UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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, 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, there was no established public market for the Registrant's common stock. Therefore, the aggregate market value of its common stock held by non-affiliates as of such date cannot be calculated. The Registrant's common stock began trading on the Nasdaq Global Select Market on October 11, 2024.

The number of shares of Registrant's Common Stock outstanding as of February 21, 2025 was 35,868,339.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement relating to the Registrant's 2025 Annual Stockholders' Meeting, to be filed within 120 days of the Registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management, and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "may," "will," "shall," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential," "goal," "objective," "seeks," 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 Annual Report 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 artificial intelligence ("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 Jumpstart Our Business Startups Act of 2012 (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 Annual Report.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report 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 Annual Report, 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 Annual Report. 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 Annual Report. 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 Annual Report 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 Annual Report to reflect events or circumstances after the date of this Annual Report 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 Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to the registration statement, of which this Annual Report 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 Annual Report by these cautionary statements.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part I. Item 1A. "Risk Factors" in this Annual Report. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- 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 have a history of net losses, and we expect to incur additional substantial losses in the foreseeable future.
- 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 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.
- We are dependent on international manufacturers and suppliers, which exposes us to foreign operational risks that may harm our business.
- 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.
- If we fail to attract and retain senior management and other key personnel, our business may be materially and adversely affected.
- 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 spend significant amounts on marketing and brand-building initiatives to acquire and retain customers, which may not be successful or cost effective.
- 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.
- 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 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.
- 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.
- Our employees, consultants and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

- Our relationships with contracted physicians to provide remote electroencephalography ("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 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.
- 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.
- 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.
- 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 rely on relationships with contracted physicians to provide remote EEG reading services to certain customers.
- 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.
- Our business and operations may suffer in the event of information technology system failures, cyber attacks, or deficiencies in our cybersecurity.
- 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.
- 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.
- 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.
- 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.
- 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.
- Our venture loan and security agreement contains restrictions that limit our flexibility in operating our business.
- Our cash deposits with financial institutions exceed insured limits.
- 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.
- Future securities issuances could result in significant dilution to our stockholders and impair the market price of our common stock.
- 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.
- Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.
- The market price of our common stock may be volatile, which could cause the value of your investment to decline.
- 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.
- Our insurance may not cover all potential losses or liabilities that may arise.

PART I

Item 1. Business.

Overview

We are a medical technology company focused on transforming the diagnosis and management of patients with serious neurological conditions. We have developed the Ceribell System, a novel, point-of-care EEG platform specifically designed to address the unmet needs of patients in the acute care setting. By combining proprietary, highly portable, and rapidly deployable hardware with sophisticated artificial intelligence ("AI")-powered algorithms, the Ceribell System enables rapid diagnosis and continuous monitoring of patients with neurological conditions. We 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. To date, the Ceribell System has been adopted by more than 500 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 "—Market Overview—Challenges of Managing Seizures in the Acute Care Setting."

A seizure is an abnormal burst of uncontrolled electrical activity in the brain which, if left untreated, can result in permanent disability or death. Seizures are often associated with epilepsy, a chronic condition that causes recurring seizures throughout an individual's life. However, seizures in the acute care setting are also commonly triggered by serious conditions such as brain tumors, traumatic brain injury, stroke, cardiac arrest, and sepsis, among others. In contrast to epileptic seizures which are short in duration and typically involve convulsions, seizures occurring in the acute care setting tend to be longer in duration and are most often non-convulsive, meaning they lack the physical symptoms that are often used to identify seizure activity, which makes empirical diagnosis extremely challenging. This creates a significant unmet need, and it is estimated that up to 92% of all seizures in the ICU are non-convulsive.

A seizure lasting longer than five minutes is known as status epilepticus, a serious medical emergency that can lead to mortality or severe and permanent brain damage. Awareness of the severity of status epilepticus has significantly increased over the last decade, with a heightened emphasis on prompt diagnosis and treatment, which are the most important factors in appropriately managing the condition and improving patient outcomes. The all-cause mortality rate associated with non-convulsive status epilepticus is approximately 18-30%. Further, patient response rates to first-line anti-seizure medication drop by approximately 30% for every hour medication is delayed from the onset of seizures. Given the impact of prompt detection on treatment success and outcomes, medical society guidelines emphasize the need for prompt EEG monitoring for patients at risk of status epilepticus.

EEG, a non-invasive test that measures electrical activity in the brain and displays this activity as continuous waveforms, is the only way to definitively confirm a seizure diagnosis. EEG was originally designed for the outpatient setting, primarily for use in the diagnosis and management of epilepsy, where the technology has been used for nearly 100 years. In the acute care setting, we believe conventional EEG systems are insufficient to meet the needs of critically ill patients as they are unable to provide the speed of diagnosis and continuous monitoring necessary for optimal patient management. These challenges are the result of multiple inherent bottlenecks in the design of conventional EEG systems and the infrastructure required to administer them. Conventional EEG systems must be operated by specialized EEG technicians who typically work limited hours, are staffed across multiple departments within the hospital, and face a national supply shortage. After arrival at the bedside, which is often delayed, EEG technicians must initiate a long, complex, and labor-intensive setup process before EEG recording can begin. The EEG recording must then be interpreted and monitored by specialized neurologists, who face similar workflow and supply shortage issues, and when available, are rarely able to continuously monitor EEG recordings in real-time. These bottlenecks result in delays in both diagnosis and monitoring. This can lead to delayed seizure detection and less informed treatment decisions, which may negatively impact clinical outcomes and have been shown to contribute to a higher cost burden for hospitals and the healthcare system.

We specifically designed the Ceribell System to address the limitations of conventional EEG in the acute care setting and dramatically improve clinical outcomes of critically ill patients at high risk of seizures. The Ceribell System integrates proprietary, highly portable hardware with AI-powered algorithms to aid in the detection and management of seizures. Our hardware is composed of 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. In May 2023, the latest generation of Clarity became the first and only device to receive 510(k) clearance

from the U.S. Food and Drug Administration ("FDA") for diagnosing electrographic status epilepticus, and subsequently received a New Technology Add-on Payment ("NTAP") from the Centers for Medicare and Medicaid Services ("CMS").

The unique features and capabilities of our system deliver numerous benefits, including:

- ***Early seizure detection and improved patient outcomes.*** The Ceribell System can be deployed in as little as five minutes by any non-specialized healthcare professional with limited training required and continuously monitors the patient for seizure activity, empowering bedside clinicians to make more informed and timely treatment decisions. This results in improved patient outcomes, including shorter hospital stays and reductions in unnecessary administration of anti-seizure medication, intubation, and patient transfers.
- ***Improved hospital and payer economics.*** We have demonstrated that the Ceribell System can deliver cost savings for hospitals and payers by decreasing the average hospital length of stay, reducing the over-administration of anti-seizure medication, and reducing unnecessary patient transfers. In addition, confirmed diagnosis of seizures may allow hospitals to receive appropriate reimbursement for the more complex and costly management of patients with multiple comorbidities.
- ***Reduced strain on key hospital personnel.*** The Ceribell System reduces reliance on EEG technicians for EEG administration and enables hospitals to better manage technician infrastructure and workflow. Additionally, Clarity allows for better triage of at-risk patients, improves resource allocation, and supports more efficient workflow for neurologists.

We have developed a large body of evidence that supports these clinical and economic benefits, including over 110 peer-reviewed publications and published conference abstracts. Our growing base of clinical evidence highlights the value of the Ceribell System to all key stakeholders, including patients, clinicians, and hospitals of different types and acuity settings. We believe our base of clinical evidence validates that the quality of Ceribell System recordings are equivalent to conventional EEG, supports the diagnostic accuracy of Clarity, and shows that use of the Ceribell System can result in improved clinical management and care. In addition, our clinical evidence supports that use of the Ceribell System can provide meaningful cost savings to hospitals and payers, appropriate reimbursement for the treatment of patients with complex conditions, and reduced strain on hospital personnel. For citations to the studies relating to the clinical evidence noted above in this paragraph, see the section titled "Business—Our Clinical Results and Economic Evidence."

Given the inherent limitations of conventional EEG systems, we believe that EEG has been significantly underutilized in the detection and management of seizures in the acute care setting. By providing our customers with a tool that can be promptly administered and leveraged to inform treatment decisions at the bedside, the Ceribell System has the ability to meaningfully expand the use of EEG to a significantly broader set of acute care patients who we believe should be monitored for non-convulsive seizures. We define our addressable market opportunity as the approximately three million acute care patients in the United States who we believe should be monitored with EEG each year due to high risk of seizures and an estimated 6,000 acute care facilities that we believe could benefit from the Ceribell System. We believe the platform nature of the Ceribell System will enable us to efficiently pursue other serious neurological conditions beyond seizures, including delirium and ischemic stroke, which could represent a significant market opportunity. For information regarding our addressable market opportunity, see "—Market Overview—Our Addressable Market Opportunity in Seizures and—Other Potential Opportunities Beyond Seizures."

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 employ a team of sales representatives, including Territory Managers ("TMs"), who are responsible for new customer acquisition and onboarding, and Clinical Account Managers ("CAMs"), who focus on ongoing account coverage to increase utilization and further support hospital onboarding. 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 have established a significant competitive advantage through multiple strategic initiatives, including investing substantial resources to create our wholly-owned intellectual property portfolio. As of December 31, 2024, we had 18 issued patents and 24 pending patent applications covering multiple aspects of our hardware and algorithms. We have also invested in building data science and AI capabilities, which would be costly and difficult to replicate. To date, our system has been used on over 200,000 patients, which we believe to be the largest database of acute care EEG recordings. Finally, we spend a significant amount of time partnering with our customers, including providing onsite training and ongoing education as well as ensuring optimal workflow and IT integration, all of which strengthens our competitive position, customer loyalty, and customer retention.

We invest in research and development efforts with the goal of driving continuous improvements in the Ceribell System, advancing our mission of becoming the standard of care for the detection and management of seizures in the acute care setting, and expanding the clinical application of our system and AI algorithms, in the acute care setting and beyond. Our research and development team includes 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 generate revenue from two recurring sources – the sale of our disposable headbands that are intended for single patient use and a monthly subscription fee charged to our hospital customers for use of Clarity, recorders, and our portal. We have experienced rapid growth since we began commercializing the Ceribell System in 2018, expanding our headcount to 281 employees in 2024. We recognized revenue of $65.4 million for the year ended December 31, 2024, compared to revenue of $45.2 million for the year ended December 31, 2023, representing 45% year-over-year growth. For the year ended December 31, 2024, we recognized a gross margin of 87% and a net loss of $40.5 million, compared to a gross margin of 84% and a net loss of $29.5 million for the year ended December 31, 2023.

Our Success Factors

We believe the continued growth of our company will be driven by the following success factors:

- ***Paradigm-shifting platform technology capable of becoming the standard of care for brain monitoring in the acute care setting.*** The Ceribell System represents a paradigm-shifting EEG solution for brain monitoring in the acute care setting, a field that has experienced minimal innovation since conventional EEG systems were developed in the 1920s. The Ceribell System was specifically designed to address the shortcomings of conventional EEG systems in the acute care setting. Unlike conventional EEG systems, the Ceribell System provides clinicians with rapid access to EEG, bedside seizure detection, and continuous monitoring, which enables more accurate treatment decisions and improved outcomes for critically ill patients. We believe the Ceribell System is positioned to become the standard of care for the detection and management of seizures in these patients. In the future, we believe the platform nature of the Ceribell System will enable us to efficiently pursue other serious neurological conditions beyond seizures, for which we have begun the technical validation process for multiple indications, including delirium and ischemic stroke. We received Breakthrough Device Designation from the FDA for delirium in September 2022.
- ***Compelling benefits supported by a robust body of clinical and real-world evidence.*** The Ceribell System was designed to optimize patient care and hospital workflow through improved EEG access, quicker detection of seizures, continuous monitoring, and improved clinical decision-making. These attributes of the Ceribell System successfully translate into improved clinical care, which has been shown to improve patient outcomes and hospital and payer economics. The clinical and economic benefits of the Ceribell System are supported by a significant body of evidence that includes over 110 peer-reviewed publications and published conference abstracts. We believe our clinical evidence and real-world case studies will continue to support the adoption of our system.
- ***Large addressable market opportunity with a significant unmet need.*** Prolonged seizures, particularly non-convulsive seizures, are highly prevalent in critically ill patients in the acute care setting and are associated with significant morbidity and mortality. While conventional EEG can be used to detect seizures in these patients, the inherent limitations of conventional EEG systems have resulted in a significant underutilization of this necessary and often lifesaving technology. By providing hospitals with 24/7 bedside assessment and continuous monitoring of seizure activity, the Ceribell System enables hospitals to promptly and more appropriately care for critically ill patients. We believe that the Ceribell System can expand the use of EEG to the approximately three million acute care patients in the United States who we believe should be monitored with EEG each year due to high risk of seizures, representing an over $2 billion annual addressable market opportunity. In addition, we believe that future indication and geographic expansion opportunities could represent a significant market opportunity.
- ***Recurring, predictable and scalable revenue model with attractive gross margins.*** We generate revenue primarily from two recurring sources – the sale of our single use, disposable headbands and a monthly subscription fee for the use of Clarity, recorders, and our portal. Once we onboard an account, we have historically observed high retention rates. We believe that

our track record of customer retention and our recurring revenue model improve the predictability of our revenue. Both our disposable headband and subscription revenue streams offer significant visibility and produce high gross margins. For the years ended December 31, 2024 and 2023, we generated gross margins of 87% and 84%, respectively, with subscription gross margins of 97% and 96%, respectively. We have also developed a highly scalable commercial model that combines TMs focused on new customer adoption and onboarding and CAMs focused on driving utilization with limited case coverage support required, which we believe will support efficient growth and greater operating leverage. We believe the attractive attributes of our business model will allow us to continue to invest in growth initiatives while driving the company towards profitability.

- ***Strong competitive position with first mover advantage.*** We have deployed a wide range of strategies to strengthen our competitive advantage. We have invested sizeable resources in developing a comprehensive and wholly-owned intellectual property portfolio, which, as of December 31, 2024, included 18 issued patents and 24 pending patent applications covering multiple aspects of our hardware and algorithms. Additionally, we have invested in building data science and AI capabilities, which would be costly and difficult to replicate. To date, our system has been used in over 200,000 patients. Portions of this database have been used to inform our proprietary, AI-powered algorithm for seizure detection and will enable us to develop algorithms for indications beyond seizures. We have also established a sophisticated onboarding program, which includes onsite training and ongoing education as well as workflow and IT integration, all of which help to build customer loyalty and strengthens our competitive position and customer retention.
- ***Established reimbursement.*** The Ceribell System enables our customers to operate under the existing reimbursement structure for EEG, which has well-established reimbursement levels via the Medicare Severity Diagnosis Related Group ("MS-DRG") classification system and Current Procedural Terminology ("CPT") codes. Given the wide variety of underlying acute conditions that may lead to seizures in critically ill patients, use of our system is reimbursed across a large and diverse base of MS-DRGs. As a result, we believe that our system is less subject to targeted reimbursement changes to individual MS-DRGs. In addition, our newest Clarity algorithm is the first neurodiagnostic to achieve both Breakthrough Device Designation from the FDA and an NTAP from CMS. For eligible patients, the NTAP enables hospitals to receive additional reimbursement for each qualifying inpatient admission during which the new Clarity algorithm is used.
- ***Experienced leadership team.*** Our senior management team consists of industry professionals with deep industry expertise across various disciplines, including medical technology, sales and marketing, engineering, data science, and manufacturing.

Our Growth Strategies

Our mission is to establish the Ceribell System as the standard of care for EEG in the acute care setting and help clinicians save patient lives. The key elements of our growth strategy include:

- ***Increase adoption of the Ceribell System by new accounts.*** There are approximately 6,000 acute care facilities with an Intensive Care Unit ("ICU") or Emergency Department ("ED") or both in the United States that we believe could benefit from the Ceribell System because the patients arriving at such facilities may experience seizures 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. As of December 31, 2024, we have successfully deployed our system to more than 500 active accounts, ranging from top academic centers to small community hospitals. We believe that all acute care facilities in the United States can benefit from the Ceribell System, and our goal is to establish our system as the standard of care for the detection and management of seizures in critically ill patients. To drive further adoption of our system, we plan to continue to expand our commercial infrastructure by adding both TMs, who focus on new account acquisition and onboarding, and CAMs, who focus on ongoing account coverage to increase utilization and further support hospital onboarding. Our commercial team engages with customers to communicate the value proposition of the Ceribell System, leveraging our large base of clinical evidence.
- ***Drive utilization of the Ceribell System within our existing customer base.*** We believe there are approximately three million acute care patients in the United States who should be monitored with EEG each year due to high risk of seizures. Currently, many of these patients are not promptly monitored by EEG, as a physician may not be aware of the risk of seizures in a given patient population. Our CAMs work to educate our customers to raise awareness of our technology, non-convulsive seizures, and the risks of delayed treatment because 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. Since implementing this approach in July 2021, we have demonstrated success in meaningfully increasing utilization within our active accounts.
- ***Continue to drive awareness of seizures in the acute care setting.*** We continue to focus on increasing awareness of the prevalence of seizures in critically ill patient populations among intensive care and emergency medicine clinicians in the

acute care setting. Based on our experience, many providers underappreciate the full spectrum of underlying conditions that may result in non-convulsive seizures, which generally cannot be reliably diagnosed on an empirical basis. We also aim to educate providers on the importance of prompt diagnosis and treatment of seizures, including the relevant medical society guidelines that recommend EEG be applied promptly when status epilepticus is suspected and in various conditions in which the risk of status epilepticus is high. We work to achieve these objectives by directly engaging with clinicians, investing in marketing initiatives, and supporting clinical research that validates the importance of early diagnosis and treatment of status epilepticus.

- ***Invest in further growing our base of clinical evidence.*** Clinical evidence is an important driver of our customers' decision-making process, and we are committed to continuing to build upon the foundation of evidence that supports our value proposition. We conduct our own clinical studies and provide support for independent investigator-initiated trials that evaluate different aspects of our system. For example, although the outcomes of clinical trials cannot be guaranteed, we are sponsoring and supporting studies to validate the impact of our system on patient outcomes and to demonstrate the reliability and diagnostic utility of Clarity, with a focus on studies that validate speed of EEG setup, ease-of-use, diagnostic accuracy, enhanced clinician confidence in treatment decisions, improved patient outcomes, and hospital and payer economics. For more information regarding the ongoing studies supported or sponsored by us, see "—Ceribell Supported or Sponsored Ongoing Studies."
- ***Continue to improve and innovate our system for use in seizures.*** 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 have introduced multiple iterations of our Clarity seizure detection algorithm, increasing both the sensitivity and specificity of the algorithm since the initial introduction, and expect to continue to drive further improvements of Clarity in the future. We are also investing in expanding the indicated age range of Clarity to include individuals below the age of 18, and filed a 510(k) application for clearance in the fourth quarter of 2024. If this application is granted, we can bring the benefits of AI-powered seizure detection and continuous monitoring to younger patients, who are already able to benefit from rapid EEG access provided by our proprietary hardware. In addition, we have received 510(k) clearance for and are continuing to develop a headset that will be able to accommodate a head size range appropriate for neonate and infant patients, which have different needs than adult and pediatric patients. We believe that these innovations have the potential to increase the utilization of our system within our established customer base.
- ***Expand into new indications and clinical use cases beyond seizures.*** We believe EEG offers one of the richest datasets of brain activity. While the clinical use of EEG has historically been limited to the identification of seizures, EEGs have been scientifically demonstrated to aid in the detection of a wide variety of other neurological conditions. We intend to leverage our proprietary database of acute care EEG recordings and our data science and AI capabilities to identify patterns in EEG waveforms that may allow us to expand the use of our system to other indications, both in the acute care setting and beyond. We have begun the technical validation process for several indications in the acute care setting. In September 2022, we received FDA Breakthrough Device Designation for the detection and monitoring of delirium, a common condition in the acute care setting characterized by episodes of confusion and disorientation that affects more than seven million hospitalized patients in the United States annually according to the American Delirium Society. We have also initiated technical and clinical work to develop an algorithm that may allow for earlier triage of stroke. We believe these indications would be accessible using our existing hardware platform and commercial infrastructure and significantly expand our total addressable market.
- ***Pursue adjacent and international markets.*** There are approximately 6,000 acute care facilities in the United States that we believe could benefit from our system. We believe that our system offers compelling benefits to other types of institutions beyond this core market, including hospitals affiliated with the Department of Defense, children's hospitals, and long-term acute care facilities. In the future, we plan to establish our presence internationally. 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 within the next two to four years and, in the future, 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.

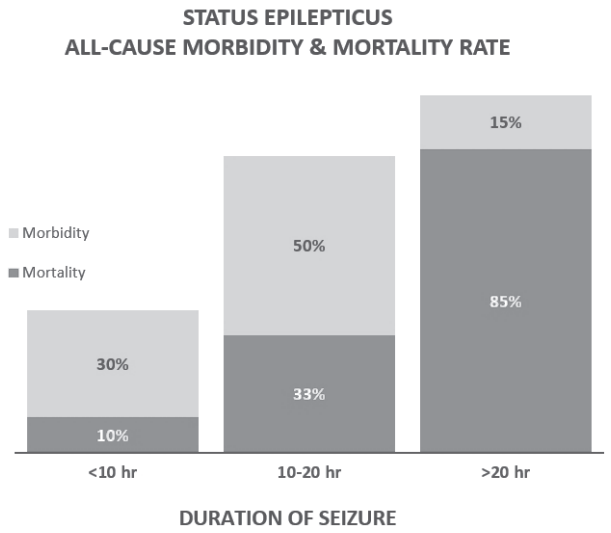
Market Overview

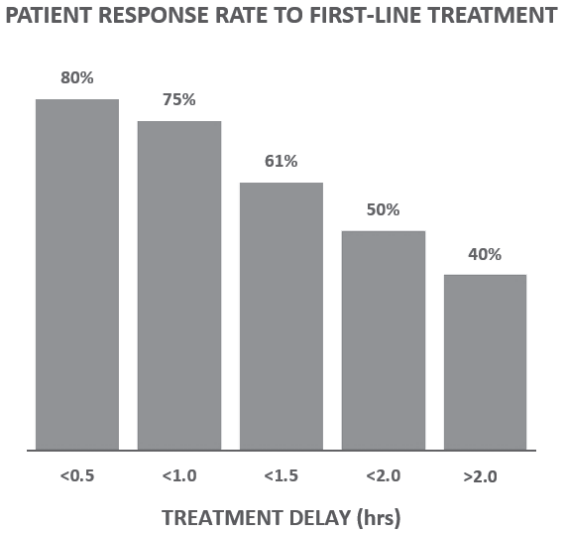
Overview of Seizures in the Acute Care Setting

A seizure is an abnormal burst of uncontrolled electrical activity in the brain that causes a range of clinical symptoms and, if undetected and left untreated, can be life threatening. Seizures generally manifest as a result of an underlying condition, which may be a chronic disorder such as epilepsy or a response to a serious, acute condition, such as brain tumors, traumatic brain injury, stroke, cardiac arrest, and sepsis, among others.

