to successfully claim infringement in court. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our trademarks or trade names may be infringed, circumvented, declared generic, or determined to be violating or infringing on other marks.

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 non-compliance 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.

Although we typically review our use of open source software to avoid subjecting our products, services or technology to conditions we do not intend, the terms of many open source software licenses have not been interpreted by United States courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products, services or technology. Moreover, our processes for monitoring and controlling our use of open source software in our products, services or technology may not be effective. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our solutions on terms that are not economically feasible, to re-engineer our products, services, or technology, to discontinue the sale of our products, services, or technology if re-engineering could not be accomplished on a timely basis, to pay statutory or other damages to the license holder, or to make generally available, in source code form, our proprietary code, any of which could materially adversely affect our business, financial condition, results of operations, and prospects.

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 Relating 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, 2024, we had NOLs of approximately $127.1 million for federal income tax purposes and $126.9 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.

Our effective tax rate may vary significantly from period to period.

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations, or rates, both within and outside the U.S., structural changes in our business, new accounting pronouncements or changes to existing accounting pronouncements, non-deductible goodwill impairments, changing interpretations of existing tax laws or regulations, changes in the relative proportions of revenue and income before taxes in the various jurisdictions in which we operate that have different statutory tax rates, the future levels of tax benefits of equity-based compensation, changes in overall levels of pretax earnings or changes in the valuation of our deferred tax assets and liabilities. Additionally, we could be challenged by state and local tax authorities as to the propriety of our sales tax compliance, and our results could be materially impacted by these compliance determinations.

In addition, our effective tax rate may vary significantly depending on the market price of our common stock. The tax effects of the accounting for share-based compensation may significantly impact our effective tax rate from period to period. In periods in which the market price of our common stock is higher than the grant price of the share-based compensation vesting in that period, we will recognize excess tax benefits that will decrease our effective tax rate. In future periods in which our stock price is lower than the grant price of the share-based compensation vesting in that period, our effective tax rate may increase. The amount and value of share-based compensation issued relative to our earnings in a particular period will also affect the magnitude of the impact of share-based compensation on our effective tax rate. These tax effects are dependent on the market price of our common stock, which we do not control, and a decline in our stock price could significantly increase our effective tax rate and adversely affect our financial condition.

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 August 16, 2022, the Inflation Reduction Act (the "IRA") was signed into law in the U.S. Among other changes, the IRA, along with subsequent regulations, imposes a minimum tax on certain corporations with book income of at least $1 billion, subject to certain adjustments, and a 1% excise tax on certain stock buybacks and similar corporate actions. Furthermore, 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.

In addition, many countries in the European Union, as well as a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws that could impact our tax obligations in the future. 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 venture loan and security agreement contains restrictions that limit our flexibility in operating our business.

We have entered into a venture loan and security agreement, dated as of February 6, 2024, by and among us, Horizon Technology Finance Corporation, as a lender and collateral agent, and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("SVB"), as a lender (the "VLSA"). Concurrent with the VLSA, we also entered into a Loan and Security Agreement with SVB for a senior revolving line of credit of up to $10.0 million (the "Revolving Facility"). As of December 31, 2024, $20.0 million in aggregate principal amount was outstanding under the VLSA, and no amount was outstanding under the Revolving Facility. The VLSA and the Revolving Facility contain various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- sell, transfer, lease, or dispose of our assets subject to certain exclusions;
- create, incur, assume, guarantee, or assume additional indebtedness, other than certain permitted indebtedness;
- encumber or permit liens on any of our assets other than certain permitted liens;

- make restricted payments, including paying dividends on, repurchasing, or making distributions with respect to any of our capital stock;
- make specified investments;
- consolidate, merge with, or acquire any other entity, or sell or otherwise dispose of all or substantially all of our assets; and
- enter into certain transactions with our affiliates.

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 VLSA and the Revolving Facility. The covenants in the VLSA and the Revolving Facility limit our ability to take certain actions and, in the event that we breach one or more covenants, the lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding of the aggregate principal amount, plus accrued interest, and foreclose on the collateral granted to it to secure such indebtedness. Such repayment could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our cash deposits with financial institutions exceed insured limits.

We maintain the majority of our cash and cash equivalents in accounts with one or more U.S. financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of financial institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial condition.

Risks Relating 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 initial public offering ("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 increased costs and are subject to additional regulations and requirements as a result of becoming a public company, which could lower our profits or make it more difficult to run our business.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We have also incurred and will continue to incur costs associated with the Sarbanes-Oxley Act and related rules implemented by the Securities and Exchange Commission (the "SEC") and the exchange on which our securities are listed. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, on our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action, and potentially civil litigation.