A seizure lasting longer than five minutes is known as status epilepticus, which is a serious medical emergency that can lead to severe long-term cognitive disability or death. The severity of status epilepticus is comparable, and in some cases higher, than other medical emergencies impacting patients in the acute care setting such as sepsis, stroke, and cardiac arrest.

Prompt detection and treatment of status epilepticus are crucial for improving patient outcomes, similar to the management of these other conditions, where early detection and treatment result in significantly improved outcomes. At the same time, we believe that, unlike sepsis, stroke, and cardiac arrest, most hospitals do not have defined protocols for identifying and treating status epilepticus. Multiple studies have established that morbidity and mortality rates for status epilepticus are strongly correlated to seizure duration. Response rates to first-line anti-seizure medication are significantly higher when the medication is administered promptly following the onset of seizures.





Given the impact of prompt detection on treatment success and outcomes, medical society guidelines emphasize the need for prompt EEG monitoring for patients at risk of status epilepticus. For example, the Neurocritical Care Society ("NCS") guidelines recommend continuous EEG monitoring within 15-60 minutes of onset of seizure for treatment of status epilepticus. Further, guidelines from the American Heart Association ("AHA") and American Stroke Association ("ASA") have confirmed the importance of EEG monitoring for certain cardiac arrest and stroke patients who are at high risk of seizures. In addition to the importance of prompt detection, continuous monitoring for seizure activity is critical to the successful management of patients, as status epilepticus may continue or reemerge even after treatment with anti-seizure medication is administered.

Challenges of Managing Seizures in the Acute Care Setting

Seizures in the acute care setting are particularly challenging to detect and often go undiagnosed given they predominantly present as non-convulsive. It is estimated that up to 92% of all seizures in the ICU are non-convulsive. EEG, which measures electrical activity in the brain, is the only test that can definitively confirm a seizure diagnosis and is critical for making informed treatment decisions. EEG converts electrical brain activity to visual, continuous waveforms, which must be interpreted by a specially trained neurologist, such as an epileptologist or neurophysiologist, to detect seizures or other neurological conditions.

Image of EEG Waveforms

Conventional EEG System and Electrodes Placement

Conventional EEG systems consist of reusable or single-use electrodes, which are manually attached to the patient's scalp, and capital equipment, which includes an amplifier, computer module, and display device for transmitting, recording, and displaying the EEG data. Conventional EEG systems were originally designed in the 1920s for use in the outpatient setting, primarily for the diagnosis and management of epilepsy. As such, they were designed with the goal of understanding the precise region of the brain in which seizure activity occurs, rather than to achieve a rapid seizure diagnosis.

In the acute care setting, rapid diagnosis and continuous monitoring are necessary for optimal patient management. While conventional EEG systems are also used in the acute care setting, the inherent limitations of these systems in the acute care setting have contributed to significant delays in seizure diagnosis and suboptimal patient care and clinical outcomes. In this context, Ceribell and numerous study authors measure the quality of patient care by the timeliness of treatment of seizures, the administration of appropriate medication, and avoidance of hospital transfers, and measure clinical outcomes by the incidence of mortality and functional disability, duration of seizure activity, and length of hospital stay associated with seizure activity. The inherent limitations of conventional systems noted above, which include long and manual processes that must be performed by specialized personnel, contribute to delayed, and in some cases outright lack of, access to EEG. For a discussion of studies evaluating patient care and clinical outcomes with conventional EEG systems compared to the Ceribell System in the acute care setting, see "—Our Clinical Results and Economic Evidence."

Conventional EEG systems require set up by specialized EEG technicians who must undergo advanced training and obtain certifications. Nationally, there is a shortage of such technicians, and the infrastructure costs required to staff technicians 24/7 are generally too high for all but the largest and most well-funded medical centers. In most community-based hospitals, EEG technicians

are generally only staffed during normal daytime business hours from Monday through Friday. This results in significant gaps in EEG coverage. For example, a hospital that has EEG technicians available for its ICU from 9:00am to 5:00pm Monday through Friday (i.e., 40 hours a week) would lack EEG coverage for 76% of each week (80 hours on weekdays, plus 48 hours on weekends). On-call services may be available outside of standard business hours, but utilizing these services results in additional delays in EEG access and incremental costs as a result of overtime pay. While large academic hospitals may provide greater EEG coverage, general workflow limitations may still result in significant delays in EEG access. Moreover, we believe that many EDs do not use EEGs as a standard practice given the significant delays in access to EEG.

Conventional EEG systems consist of large and cumbersome capital equipment which is generally not stored in the acute care setting due to space constraints and, as such, must be located and transported to the patient. When the EEG technician finally arrives at the bedside with the equipment, the setup process is long, complex, and labor-intensive. The EEG technician will measure the patient's head to determine electrode placement, then manually part the patient's hair, scrub the skin to remove dead skin cells, apply a conductive gel to form electrical connectivity between the skin and the EEG electrode and then tape the electrode to the patient's skin. This process is repeated for each individual electrode and typically takes up to 30 minutes to complete. The combination of these factors can result in multi-hour, or even multi-day, delays in EEG administration and interpretation in the acute care setting. Such delays are significantly longer than recommendations from NCS guidelines and do not sufficiently meet the needs of patients at risk of seizure. Further, at non-academic, community hospitals, patients who experience status epilepticus may see further delays in receiving an EEG due to staffing limitations.

Once EEG signal is acquired, the recording must be interpreted by a specially trained neurologist. Similar to EEG technicians, there is a nationwide shortage of neurologists, with demand estimated to exceed supply by almost 20%. EEG interpretation is a complicated and time-consuming task, as each page of EEG data typically only represents 15 seconds of brain activity. Neurologists are not always immediately available to interpret urgent EEG requests, further contributing to delays in diagnosis. A peer-reviewed publication of survey results from 97 respondent hospitals showed a majority of physicians at such hospitals reviewed EEG results only twice or less a day, and only 5% of such hospitals continuously reviewed EEGs records. When neurologists only review EEGs periodically, diagnosis of seizures that emerge after initial review can be delayed and can restrict the clinician's ability to provide optimal care.

Due to the delays in diagnosis caused by the many inherent limitations of conventional EEG, bedside clinicians are often left with three unappealing choices – wait until an EEG test is administered and a diagnosis is made to treat the patient, treat the patient empirically without the benefit of EEG data, or transfer the patient to a better equipped facility. The decision to delay treatment for hours until EEG is administered would likely result in poor outcomes, such as long-term cognitive impairment or even death, if the patient is indeed experiencing status epilepticus. The decision to treat empirically without an EEG creates the potential for unnecessary treatment with anti-seizure medication, likely resulting in preventable intubation and increased length of stay. In addition, treating the patient prophylactically runs counter to medical society guidelines published by both the AHA and ASA given the potential for unnecessary comorbidities. The decision to transfer a patient to another institution would result in further delays in potentially necessary treatment and will result in increased costs related to transporting the patient. None of these choices is appealing to clinicians as they are likely to result in poor clinical outcomes for the patient as well as imposing cost burdens on the hospital and payers.

For citations to the studies relating to the benefits of the Ceribell System discussed above, see "—Our Clinical Results and Economic Evidence."

Our Addressable Market Opportunity in Seizures

Given the inherent limitations of conventional EEG systems, we believe that EEG has been significantly underutilized in the detection and management of seizures in the acute care setting. By providing our customers with a tool that can be promptly administered and leveraged to inform treatment decisions at the bedside, we believe the Ceribell System has the ability to meaningfully expand the use of EEG to a significantly broader set of acute care patients who should be monitored due to high risk of seizures. Based on the experiences of several hospital customers that have studied the impact of the Ceribell System on their institutions, we believe that adoption of the Ceribell System will drive an increase in EEG testing volumes.

Our total addressable market opportunity estimated at over $2 billion represents the potential opportunity from the sale of single-use headbands, as well as the potential opportunity from the sale of the Ceribell System hardware and subscriptions to recorders, Clarity and our portal, in each case to acute care facilities. The potential opportunity from the sale of single-use headbands reflects an estimated three million acute care patients in the United States who we believe should be monitored with EEG each year due to high risk of seizures based on clinical literature and medical society guidelines, and the potential opportunity from the sale of the Ceribell system and subscriptions reflects an estimated 6,000 acute care facilities that we believe could benefit from the Ceribell system for such patients.

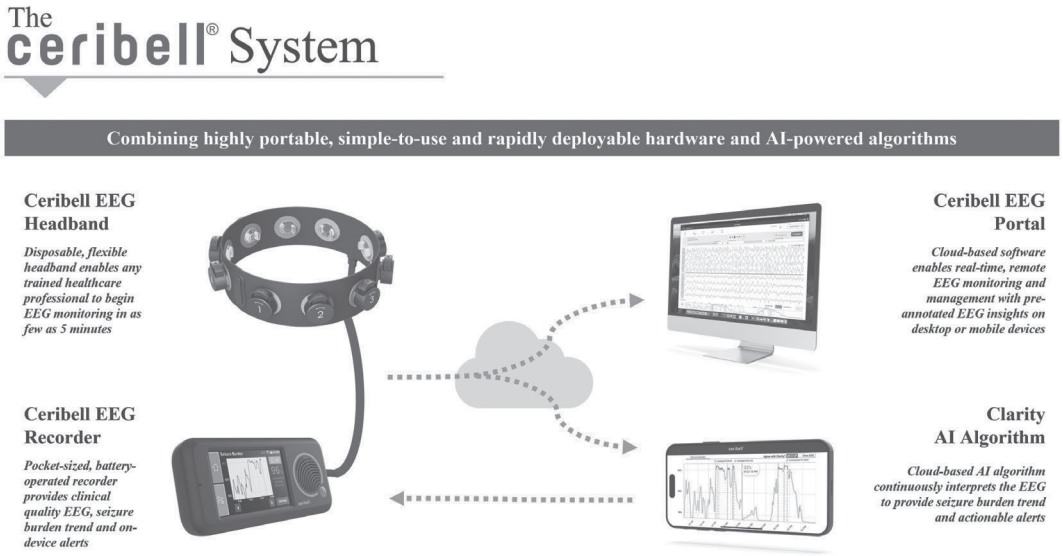
While our current commercial focus is on the United States, we have received a CE Mark for the Ceribell System in Europe, and we intend to pursue additional regulatory clearances in Europe within the next two to four years and, in the future, elsewhere outside of the United States. However, at this stage of our development we do not have more specific intended timing for pursuing additional regulatory clearances in Europe or commercializing our product in Europe. We also plan to engage in market access initiatives in attractive international regions in which we see significant opportunity. We believe acute care EEG monitoring is also underutilized worldwide and that a significant opportunity exists for the Ceribell System to improve patient care and neurologic monitoring.

Other Potential Opportunities Beyond Seizures

In the future, we intend to leverage our proprietary database of EEG recordings and our data science and AI capabilities to identify patterns in EEG waveforms that would allow us to expand the use of our system. We believe that our system can be deployed with novel algorithms for various indications in the acute care setting using our existing hardware platform and commercial infrastructure, which would enable us to monitor patients for multiple neurological conditions simultaneously. We have already begun the technical validation process for multiple additional indications in the acute care setting. In September 2022, we received FDA Breakthrough Device Designation for the detection of delirium, a common condition in the acute care setting characterized by episodes of confusion and disorientation. Delirium is estimated to affect more than seven million hospitalized patients in the United States annually according to the American Delirium Society, and failure to diagnose delirium has been associated with a two-fold increase in six-month mortality. We have also initiated technical and clinical work to develop an algorithm that may allow for earlier triage of ischemic stroke. Although we have not yet applied for marketing authorization from the FDA for the use of the Ceribell System relating to delirium or ischemic stroke, we believe that the Ceribell System could positively impact the current diagnostic practices for both delirium and ischemic stroke. According to the American Delirium Society, over seven million hospitalized people suffer from delirium in the United States annually, and according to the Centers for Disease Control, more than 650,000 people suffer an ischemic stroke in the United States each year. We believe expansion of our indications could thus represent a significant market opportunity. Prior to commercialization within these indications, we would need to apply for and obtain the required marketing authorizations. Based on our current development plans, we expect to apply for marketing authorization with the FDA for the use of the Ceribell System within these indications within the next two to four years. However, these expectations are subject to change based on various factors. Even if we successfully apply for marketing authorization for these indications, there is no guarantee that we will obtain the marketing authorizations within these indications the expected timeline, or at all, and at this stage in our development plans we do not have an intended timeline for commercialization of the products or services related to the delirium or ischemic stroke indications. For more information regarding the ongoing studies supported or sponsored by us relating to these two indications, see "—Ceribell Supported or Sponsored Ongoing Studies." We also plan to expand delivery of our product in other clinical settings and develop biomarkers for neurological and psychiatric conditions.

Our Solution

We designed the Ceribell System to address the limitations of conventional EEG in the acute care setting and dramatically improve clinical outcomes of critically ill patients at risk of seizures. The Ceribell System is a novel, point-of-care EEG platform that integrates proprietary, highly portable, and simple-to-use hardware with AI-powered algorithms to aid in the detection and management of seizures. We currently commercialize our system in the United States, where it has been adopted by more than 500 active accounts and used on over 200,000 patients to date.



Our hardware is composed of a disposable, flexible headband and a pocket-sized, battery-operated recorder used to capture and wirelessly transmit EEG signals generated by the headband. The raw EEG data is accessible through our web portal that enables real-time remote review by neurologists. The data captured by the recorder is also monitored by Clarity, our AI-powered seizure detection algorithm. Leveraging our proprietary database of EEG recordings, Clarity is designed to interpret a patient's EEG waveforms and display actionable insights regarding seizure activity on the recorder, including automatic alerts in the event of non-convulsive status epilepticus. Since launching, we have regularly updated the Clarity algorithm using additional data and our AI capabilities to enhance its performance.

We believe the Ceribell System eliminates many of the limitations and inherent bottlenecks in the conventional EEG infrastructure that lead to suboptimal patient care, offering the following highly differentiated features and capabilities:

- ***Rapid setup by any trained healthcare professional.*** The Ceribell System is highly portable and designed for rapid setup, enabling initiation of EEG in as little as five minutes with limited training required. The system is straightforward and intuitive, and we are generally able to train new users and establish proficiency in approximately one hour. This allows the Ceribell System to be applied by any non-specialized healthcare professional with approximately one hour of training required, reducing reliance on specialized EEG technicians and eliminating one of the biggest bottlenecks in the conventional EEG infrastructure.
- ***Bedside EEG interpretation.*** Clarity, our AI-powered algorithm, analyzes and converts EEG waveforms into a seizure burden trend, which can be interpreted by any licensed clinician at the bedside to provide actionable information on seizure activity. This can be used to support prompt diagnosis, inform better patient care, and determine whether the patient is responding to treatment.
- ***Continuous, automated patient monitoring.*** Through Clarity, the Ceribell System makes continuous monitoring for potential seizure activity much easier and automatically alerts clinicians in the event of suspected seizure activity so that appropriate care can be promptly administered.
- ***Remote access to EEG data with AI-powered insights.*** The Ceribell System features our cloud-based portal, an intuitive EEG management platform which enables remote access to EEG data on any web-enabled device and provides AI-powered insights to simplify and support efficient EEG interpretation by any licensed clinician without requiring bedside presence.

Key Benefits of the Ceribell System

The differentiated features of the Ceribell System enable our hospital customers to offer optimal patient care while delivering improved economics for both the hospital and payers. The benefits delivered by the Ceribell System include:

- ***Early seizure detection and improved patient outcomes.*** The Ceribell System can be quickly deployed by any non-specialized healthcare professional with limited training required, reducing the time required to begin an EEG test to as little as five minutes, compared to several hours or potentially days for conventional EEG systems. Once the Ceribell System is applied, Clarity automatically and continuously monitors the patient for seizure activity, further reducing time to diagnosis and empowering bedside clinicians to make real-time decisions and optimize treatment. Peer-reviewed studies indicate that this results in improved patient care and outcomes, including shorter hospital stays and reductions in unnecessary administration of anti-seizure medication, intubation, and patient transfers.
- ***Improved hospital and payer economics.*** By providing hospitals with 24/7 access to EEG without a significant incremental investment in personnel and capital equipment, we believe that the Ceribell System has the potential to reduce the cost burdens associated with the monitoring and management of seizures in the acute care setting for both hospitals and payers. We have demonstrated that the Ceribell System can deliver cost savings for hospitals and payers by decreasing hospital length of stay, reducing the over-administration of anti-seizure medication, and reducing unnecessary patient transfers. Hospital inpatient care for patients diagnosed with non-convulsive status epilepticus is often more complex and costly than management of patients without this condition. A confirmed diagnosis of seizure may qualify an inpatient stay as involving a complication or comorbidity ("CC") or major complication or comorbidity for certain conditions under the MS-DRG classification system, which may allow hospitals to receive appropriate reimbursement for care of patients with more complex conditions.
- ***Reduced strain on key hospital personnel.*** The Ceribell System reduces strain on EEG technicians and neurologists. For the former, the Ceribell System reduces reliance on EEG technicians for EEG administration and enables hospitals to better manage technician infrastructure and workflow. For the latter, Clarity allows for better triage of at-risk patients, improves resource allocation, and supports more efficient workflow for neurologists.

For citations to the studies relating to the benefits of the Ceribell System discussed above, see the section titled "Business—Our Clinical Results and Economic Evidence."

Key Components of the Ceribell System

Hardware

The Ceribell System includes two proprietary hardware components – a headband and a recorder. Both components received 510(k) clearances from the FDA in 2017 and, together, are used to acquire EEG signals.

The headband is a disposable, single-use headband composed of ten non-invasive electrodes, each pre-filled with conductive gel, affixed to a flexible band that fits comfortably around the crown of a patient's head. Each electrode is housed within a small knob that, when turned, parts the patient's hair and preps the patient's skin using an array of prongs with a light abrasive surface. After skin prep, a plunger affixed to each knob is depressed and the conductive gel is released, forming an electrical connection between the scalp and the electrode. These simple steps effectively replicate the process that is performed by EEG technicians during conventional EEG setup in a manner simple enough that it can be completed in as little as five minutes by any trained healthcare professional. Each headband is intended for use on a single patient.

The recorder is a pocket-sized, battery-operated reusable device designed to record and store EEG signals generated by the headband. The recorder establishes device-to-cloud communication through a secure Wi-Fi connection. The recorder features a digital screen which displays the raw EEG data as well as our proprietary seizure burden trend line produced by our AI-powered seizure detection algorithm, Clarity, and provides alerts when significant seizure activity is suspected. During setup, the recorder provides prompts on its digital screen to ensure that each electrode has made proper contact with the skin, with a green light indicating that the electrode connection is strong. These prompts are designed to ensure our electrodes meet the same connection quality standards as conventional EEG. The recorder also enables healthcare providers to input relevant details, such as patient information and annotations of treatments administered to the patient, which help providers assess the impact and efficacy of treatment.

Headband Placement and Recorder

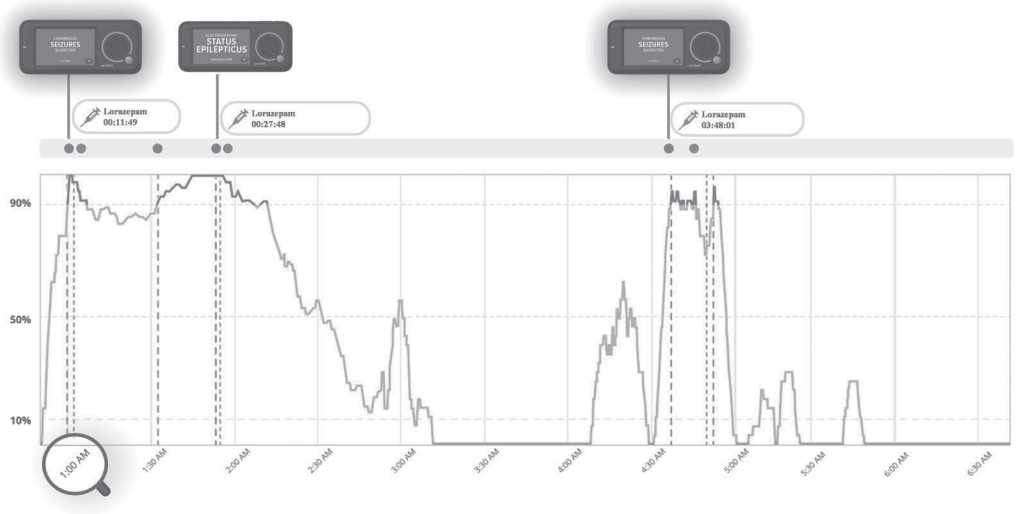
Recorder Confirmation of Electrode Connection

Algorithms

Through our extensive database of EEG recordings and our data science and AI expertise, we have developed proprietary algorithms that power some of the most critical features of our system by converting raw EEG waveforms into actionable clinical insights.

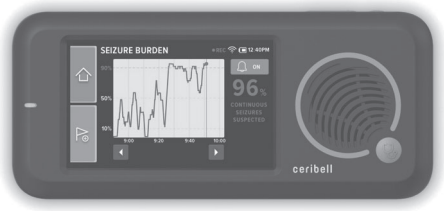
We currently commercialize Clarity, our seizure detection algorithm that continuously interprets raw EEG data captured every ten seconds across all ten electrodes of the headband and assesses a multitude of EEG features to determine if seizure activity is present. It then converts this data into a metric known as seizure burden, which measures the quantum of seizure activity detected in a rolling five-minute interval (for example, a 90% seizure burden indicates 4.5 minutes of seizure activity in the last five minutes). Seizure burden is displayed on the digital screen of the recorder as a simple chart that can be easily understood by clinicians without formal EEG interpretation training. This provides clinicians with the vital, real-time data needed to rapidly identify and treat seizures and to evaluate the efficacy of anti-seizure medication. A seizure burden that exceeds 90% suggests the patient is potentially in non-convulsive status epilepticus. When Clarity detects a seizure burden of 90% or greater, it generates a visual and audio alert that is delivered by the recorder, helping the bedside clinician to act promptly to review the alert from Clarity and provide timely care. A seizure burden between 1% and 89% suggests shorter duration seizures or a seizure-like abnormality, which may warrant alerting the neurology team. When Clarity detects a 0% seizure burden, which suggests no ongoing seizure activity, clinicians may be able to more confidently rule out status epilepticus. While EEGs can only be interpreted by a neurologist, Clarity alerts provide information in real time that bedside clinicians can act on immediately to inform treatment decisions. We believe that by enabling bedside clinicians who are not neurologists to review the output of Clarity and provide timely care as well as determine more selectively when neurologist interpretation is required, the Ceribell System helps mitigate the effect of delays in EEG interpretation and neurologist shortages.

Seizure Burden Display

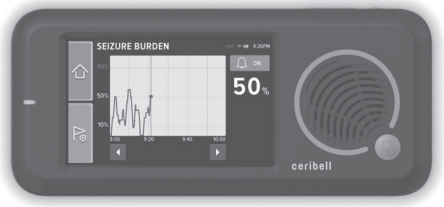


Continuous Seizure Monitoring and Seizure Activity Alerts

0% seizure burden – Likely rule out seizure activity



>90% seizure burden – Potential non-convulsive status epilepticus



1-89% seizure burden - Likely seizure activity or epileptiform abnormality
(i.e., unusual brain signals resembling those in epilepsy)

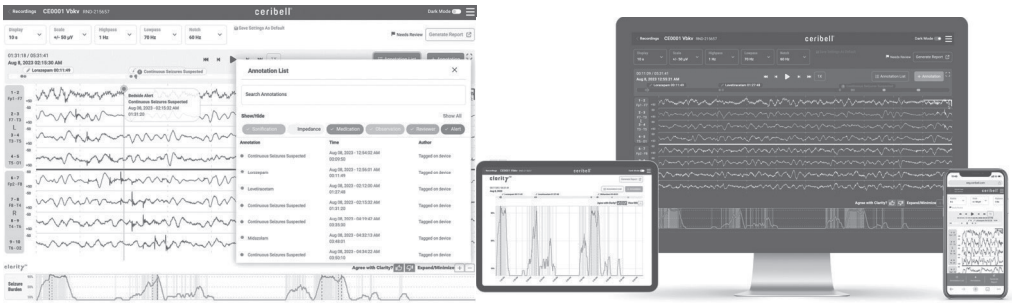
Non-convulsive status epilepticus alert

We are continuously improving our Clarity algorithm and have released software updates to our customers. In May 2023, the latest generation of our Clarity algorithm became the first and only device to receive 510(k) clearance from FDA for the diagnosis of electrographic status epilepticus ("ESE"), which refers to status epilepticus which can be diagnosed using EEG alone without the benefit of additional clinical information. The clearance follows prior receipt of Breakthrough Device Designation from the FDA and subsequent receipt of an exclusive NTAP code from CMS.

Ceribell EEG Portal

Our EEG portal is a cloud-based secured portal that enables real-time remote access to a patient's EEG data. The portal can be accessed by clinicians anywhere and anytime using any web browser or mobile applications. The portal enables simple sorting and filtering of EEG recordings, makes it easy to annotate EEGs, and offers an extensive EEG reference library with a database of expertly annotated sample cases. In addition, the raw EEG waveforms viewed through the portal are overlaid with the seizure burden curve produced by Clarity, providing clinicians with interpretation assistance.

Intuitive Interface Accessible through Web or Mobile Applications



Reading Services

In 2024, Ceribell entered into agreements with two tele-neurology providers to offer remote EEG interpretation services to customers. These agreements are non-exclusive and have terms ranging from 18 months to 36 months and allow for termination by either party for convenience and for material breach, subject to customary notice and cure periods. Under the terms of these agreements, the tele-neurology providers have agreed to contract with customers directly to provide reading services during the term of the agreements. We believe that this product offering may help service a subset of our customer population where neurology infrastructure is insufficient to meet the demand for interpretation of EEGs using the Ceribell System. Currently, this remains a nascent product offering that is used by only a small number of customers. For information regarding risks relating to this product offering and state laws prohibiting the corporate practice of medicine or fee splitting, see "Risk Factors–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."

Sales and Marketing

Sales

We generate revenue primarily from two recurring sources – the sale of our single use, disposable headbands and a monthly subscription fee charged to our customers for use of Clarity, recorders and the portal. We sell the Ceribell System in the United States through our direct sales organization. We employ a team of sales representatives, including TMs, who are responsible for new customer acquisition, and CAMs, who are responsible for ongoing account coverage, with the primary objective of raising awareness of non-convulsive status epilepticus and gaining more customer support of the Ceribell solution. TMs and CAMs are also jointly responsible for onboarding customers. Together, this team is focused on driving new account growth and greater utilization, and delivering high-quality customer experiences. In addition to TMs and CAMs, our commercial organization includes other personnel who are responsible for hospital system relationship management, sales training, launch support, technical assistance, and hospital IT integration and other activities.

Our TMs drive adoption of our system in new accounts by engaging with key decision makers to introduce the compelling value proposition of the Ceribell System. They are responsible for identifying key customer prospects, educating them on the value of our system and gaining their commitment to acquire our system. Given the Ceribell System's multi-faceted value proposition, driving new account adoption involves multiple stakeholders. Our TMs initially focus on engaging with and gaining the support of intensive care and emergency medicine clinicians, neurologists, and nursing staff, among other clinicians. These individuals have firsthand experience with the limitations of conventional EEG systems in the acute care setting and, as such, often play an important role in championing support for our system across the institution. Our TMs work to gain the support of other key stakeholders, including executive leadership, who are responsible for resource allocation and financial management. In addition to driving new account growth, our TMs, in coordination with our CAMs, play a critical role in site onboarding, training, and launch.

Our CAMs are focused on driving increased utilization and penetration within existing accounts, ongoing account coverage, and further supporting customer onboarding. CAMs initially work in close coordination with TMs during the site onboarding phase to ensure a successful launch. We have a highly tailored onboarding program that involves training hospital staff, supporting customers in designing workflows, and integrating with the hospital's IT system. In the future, we intend to add integration with our customers' electronic health record systems. We believe that the time we spend supporting our customers during the onboarding process builds customer loyalty and strengthens our competitive position. Once the customer onboarding is complete, CAMs fully assume responsibility for the account. CAMs provide ongoing physician education and training support to promote an excellent user experience and drive greater utilization of our system within the hospital by reinforcing our value proposition and increasing disease state awareness. CAMs are also focused on expanding the use of the Ceribell System into additional departments within the hospital.

In the future, we plan to establish our presence internationally. 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 within the next two to four years and, in the future, elsewhere outside of the United States. However, at this stage of our development we do not have more specific intended timing for pursuing additional regulatory clearances in Europe or commercializing our product in Europe. We also plan to engage in market access initiatives in attractive international regions in which we see significant opportunity.

Marketing

In addition to our direct sales efforts, we invest in marketing initiatives to increase awareness of our technology and the prevalence of seizures in critically ill patient populations within the acute care setting. Based on our experience, many intensive care and emergency medicine clinicians underappreciate the prevalence of seizures, particularly non-convulsive seizures, associated with common acute conditions. Through our marketing and educational efforts, we reinforce the prevalence and severity of status epilepticus, the criticality of prompt diagnosis and treatment, and the limitations of conventional EEG systems in the acute care setting.

Our marketing team ensures our representation and presence at national and regional medical society conferences, where our commercial team meets with key opinion leaders and society chairs to discuss greater collaboration as well as generates prospective customer leads. Additionally, we create and distribute content for digital engagement to educate prospective customers on status epilepticus and the Ceribell System through our website, email, social media, and advertisements. We believe our marketing programs are essential to increasing adoption of our system and expanding the use of EEG monitoring in the acute care setting to address the significant unmet needs of critically ill patients at risk of seizures.

Our Clinical Results and Economic Evidence

A robust body of evidence supports the clinical and economic benefits of the Ceribell System for the detection of seizures and management of patients at risk of nonconvulsive status epilepticus in the acute care setting. The Ceribell System has been the subject of over 20 peer-reviewed publications and over 65 abstracts and posters. We believe our base of clinical evidence supports the value of the Ceribell System to all key stakeholders, including patients, clinicians, hospitals, and payers across different hospital types and acute care settings.

Validated Technical Characteristics and Performance

- ***Signal Quality Concordant to Conventional EEG.*** Studies have shown that the Ceribell System and conventional EEG provide largely concordant data, meaning that the quality of the recordings are generally equivalent.
- ***Reduced Montage is Effective.*** Studies have demonstrated that the reduced montage in the Ceribell System preserved key features of conventional EEG, and that focal seizures in the area of the brain not covered by the reduced montage are very rare in patients in the acute care setting.

- ***Diagnostic Accuracy of Clarity.*** The diagnostic accuracy of the Clarity algorithm is typically evaluated by comparing the determination of the Clarity algorithm to a diagnosis made by a panel of neurologists following review of the EEG recording produced by our system. These studies generally demonstrate that the Clarity algorithm is specific and sensitive in detecting non-convulsive status epilepticus. Clarity's algorithm can detect nonconvulsive status epilepticus with 87% to 100% sensitivity, 93% to 98% specificity, and 99% to 100% negative predictive value.

Improved Clinical Management and Care

- ***Rapid Diagnosis and Ease of Use.*** The Ceribell System greatly reduces time to EEG setup (i.e., time from EEG order to EEG acquisition) and time to interpretation or diagnosis with the Ceribell System. It takes a median of five minutes to set up a Ceribell EEG, while conventional EEGs take a median of 239 minutes (nearly 4 hours) for arrival and set-up time (even with EEG technicians available 24/7 on site or on-call). There is also a significantly faster median door-to-EEG time of 5.9 hours for Ceribell, compared to 25.3 hours for conventional EEG. Additionally, setup and time to interpretation by conventional EEG systems were subject to delays ranging from 1.8 to 11.2 hours. The Ceribell System is designed to ease of learning and implementation. Surveyed physicians consistently rated the system easy to use (4.7 on a scale of 1-5), and a study noted that it "can be set up in minutes by nurses or physicians or any other user."
- ***Reduced Length of Stay.*** Several studies have shown that the Ceribell System is associated with reduced length of stay in the hospital or ICU. For example, one study found that patients at three large academic hospitals who were initially evaluated with the Ceribell System had a median ICU length of stay that was approximately four days shorter compared to those who received conventional EEG. Another study at a community hospital showed a median length of stay decrease of three days after adoption of the Ceribell System, and a third found a decreased length of stay of 0.4 days in ICU and 1.2 days in hospital.
- ***Improved Decision Making and Clinical Management.*** A number of studies have indicated that the Ceribell System helps support appropriate clinical management of seizure patients by improving physicians' ability to quickly and confidently diagnose or rule out a seizure. For example, studies have found that the Ceribell System allowed physicians to change clinical management for approximately 53% of patients; modify diagnostic suspicion for seizure and nonconvulsive status epilepticus for approximately 40% of patients and treatment decisions in 20% of patients; reduce over-treatment for non-seizure patients by avoiding anti-seizure treatment escalation in 43% of patients; potentially reduce intubation and parenteral anti-seizure medicine by 51%; and expedite disposition of cases in 21% of patients . A recent study found that the seizure burden assessed by Clarity correlated with functional outcomes, and in a matched analysis use of the Ceribell System was associated with better clinical outcomes for ICU patients with nonconvulsive seizures.
- ***Fewer Patient Transfers.*** Studies have provided evidence that access to the Ceribell System reduces patient transfers from community hospitals to facilities with greater access to conventional EEG systems. For example, one study found that the use of the Ceribell System enabled physicians to avoid transferring 94% of patients who would have met the criteria for EEG-related transfer before implementing the Ceribell System.

Supports Hospital and Payer Economics

- ***Meaningful Cost Savings.*** The Ceribell System is designed to enable around-the-clock access to EEG without significant investment in staff and equipment. Studies have demonstrated that the clinical benefits described above, such as reduced transfers, reduced length of stay, and reduced use of antiseizure medication, as well as adequate treatment of status epilepticus, could result in cost savings for the hospital and payers. One study estimated approximately $14,000 net positive value per patient (not accounting for Ceribell System costs) in two community hospitals, based on avoided transfer costs and applicable reimbursement. Two different studies at community hospitals projected, respectively, total annual cost savings of nearly $740,000 related to reduced length of stay and ED discharges, and transportation cost savings of more than $39,000 in 16 months based on reduced patient transfers and a third-party estimate of ambulance costs. In a fourth study of the Ceribell System, a decision-analytic model projected savings of $3,971 per patient hospitalized for coma or encephalopathy, due to reduction in both the ICU and hospital length of stay.
- ***Appropriate Reimbursement for Complex Patients.*** When seizures are accurately identified as a comorbidity of another condition, hospitals may appropriately code the patient as having a comorbid condition or major comorbid condition. One study showed that the improved seizure detection and diagnosis offered by the Ceribell System may support appropriate complication or comorbidity DRG payments from seizure diagnoses, with the study reporting additional annual revenue of $145,580 from more accurate MS-DRG coding.
- ***Reduced Strain on Hospital Personnel.*** The Ceribell System is designed to reduce reliance on EEG technicians for EEG set up and better control of technician infrastructure and workflow. It is simple to use and can be applied by non-specialized

healthcare professionals trained on the system, which can mitigate burdens on healthcare staff and users of EEG. In a study examining potential reduction in workforce demands due to use of on-call EEG technicians, ten EEG tests were conducted using the Ceribell System, and 40 using conventional EEG systems as a control. No EEG technicians were called to the hospital after hours for any of the tests using the Ceribell System, while technicians were called in to assist with 15 (38%) of the control studies in which conventional EEG systems were used.

Customer Agreements

We generate revenue primarily from two recurring sources – sales of our disposable headbands which are intended for single patient use, and a subscription service fee charged to our customers on an annual or monthly basis for use of Clarity, recorders, and our portal. In exchange for the subscription service fee, the customer and its authorized users are granted access to the cloud-based portal platform, use of a specified number of recorders, and the Clarity algorithm identifying areas of potential seizure activity.

Customers are invoiced for subscription fees monthly in advance, with all amounts due generally within 30 days of the date of the applicable invoice. Annual subscription fees are invoiced once per year, in the month the subscription service is activated or renewed. Generally, subscriptions automatically renew unless either party gives the other at least 30 days' written notice of its intent not to renew. In addition, either party may terminate the subscription for a material breach that is not cured within 30 days of notice of the breach. We can immediately terminate a subscription if the customer distributes or attempts to assign or sublicense any rights granted. Customers own all rights to data they upload or make available to Ceribell through use of our products or services. We have the right to use (but not sell) such data for our business purposes, obligations, and improvement of the Ceribell System, and we own any derivatives of the data that we develop. We provide product warranties for our recorders and headbands, which in aggregate are not a material liability. In addition, we have generally agreed to indemnify customers from third party claims regarding a defect in the product, breach of a product representation or warranty, or infringement of U.S. intellectual property rights.

Coverage and Reimbursement for Ceribell

We derive substantially all of our revenue from healthcare providers and hospitals that use the Ceribell System in the United States. These facilities and providers, in turn, bill third-party payers, including private insurers, Medicare, and Medicaid, for the services and items they provide to patients. The Ceribell System enables our customers to operate under the existing reimbursement structure for EEG, which has well-established reimbursement levels via the MS-DRG classification system and CPT codes. Government and commercial payers generally provide coverage for EEG under this framework.

The Ceribell System is most commonly deployed in the hospital inpatient setting. For Medicare, inpatient acute-care hospitals are paid under the inpatient prospective payment system ("IPPS"). The IPPS pays a flat rate based on the average charges across all hospitals for specific diagnoses, regardless of whether that particular patient costs more or less. Under the IPPS, each case is categorized into a MS-DRG, which is derived from ICD-10 codes that describe the patient's diagnoses and procedures performed during the hospital stay. While MS-DRGs and CPT codes are generally employed by both private insurers and government payers, payment rates often differ. Base MS-DRGs may contain subgroups to identify patients with a diagnosed complication or comorbidity or major complication or comorbidity, which may qualify the admission for a higher payment amount intended to reflect the increased resources needed to treat patients with secondary complications or comorbidities. Seizure is considered a comorbidity that typically qualifies as a complication or comorbidity or major complication or comorbidity. Additional, temporary payment is available for new medical services and technologies designated as eligible by CMS for a New Technology Add-on Payment ("NTAP"), if certain criteria are met. In August 2023, CMS approved an NTAP under the IPPS for our newest Clarity algorithm, effective October 1, 2023 for a period of three years.

The physicians who interpret the EEG data provided by the Ceribell System are typically neurologists, and they may seek reimbursement for their services using a variety of Category I CPT codes. These services are described by routine EEG codes, such as CPT codes 95812, 95813, 95816, and 95819, and longer-term EEG codes such as 95717 and 95719. These codes are the same CPT codes used to report physician services for the professional services associated with conventional EEG monitoring. Reimbursement for the facility in the hospital outpatient setting is determined by Medicare's Ambulatory Payment Classification ("APC") system, which assigns CPT codes to certain groupings identified by an APC code. Hospitals receive reimbursement based on the APC group to which the physician service or procedure performed is assigned.

Research and Development

We invest in research and development efforts with the goal of driving continuous improvements in the Ceribell System. We are advancing our mission of becoming the standard of care for the detection and management of seizures in the acute care setting, and expanding the clinical indications of our system and AI algorithms in the acute care setting and beyond (such as home use). Our research and development team includes 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 are investing in expanding the age range of Clarity to include individuals below the age of 18, and filed a 510(k) application for clearance in the fourth quarter of 2024. If this application is granted, we can bring the benefits of AI-powered seizure detection and continuous monitoring to younger patients, who are already able to benefit from rapid EEG access provided by our proprietary hardware. In addition, we have received 510(k) clearance for and are continuing to develop a headset that will be able to accommodate a head size range appropriate for neonate and infant patients, which have different needs than adult and pediatric patients.

We also invest in developing algorithms for new indications. Since 2022, we have developed two separate AI-powered algorithms that have been designated as Breakthrough Devices by the FDA. These designations include diagnosis of electrographic status epilepticus and detection of delirium.

In May 2023, the latest generation of our Clarity algorithm received FDA clearance and we have since begun actively marketing alongside our other FDA-cleared hardware and software solutions. It is the first FDA-cleared software indicated for the diagnosis of ESE. Our delirium and ischemic stroke algorithms remain under development, with ongoing research and active clinical studies. Beyond our current indications, we continue to explore other potential opportunities to leverage our AI algorithms to improve neurological care.

Manufacturing and Supply

We manage all aspects of manufacturing, supply chain, and distribution of the headband and recorder from our facility in Sunnyvale, California. We have partnered with two ISO 13485 certified contract manufacturers ("CM") in China to manufacture and assemble our headband, with final inspection and labeling completed at our facility. See "Supply Agreements" for more information regarding our agreements with these CMs. The components for our recorder are procured from various suppliers and shipped to our facility for final assembly. We believe our current manufacturing capacity is sufficient to meet our current and expected near term growth. We also maintain incremental supply of finished goods, subassembly, and individual components for both the headband and recorder to mitigate potential supply disruptions.

We are registered with the FDA as a medical device manufacturer and licensed by the State of California to manufacture and distribute medical devices. We are required to manufacture our products in compliance with the FDA's Quality System Regulation (21 C.F.R. Part 820). We have been ISO 13485 certified since January 2018 with a recertification audit occurring in August 2023. To date, no major non-conformities have been identified in any FDA or ISO audit.

We employ a rigorous supplier assessment, qualification, and selection process targeted to suppliers that meet the requirements of the FDA and the International Organization for Standardization and quality standards supported by internal policies and procedures. Our quality assurance process monitors supplier performance through qualification and periodic supplier reviews and audits.

Headband

We rely on two primary CMs in China to complete the manufacturing, primary assembly, and inspection of our headband. The CMs ship the assembled headbands to our facility in Sunnyvale, California for final processing, inspection, and labeling. We have redundant vendors for major components or subassemblies of the headband.

Recorder

The recorder comprises three primary components: a printed circuit board, a battery pack and an LCD screen. We have redundant vendors for major components of the recorder, other than the LCD screen, and recorders are assembled, tested and packaged at our facility in Sunnyvale, California.

Supply Agreements

In January 2022, we entered into a corporate supply agreement with Shenzhen Everwin Precision Technology Co., Ltd. ("Shenzhen"), a CM based in China, for the supply of our small and large headbands, pursuant to which we make purchases on a purchase order basis. The terms of the supply agreement were subsequently amended in March 2023 (as amended, the "Everwin Agreement"). The Everwin Agreement was effective beginning on January 10, 2022 with an initial term extending to January 2025, which automatically renews for additional one-year periods. The automatic renewals are subject to either party's right to terminate the Everwin Agreement without cause by providing notice at least 120 days prior to expiration of the initial term or any one-year renewal period. Either party may terminate the Everwin Agreement if the other party materially breaches the agreement and fails to cure the breach within 30 days after notice of such breach from the terminating party. We may terminate the Everwin Agreement for convenience upon 30 days prior written notice. The Everwin Agreement grants us a perpetual, irrevocable, worldwide, non-exclusive, royalty-free,

fully paid up, transferable right and license to all information and materials necessary for the manufacture, supply and support of the products that Shenzhen provides to us.

We have also entered into a corporate supply agreement with Ease Care, a CM under the management of Luxen and Kersen based in China, pursuant to which we expect to begin making purchases on a purchase order basis in the second half of 2024 for the supply of our small and large headbands (the "Ease Care Agreement"). The Ease Care Agreement was effective beginning in February 2024 with an initial term of two years, which automatically renews for additional one-year periods. The automatic renewals are subject to either party's right to terminate the Ease Care Agreement without cause by providing notice at least 120 days prior to expiration of the initial term or any one-year renewal period. Either party may terminate the Ease Care Agreement if the other party materially breaches the agreement and fails to cure the breach within 30 days after notice of such breach from the terminating party. We may terminate the Ease Care Agreement for convenience upon 90 days prior notice. The Ease Care Agreement grants us a perpetual, irrevocable, worldwide, non-exclusive, royalty-free, fully paid up, transferable right and license to all information and materials necessary for the manufacture, supply and support of the products that Ease Care provides to us.

Competition

The primary competition that we face is from conventional EEG systems, which are used in the majority of hospitals in the United States. These systems are primarily used for outpatient epilepsy diagnosis but are often deployed to the acute care setting for use in patients at risk of seizure. The two primary providers of conventional EEG systems in the United States are Natus Medical Incorporated and Nihon Kohden Corporation.