If we are unable to design, implement, and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, beginning with our second Annual Report on Form 10-K, we will be required to furnish a report by management on the effectiveness of our internal control over financial reporting, pursuant to the rules and regulations of the SEC regarding compliance with Section 404 of the Sarbanes-Oxley Act. The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. We have in the past identified control deficiencies including material weaknesses and may identify control deficiencies, including material weaknesses in our internal control over financial reporting, in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. Further, if we identify one or more material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we or, if required, our auditors, are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, which could require additional financial and management resources. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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 VLSA, 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 may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will be comprised 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.

Future securities issuances could result in significant dilution to our stockholders and impair the market price of our common stock.

Future issuances of shares of our common stock, or the perception that these sales may occur, could depress the market price of our common stock and result in dilution to existing holders of our common stock. Also, to the extent outstanding options to purchase shares of our common stock are exercised or options, restricted stock units or other stock-based awards are issued or become vested, there will be further dilution. The amount of dilution could be substantial depending upon the size of the issuances or exercises. Furthermore, we may issue additional equity securities that could have rights senior to those of our common stock. As a result, holders of our common stock bear the risk that future issuances of debt or equity securities may reduce the value of our common stock and further dilute their ownership interest.

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.

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 April 30, 2025, our executive officers, directors, owners of more than 5% of our capital stock and their respective affiliates beneficially owned approximately 60% 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 acquiror;
- 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 acquiror from conducting a solicitation of proxies to elect the acquiror'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.

Claims for indemnification by our directors, officers, and other employees or agents may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors, officers and certain other employees provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our Board of Directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees, and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaws provisions to reduce our indemnification obligations to directors, officers, employees, and agents.

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 is 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 factor, 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 payor 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 devices 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.

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

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

General Risk Factors

If we engage in acquisitions or strategic partnerships, it may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary offerings, intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property, and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing operations in pursuing such a strategic merger or acquisition;
- loss of key personnel and uncertainties in our ability to maintain key business relationships;
- uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or future products and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition or partnership opportunities, and even if we do locate such opportunities, we may not be able to successfully bid for or obtain them due to competitive factors or lack of sufficient resources. This inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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. If such an event were to affect our supply chain, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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, and any legal or arbitration proceedings could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement, causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our insurance may not cover all potential losses or liabilities that may arise.

We are not insured against all potential losses or liabilities that may arise, as insurance coverage may be unavailable, not cost-effective, or subject to significant limitations. For example, we are not insured against business interruptions suffered by third parties that we depend on, environmental liabilities or patent infringement, among other types of risks. Furthermore, no assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. If a loss or liability occurs that is not or not fully covered by insurance, we may be required to pay substantial amounts, which could adversely affect its cash position and results of operations.

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

Unregistered Sale 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.

The net proceeds from our IPO have been used and will be used, together with our existing cash and cash equivalents: (i) to fund sales and marketing efforts; (ii) to fund research and product development activities, including to advance our delirium and ischemic stroke indications through completion of clinical studies related to our Clarity algorithm; and (iii) for general corporate purposes, including working capital, operating expenses, and capital expenditures.

There has been no material change in the intended use of proceeds from our IPO as described in our Prospectus.

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	May 22, 2025	X		180,000	April 30, 2026
Josef Parvizi, M.D., Ph.D. *Director, Chief Medical Advisor, and Co-Founder*	Terminate[(1)]	June 25, 2025	X		180,000	April 30, 2026
Raymond Woo, Ph.D. *Chief Technology Officer*	Adopt	May 28, 2025	X		120,008	May 19, 2026

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

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

[(1)]Dr. Parvizi's trading plan, originally adopted on May 22, 2025, was terminated on June 25, 2025 due to a clerical error in the drafting of the plan. No trades were executed under the plan prior to its termination.

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†	Amendment No. 4 to the Exclusive (Equity) Agreement effective June 15, 2015, by and between the Board of Trustees of the Leland	8-K	6/20/2025	10.1	

	Stanford Junior University and Ceribell, Inc., dated June 12, 2025.	
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 with Embedded Linkbase Documents.	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).	X

† Portions of the exhibit, marked by brackets, have been omitted because the omitted information is (i) not material and (ii) the type of information that the registrant customarily and actually treats as private or confidential.

* The certification attached as Exhibit 32.1 and Exhibit 32.2 that accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, is 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: August 5, 2025

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

Date: August 5, 2025

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)) for the registrant and have:

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

   (b) [Omitted];

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

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

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

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

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

Date: August 5, 2025

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)) for the registrant and have:

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

   (b) [Omitted];

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

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

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

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

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

Date: August 5, 2025

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 ending June 30, 2025 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: August 5, 2025

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 ending June 30, 2025 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: August 5, 2025

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