We also face competition from companies that have designed or aim to design rapid EEG systems or EEG systems specifically for use in the acute care setting, including Nihon Kohden, and Natus. These products focus on one or more aspects of the shortcomings of conventional EEG in the acute care setting including time to setup, reliance on specially trained technicians, size of capital equipment, or lack of bedside diagnosis and monitoring capabilities.

We believe that the primary competitive factors in the acute EEG market are:

- reliable EEG signal quality;
- algorithm sensitivity or specificity;
- ease of use (including required training);
- time to diagnosis;
- monitoring features;
- customer support and service;
- integration within hospital IT systems and clinical workflows;
- strength and volume of clinical evidence;
- economic benefits and cost savings;
- pricing and reimbursement strategies;
- ability to manage infection risk;
- form factor impact on patient positioning; and
- technology enhancements (such as length of battery life).

We believe we have established a compelling value proposition to compete favorably in this market.

Stanford Agreement

In June 2015, we entered into a license agreement with the Board of Trustees of the Leland Stanford Junior University ("Stanford University"), as amended in September 2015, April 2017, and March 2022 (the "Stanford Agreement"). Pursuant to the Stanford Agreement, Stanford University granted to us a worldwide, term-limited exclusive license under certain patent rights owned or controlled by Stanford University to make, use and sell certain portable devices in connection with brain wave activity.

As consideration for the license granted under the Stanford Agreement, we paid a non-refundable license issue fee of $42,000 in two equal installments and issued 221,712 shares of our common stock, of which 158,880 shares were issued to Stanford University and 62,832 shares were issued to the inventors of the licensed patents under the Stanford Agreement (one of whom was Josef Parvizi, M.D., Ph.D., who is our co-founder and board member). We paid Stanford University $36,000 upon the achievement of a specific commercial milestone event in 2018. There are no additional milestone payments that are due under the agreement. We are paying Stanford University an annual license maintenance fee of $20,000 that is creditable against the mid-single digit percentage royalty payment that we are required to make to Stanford University, which is based on the net sales of licensed products covered by the licensed patent rights or otherwise includes certain other technologies that Stanford University provided to us pursuant to the terms of the Stanford Agreement. We also agreed to pay Stanford University a low twenties percentage range of non-royalty sublicense related revenue that we receive from third party sublicensees. We agreed to pay Stanford University $100,000 prior to any assignment of the license, including if we are acquired by a third party or if we sell all or substantially all of our assets to which the Stanford Agreement relates.

The Stanford Agreement is exclusive until June 15, 2025. In a March 2022 amendment, we agreed to pay Stanford an option fee of $80,000 to extend exclusivity for the life of the patent, of which $60,000 was paid as of December 31, 2024, and the remaining balance of $20,000 is due in April 2025, which will be waived if we exercise the option at any point until June 15, 2025, by paying an option exercise fee of $250,000. If we decide not to pay the option exercise fee, our rights will convert to a non-exclusive license.

The Stanford Agreement is subject to the Bayh-Dole Act, which provides federal agencies with certain march-in rights and imposes certain domestic manufacturing requirements. See the section titled “Risk Factors—Risks Related to Our Intellectual Property” for a more comprehensive description of risks related to our intellectual property.

Stanford University may terminate the Stanford Agreement in the event, we (i) are delinquent on any report or payment; (ii) are not diligently developing and commercializing the licensed products; (iii) are in breach of the agreement; or (iv) provide any false report, and any of these events remains uncured for 30 days following written notice of such event. We may terminate the Stanford Agreement at any time upon 30 days’ advance written notice to Stanford University.

Intellectual Property

We seek to protect the intellectual property and proprietary technology that we consider important to our business. We pursue patent applications that cover our technologies and product candidates and methods of using the same, as well as any other relevant inventions and improvements that are considered commercially important to the development of our business. Our success depends in part on our ability to: (a) obtain, maintain, protect and enforce intellectual property and other proprietary rights for our current and future technology, inventions, improvements, and know-how we consider important to our business, (b) preserve the confidentiality of our trade secrets, (c) operate without infringing, misappropriating, or violating the intellectual property and other proprietary rights of others, and (d) prevent others from infringing, misappropriating, or violating our intellectual property and other proprietary rights.

We have developed, and are continuing to develop, a comprehensive intellectual property portfolio related to EEG monitoring in the acute care setting, including system hardware and algorithms for seizure detection as well as other medical conditions. As of December 31, 2024, our patent portfolio contains 42 total issued utility patents and pending utility patent applications, and includes patents and patent applications that are solely owned by us, exclusively licensed from Stanford University, and co-owned with Stanford University. Of the 42 total patents and patent applications, 16 patents and patent applications are directed to the Ceribell System, eight patents and patent applications are directed to EEG algorithms for seizure detection that run on the Ceribell System, and nine patents and patent applications are directed to EEG sonification. The 16 Ceribell System patents and patent applications are solely owned by us and include four issued U.S. patents, which expire in 2036 or 2038, four pending U.S. patent applications, and eight foreign patents and patent applications filed in countries including China and Hong Kong, Europe, and Japan. Of these eight foreign patents and patent applications, one patent is granted in Europe, one patent is granted in China, and two patents are granted in Japan. The eight EEG algorithm patents and patent applications for seizure detection are solely owned by the company and include one issued U.S. patent, which expires in 2039, one pending U.S. patent application, and six pending foreign patent applications filed in Australia, Canada, China and Hong Kong, Europe, and Japan. The nine EEG sonification patents and patent applications include six issued U.S. patents and three pending U.S. patent applications. Of the six issued U.S. patents, one patent expiring in 2039 is solely owned by us, four patents expiring between 2034 and 2036 are exclusively licensed from Stanford University, and one patent expiring in 2036 is co-owned with Stanford University. We continue to seek to expand the scope of our patent protection for our technology.

Our use of the foregoing exclusively licensed patents and pending patent applications is subject to the terms and conditions of the Stanford Agreement. See the section titled “—Stanford Agreement.”

In addition to patents, we also rely upon trademarks, trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We maintain and are seeking registered trademarks. We have certain know-how and trade secrets

relating to our EEG monitoring technology. We rely on trade secrets to protect certain aspects of our technology related to our current and future seizure detection algorithms. However, trade secrets can be difficult to protect. We seek to protect our proprietary information, including trade secrets, in part, by using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees. We also have a trade secret policy that our employees are required to comply with, and have confidentiality agreements and/or invention assignment agreements with our employees, commercial partners and consultants. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises and physical and electronic security of our information technology systems. See the section titled "Risk Factors—Risks Related to Our Intellectual Property" for a more comprehensive description of risks related to our intellectual property.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Government Regulation

Our products and operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our product candidates are subject to regulation as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), as implemented and enforced by the FDA.

United States Regulation of Medical Devices

The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

FDA premarket clearance and approval requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, or approval of a premarket approval ("PMA") application. Under the FDCA, medical devices are classified into one of three classes —Class I, Class II, or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness.

Class I includes devices with the lowest risk to the patient for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation (the "QSR"), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, as well as any special controls deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting and some implantable devices, devices that have a new intended use, or devices that use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA, requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. The products we currently market are classified as Class II devices and have received FDA marketing authorization through the 510(k) clearance process.

510(k) Clearance marketing pathway

To obtain 510(k) clearance, a manufacturer must submit to the FDA a premarket notification demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously-cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements. The PMA process requires that the manufacturer demonstrate that the device is safe and effective for its intended uses, which generally requires the submission of extensive data, including results from pre-clinical studies and human clinical trials. A PMA must also contain a full description of the device and its components, the methods, facilities, and controls used for manufacturing, and proposed labeling. The PMA process is burdensome, and in practice, the FDA's review of a PMA application may take up to several years following initial submission. Alternatively, a manufacturer can request a risk-based classification determination for a novel device in accordance with the "*de novo*" process, described below. We currently do not market any medical devices pursuant to a PMA.

After a device receives 510(k) clearance or *de novo* classification, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* request or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained or a *de novo* request is granted. In these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

De novo classification process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a route to market for low-to-moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Pursuant to the Food and Drug Administration Safety and Innovation Act (the "FDASIA") manufacturers may request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not-substantially-equivalent determination. *De novo* classification requests are subject to the payment of user fees.

Under FDASIA, FDA is required to classify the device within 120 days following receipt of the *de novo* request, although the process may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. If FDA grants the *de novo* request, the device may be legally marketed in the United States. However, the FDA may reject the request if the FDA identifies a legally marketed predicate device that would be appropriate for a 510(k) notification, determines that the device is not low-to-moderate risk, or determines that General Controls would be inadequate to control the risks and/or special controls cannot be developed. After a device receives *de novo* classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another *de novo* request or even PMA approval.

Medical device clinical trials

Clinical trials are sometimes required to support 510(k) or *de novo* submissions. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE"), regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with

abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or presents a potential for serious risk to a patient in some other way. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board (the "IRB"), for each clinical site. The IRB is responsible for the initial and continuing review of the clinical study, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, such as strategic business decisions or a belief that the risks to study subjects may outweigh the anticipated benefits.

Expedited development and review programs

Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device-led combination products that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment and review, while preserving the statutory standards for PMA approval, 510(k) clearance and *de novo* classification. The program is available for medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device Designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff; use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device; opportunities for more efficient and flexible clinical study design; and prioritized review of premarket submissions. When reviewing Breakthrough Device Designation requests, the FDA may require a combination of literature or preliminary bench, animal or clinical data to demonstrate a reasonable likelihood of clinical and technological success. Receiving a Breakthrough Device Designation from the FDA does not guarantee that the FDA will grant marketing authorization for the device.

Post-market regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;

- clearance or approval of product modifications to cleared devices or devices authorized through the de novo classification process that could significantly affect safety or effectiveness, or that would constitute a major change in intended use of such devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shutdown of, or restrictions on, manufacturing operations and the recall or seizure of marketed products. The discovery of previously unknown problems with marketed medical devices, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions, among others:

- warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees, and civil penalties;
- recalls, withdrawals, or administrative detention or product seizures;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for devices being shipped to foreign markets; or
- criminal prosecution.

We are also subject to regulation by the California Department of Public Health Food and Drug Branch ("FDB") through the Medical Device Safety Program. We must maintain a California Medical Device Manufacturing license. Our facilities may be subjected to scheduled or unscheduled inspections by the FDB.

Healthcare Fraud and Abuse Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, and other healthcare fraud and abuse laws.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal false claims laws, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, 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.

In addition, the civil monetary penalties statute, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as business associates, independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals such as physician assistants and nurse practitioners, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Several states in which we operate have also adopted fraud and abuse laws similar to those described above. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any payer, including patients and commercial insurers, not just those reimbursed by a federally funded healthcare program.

Violations of fraud and abuse laws, including federal and state anti-kickback and false claims laws, may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement, and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement Regulation

In the United States, our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for our products and related services. Use of the Ceribell System is reimbursed under existing physician and hospital codes. 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 when the Ceribell System is used. Failure by physicians, hospitals, and other users of our products to obtain adequate

reimbursement from third-party payers for services performed with our products, or adverse changes in government and private third-party payers' coverage and reimbursement policies, could adversely impact demand for our products.

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

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement levels. Third-party payers regularly update reimbursement amounts and, from time to time, revise the methodologies used to determine reimbursement amounts. These changes include routine updates to payments to hospitals under the IPPS. These updates could directly impact the demand for our products.

We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industries to reduce the costs of products and services. Third-party payers are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, and exploration of more cost-effective methods of delivering healthcare. In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita (patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

Although we do not currently sell into international markets, we note that reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that our products will be considered cost-effective by third party payers, that an adequate level of reimbursement will be available or that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably. More and more, local, product-specific reimbursement law is applied as an overlay to medical device regulation, which has provided an additional layer of clearance requirements.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures 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.

The implementation of the Affordable Care Act (the "ACA") in the United States, for example, substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly affected medical device manufacturers. The ACA, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and 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. Additionally, the ACA expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Since its enactment, there have been judicial, executive and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on its constitutionality.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, 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, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Additionally, 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 reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Employees and Human Capital Resources

As of December 31, 2024, we had 281 full-time employees. None of our employees are represented by a labor union or party to a collective bargaining agreement.

Our human capital objectives include retaining and incentivizing existing employees and recruiting and integrating new employees. The principal purposes of our compensation program, including our equity incentive plans, are to attract, retain and appropriately motivate employees, consultants and directors through the granting of stock-based compensation awards and cash-based bonus awards.

Corporate Information

Our corporate headquarters is located at 360 N. Pastoria Avenue, Sunnyvale, California 94085. Our telephone number is (800) 436-0826. We use our website at www.ceribell.com to communicate important information about our company, including news releases and financial information. We also make available on our investor relations webpage, free of charge, copies of our Securities and Exchange Commission ("SEC") filings and submissions, which can be found at the SEC's website, www.sec.gov, as soon as reasonably practicable after electronically filing or furnishing such documents with the SEC. Stockholders may also request copies of these documents by writing to our Corporate Secretary at the address above. Website references are provided throughout this document for convenience only. The contents of these websites do not constitute a part of this Annual Report and shall not be deemed incorporated by reference into this Annual Report unless expressly noted.

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 Annual 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 281 employees in 2024. 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 years ended December 31, 2024 and 2023, we incurred net losses of $40.5 million and $29.5 million, respectively. As of December 31, 2024, we had an accumulated deficit of $166.9 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 and a number of smaller 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, our competitors may be able to offer products that are more technologically advanced, cost-effective, or attractive than the Ceribell System, and 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 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. In February 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, 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.

In addition, 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.

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 may in the future become involved in lawsuits to protect or enforce our intellectual property rights. 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." Our rights to use such intellectual property rights in our business are 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.

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," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of our IPO is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after our IPO if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. 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 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 any guidance that we provide to the public, 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 Annual Report and in our other public filings and public statements. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic uncertainty. If actual circumstances differ from those in our assumptions, our operating and financial results could fall below our publicly announced guidance or the expectations of investors. If, in the future, our operating or financial results for a particular period do not meet any guidance we provide 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 December 31, 2024, our executive officers, directors, owners of more than 5% of our capital stock and their respective affiliates beneficially owned a substantial amount 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 will 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, the expectation of future sales of our common stock by us or our stockholders, and/or the anticipation of lock-up releases;
- 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, 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 will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the market price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. As part of our risk management program, we reference various security industry frameworks and other guidance, including the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF), HIPAA, Service Organization Control Type 2 (SOC 2 Type II), and Sarbanes-Oxley IT General Controls (SOX ITGC), to help us assess, identify and manage cybersecurity risks relevant to our business. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF, HIPAA, SOC 2 Type II, and SOX ITGC as guides to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall risk management program, and shares common methodologies, reporting channels and governance processes that apply across the risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Key elements of our cybersecurity risk management program include but are not limited to the following:

- risk assessments are performed and designed to help identify material risks from cybersecurity threats to our critical systems and information;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers or third party software, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, including incident response personnel;
- an incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party vendor risk management process for key service providers based on the security teams assessment of their criticality to our operations and respective risk profile.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. See the risk factor titled, “Our business and operations may suffer in the event of information technology system failures, cyber attacks, or deficiencies in our cybersecurity.” for additional information.

Cybersecurity Governance

Our Board of Directors considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee oversight of cybersecurity risks, including oversight of management’s implementation of our cybersecurity risk management program.

The Audit Committee receives quarterly reports from management on our cybersecurity risks. In addition, management updates the Committee, where it deems appropriate, regarding cybersecurity incidents it considers to be significant or potentially significant.

The Audit Committee reports to the full Board of Directors regarding its activities, including those related to cybersecurity. The full Board of Directors also periodically receives briefings from management on our cybersecurity risk management program. Members of the Board of Directors receive presentations on cybersecurity topics from our Executive Director Information Security as part of the Board of Directors’ continuing education on topics that impact public companies.

Our management team, including the Executive Director of Information Security and Chief Technology Officer (CTO), are responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management team's experience includes a cumulative 22 years of experience in assessing and managing risk throughout organizations. In addition, hold industry specific certifications such as Certified Information Systems Auditor (CISA) and Certified Data Privacy Solutions Engineer (CDPSE).

Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel, threat intelligence, other information obtained from governmental, public or private sources, including external consultants engaged by us, and alerts and reports produced by security tools deployed in our IT environment.

Item 2. Properties.

Our corporate headquarters is in Sunnyvale, California, where we lease a 15,600 square foot facility pursuant to a lease agreement which commenced on November 1, 2021, and expires on January 31, 2027. To support our growth, the Company entered into an operating lease agreement for a 11,600 square foot facility for additional office and warehouse space in Sunnyvale, California in May 2024. The lease commenced when the Company obtained early use of the property beginning on June 1, 2024, and terminates on January 31, 2027.

Our existing facility will continue to support our research and development, finance, marketing, and administrative teams. We believe that our existing and new facilities are adequate to support our expansion through the end of the facilities' lease periods. We believe that suitable additional or alternative space would be available in the future as required on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may be involved in 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. Future litigation may be necessary to defend ourselves, our partners, and our customers by determining the scope, enforceability, and validity of third-party proprietary rights, to establish our proprietary rights or for other matters. Involvement in such 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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "CBLL."

Holders of Record

As of February 21, 2025, there were approximately 170 registered holders of record of our common stock. The actual number of holders is greater than this number and includes stockholders who are beneficial owners but whose shares are held in "street name" by banks, brokers, and other financial institutions. This number of record holders also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We do not expect to pay dividends on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings, if any, will be used for the operation and growth of our business. Any future determination to declare cash dividends would be subject to the discretion of our Board of Directors and would depend upon various factors, including our results of operations, financial condition and capital requirements, restrictions that may be imposed by applicable law and our contracts and other factors deemed relevant by our Board of Directors.

Use of Proceeds from our Initial Public Offering

On October 10, 2024, our registration statement on Form S-1 (File No. 333-281784) relating to our initial public offering (the "IPO") became effective pursuant to which we issued and sold 12,196,969 shares of our common stock at a public offering price of $17.00 per share. We received net proceeds of $187.8 million, after deducting the underwriting discounts, commissions and offering expenses. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities. There has been no material change in the planned use of proceeds from the IPO from that described in our Final Prospectus dated October 10, 2024 and filed with the SEC pursuant to Rule 424(b)(4) on October 11, 2024.

Recent Sales of Unregistered Securities

None.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. 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 financial statements and related notes included elsewhere in this Annual Report. 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 Annual Report, particularly in "Risk Factors" and "Special Note Regarding Forward-Looking Statements."

Overview

We are a medical technology company focused on transforming the diagnosis and management of patients with serious neurological conditions. We have developed the Ceribell System, a novel, point-of-care EEG platform specifically designed to address the unmet needs of patients in the acute care setting. By combining proprietary, highly portable, and rapidly deployable hardware with sophisticated 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. To date, the Ceribell System has been adopted by more than 500 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 this Annual Report.

We specifically designed the Ceribell System to address the limitations of conventional EEG in the acute care setting and dramatically improve clinical outcomes of critically ill patients at high risk of seizures. The Ceribell System integrates proprietary, highly portable hardware with AI-powered algorithms to aid in the detection and management of seizures. Our hardware is composed of 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 December 31, 2024, we had an accumulated deficit of $166.9 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 December 31, 2024, we had $194.4 million in cash and cash equivalents. On October 15, 2024, we closed our initial public offering (our "IPO") pursuant to which we sold 12,196,969 shares of our common stock at a price to the public of $17.00 per share. We received net proceeds of $187.8 million from the IPO after deducting underwriting discounts and commissions and offering expenses. 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 December 31, 2024, we had over 500 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. 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 Annual Report.

Operating Expenses

Research and Development

Research and development expenses are incurred in connection with the advancement of the Ceribell System with the goal to improve and expand on 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, interest expense on our term loans, and change in the fair value of the warrant liability. 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 are recognized in the income statement each quarter until the warrants are exercised, expire, or become exercisable into shares of common stock.

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 Years ended December 31, 2024 and 2023

The following tables set forth our results of operations for the periods presented (in thousands, except percentages) 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.

	Year ended December 31,			
	2024	2023	$ Change	% Change
Revenue				
Product revenue	$ 50,079	$ 34,568	$ 15,511	45%
Subscription revenue	15,365	10,657	4,708	44%
Total revenue	**65,444**	**45,225**	20,219	45%
Cost of revenue				
Product cost of goods sold	8,209	6,630	1,579	24%
Subscription cost of revenue	485	432	53	12%
Total cost of revenue	**8,694**	**7,062**	1,632	23%
Gross profit	**56,750**	**38,163**	18,587	49%
Operating expenses:				
Research and development	13,562	8,995	4,567	51%
Sales and marketing	49,055	38,922	10,133	26%
General and administrative	33,842	20,287	13,555	67%
Total operating expenses	**96,459**	**68,204**	**28,255**	**41%**
Loss from operations	**(39,709)**	**(30,041)**	**(9,668)**	**32%**
Interest and other income (expense), net	(746)	588	(1,334)	NM*
Loss before provision for income taxes	**(40,455)**	**(29,453)**	**(11,002)**	**37%**
Provision for income taxes	—	(11)	11	-100%
Net loss	**$ (40,455)**	**$ (29,464)**	**$ (10,991)**	**37%**

** Not Meaningful*

Comparison of the Years ended December 31, 2024 and 2023

Revenue

Product revenue for the year ended December 31, 2024 ("fiscal year 2024"), increased $15.5 million, or 45%, compared to the year ended December 31, 2023 ("fiscal year 2023"). Product revenue growth was 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 fiscal year 2024, increased $4.7 million, or 44%, compared to fiscal year 2023. Subscription revenue growth was primarily driven by an increase in new customer subscriptions.

Cost of Revenue

Product cost of revenue for fiscal year 2024, increased $1.6 million, or 24%, compared to fiscal year 2023. 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 unit cost of materials.

Subscription cost of revenue for fiscal year 2024, increased $0.05 million, or 12%, compared to fiscal year 2023. 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 and Gross Margin

The following table sets forth our gross profit and gross margin for the periods presented (in thousands, except percentages).

	Year ended December 31,			
	2024	2023	$ Change	% Change
Gross profit	$ 56,750	$ 38,163	$ 18,587	49%
Gross margin	87%	84%		3%
Product gross profit	41,870	27,938	13,932	50%
Product gross margin	84%	81%		3%
Subscription gross profit	14,880	10,225	4,655	46%
Subscription gross margin	97%	96%		1%

Gross profit increased $18.6 million, or 49%, for fiscal year 2024, compared to fiscal year 2023. The increase was 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 increased $4.6 million, or 51%, for fiscal year 2024, compared to fiscal year 2023. The increase was primarily due to an increase of $2.6 million in personnel and related expenses directly associated with an increase in headcount and stock-based compensation, as well as an increase of $1.5 million in clinical study and professional expenses.

Sales and Marketing Expenses

Sales and marketing expenses increased $10.1 million, or 26%, for fiscal year 2024, compared to fiscal year 2023. The increase was primarily due to an increase in personnel and related expenses directly associated with an increase in headcount and commissions.

General and Administrative Expenses

General and administrative expenses increased $13.6 million, or 67%, for fiscal year 2024, compared to fiscal year 2023. The increase was primarily due to an increase of $7.9 million in personnel and related expenses directly associated with an increase in headcount and stock-based compensation, an increase of $4.3 million in legal, accounting, and professional service fees related to our transition to a public company, and an increase of $1.1 million in administrative expenses driven by increased software, facilities, and other administrative expenses.

Interest and Other Income (Expense), net

Interest and other income (expense), net decreased $1.3 million for fiscal year 2024, compared to fiscal year 2023. The decrease was primarily due to a $0.4 million increase in interest expense related to debt and $1.5 million in other expense as a result of the change in fair value of the warrant liability, offset by an increase of $0.5 million interest income related to an increase in cash.

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 December 31, 2024, our principal sources of liquidity consisted of $194.4 million of cash and cash equivalents 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.

Cash Flows

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

	Year ended December 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (35,043)	$ (29,159)
Net cash used in investing activities	$ (1,598)	$ (1,763)
Net cash provided by (used in) financing activities	$ 196,516	$ (2,818)

Operating Activities

Net cash used in operating activities during fiscal year 2024, consisted primarily of our net loss of $40.5 million, offset by non-cash charges of stock-based compensation of $5.4 million, depreciation and amortization of $1.1 million, and the change in fair value of our redeemable convertible preferred stock warrants. Additionally we had a net increase in operating assets of $5.8 million and a net decrease in operating liabilities of $2.6 million. Net operating assets increased due to the timing of inventory purchases and accounts receivable due to the overall increase in sales in fiscal year 2024. Net operating liabilities decreased primarily due to timing of payments.

Net cash used in operating activities during fiscal year 2023, consisted primarily of our net loss of $29.5 million, offset by non-cash charges of stock-based compensation of $2.7 million, and a net increase in operating assets of $6.1 million, partially offset by a net increase in operating liabilities of $2.4 million. Net operating assets increased due to the timing of inventory purchases and accounts receivable due to the overall increase in sales in fiscal year 2023. Net operating liabilities increased primarily due to increased accrued payroll, bonus, and commissions due to increased headcount.

Investing Activities

Net cash used in investing activities during fiscal years 2024 and 2023 was $1.6 million and $1.8 million, respectively, and consisted of purchases of equipment and purchases of components for recorders provided to customers.

Financing Activities

Net cash provided by financing activities during fiscal year 2024, consisted primarily of $187.8 million in proceeds from the IPO net of issuance costs, $7.6 million in net proceeds from debt issuance, and $1.1 million in proceeds from the exercise of options.

Net cash used in financing activities during fiscal year 2023, consisted primarily of $3.8 million in debt repayment.

Contractual Obligations and Commitments

Our contractual obligations as of December 31, 2024 include:

Debt — Principal payments required on long-term debt outstanding as of December 31, 2024, 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 December 31, 2024, estimated contractual obligations for operating lease payments were $2.4 million due within 28 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.

See Note 2 to our financial statements elsewhere in this Annual Report for information about our significant accounting policies and how estimates are involved in the preparation of our financial statements. We believe the following reflect the critical accounting estimates used in the preparation of our financial statements.

Valuation of Warrants

We have issued freestanding warrants to purchase shares of redeemable convertible preferred stock in connection with our term loans. We classified these warrants as a liability because they contain liquidation features that are not solely within our control. We record the fair value of the warrant on the balance sheet at the inception of such classification and adjust to fair value at each financial reporting date. Our assumptions with regard to the warrant valuation are based on estimates of the valuation of the underlying preferred stock, volatility, and risk free interest rates, and such estimates could vary significantly. The changes in the fair value of the warrants were recorded as a component of non-operating income or expense in the Statements of Operations and Comprehensive Loss. Upon the close of our IPO, the warrants converted on a 1:1 basis to be exercisable for shares of common stock, at which time the liability was reclassified to equity.

Valuation of Common Stock

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*. In the absence of a public trading market prior to our IPO, our Board of Directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option grant, including the following factors:

- our stage of development;
- our history and the timing of the introduction of new solutions and services;
- our actual operating results and performance and financial condition, including our levels of available capital resources;
- current business conditions and projections;
- the prices, rights, preferences, and privileges of our redeemable convertible preferred stock relative to those of our common stock;
- U.S. market and economic conditions;
- conditions of the U.S. medical device industry;
- the stock price performance, volatility, and valuation multiples of comparable publicly-traded companies;
- the likelihood and timing of achieving a liquidity event, such as an initial public offering or a merger or acquisition of our business given prevailing market conditions;
- the prices of redeemable convertible preferred stock sold by us to third-party investors in arms-length transactions;
- recent secondary stock transactions in shares of our preferred and common stock;
- relevant mergers and acquisitions in targeted industries;
- the lack of marketability of our common stock; and
- contemporaneous valuations performed by third-party valuation firms.

Our Board of Directors determined the income approach and market approach, including the back-solve method, were the most appropriate methods for estimating our enterprise value. Under the income approach, we estimated the value based upon our projected financial performance. Under the back-solve method in the market approach, we estimated the value based upon our prior sales of redeemable convertible preferred stock to unrelated third parties, as well as secondary transactions undertaken in our preferred securities, using the option pricing method (the "OPM"). The back-solve analysis considered the post-transaction liquidation preferences, participation caps, dividends, conversion features, and our capital structure immediately following the closing of each financing round. Other market approaches included analyses based on the valuation of comparable publicly traded companies and mergers and acquisitions observed in related industries. We then applied these derived multiples or values to our financial metrics to estimate our market value.

In addition, we also considered any secondary transactions involving our common stock. In our evaluation of such transactions, we considered the facts and circumstances of each such transaction to determine the extent to which they represented a fair value

exchange. Factors considered include transaction volume, timing, whether such transactions occurred among willing and unrelated parties, and whether such transactions involved investors with access to our financial information.

For valuations performed prior to September 30, 2023, the allocation of these enterprise values to each part of our capital structure, including our common stock and redeemable convertible preferred stock, was done utilizing the OPM. The OPM treats the rights of the holders of redeemable convertible preferred and common stock as equivalent to call options on any value of the enterprise above certain break points of value based upon the liquidation preferences of the holders of redeemable convertible preferred stock, as well as their rights to participation and conversion. Thus, the estimated value of the common stock can be determined by estimating the value of its portion of each of these call option rights. The OPM back-solve derives the implied equity value of a company from a recent transaction involving our own securities issued on an arms-length basis.

For our valuations performed on or after September 30, 2023, the allocation of these enterprise values to each our share classes was done utilizing the hybrid method. The hybrid method is a hybrid between the probability-weighted expected returns method (the "PWERM") and the OPM. The PWERM considers the enterprise value under various exit scenarios including an initial public offering (the "IPO Scenario") and staying private, our estimate of the timing of each scenario and weightings based on our estimate of the probability of each event occurring. Our equity value under the IPO Scenario was estimated based on benchmarking analyses performed by the company and its bankers using market data observed for companies with recent IPOs. The equity value under the IPO Scenario was allocated to our capital stock using an IPO scenario analysis that contemplates the timing, size, valuation, and probability of an IPO event in the future. The stay private scenario estimated our equity value using an income approach based on our financial projections and market approaches based on the valuation of comparable publicly traded companies and mergers and acquisitions observed in related industries. Further, we used the OPM back-solve method and market indexing valuation method under the market approach with respect to the secondary transactions in our redeemable convertible preferred stock. The equity value was then allocated to our capital stock based on the OPM.

After the equity value is determined and allocated to the various share classes, a discount for lack of marketability ("DLOM") is applied to arrive at the fair value of the common stock. A DLOM is meant to account for the lack of marketability of a stock that is not traded on public exchanges. For financial reporting purposes, we considered the amount of time between the valuation date and the grant date of our stock options to determine whether to use the latest common stock valuation or a straight-line interpolation between the two valuation dates. This determination included an evaluation of whether the subsequent valuation indicated that any significant change in valuation had occurred between the previous valuation and the grant date.

For valuations after the completion of our IPO, the fair value of each share of underlying common stock is based on the closing price of our common stock as reported on the date of grant on the Nasdaq stock exchange.

Valuation of Common Stock Options for Stock-Based Compensation

We maintain an equity incentive plan to provide long-term incentives for employees, consultants and members of the Board of Directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors. We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards granted, including employee stock options.

We account for stock-based compensation awards, including stock options to employees and non-employees, based on their estimated grant date fair value. We estimate the fair value of our stock options using the Black-Scholes option-pricing model.

We recognize fair value of stock options, which vest based on continued service, on a straight-line basis over the requisite service period, which is generally four years. For performance-based grants, we estimate when and if they will be earned. If we consider such award to be probable, we recognize expense over the estimated service period, which would be the estimated period of performance. If we do not consider such awards probable of achievement, we recognize no amount of stock-based compensation. There were 118,999 performance-based option awards outstanding as of December 31, 2024 and 64,527 performance-based option awards outstanding as of December 31, 2023. We account for forfeitures as they occur.

Determining the grant date fair value of options using the Black-Scholes option pricing model requires management to make assumptions and judgments. Changes in the assumptions can materially affect the fair value and ultimately the amount of stock-based compensation expense recognized. These inputs are subjective and generally require significant analysis and judgment to develop. Changes in the following assumptions can materially affect the estimate of the fair value of stock-based compensation:

- *Fair Value of Common Stock*—The absence of an active market for our common stock requires us to estimate the fair value of our common stock. See "—Valuation Common Stock" above.

- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. We estimated the expected term based on an average of the midpoint of the requisite service period and the contractual term, and the historical exercise behavior.
- *Expected Volatility*—Since there has been no public market for our common stock and lack of company specific historical volatility, we have determined the share price volatility for options granted based on an analysis of the volatility of a peer group of publicly traded companies. In evaluating similarity, we consider factors such as industry, stage of life cycle, and size.
- *Risk-Free Interest Rate*—The risk-free interest rate is calculated using the average of the published interest rates of U.S. Treasury zero-coupon issues with maturities that are commensurate with the expected term.
- *Dividend Yield*—The dividend yield assumption is zero, as we have no history of, or plans to make, dividend payments.

The following weighted-average assumptions were used for the Black-Scholes option pricing model:

	Year ended December 31,	
	2024	2023
Expected term (in years)	5.4	5.1
Expected volatility	68.0%	75.4%
Risk-free interest rate	4.1%	4.2%
Dividend yield	—	—

Upon the completion of our IPO, our common stock was publicly traded and is therefore subject to potentially significant fluctuations in the market price. Increases and decreases in the market price of our common stock also increase and decrease the fair value of our stock-based awards granted in future periods.

See Note 11 to our financial statements included elsewhere in this Annual Report for further details.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. As a result, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies and our financial statements may not be comparable to other public companies that comply with new or revised accounting pronouncements as of public company effective dates. The JOBS Act also exempts us from having to provide an attestation and report from our independent registered public accounting firm on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

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

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

Recently Issued Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934, as amended and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of CeriBell, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of CeriBell, Inc. (the "Company") as of December 31, 2024 and 2023, and the related statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit, and of cash flows for the years then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/PricewaterhouseCoopers LLP
San Jose, California
February 25, 2025

We have served as the Company's auditor since 2022.

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

	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 194,370	$ 34,495
Accounts receivable, net	10,878	7,955
Inventory	6,937	5,868
Contract costs, current	1,837	1,515
Prepaid expenses and other current assets	3,250	2,130
Total current assets	**217,272**	**51,963**
Property and equipment, net	2,313	1,577
Operating lease right-of-use assets	2,132	2,160
Contract costs, long-term	1,507	1,238
Other non-current assets	2,188	1,984
Total assets	**$ 225,412**	**$ 58,922**
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities		
Accounts payable	$ 1,143	$ 732
Accrued liabilities	10,052	7,540
Contract liabilities, current	97	206
Notes payable, current	—	11,833
Operating lease liability, current	1,088	694
Other current liabilities	609	595
Total current liabilities	**12,989**	**21,600**
Long-term liabilities		
Notes payable, long-term	19,558	—
Contract liabilities, long-term	30	44
Other liabilities, long-term	356	441
Operating lease liability, long-term	1,314	1,677
Total long-term liabilities	**21,258**	**2,162**
Total liabilities	**$ 34,247**	**$ 23,762**
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, $0.001 par value;		
Authorized shares: none and 46,624,838 shares as of December 31, 2024 and December 31, 2023, respectively		
Issued and outstanding shares: none and 17,817,643 shares as of December 31, 2024 and December 31, 2023, respectively		
Aggregate liquidation preference of none and $152,590 as of December 31, 2024 and December 31, 2023, respectively	—	147,412
Stockholders' deficit		
Preferred stock, $0.001 par value;		
Authorized shares: 10,000,000 and none shares as of December 31, 2024 and December 31, 2023, respectively		
Issued and outstanding shares: none as of December 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.001 par value;		
Authorized shares: 500,000,000 and 76,046,350 as of December 31, 2024 and December 31, 2023, respectively		
Issued and outstanding shares: 35,850,606 and 5,430,298 as of December 31, 2024 and December 31, 2023, respectively	36	5
Additional paid-in capital	358,073	14,232
Accumulated deficit	(166,944)	(126,489)
Total stockholders' deficit	**191,165**	**(112,252)**
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	**$ 225,412**	**$ 58,922**

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

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

	Year ended December 31,	
	2024	**2023**
Revenue		
Product revenue	$ 50,079	$ 34,568
Subscription revenue	15,365	10,657
Total revenue	**65,444**	**45,225**
Cost of revenue		
Product cost of goods sold	8,209	6,630
Subscription cost of revenue	485	432
Total cost of revenue	**8,694**	**7,062**
Gross profit	**56,750**	**38,163**
Operating expenses		
Research and development	13,562	8,995
Sales and marketing	49,055	38,922
General and administrative	33,842	20,287
Total operating expenses	**96,459**	**68,204**
Loss from operations	**(39,709)**	**(30,041)**
Interest expense	(1,992)	(2,098)
Change in fair value of warrant liability	(1,496)	48
Other income, net	2,742	2,638
Loss, before provision for income taxes	**(40,455)**	**(29,453)**
Provision for income tax expense	—	(11)
Net loss and comprehensive loss	**$ (40,455)**	**$ (29,464)**
Net loss per share attributable to common stockholders:		
Basic and diluted	(3.39)	(5.56)
Weighted-average shares used in computing net loss per share attributable to common stockholders:		
Basic and diluted	11,949,973	5,303,715

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

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

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in-Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Par Value			
Balance December 31, 2022	**17,817,643**	**$ 147,412**	**5,123,735**	**5**	**$ 10,622**	**$ (97,025)**	**$ (86,398)**
Issuance of common stock pursuant to stock option exercises	—	—	306,563	—	932	—	932
Stock-based compensation	—	—	—	—	2,678	—	2,678
Net loss	—	—	—	—	—	(29,464)	(29,464)
Balance December 31, 2023	**17,817,643**	**$ 147,412**	**5,430,298**	**5**	**$ 14,232**	**$ (126,489)**	**$ (112,252)**
Conversion of redeemable convertible preferred stock to common stock on IPO	(17,817,643)	(147,412)	17,817,643	18	147,394	—	147,412
Conversion of redeemable convertible preferred stock warrants to common stock warrants on IPO	—	—	—	—	2,134	—	2,134
Issuance of common stock upon IPO, net of offering costs of $5.0 million	—	—	12,196,969	12	187,774	—	187,786
Issuance of restricted stock awards	—	—	1,239	—	—	—	—
Issuance of common stock pursuant to stock option exercises	—	—	404,457	1	1,128	—	1,129
Stock-based compensation	—	—	—	—	5,411	—	5,411
Net loss	—	—	—	—	—	(40,455)	(40,455)
Balance December 31, 2024	**—**	**$ —**	**35,850,606**	**36**	**$ 358,073**	**$ (166,944)**	**$ 191,165**

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

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

	Year ended December 31,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (40,455)	$ (29,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,141	847
Noncash lease expense	59	(19)
Stock-based compensation expense	5,411	2,678
Amortization of debt discount	382	363
Change in fair value of warrant liability	1,496	(48)
Loss on disposal of property and equipment and recorders	95	181
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,923)	(2,660)
Inventory	(1,068)	(1,794)
Prepaid expenses and other current assets	(1,121)	(965)
Contract costs	(591)	(773)
Other non-current asset	(65)	113
Accounts payable	250	309
Accrued liabilities and other current liabilities	2,469	2,166
Contract liabilities	(123)	(93)
Net cash used in operating activities	**(35,043)**	**(29,159)**
Cash flows from investing activities		
Purchases of recorder components and recorders	(258)	(780)
Purchases of property and equipment	(1,340)	(983)
Net cash used in investing activities	**(1,598)**	**(1,763)**
Cash flows from financing activities		
Repayment of debt	—	(3,750)
Proceeds from exercise of common stock pursuant to stock option exercises	1,129	932
Proceeds from debt issuance	7,905	—
Debt issuance cost	(304)	—
Payment of deferred IPO offering costs	(5,048)	—
Proceeds from IPO, net of commissions	192,834	—
Net cash provided by (used in) financing activities	**196,516**	**(2,818)**
Net increase (decrease) in cash and cash equivalents	**159,875**	**(33,740)**
Cash and cash equivalents, beginning of period	34,495	68,235
Cash and cash equivalents, end of period	**$ 194,370**	**$ 34,495**
Supplemental disclosure of cash flow information		
Cash paid for interest	**$ 1,952**	**$ 1,734**
Right-of-use asset obtained in exchange for operating lease obligation	**778**	—
Property and equipment included in accounts payable and accrued expenses	**99**	—
Recorder components included in accounts payable and accrued expenses	**69**	—
Conversion of redeemable convertible preferred stock into common stock on completion of IPO	**147,412**	—

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

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 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.

Initial Public Offering

On October 15, 2024, the Company completed its initial public offering ("IPO") of 12,196,969 shares of its common stock, which includes 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 net proceeds to the Company from the IPO were approximately $187.8 million, after deducting underwriting discounts and commissions, and offering expenses. Immediately prior to the closing of the Company's IPO on October 15, 2024, all shares of the Company's redeemable convertible preferred stock converted one for one into shares of the Company's common stock and all warrants exercisable for redeemable convertible preferred stock converted into warrants exercisable for common stock.

Liquidity

As of December 31, 2024, the Company's principal sources of liquidity consisted of $194.4 million of cash and cash equivalents.

The Company has incurred operating losses and negative cash flows from operations since its inception. On December 31, 2024, and December 31, 2023, the Company had an accumulated deficit of $166.9 million and $126.5 million, respectively. 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.

On October 15, 2024, the Company completed its IPO and received net proceeds of $187.8 million after deducting underwriting discounts, commissions and offering expenses.

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 has increased inventory purchases 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"). The Company made immaterial revisions to change the classification of cash outflows for the acquisition of recorders and related components from cash outflow from operations to cash outflow from investing in the amount of $0.8 million for the year ended December 31, 2023. The Company also made immaterial revisions to change the classification of recorders and related components not placed into service from inventory to other non-current assets in the amount of $1.3 million and the classification of warrants for convertible preferred stock from other current liabilities to other liabilities, long term in the amount of $0.3 million at December 31, 2023.

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 IPO), and valuation of the Company's options to purchase common stock for purposes of accounting for stock-based compensation.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less on the date of acquisition to be cash equivalents. As of December 31, 2024, and December 31, 2023, cash and cash equivalents consist of cash in business checking accounts, demand deposit accounts, and money market funds.

Accounts Receivable

The Company records accounts receivables at the invoiced amount. The Company maintains an allowance for credit losses for any receivables the Company may be unable to collect. The Company estimates uncollectible receivables on an individual basis based on the receivables' age, customers' expected ability to pay and collection history, and current economic conditions, among other factors that may affect customers' ability to pay. The Company uses its judgment, based on the best available facts and circumstances, and records an allowance against amounts due to reduce the receivable to the amount that is expected to be collected. Allowances for credit losses are immaterial and included in accounts receivable, net on the balance sheets.

Inventory

Inventory is recorded at the lower of cost or net realizable value, which approximates actual cost on the first-in, first-out basis. Inventory costs include direct materials, direct labor, and normal manufacturing overhead. The Company uses third party contract manufacturers to complete the manufacturing and assembly of material components on site. Final quality inspection and packaging is performed at the Company's headquarters. Prior to the quality inspection and packaging, the inventory is considered component material. The Company periodically assesses the recoverability of all inventories to determine whether adjustments for impairment are required. The Company evaluates the related commercial mix of finished goods and other general obsolescence and impairment criteria in assessing the recoverability of the Company's inventory and records a provision for excess, expired, and obsolete inventory based primarily on estimates of forecasted demand. Judgment is required in determining these provisions, and a change in the timing or level of demand for products, as compared to forecasted amounts, may result in recording additional provisions for excess, expired, and obsolete inventory in the future.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation and amortization. Maintenance and repairs are charged to expense as incurred, and leasehold improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation and amortization are removed from the balance sheet and any resulting gain or loss is reflected in the statement of operations in the period realized. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets in accordance with the following table:

Fixed asset category	Estimated useful life
Furniture and fixtures	36 months
Computer equipment and software	36 months
Laboratory and manufacturing equipment	36 months
Leasehold improvements	Shorter of the useful life or term of the lease

Right-of-Use Assets and Lease Liabilities

The Company determines if an arrangement is a lease, or contains a lease, at inception. The Company recognizes on its balance sheets operating lease liabilities representing the present value of future lease payments and an associated operating lease right-of-use (ROU) asset for any operating lease with a term greater than one year. As the Company leases do not provide an implicit rate, the Company generally uses an incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a term similar to the lease arrangement. Significant judgment is required in determining the incremental collateralized borrowing rate. Lease expense is recognized on a straight-line basis over the lease term.

Redeemable Convertible Preferred Stock and Warrants

The holders of the outstanding shares of redeemable convertible preferred stock do not have stated redemption rights; however, the holders of the redeemable convertible stock are entitled to preferential payments in the event of a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the Company's assets or intellectual property, the acquisition of the Company by another entity by means of any reorganization, merger, or consolidation following which the Company's stockholders as of immediately prior to such acquisition fail to hold at least 50% of the voting power of the resulting entity, or a liquidation, dissolution or winding up of the Company (a "Deemed Liquidation Event"). Because a Deemed Liquidation Event is not solely within the Company's control, all shares of redeemable convertible preferred stock have been presented outside of permanent equity in the accompanying Balance Sheet for December 31, 2023. Immediately prior to the closing of the Company's IPO on October 15, 2024, all shares of the Company's redeemable convertible preferred stock converted into shares of the Company's common stock.

In addition, the Company issued freestanding warrants to purchase redeemable convertible preferred stock. The redeemable convertible preferred stock warrants were subject to remeasurement at each balance sheet date, and any change in fair value was

recognized as a component of non-operating income or expense in the Statements of Operations and Comprehensive Loss. The Company uses the Black-Scholes option-pricing model to determine the fair value of the warrants. 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 were reclassified from long-term liabilities to equity. The warrants are currently exercisable and are included in Additional Paid-In Capital as of December 31, 2024, and in Other liabilities, long-term on the accompanying Balance Sheet as of December 31, 2023.

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 constituted 10% of the Company revenue for the years ended December 31, 2024, or 2023. No customers constituted 10% of the Company's accounts receivable balance as of December 31, 2024, or December 31, 2023.

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 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.

Other Non-Current Assets

Other non-current assets include recorders, recorder components, and recorders at customer locations, as well as non-current deposits. The estimated useful life of recorders is three years and depreciation commences when recorders are placed into service at customer locations.

Deferred IPO Offering Costs

Deferred IPO offering costs, consisting of legal fees, consulting fees, and accounting fees relating to the initial public offering are capitalized. The deferred IPO offering costs were offset against offering proceeds and reclassified as a reduction to equity upon the closing of the offering in the fourth quarter of 2024. The Company had no deferred IPO offering costs capitalized as of December 31, 2024 and December 31, 2023.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets, principally Property and Equipment and Right of Use Assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. There have been no such impairments of long-lived assets recognized to date.

Cost of Revenue

Cost of revenue consists of direct and indirect costs related to the manufacturing of the Company's products as well as hosting costs for the Company's Clarity and EEG portal subscription services. Direct costs include headband costs, depreciation of recorders at customer locations, and costs related to assembly and testing performed by the Company's employees. Indirect costs consist of allocated overhead for employee costs and facility costs. Shipping and handling costs incurred for inventory purchases and product shipments as well as tariffs are recorded in cost of revenue in the statements of operations and comprehensive loss.

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. All of the Company's revenue was in the United States for the years ended December 31, 2024, and 2023. Long-lived assets held outside of the United States are $0.9 million as of December 31, 2024, and $0.7 million as of December 31, 2023.

License Agreement

The Company has entered into 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. The estimated future minimum payments are less than $0.1 million per year through the end of the patents' lives. The Company has an option to extend the exclusivity of the license to the date the last licensed patent expires upon payment of a term exercise fee.

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 $0.2 million, for both years ended December 31, 2024, and 2023.

Research and Development

Research and development costs are charged to operations in the period incurred. Research and development costs include, but are not limited to, payroll and personnel and stock-based compensation expenses, laboratory supplies, consulting costs, and allocated overhead, including rent, equipment, depreciation, and utilities.

Intellectual Property Costs

Costs to secure, defend, and maintain patents, including those incurred in connection with filing and prosecuting patent applications, are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred for patent-related expenditures are classified as general and administrative expenses in the statements of operations and comprehensive loss.

Advertising Costs

The Company charges advertising costs to expense as incurred. Advertising costs were $0.4 million and $0.5 million, for the years ended December 31, 2024, and 2023, respectively.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, stock options, and warrants to purchase convertible preferred stock on an as-converted basis are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities, as the redeemable convertible preferred stock is considered a participating security because it participates in dividends with common stock. The holders of redeemable convertible preferred stock do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods. As of December 31, 2024, no participating securities remain outstanding.

Stock-Based Compensation

The Company accounts for stock-based compensation for employee and non-employee awards in accordance with ASC 718, *Compensation - Stock Compensation.* ASC 718 requires the recognition of compensation expense, using a fair value-based method, for costs related to all service-based share-based payments, including stock options.

The Company estimates the fair value of options granted to employees on the grant date using the Black-Scholes option valuation model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation, including the value of the Company's stock, the expected volatility of the Company's common stock, the expected term (based on an average of the midpoint of the requisite service period and the contractual term, and the historical exercise behavior), the risk-free interest rate and expected dividends.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2024, and 2023, there was no difference between net loss and comprehensive loss.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's balance sheets and income tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and the tax bases of assets and liabilities and for loss and credit carryforwards using the enacted rates expected to be in effect when the differences are expected to reverse. The Company evaluates the realizability of its deferred tax assets and records a valuation allowance if it is more likely than not that some or all of the deferred tax assets may not be realized.

The Company assesses its income tax positions and records tax benefits based upon management's evaluation of the facts, circumstances, and information available at the reporting date. The Company accounts for uncertainty in income taxes based on the guidance within ASC 740-10, which requires a more-likely-than-not threshold for financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, no tax benefit is recognized in the financial statements. The Company classifies interest and penalties on uncertain tax positions as income tax expense.

Recently Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board (the "FASB") issued Account Standards Update ("ASU") 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* The amendment simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The new standard requires entities to provide expanded disclosures about the terms and features of convertible instruments, how the instruments have been reported in the entity's financial statements, and information about events, conditions, and circumstances that can affect how to assess the amount or timing of an entity's future cash flows related to those instruments. On January 1, 2024, the Company adopted ASU 2020-06, which had an immaterial impact on its financial statements.

In November 2023, the FASB issued ASU 2023-07 Segment Reporting—Improvements to Reportable Segment Disclosures. The amendment expands segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker (CODM), the amount and description of other segment items, permits companies to disclose more than one measure of segment profit or loss, and requires all annual segment disclosures to be included in the interim periods. The amendments do not change how an entity identifies its operating segments, aggregates those operating segments, or applies quantitative thresholds to determine its reportable segments. On December 31, 2024, the Company adopted ASU 2023-07, which had a disclosure only impact on its financial statements.

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 of ASU 2023-09 will impact the Company's disclosures only and the Company is evaluating the effect of adopting the new disclosure requirements.

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. The Company is currently evaluating the impact this ASU will have on our disclosures.

3. Revenue

Revenue Recognition

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers*. ASC 606 established a principle for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. The core principle of ASC 606 is to recognize revenue to depict the transfer of promised goods or services to the Company's customers.

Under Topic 606, the Company recognizes revenue through the following steps:

(1) Identification of a contract with a customer

(2) Identification of the performance obligations in the contract, including the evaluation of performance obligations and the distinct goods or services in a contract

(3) Determination of the transaction price

(4) Analysis of the Standalone Selling Price (SSP) and allocation of the transaction price to the performance obligations in the contract, as appropriate

(5) Recognition of revenue when, or as, the performance obligation is satisfied

The Company accounts for a contract when both parties have approved the contract and the Company is committed to perform its obligations, the rights of the parties are identified, payment terms (generally net 30 days) are identified, the contract has commercial substance, and collectability of consideration is probable.

Revenue is recognized upon transfer of control of promised products to the customer in an amount reflecting the consideration that is expected to be received in exchange for those products. The Company enters into contracts that include one or more products that are generally capable of being distinct and accounted for as individual performance obligations, in addition to a monthly subscription fee that is generally capable of being distinct and accounted for as an individual performance obligation.

Identification and Satisfaction of Performance Obligations

The Company's revenue is derived from the sale of its products to medical groups and hospitals through its direct sales force throughout the U.S. Performance obligations in the Company's contracts that are satisfied at a point in time include EEG headbands and EEG recorders sold to customers. The Company recognizes revenue for its EEG recorders sold separately from subscriptions and its EEG headbands upon transfer of control to the customer at a point in time. Performance obligations in the Company's contracts that are satisfied over time include the EEG portal and Clarity software-as-a-service (SaaS) subscription products. For its Clarity and portal subscription products, the Company recognizes revenue ratably over the period in which the customer has the ability to consume and receive benefit from its access to the subscription, which is generally month to month. The Company's Clarity subscriptions include the use of EEG recorders by the customer over the subscription term. The Company identifies the EEG recorders used in conjunction with a subscription as an operating lease component in its arrangements with its customers and identifies the subscription as a non-lease component in its arrangements with its customers, which the Company determined to be predominant. The lease and non-lease revenue components have similar patterns of revenue recognition, and as such, allows the Company to elect the practical expedient to not separate the lease and non-lease components. Therefore, the overall arrangement is accounted for under ASC 606.

The consideration associated with customer contracts includes both fixed and variable amounts. Variable consideration includes discounts, rebates, credits, incentives, penalties, or other similar items. The amount of consideration that can vary is not material as a percentage of total annual consideration. Variable consideration estimates are reassessed at each reporting period until the contingency is resolved. The changes to the transaction price due to a change in estimated variable consideration are recorded as an adjustment to revenue in the period the estimate is changed. Changes to variable consideration are tracked and material changes are disclosed. Such changes were immaterial for the years ended December 31, 2024, and 2023.

The Company excludes sales tax from the transaction price and presents, as an accounting policy election, amounts collected from customers for sales and other taxes net of the related amounts remitted.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the basis of revenue recognition in accordance with GAAP. To determine the proper revenue recognition method for contracts, the Company evaluates whether two or more contracts should be combined and accounted for as one single contract and whether the combined or single contract should be accounted for as more than one performance obligation. This evaluation requires judgment, and the decision to combine a group of contracts or separate the combined or single contract into multiple performance obligations could change the amount of revenue and profit recorded in a given period.

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):

	Year ended December 31,	
	2024	2023
EEG recorders and EEG headbands, point in time	$ 50,079	$ 34,568
EEG portal and Clarity subscriptions, over time	15,365	10,657
Total Revenue	**$ 65,444**	**$ 45,225**

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):

	Year ended December 31,	
	2024	2023
Contract cost balance beginning of the period	$ 2,753	$ 1,981
Contract costs capitalized during the year	2,592	2,304
Contract costs amortized during the year	(2,001)	(1,532)
Contract Costs as of period end	**$ 3,344**	**$ 2,753**

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):

	Year ended December 31,	
	2024	2023
Contract Liabilities balance beginning of the period	$ 250	$ 343
Additional Contract Liabilities revenue during the period	904	763
Contract Liabilities balance recognized during the period	(1,027)	(856)
Balance as of period end	**$ 127**	**$ 250**

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 3 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):

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**

December 31, 2023	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	**$ 33,831**	**$ —**	**$ —**	**$ 33,831**
Total Assets, at fair value	**$ 33,831**	**$ —**	**$ —**	**$ 33,831**
Liabilities				
Warrant liability	**$ —**	**$ —**	**$ 334**	**$ 334**
Total Liabilities, at fair value	**$ —**	**$ —**	**$ 334**	**$ 334**

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

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.

The value of the warrants to purchase the Company's redeemable convertible preferred stock is dependent on the inputs for which there is little or no market data, in particular the value of the Company's stock. As a result, the valuation of the warrants to purchase the Company's redeemable convertible preferred stock is categorized as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the lowest level of significance of the unobservable inputs to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable inputs, observable inputs (that is, components that are actively quoted and can be validated to external sources). Accordingly, the gain or loss for changes in fair value recognized in the statements of operations and comprehensive loss are due in part, to observable factors that are part of the Level 3 methodology recognized. The fair values could change significantly based on future market conditions. 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 are currently exercisable and are included in Additional Paid-In Capital as of December 31, 2024, and in Other liabilities, long-term on the accompanying Balance Sheet as of December 31, 2023.

The fair value of the warrant liability at December 31, 2023, was determined using the Black-Scholes option pricing model using the following assumptions, as well as the estimates of the valuation of the underlying preferred stock:

	December 31, 2023
Expected term (in years)	6.00 - 7.00
Expected volatility	67.10% - 76.00%
Risk-free interest rate	3.55% - 4.60%
Dividend yield	—

5. Balance Sheet Details

Inventory

Inventory consists of the following (in thousands):

	December 31, 2024	December 31, 2023
Component materials	$ 4,094	$ 3,405
Finished goods	2,843	2,463
Total	**$ 6,937**	**$ 5,868**

Property and Equipment, net

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

	December 31, 2024	December 31, 2023
Furniture and fixtures	$ 713	$ 589
Computer equipment and software	391	515
Laboratory and manufacturing equipment	1,505	1,106
Leasehold improvements	810	348
Construction in progress	586	387
Total Property and Equipment	**4,005**	**2,945**
Less: accumulated depreciation and amortization	1,692	1,368
Property and Equipment, Net	**$ 2,313**	**$ 1,577**

Depreciation and amortization expense was $0.7 million and $0.5 million for the years ended December 31, 2024, and 2023, respectively.

Other Non-Current Assets

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

	December 31, 2024	December 31, 2023
Recorders at customer locations	$ 1,288	$ 969
Less: accumulated depreciation of recorders at customer locations	(822)	(484)
Recorders at customer locations, net	**466**	**485**
Recorders and related components	1,159	1,347
Deferred debt financing cost	346	—
Other non-current assets	217	152
Total non-current assets	**$ 2,188**	**$ 1,984**

Recorder depreciation expense was $0.4 million and $0.3 million for the years ended December 31, 2024, and 2023, respectively.

Accrued Liabilities

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

	December 31, 2024	December 31, 2023
Accrued bonuses and payroll	$ 4,391	$ 3,132
Accrued commissions	3,419	2,190
Professional fees and other costs	2,114	2,106
Other	128	112
Total	**$ 10,052**	**$ 7,540**

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. There has been no Company matching of employee contributions to the plan through December 31, 2024, and December 31, 2023.

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. The Company is not presently a party to any litigation. Legal fees are expensed in the period in which they are incurred. As of December 31, 2024, and December 31, 2023, there were no litigation liabilities recorded.

8. Leases

In May 2024, the Company entered into an operating lease agreement for additional office and warehouse space in Sunnyvale, California. The lease commenced when the Company obtained early use of the property beginning on June 1, 2024. The lease terminates on January 31, 2027.

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):

	December 31, 2024	December 31, 2023
Operating Lease		
Operating lease right-of-use asset	**$ 2,132**	**$ 2,160**
Operating lease liability, current	1,088	694
Operating leases liability, long-term	1,314	1,677
Total operating lease liabilities	**$ 2,402**	**$ 2,371**
Weighted average remaining lease term (years)	2.1	3.1
Weighted average remaining discount rate	7.24%	6.25%

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

	December 31, 2024	December 31, 2023
Operating lease expense	$ 983	$ 823
Variable lease expense	304	303
Total lease expense	**$ 1,287**	**$ 1,126**
Total cash payments for amounts included in the measurement of lease liabilities	**$ 911**	**$ 795**

The Company leases office space and warehouse space under non-cancelable operating leases. As of December 31, 2024, the future minimum lease payments under the non-cancelable operating lease are as follows (in thousands):

Operating Leases:	December 31, 2024
2025	$ 1,216
2026	1,255
2027	107
Total undiscounted lease payments	2,578
Imputed interest	(176)
Net Lease Liabilities	**$ 2,402**

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 $20,000,000 in principal ("Term Loan"), including $6,000,000 from SVB ("SVB Loan") and $14,000,000 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 $30,000,000 ("Outstanding Commitment") in three additional tranches of $10,000,000 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 December 31, 2024. In each of the three additional tranches, $3,000,000 is allocated to SVB, and $7,000,000 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 $35,000 upon funding of each additional tranche.

Upon execution of the VLSA, the Company paid to the Lenders $245,000 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 $304,000. 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 $150,000 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 $11,250,000 and end-of-term fees of $845,000 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 $10,000,000 ("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 $300,000 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) $535,000 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) $347,000 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) $116,000 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 December 31, 2024.

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 December 31, 2024, 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 December 31, 2024.

Notes payable consists of the following (in thousands):

	December 31, 2024	December 31, 2023
Principal of notes payable	$ 20,000	$ 11,250
End of term fee accretion	113	647
Unamortized debt issuance costs	(555)	(64)
Carrying value of Notes Payable	**$ 19,558**	**$ 11,833**

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

10. Redeemable Convertible Preferred Stock and Warrants

Under the Company's Amended and Restated Certificate of Incorporation, the Company is authorized to issue none and 46,624,838 shares of $0.001 par value redeemable convertible preferred stock as of December 31, 2024, and December 31, 2023, respectively.

Immediately prior to the closing of the Company's IPO on October 15, 2024, all shares of the Company's redeemable convertible preferred stock converted into shares of the Company's common stock.

As of December 31, 2023, the designated and outstanding redeemable convertible preferred stock are as follows:

Series	Number of Shares Authorized	Number of Shares Issued and Outstanding	Liquidation Preference	Liquidation Preference per Share	Net Carrying Value (in thousands)
Seed	3,130,799	1,218,208	$ 1,003,000	$ 0.8233	$ 1,003
A	7,778,774	3,026,755	13,488,394	4.4564	9,149
B	12,115,096	4,648,714	35,581,190	7.6540	35,396
C-1	22,973,771	8,837,401	101,523,315	11.4900	100,876
C-NV	626,398	86,565	994,459	11.4900	988
Total	**46,624,838**	**17,817,643**	**$ 152,590,358**		**$ 147,412**

The holders of the outstanding shares of redeemable convertible preferred stock did not have stated redemption rights; however, the holders of the redeemable convertible stock were entitled to preferential payments in the event of Deemed Liquidation Event.

The rights, preferences and privileges of the redeemable convertible preferred stockholders were as follows:

Voting

Other than the non-voting holders of Series C-NV redeemable convertible preferred stock, the holders of redeemable convertible preferred stock were entitled to vote on all matters on which the common stockholders are entitled to vote. Holders of redeemable convertible preferred stock and common stock vote together as a single class, with respect to any matter upon which holders of common stock have the right to vote. Each holder of redeemable convertible preferred stock was entitled to the number of votes equal to the number of common stock shares into which the shares held by such holder are convertible. The holders of a majority of the voting shares were able to elect all of the directors.

Dividends

When, as, and if declared by the Board of Directors, the Company would have declared dividends on the Series C preferred stock (the "Series C Dividends") at an annual rate of $0.9190 per share (the "Series C Dividend Rate") according to the number of shares of Series C preferred stock held by such holders. The right to receive dividends on shares of Series C preferred stock was not cumulative, and no right to dividends accrued to holders of Series C preferred stock by reason of the fact that dividends on said shares were not declared or paid in any calendar year. Payment of any dividends to the holders of Series C preferred stock would have been payable in preference and priority to any declaration or payment of any dividend distribution on Series B preferred stock, Series A preferred stock, Series Seed preferred stock and common stock of the Company and the Company would not have declared, paid or set aside any dividends on shares of any other class or series of capital stock of the Company unless the holders of the Series C preferred stock then outstanding would have first received, or simultaneously received, the Series C Dividends.

When, as, and if declared by the Board of Directors, the Company would have declared dividends on the Series B preferred stock (the "Series B Dividends") at an annual rate of $0.6124 per share (the "Series B Dividend Rate") according to the number of shares of Series B preferred stock held by such holders. The right to receive dividends on shares of Series B preferred stock was not cumulative, and no right to dividends accrued to holders of Series B preferred stock by reason of the fact that dividends on said shares were not declared or paid in any calendar year. Payment of any dividends to the holders of Series B preferred stock would have been payable in preference and priority to any declaration or payment of any dividend distribution on Series A preferred stock, Series Seed preferred stock and common stock of the Company and the Company would not have declared, paid or set aside any dividends on shares of any other class or series of capital stock of the Company (other than the Series C Dividends) unless the holders of the Series B preferred stock then outstanding would have first received, or simultaneously received, the Series B Dividends.

When, as, and if declared by the Board of Directors, the Company would have declared dividends on the Series A preferred stock (the "Series A Dividends") at an annual rate of $0.3565 per share (the "Series A Dividend Rate") according to the number of shares of Series A preferred stock held by such holders. The right to receive dividends on shares of Series A preferred stock was not cumulative, and no right to dividends accrued to holders of Series A preferred stock by reason of the fact that dividends on said shares were not declared or paid in any calendar year. Payment of any dividends to the holders of Series A preferred stock would have been payable in preference and priority to any declaration or payment of any dividend distribution on Series Seed preferred stock and common stock of the Company and the Company would not have declared, paid or set aside any dividends on shares of any other class or series of capital stock of the Company (other than the Series C Dividends and the Series B Dividends) unless the holders of the Series A preferred stock then outstanding would have first received, or simultaneously received, the Series A Dividends.

After the payment or setting aside for payment of the dividends for Series A, B, and C Dividends, when, as, and if declared by the Board of Directors, the Company would have declared dividends pro rata on the common stock and the preferred stock on a pari passu basis according to the number of shares of common stock held by such holders. For this purpose each holder of shares of preferred stock was treated as holding the greatest whole number of shares of common stock then issuable upon conversion of all shares of preferred stock held by such holder. No dividends have been declared to date.

Liquidation

In the event of any liquidation, including a deemed liquidity event, dissolution, or winding up of the Company, either voluntary or involuntary, the holders of Series C redeemable convertible preferred stock first were entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, Series B, Series A and Series Seed redeemable convertible preferred stock, an amount equal to the greater of the sum $11.49 per share as adjusted for any stock splits, stock dividends, combinations, recapitalizations plus all declared but unpaid dividends on such shares, and such amount per share as would have been payable had all shares of Series C and redeemable convertible preferred stock been converted into common stock prior to such liquidation, dissolution, or winding up of the Company.

Upon completion of the distribution of the full amount of Series C, the holders of Series B were entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, Series A and Series Seed convertible preferred stock, an amount equal to the greater of the sum $7.6540 per share, as adjusted for any stock splits, stock dividends, combinations, recapitalizations plus all declared but unpaid dividends on such shares, and such amount per share as would have been payable had all shares of Series B redeemable convertible preferred stock been converted into common stock prior to such liquidation, dissolution, or winding up of the Company.

Upon completion of the distribution of the full amount to Series C and Series B redeemable convertible preferred shareholders, the holders of Series A and Series Seed convertible preferred stock were entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, for each share of Series A convertible preferred stock, an amount equal to the greater of the sum of $4.4564, as adjusted for any recapitalizations plus all declared but unpaid dividends on such shares, and such amount per share as would have been payable had all shares of Series A redeemable convertible preferred stock been converted into common stock immediately prior to such liquidation, dissolution, or winding up of the Company, and for each share of Series Seed redeemable convertible preferred stock, $0.8233 and an amount equal to all declared but unpaid dividends on such shares as adjusted for any recapitalizations.

If the assets legally available for distribution were insufficient to cover the amounts owed to the holders of Series A and Series Seed convertible preferred stock together as a class, the assets would have been distributed with equal priority and pro rata among the holders of both Series A and Series Seed redeemable convertible preferred stock in proportion to the full amounts that they would have received had funds been sufficient.

Upon completion of the distributions of the full amount required to the holders of Series C, Series B, Series A, and Series Seed redeemable convertible preferred stock, all of the remaining assets of the Company available for distribution to stockholders would have been distributed among the holders of common stock and Series Seed redeemable convertible preferred stock pro rata based on the number of shares of common stock held by each (treating the shares of Series Seed redeemable convertible preferred stock for this purpose as if they had been converted to shares of common stock at the then-effective conversion price for such shares).

Conversion

Each share of redeemable convertible preferred stock was convertible at the option of the holder into that number of common shares that is equal to the original issuance price of the redeemable convertible preferred stock divided by the conversion price, subject to adjustment for events of dilution. Upon conversion, holders of Series C-NV convertible preferred stock could have elected to receive non-voting common stock or common stock on the same terms. The original issuance price is equal to $0.8233 per Series Seed preferred share, $4.4564 per Series A preferred share, $7.6540 per Series B preferred share, and $11.49 per Series C preferred share. As of December 31, 2023, all redeemable convertible preferred units were convertible into common shares at a one-for-one conversion ratio.

The Company closed its IPO on October 15, 2024, and all of the outstanding shares of convertible preferred stock were automatically converted into common stock.

Warrants

Effective February 6, 2024, the Company, Horizon, and SVB entered into a $60 million financing commitment, consisting of a $50 million term loan commitment and a $10 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 new 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.

	Series B	Series C-1	Common Stock	Common Stock	Total warrants
Balance December 31, 2023	**45,726**	**15,228**	**—**	**—**	**60,954**
Exercise price per warrant	$ 7.6540	$ 11.49			
Warrants issued	—	41,345	—	—	41,345
Conversion of redeemable convertible preferred stock warrants to common stock warrants	(45,726)	(56,573)	45,726	56,573	—
Balance December 31, 2024	**—**	**—**	**45,726**	**56,573**	**102,299**
Exercise price per warrant	$ 7.6540	$ 11.49	$ 7.6540	$ 11.49	

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. 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 are included in Additional paid-in capital as of December 31, 2024, and in Other liabilities, long-term on the accompanying Balance Sheet as of December 31, 2023. The change in the value of the warrant liability for the years ended December 31, 2024, and 2023, is summarized in the following table (in thousands).

The following table presents the fair value activity for the warrant liability (in thousands):

Balance December 31, 2022	**$**	**382**
Issuance of warrants		—
Changes in fair value of warrants		(48)
Balance December 31, 2023	**$**	**334**
Issuance of warrants		304
Changes in fair value of warrants		1,496
Conversion of redeemable convertible preferred stock warrants to common stock warrants		(2,134)
Balance December 31, 2024	**$**	**—**

11. Stockholders' Deficit

Common Stock

The Company is authorized to issue 500,000,000 and 76,046,350 shares of $0.001 par value common stock as of December 31, 2024, and December 31, 2023, respectively. Authorized shares of common stock as of December 31, 2023, include 626,398 shares of non-voting common stock, none of which were outstanding.

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 December 31, 2024, and December 31, 2023, no dividends had been declared.

As of December 31, 2024, and December 31, 2023, the Company had reserved common stock for future issuance as follows:

	December 31, 2024	*December 31, 2023*
Conversion of Series Seed redeemable convertible preferred stock	—	1,218,208
Conversion of Series A redeemable convertible preferred stock	—	3,026,755
Conversion of Series B redeemable convertible preferred stock	—	4,648,714
Conversion of Series C redeemable convertible preferred stock	—	8,923,966
Conversion of Series B warrants	—	45,726
Conversion of Series C-1 warrants	—	15,228
Conversion of Common Stock warrants	102,299	—
Outstanding options under the 2014 Plan	4,071,179	4,746,527
Outstanding options under the 2024 EIP	1,527,395	—
Outstanding options under the 2024 Plan	109,496	—
Outstanding RSUs under the 2024 EIP	18,604	—
Outstanding RSUs under the 2024 Plan	316,907	—
Options reserved for future issuance under the 2014 Plan	—	409,017
Options reserved for future issuance under the 2024 EIP	—	—
Options and awards reserved for future issuance under the 2024 Plan	3,964,620	—
Total	**10,110,500**	**23,034,141**

Equity Incentive Plans

In 2014, the Board of Directors adopted the 2014 Stock Incentive Plan (the "2014 Plan") under which incentive stock options ("ISO"), non-statutory stock options ("NQ"), restricted stock, restricted stock units ("RSU"), stock appreciation rights ("SAR"), dividend equivalent rights, performance stock units ("PSU"), and performance shares may be granted to its employees, directors, and consultants. To date only ISO and NQ awards have been granted. The Board of Directors determines the terms and conditions of the awards, including the number of awards to be granted and vesting criteria at the time of grant. The term of each option shall be stated in the option agreement; however, the term shall be no more than ten years from the date of the grant thereof. Options granted under the 2014 Plan generally vest over a four-year period starting from the date specified in each agreement. Stock options must be granted with an exercise price no less than the stock's fair market value at the date of grant. Except for as-needed increases in the size of the total option pool, the 2014 Plan has had no major changes since its inception.

On April 23, 2024, the Board of Directors terminated the 2014 Plan and adopted the 2024 Equity Incentive Plan (the "2024 EIP"). An aggregate of 3,610,238 shares of the Company's common stock under the 2014 Plan plus forfeited shares to the Company under the 2014 Plan may be issued under the 2024 EIP. Upon termination of the 2014 Plan, no additional awards will be granted under the 2014 Plan. Under the 2024 EIP, ISOs, NQs, RSUs, and other stock-based awards may be granted to its employees, directors, and consultants. To date, only ISO, NQ, and performance-based awards have been granted. The Board of Directors determines the terms and conditions of the awards, including the number of awards to be granted and vesting criteria at the time of grant. The term of each option shall be stated in the option agreement; however, the term shall be no more than ten years from the date of the grant thereof. Stock options must be granted with an exercise price no less than the stock's fair market value at the date of grant.

On October 9, 2024, the Board of Directors terminated the 2024 EIP and adopted the 2024 Incentive Award Plan (the "2024 Plan"). An aggregate of 4,366,326 shares of the Company's common stock under the 2024 EIP plus forfeited shares to the Company under the 2014 Plan and 2024 EIP may be issued under the 2024 Plan plus an increase commencing on the first day of each calendar year beginning January 1, 2025, and continuing annually on the anniversary thereof through (and including) January 1, 2034, equal to the lesser of 5% of the shares of all classes of the Company's common stock outstanding on the last day of the immediately preceding fiscal year (calculated on an as-converted basis) and such smaller number of shares as determined by the Board of Directors. Upon termination of the 2024 EIP, no additional awards will be granted under the 2024 EIP. Under the 2024 Plan, ISOs, NQs, RSUs, PSUs, and other stock-based awards may be granted to its employees, directors, and consultants. To date, ISO, NQ, RSUs, and performance-based awards have been granted. The Board of Directors determines the terms and conditions of the awards, including the number of awards to be granted and vesting criteria at the time of grant. The terms of each option and award shall be stated in the agreement; however, the term shall be no more than ten years from the date of the grant thereof. Stock options must be granted with an exercise price no less than the stock's fair market value at the date of grant.

Option activity under the plans is as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Balance at December 31, 2023	**4,746,527**	**$ 4.04**	**8.17**	**13,383**
Options granted	1,823,249	12.16		
Options exercised	(404,457)	2.82		
Options forfeited	(457,249)	5.54		
Balance at December 31, 2024	**5,708,070**	**6.60**	**7.71**	**110,063**
Options vested and expected to vest at December 31, 2024	5,708,070	6.60	7.71	110,063
Options exercisable at December 31, 2024	2,828,416	$ 4.11	6.71	61,573

The weighted-average grant-date fair value of options granted during the years ended December 31, 2024 and 2023 was $7.46 and $3.22 per share, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2024 and 2023 was $4.0 million and $0.4 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, 2023	—	$ —
Granted	336,750	23.51
Vested	(1,239)	16.81
Cancelled	—	—
Unvested at December 31, 2024	**335,511**	**23.53**

The total fair value of shares vested during the year ended December 31, 2024 was $0.02 million. No restricted stock units were granted or vested in 2023.

Stock-Based Compensation

As of December 31, 2024, the aggregate unrecognized compensation costs related to outstanding unvested options and RSUs under the 2014 Plan, 2024 EIP, and 2024 Plan was $24.0 million. The Company expects to recognize those costs over a weighted average period of 2.9 years.

The Company estimated the fair value of stock options and RSUs granted prior to being publicly traded using the Black-Scholes option-pricing model. 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:

	Year ended December 31,	
	2024	2023
Expected term (in years)	5.4	5.1
Expected volatility	68.0%	75.4%
Risk-free interest rate	4.1%	4.2%
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):

	Year ended December 31,	
	2024	2023
Cost of revenue	$ 47	$ —
Research and development	813	469
Sales and marketing	1,463	697
General and administrative	3,088	1,512
Total stock-based compensation expense	**$ 5,411**	**$ 2,678**

The total fair value of options and RSUs vested during the period are $4.2 million and $2.4 million for the years ended December 31, 2024, and 2023, respectively. 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 118,999 and 64,527 of option awards outstanding as of December 31, 2024, and December 31, 2023, 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 $0.4 million for the years ended December 31, 2024, and 2023, respectively.

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):

	Year ended December 31,	
	2024	2023
Net loss attributable to common stockholders	$ (40,455)	$ (29,464)
Weighted-average shares outstanding, basic and diluted	11,950	5,304
Net loss per share, basic and diluted	**$ (3.39)**	**$ (5.56)**

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):

	Year ended December 31,	
	2024	2023
Redeemable convertible preferred stock	—	17,818
Warrants	102	61
Equity plan stock options outstanding	5,708	4,747
Restricted stock units	336	—
Total	**6,146**	**22,626**

13. Income Taxes

Company recorded no income tax expense for the years ended December 31, 2024 and 2023.

The following table presents a reconciliation of the statutory federal rate and the Company's effective tax rate for the periods presented.

	Year ended December 31,	
Rate reconciliation	2024	2023
Statutory rate	21.0%	21.0%
State tax	5.1%	7.9%
Permanent differences	(3.0)%	(1.1)%
Research credits	0.5%	1.0%
Change in valuation allowance	(23.6)%	(28.8)%
Effective tax rate	**0.0%**	**0.0%**

The significant components of the net deferred tax assets are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets		
Net operating loss carryforward	$ 34,766	$ 28,798
Capitalized research and development	5,432	3,227
Research and development credits	2,102	1,761
Lease liability	638	631
Stock-based compensation	790	418
Accruals and reserves	1,265	64
Fixed assets	116	81
Total deferred tax assets	**$ 45,109**	**$ 34,980**
Deferred tax liabilities		
ROU asset	(566)	(575)
Deferred commission	(888)	(732)
Prepaids	(562)	(459)
Bonus adjustment	(275)	—
Total deferred tax liabilities	**(2,291)**	**(1,766)**
Valuation allowance	**(42,818)**	**(33,214)**
Net deferred tax asset	$ —	**$ —**

No tax benefit has been recorded through December 31, 2024, because, given the history of operating losses, the Company believes it is more likely than not that the deferred tax asset will not be realized, and a full valuation allowance has been provided. The change in the valuation allowance for the years ended December 31, 2024, and 2023 was $9.6 million and $8.5 million, respectively.

As of December 31, 2024, the Company had federal and state net operating loss carryforwards of $127.1 million and $126.9 million, respectively, available to reduce future taxable income, if any. As of December 31, 2023, the Company had federal and state net operating loss carryforwards of $105.0 million and $104.8 million, respectively, available to reduce future taxable income, if any. The federal net operating loss carryforwards generated prior to January 1, 2018, of $5.0 million and state net operating losses will begin to expire in 2035. The remaining federal net operating loss carryforwards of $122.1 million will not expire. Net federal operating losses generated after December 31, 2017 are not limited as they can be carried forward indefinitely, subject to an 80% income limitation. As of December 31, 2024, the Company had federal and state research and development credits of $1.4 million and $1.5 million, respectively. As of December 31, 2023, the Company had federal and state research and development credits of $1.1 million and $1.4 million, respectively. The federal research and development credits will begin to expire in 2035. The state research and development credit will not expire.

Utilization of some of the federal and state net operating losses and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986 ("Internal Revenue Code") and similar state provisions. The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. Due to ownership changes since inception, the Company's net operating losses may be limited as to their usage. In the event the Company has additional changes in ownership, utilization of the carryforwards could be further restricted. The Company performed an Internal Revenue Code Section 382 study in 2023 and there was no change in ownership identified. A study has not yet been performed for 2024. If there was an ownership change, there could be an annual limitation that may result in the expiration of net operating losses and credits before utilization.

Beginning in 2022, additional changes under the U.S. Tax Cuts and Jobs Act came into effect, including the mandatory capitalization and amortization of research and development expenses. These provisions require the Company to capitalize research and experimental expenditures and amortize them on the U.S. tax return over five or fifteen years, depending on where research is conducted.

The Company accounts for uncertainty in income taxes under ASC topic 740. ASC 740 requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. It also provides guidance on the recognition, measurement, classification, and interest and penalties related to uncertain tax positions. The Company has netted its current gross unrecognized tax benefits against its deferred tax assets.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits (in thousands):

Balance, January 1, 2023	**$**	**333**
Increases related to current tax positions		175
Changes related to prior tax positions		(33)
Balance, December 31, 2023	**$**	**475**
Increases related to current tax positions		140
Changes related to prior tax positions		(59)
Balance, December 31, 2024	**$**	**556**

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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 Annual Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2024.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) of the Exchange Act) during the quarter ended December 31, 2024, 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.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

On December 12, 2024, David Foehr, the Company's Senior Vice President, Finance, adopted a 10b5-1 trading plan, which is designed to be in effect until December 15, 2025. The aggregate number of shares of common stock available to be sold pursuant to Mr. Foehr's 10b5-1 plan is 17,223 and such shares will not be available for sale pursuant to so such plan until after April 8, 2025. Mr. Foehr's 10b5-1 plan is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

On December 13, 2024, Xingjuan (Jane) Chao, Ph.D., the Company's President and Chief Executive Officer and a member of the Company's Board of Directors, adopted a 10b5-1 trading plan, which is designed to be in effect until December 31, 2025. The aggregate number of shares of common stock available to be sold pursuant to Dr. Chao's 10b5-1 plan is 395,000 and such shares will not be available for sale pursuant to so such plan until after April 8, 2025. Dr. Chao's 10b5-1 plan is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

Appointment of Chief Revenue Officer

On February 25, 2025, the Company announced that it intends to appoint Sean Manni to the position of Chief Revenue Officer. Mr. Manni, age 50, has served as the Company's Senior Vice President, Sales, since April 2024. Prior to that, he served as the Vice President, North America Sales of Omnicell, Inc., a healthcare technology company ("Omnicell"), from 2019 to 2024. Mr. Manni also held other positions of increasing responsibility at Omnicell between 2008 and 2019. He holds a B.A. in sociology/criminal justice from East Stroudsburg University of Pennsylvania.

Departure of Chief Business Officer

Joshua Copp, the Company's Chief Business Officer, will be departing from the Company as of March 19, 2025. Mr. Copp's departure will be subject to a separation agreement, which will include severance payments and other customary provisions. The Company expects to finalize and enter into the separation agreement with Mr. Copp in the near future, and the finalized agreement will be filed as an exhibit to the Company's next Quarterly Report on Form 10-Q.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2024.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. A current copy of the code is posted on the Investors——Corporate Governance section of our website, which is located at www.ceribell.com

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of the Nasdaq Global Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

We have adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of our securities by directors, officers, and employees that are designed to promote compliance with insider trading laws, rules, and regulations, and applicable Nasdaq listing standards, as well as procedures designed to further the foregoing purposes. A copy of our insider trading policy is filed with this Annual Report as Exhibit 19.1.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2024.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this Annual Report:

a) Financial Statements. See Index to Financial Statements included in the financial statements in this Annual Report.

b) Financial Statement Schedules. All financial statement schedules are omitted because they are not applicable or required, or the information required to be set forth therein is included in the financial statements or notes thereto included in the Index to Financial Statements of this Annual Report.

c) Exhibits. The exhibits required to be filed as part of this Annual Report are listed in the Exhibit List attached hereto and are incorporated herein by reference.

Exhibit Index

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	
4.01	Form of Common Stock Certificate.	S-1/A	9/19/2024	4.01	
4.02	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.				X
4.03	Warrant to Purchase Shares of Series Preferred Stock, dated May 1, 2020, issued to Horizon Technology Finance Corporation (Loan A).	S-1	8/26/24	4.03	
4.04	Warrant to Purchase Shares of Series Preferred Stock, dated May 1, 2020, issued to Horizon Technology Finance Corporation (Loan B).	S-1	8/26/24	4.04	
4.05	Amended and Restated Warrant to Purchase Shares of Series Preferred Stock, dated May 1, 2020, issued to Horizon Technology Finance Corporation (Loan C), as amended on March 10, 2022.	S-1	8/26/24	4.05	
4.06	Amended and Restated Warrant to Purchase Shares of Series Preferred Stock, dated May 1, 2020, issued to Horizon Technology Finance Corporation (Loan D), as amended on March 10, 2022.	S-1	8/26/24	4.06	
4.07	Warrant to Purchase Shares of Series Preferred Stock, dated May 1, 2020, issued to Horizon Technology Finance Corporation (Loan E).	S-1	8/26/24	4.07	
4.08	Warrant to Purchase Shares of Series Preferred Stock, dated May 1, 2020, issued to Horizon Technology Finance Corporation (Loan F).	S-1	8/26/24	4.08	
4.09	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated March 10, 2022, issued to Horizon Technology Finance Corporation (Loan C).	S-1	8/26/24	4.09	
4.10	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated March 10, 2022, issued to Horizon Technology Finance Corporation (Loan D).	S-1	8/26/24	4.10	
4.11	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated March 10, 2022, issued to Horizon Technology Finance Corporation (Loan G).	S-1	8/26/24	4.11	
4.12	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated March 10, 2022, issued to Horizon Technology Finance Corporation (Loan H).	S-1	8/26/24	4.12	
4.13	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated March 10, 2022, issued to Horizon Technology Finance Corporation (Loan I).	S-1	8/26/24	4.13	
4.14	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated March 10, 2022, issued to Horizon Technology Finance Corporation (Loan J).	S-1	8/26/24	4.14	
4.15	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Silicon Valley Bank, a Division of First-Citizens Bank & Trust Company. (Closing Warrant).	S-1	8/26/24	4.15	
4.16	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Horizon Technology Finance Corporation. (Loan B).	S-1	8/26/24	4.16	
4.17	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Horizon Technology Finance Corporation. (Loan C).	S-1	8/26/24	4.17	

4.18	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Horizon Technology Finance Corporation. (Loan D).	S-1	8/26/24	4.18	
4.19	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Horizon Technology Finance Corporation. (Loan F Commitment).	S-1	8/26/24	4.19	
4.20	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Horizon Technology Finance Corporation. (Loan G Commitment).	S-1	8/26/24	4.20	
4.21	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Horizon Technology Finance Corporation. (Loan I Commitment).	S-1	8/26/24	4.21	
4.22	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Horizon Technology Finance Corporation. (Loan J Commitment).	S-1	8/26/24	4.22	
4.23	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Horizon Technology Finance Corporation. (Loan L Commitment).	S-1	8/26/24	4.23	
4.24	Warrant to Purchase Shares of Series C-1 Preferred Stock, dated February 6, 2024, issued to Horizon Technology Finance Corporation. (Loan M Commitment).	S-1	8/26/24	4.24	
10.01	Lease Agreement dated July 2021, by and between WTA Pastoria II LLC and CeriBell, Inc.	S-1	8/26/2024	10.01	
10.02	Letter Agreement dated October 5, 2021, by and between WTA Pastoria II LLC and CeriBell, Inc.	S-1	8/26/2024	10.02	
10.03	Standard Industrial/Commercial Multi-Tenant Lease, dated May 17, 2024, by and between George Yagmourian and Josefa Yagmourian, Trustees of the Yagmourian 1984 Living Trust dated October 10, 1984 and CeriBell, Inc.	S-1	8/26/2024	10.03	
10.04	Loan and Security Agreement, dated February 6, 2024, by and between CeriBell, Inc. and Silicon Valley Bank.	S-1	8/26/2024	10.04	
10.05	Venture Loan and Security Agreement, dated February 6, 2024, by and among CeriBell, Inc., Horizon Technology Finance Corporation and Silicon Valley Bank.	S-1	8/26/2024	10.05	
10.06	First Amendment to Venture Loan and Security Agreement, dated February 14, 2025, by and among CeriBell, Inc., Horizon Technology Finance Corporation and Silicon Valley Bank.				X
10.07†	Exclusive (Equity) Agreement, dated June 15, 2015, by and between the Board of Trustees of the Leland Stanford Junior University and CeriBell, Inc.	S-1	8/26/2024	10.06	
10.08†	Amendment No. 1 to the License Agreement effective the 15th Day of June 2015 by and between the Board of Trustees of the Leland Stanford Junior University and CeriBell, Inc., dated September 14, 2015.	S-1	8/26/2024	10.07	
10.9†	Amendment No. 2 to the License Agreement effective the 15th Day of June 2015 and amended the 14th Day of September 2015, by and between the Board of Trustees of the Leland Stanford Junior University and CeriBell, Inc., dated April 1, 2017.	S-1	8/26/2024	10.08	
10.10†	Amendment No. 3 to the License Agreement effective the 15th Day of June 2015, by and between the Board of Trustees of the Leland Stanford Junior University and CeriBell, Inc., dated March 8, 2022.	S-1	8/26/2024	10.09	
10.11#	2024 Incentive Award Plan.	S-1/A	10/7/2024	10.14	
10.12#	Form Agreements under 2024 Incentive Award Plan.	S-1/A	10/7/2024	10.15	
10.13#	2024 Employee Stock Purchase Plan.	S-1/A	10/7/2024	10.16	
10.14#	Non-Employee Director Compensation Program.	S-1/A	9/19/2024	10.17	
10.15#	Form of Indemnification Agreement for Directors and Officers.	S-1/A	9/19/2024	10.18	
10.16#	Employment Agreement, by and between CeriBell, Inc. and Xingjuan (Jane) Chao, Ph.D.	S-1/A	8/26/2024	10.19	

10.17#	Employment Agreement, by and between CeriBell, Inc. and Scott Blumberg.	S-1/A	8/26/2024	10.20	
10.18#	Employment Agreement, by and between CeriBell, Inc. and Joshua Copp.	S-1	8/26/2024	10.21	
10.19#	Employment Agreement, by and between CeriBell, Inc. and Raymond Woo, Ph.D., as amended.	S-1/A	10/7/2024	10.22	
10.20#	Form of Executive Change in Control and Severance Agreement.	S-1/A	9/19/2024	10.23	
10.21#	Consulting Agreement, dated May 7, 2018, and Amendment No.1 to Consulting Agreement, dated October 2, 2024, by and between CeriBell, Inc. and Josef Parvizi.	S-1/A	10/7/2024	10.28	
10.22	Corporate Supply Agreement, dated January 10, 2022, by and between CeriBell, Inc. and Shenzhen Everwin Precision Technology Co., Ltd.	S-1	8/26/2024	10.24	
10.23	Corporate Supply Agreement Amendment, dated March 7, 2023, by and between CeriBell, Inc. and Shenzhen Everwin Precision Technology Co., Ltd.	S-1	8/26/2024	10.25	
10.24	Corporate Supply Agreement, dated February 1, 2024, by and between CeriBell, Inc. and Ease Care under the management of Luxen and Kersen.	S-1	8/26/2024	10.26	
19.1	Insider Trading Compliance Policy and Procedures.				X
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.				X
24.1	Power of Attorney (included on signature page to this Annual Report on Form 10-K).				
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
32.3*	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
97	Policy Relating to Recovery of Erroneously Awarded Compensation.				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

# Indicates management contract or compensatory plan.

† 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 Annual Report 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.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

CeriBell, Inc.

Date: February 25, 2025

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Xingjuan (Jane) Chao, Ph.D. and Scott Blumberg, and each of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agents full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Xingjuan (Jane) Chao, Ph.D. Xingjuan (Jane) Chao, Ph.D.	President, Chief Executive Officer, and Director *(Principal Executive Officer)*	February 25, 2025
/s/ Scott Blumberg Scott Blumberg	Chief Financial Officer *(Principal Financial Officer)*	February 25, 2025
/s/ David Foehr David Foehr	Senior Vice President, Finance *(Principal Accounting Officer)*	February 25, 2025
/s/ Rebecca Robertson Rebecca Robertson	Chair of the Board of Directors	February 25, 2025
/s/ Juliet Tammenoms Bakker Juliet Tammenoms Bakker	Director	February 25, 2025
/s/ William W. Burke William W. Burke	Director	February 25, 2025
/s/ Lucian Iancovici, M.D. Lucian Iancovici, M.D.	Director	February 25, 2025
/s/ Josef Parvizi, M.D., Ph.D. Josef Parvizi, M.D., Ph.D.	Director	February 25, 2025
/s/ Joseph M. Taylor Joseph M. Taylor	Director	February 25, 2025

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE EXCHANGE ACT OF 1934, AS AMENDED (THE "EXCHANGE ACT")

The following descriptions of the common stock of CeriBell, Inc. (the "Company," "we," "us," and "our") and certain provisions of our Amended and Restated Certificate of Incorporation, as amended from time to time (the "Certificate of Incorporation"), Amended and Restated Bylaws, as amended from time to time (the "Bylaws"), and Amended and Restated Investors' Rights Agreement, dated April 22, 2021, by and among the Company and the investors listed therein, as amended on September 16, 2022 (the "Investors' Rights Agreement") is a summary and is qualified in its entirety by reference to the full text of our Certificate of Incorporation, Bylaws and Investors' Rights Agreement and applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL").

General

Our Certificate of Incorporation authorizes capital stock consisting of 500,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors.

Dividend Rights

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available.

Right to Receive Liquidation Distribution

In the event of our liquidation, dissolution, or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

No Preemptive or Similar Rights

Holders of our common stock have no preemptive, conversion, or subscription rights, and there are no redemption or sinking-fund provisions applicable to our common stock. The rights, preferences, and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our Certificate of Incorporation, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights,

dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, or preventing a change in control of our Company that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Registration Rights

Certain holders of shares of our common stock are entitled to certain rights with respect to registration of such shares under the Securities Act of 1933, as amended (the "Securities Act"). These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our Investors' Rights Agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions, stock transfer taxes, fees and disbursements of more than one special counsel for the holders, and the compensation of regular employees of the company, of the shares registered pursuant to the demand, piggyback, and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback, and Form S-3 registration rights described below will terminate upon the earliest to occur of (1) the date five years after the consummation of our Initial Public Offering ("IPO") or (2) with respect to each stockholder, such time after the completion of the IPO at which Rule 144 of the Securities Act or another similar exemption under the Securities Act is available for the sale of all of such stockholder's shares without limitation, during a three-month period without registration.

Demand Registration Rights

Certain holders of shares of our common stock are entitled to certain demand registration rights. Beginning six months following the IPO, investors holding, collectively, not less than 20% of registrable securities may, on not more than two occasions, request that we register all or a portion of their shares, subject to certain specified exceptions. Such request for registration must cover securities the anticipated aggregate offering price of which is at least $25.0 million and the proposed sale price of which is at least $22.98 per share. If such holders exercise their demand registration rights, then they will be entitled to register their shares, subject to specified conditions and limitations in the corresponding offering.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to specified conditions and limitations.

S-3 Registration Rights

Certain holders of shares of our common stock are entitled to certain Form S-3 registration rights. Any holder or holders of registrable securities may, with respect to not more than two such registrations within any 12-month period, request that we register all or a portion of their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to specified exceptions. Such request for registration on Form S-3 must cover securities with aggregate proceeds, net of underwriting discounts and expenses related to the issuance, which equal or exceed $3.0 million. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Warrants

The following table sets forth information about outstanding warrants to purchase shares of our stock as of December 31, 2024.

Class of Stock Underlying	Issue Date	Number of Shares of Common Stock Underlying Warrants	Exercise Price Per Share	Expiration Date
Common Stock	5/1/2020	45,726	$ 7.6540	May 1, 2030
Common Stock	3/10/2022	15,228	$ 11.49	March 10, 2032
Common Stock	2/6/2024	41,345	$ 11.49	February 6, 2034

Anti-Takeover Provisions

Among other things, our Certificate of Incorporation and Bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences, and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors are classified into three classes of directors, divided as nearly as equal in number as possible;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66 2/3% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing and also specify requirements as to the form and content of a stockholder's notice;

- provide that special meetings of our stockholders may be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors constituting the board, and not by our stockholders; and
- does not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66 2/3% of the voting power of all of our then-outstanding common stock.

The combination of these provisions make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in control of our company.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in control or management of our company. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our 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; any action asserting a claim against us arising pursuant to the DGCL, our Certificate of Incorporation, or our 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 Certificate of Incorporation also provides that the federal district courts of the United States of America are the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees, or agents and arising under the Securities Act. Nothing in our Certificate of Incorporation or 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 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 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.

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 are not 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.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 $^{2}/_{3}$% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge, or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Limitations on Liability and Indemnification Matters

Our Certificate of Incorporation and Bylaws limit our directors' and officers' liability and provide that we shall indemnify our directors and officers to the fullest extent permitted under the DGCL. The DGCL provides that directors and officers of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors or officers, except for liability for any:

- transaction from which the director or officer derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's or officer's duty of loyalty to the corporation or its stockholders.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

The DGCL, our Certificate of Incorporation, and our Bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment, or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with our directors and officers. These indemnification agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as a director or officer, or any other company or enterprise to which the person provides services at our request.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our Certificate of incorporation and Bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, LLC. The transfer agent and registrar's address is 51 Mercedes Way, Edgewood, NY 11717.

Stock Exchange Listing

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "CBLL."

FIRST AMENDMENT TO
VENTURE LOAN AND SECURITY AGREEMENT

This FIRST AMENDMENT TO VENTURE LOAN AND SECURITY AGREEMENT (this "Agreement"), dated as of February 14, 2025 is entered into by and among CERIBELL, INC., a Delaware corporation ("Borrower"), SILICON VALLEY BANK, A DIVISION OF FIRST-CITIZENS BANK & TRUST COMPANY ("SVB") as lender, HORIZON FUNDING TRUST 2022-1 ("Horizon Trust"), as assignee of HORIZON TECHNOLOGY FINANCE CORPORATION ("Horizon") as lender, HORIZON FUNDING I, LLC ("HFI"), as an assignee of Horizon as lender, and Horizon, as lender and collateral agent (together with SVB, Horizon Trust and HFI, collectively, "Lenders" and, individually, each a "Lender", and in its capacity as collateral agent, "Collateral Agent").

RECITALS

A. Borrower, Lenders and Collateral Agent are parties to a certain Venture Loan and Security Agreement dated as of February 6, 2024 (as amended, restated, supplemented or otherwise modified from time to time, the "Loan Agreement"), pursuant to which, among other things, (i) SVB provided to Borrower a loan in the original principal amount of Six Million Dollars ($6,000,000) ("Loan A"), which Loan A is evidenced by a certain Secured Promissory Note (Loan A) executed by Borrower in favor of SVB, dated February 6, 2024 (the "Loan A Note"), and (ii) Horizon provided to Borrower (a) a loan in the original principal amount of Five Million Dollars ($5,000,000) ("Loan B"), which Loan B is evidenced by a certain Secured Promissory Note (Loan B) executed by Borrower in favor of Horizon, dated February 6, 2024 (the "Loan B Note"), (b) a loan in the original principal amount of Five Million Dollars ($5,000,000) ("Loan C"), which Loan C is evidenced by a certain Secured Promissory Note (Loan C) executed by Borrower in favor of Horizon, dated February 6, 2024 (the "Loan C Note"), and (c) a loan in the original principal amount of Four Million Dollars ($4,000,000) ("Loan D"), which Loan D is evidenced by a certain Secured Promissory Note (Loan D) executed by Borrower in favor of Horizon, dated February 6, 2024 (the "Loan D Note"), (iii) SVB has made available to Borrower additional loans in the aggregate principal amount not to exceed Nine Million Dollars ($9,000,000) upon the satisfaction by Borrower of certain conditions, (iv) Horizon has made available to Borrower additional loans in the aggregate principal amount not to exceed Twenty-One Million Dollars ($21,000,000) upon the satisfaction by Borrower of certain conditions, and (v) Collateral Agent and Lenders have been granted a security interest in all assets of Borrower, except with respect to Borrower's Intellectual Property (as defined in the Loan Agreement) and as set forth in Section 4.1 of the Loan Agreement.

B. On or about February 6, 2024, Horizon assigned all of its right, title and interest in and to the Loan B Note to Horizon Trust.

C. On or about February 6, 2024, Horizon assigned all of its right, title and interest in and to the Loan C Note to Horizon Secured Loan Fund I LLC, which then assigned all of its right, title and interest in and to the Loan C Note to HFI.

D. On or about February 6, 2024, Horizon assigned all of its right, title and interest in and to the Loan D Note to Horizon Secured Loan Fund I LLC, which then assigned all of its right, title and interest in and to the Loan D Note to HFI.

E. Borrower has requested that Lenders amend the Loan Agreement to revise certain Commitment Termination Dates.

F. Lenders are willing to grant such request, but only to the extent, and in accordance with the terms, and subject to the conditions, set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the above recitals and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower and Lenders hereby agree as follows:

1. Definitions; Interpretation. Unless otherwise defined herein, all capitalized terms used herein and defined in the Loan Agreement shall have the respective meanings given to those terms in the Loan Agreement. Other rules of construction set forth in the Loan Agreement, to the extent not inconsistent with this Agreement, apply to this Agreement and are hereby incorporated by reference.

2. Confirmation. Borrower hereby acknowledges and agrees that: (i) the Loan Agreement sets forth the legal, valid, binding and continuing obligations of Borrower to Lenders, and (ii) the Obligations to Lenders under the Loan Agreement are secured by validly perfected security interests in all assets of Borrower, except with respect to Borrower's Intellectual Property, as set forth in Section 4.1 of the Loan Agreement. Borrower represents and warrants that no Default or Event of Default has occurred and is continuing under the Loan Agreement or the other Loan Documents.

3. Amendments to Loan Agreement. Subject to the occurrence of the Amendment Effective Date, Collateral Agent, Borrower and Lenders hereby agree that the columns "COMMITMENT AMOUNTS" and "COMMITMENT TERMINATION DATES" appearing on the cover page of the Loan Agreement are deleted in their entirety and replaced with the following:

"**COMMITMENT AMOUNTS:**	**COMMITMENT TERMINATION DATES:**
Loan A [TR 1]: $6,000,000 (SVB)	Loan A: February 6, 2024
Loan B [TR 1]: $5,000,000 (HRZN)	Loan B: February 6, 2024
Loan C [TR 1]: $5,000,000 (HRZN)	Loan C: February 6, 2024
Loan D [TR 1]: $4,000,000 (HRZN)	Loan D: February 6, 2024
Loan E [TR 2]: $3,000,000 (SVB)	Loan E: June 30, 2026
Loan F [TR 2]: $3,500,000 (HRZN)	Loan F: June 30, 2026
Loan G [TR 2]: $3,500,000 (HRZN)	Loan G: June 30, 2026
Loan H [TR 3]: $3,000,000 (SVB)	Loan H: September 30, 2026
Loan I [TR 3]: $3,500,000 (HRZN)	Loan I: September 30, 2026
Loan J [TR 3]: $3,500,000 (HRZN)	Loan J: September 30, 2026
Loan K [TR 4]: $3,000,000 (SVB)	Loan K: December 31, 2026
Loan L [TR 4]: $3,500,000 (HRZN)	Loan L: December 31, 2026
Loan M [TR 4]: $3,500,000 (HRZN)	Loan M: December 31, 2026"

4. Conditions to Effectiveness. Collateral Agent and Lenders' waiver, consent and agreement herein are expressly conditioned on the following (the date of satisfaction of such conditions precedent being the "Amendment Effective Date"):

(a) Borrower executing and delivering to Lenders:

(i) an executed copy of this Agreement;

(ii) an executed copy of that certain Acknowledgement and Reaffirmation of Subordination Agreement, dated as of the date hereof, by and between Collateral Agent and Lenders in their capacities as subordinated creditors, SVB in its capacity as senior creditor, and Borrower; and

(iii) an executed copy of the Updated Perfection Certificate;

(b) each of the representations and warranties made in this Agreement shall be true and correct on and as of the date hereof as if made on and as of such date, both before and after giving effect to this Agreement in all material respects (except with respect to any such representation or warranty which is already qualified by a materiality qualifier, in which case such representation or warranty shall be true in all respects, and where such representations and warranties expressly relate to an earlier date, in which case such representations and warranties are true and correct as of such earlier date);

(c) Borrower's payment to Horizon of a commitment extension fee of One Hundred Five Thousand and 00/100 Dollars ($105,000.00);

(d) Borrower's payment to SVB of a commitment extension fee of Forty-Five Thousand and 00/100 Dollars ($45,000.00);

(e) Borrower's payment to Horizon of its legal fees incurred in connection with this Agreement in the amount of Two Thousand Five Hundred Dollars ($2,500); and

(f) Borrower's payment to SVB of its legal fees incurred in connection with this Agreement in the amount of Five Thousand Dollars ($5,000).

5. Representations and Warranties. To induce Lenders and Collateral Agent to enter into this Agreement, Borrower hereby represents and warrants to Lenders and Collateral Agent as follows:

(a) At and as of the date of this Agreement and both prior to and after giving effect to this Agreement, each of the representations and warranties contained in the Loan Agreement is true and correct in all material respects (except with respect to any such representation or warranty which is already qualified by a materiality qualifier, in which case such representation or warranty shall be true and correct in all respects, and where such representations and warranties expressly relate to an earlier date, in which case such representations and warranties are true and correct as of such earlier date). Borrower understands and agrees that in modifying the existing Obligations, Lenders and Collateral Agent are relying upon Borrower's representations, warranties, and agreements, as set forth in the Loan Documents.

(b) Borrower has all necessary power and authority to execute, deliver, and perform in accordance with the terms thereof, each of this Agreement and the Loan Agreement, as amended by this Agreement. Borrower has all requisite power and authority to own and operate its Property and to carry on its businesses as now conducted.

(c) The organizational documents of Borrower delivered to Collateral Agent and each Lender on the Closing Date have been amended, supplemented or restated as reflected in the attached Exhibits A and B (Amended and Restated Bylaws and Amended and Restated Certificate of Incorporation), which are and continue to be in full force and effect. All other organizational documents of Borrower delivered to Collateral Agent and each Lender on the Closing Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect.

(d) The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Agreement, have been duly authorized by all necessary action on the part of Borrower.

(e) The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Agreement, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower.

(f) The execution and delivery by Borrower of this Agreement and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Agreement, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made.

(g) This Agreement has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

6. Effect of Agreement. On and after the date hereof, each reference to the Loan Agreement in the Loan Agreement or in any other document shall mean the Loan Agreement as amended by this Agreement. Except as expressly provided hereunder, the execution, delivery and effectiveness of this Agreement shall not operate as a waiver of any right, power, or remedy of Lenders, nor constitute a waiver of any provision of, under or in connection with any Loan Document. Except to the limited extent expressly provided herein, nothing contained herein shall, or shall be construed to (nor shall Borrower ever argue to the contrary) (i) amend or modify the Loan Agreement or any other Loan Document, (ii) modify, waive, impair, or affect any of the covenants, agreements, terms and conditions thereof, or (iii) waive the due keeping, observance and/or performance thereof, each of which is hereby ratified and confirmed by Borrower. Except as amended above, the Loan Agreement remains in full force and effect.

7. Release by Borrower.

(a) FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Collateral Agent, Lenders and their present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Agreement (collectively "Released Claims"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

(b) By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters,

disputes and differences, known or unknown, suspected or unsuspected; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Collateral Agent or any Lender with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

(c) This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Collateral Agent and each Lender to enter into this Agreement, and that none of Collateral Agent nor any Lender would not have done so but for such Person's expectation that such release is valid and enforceable in all events.

(d) Borrower hereby acknowledges and agrees that Borrower has no offsets, defenses, claims, or counterclaims against Collateral Agent or any Lender with respect to the Obligations, or otherwise, and that if Borrower now has, or ever did have, any offsets, defenses, claims, or counterclaims against Collateral Agent or any Lender, whether known or unknown, at law or in equity, all of them are hereby expressly WAIVED and Borrower hereby RELEASES Collateral Agent or such Lender from any liability thereunder.

8. Updated Perfection Certificate. In connection with this Agreement, Borrower has delivered an updated Perfection Certificate (the "Updated Perfection Certificate"). Borrower, Collateral Agent and Lenders acknowledge and agree that, from and after the date of this Agreement, each reference in the Loan Documents to the "Perfection Certificate" shall be deemed to be a reference to the Updated Perfection Certificate. Borrower acknowledges, confirms and agrees the disclosures and information Borrower provided to Collateral Agent and Lenders in the Updated Perfection Certificate have not changed as of the date hereof.

9. Prior Agreement. This Agreement is not a novation and the terms and conditions of this Agreement shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. In the event of any conflict or inconsistency between this Agreement and the terms of such documents, the terms of this Agreement shall be controlling, but such document shall not otherwise be affected or the rights therein impaired.

10. Fees and Expenses. Borrower shall pay to Collateral Agent and each Lender on the date of this Agreement all fees and expenses set forth in Section 4(c), 4(d), 4(e) and 4(f) above.

11. Miscellaneous. This Agreement shall constitute a Loan Document under the Loan Agreement. The failure to comply with a covenant (if any) contained herein shall constitute an Event of Default, without any cure period, under the Loan Agreement. All obligations included in this Agreement (including, without limitation, all obligations for the payment of principal, interest, fees, and other amounts and expenses) shall constitute Obligations and be secured by the

Collateral. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12. Post-Closing Condition. Borrower shall make commercially reasonable efforts to deliver to each Lender, in form and substance acceptable to each Lender, within forty-five (45) days of the Amendment Effective Date (or such later date as the Lenders may determine in their sole discretion), a duly executed landlord consent in favor of Collateral Agent from the landlord of 625 Pastoria Ave., Sunnyvale, CA 94085, Santa Clara.

13. Headings. Headings in this Agreement are for convenience of reference only and are not part of the substance hereof.

14. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to conflicts of law rules.

15. Counterparts. This Agreement may be executed in any number of counterparts, including by electronic or facsimile transmission, each of which when so delivered shall be deemed an original, but all such counterparts taken together shall constitute but one and the same instrument.

16. Integration. This Agreement and the Loan Documents constitute and contain the entire agreement of Borrower and Lenders with respect to their respective subject matters, and supersede any and all prior agreements, correspondence and communications.

17. Confidentiality. Section 14 of the Loan Agreement applies to this Agreement.

[*Remainder of page intentionally left blank*]

IN WITNESS WHEREOF, Collateral Agent, Borrower and Lenders have caused this Agreement to be executed as of the day and year first above written.

Name: Gerald A. Michaud
Title: Manager

BORROWER:

CERIBELL, INC.

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

COLLATERAL AGENT and LENDER:

HORIZON TECHNOLOGY FINANCE CORPORATION

By: /s/ Gerald A. Michaud
Name: Gerald A. Michaud
Title: President

LENDERS:

HORIZON FUNDING TRUST 2022-1
By: Horizon Technology Finance Corporation, its agent

By: /s/ Gerald A. Michaud
Name: Gerald A. Michaud
Title: President

HORIZON FUNDING I, LLC
By: Horizon Secured Loan Fund I LLC, its sole member

By: /s/ Gerald A. Michaud

FIRST-CITIZENS BANK & TRUST COMPANY

By: /s/ Matt Perry
Name: Matt Perry
Title: Managing Director

[Signature Page to First Amendment to Loan and Security Agreement – Ceribell]

EXHIBIT A
AMENDED AND RESTATED BYLAWS

(Omitted)

EXHIBIT B
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

(Omitted)

CeriBell, Inc.

Insider Trading Compliance Policy and Procedures

Federal and state laws prohibit trading in the securities of a company while in possession of material nonpublic information or in breach of a duty of trust or confidence. These laws also prohibit anyone who is aware of material nonpublic information from providing this information to ("tipping") others who may trade ("tippees"). Violating such laws can undermine investor trust, harm the reputation and integrity of CeriBell, Inc. (together with its subsidiaries (if applicable), the "Company"), and result in dismissal from the Company or even serious criminal and civil charges against the individual and the Company. The Company reserves the right to take whatever disciplinary or other measures it determines in its sole discretion to be appropriate in any particular situation, including disclosure of wrongdoing to governmental authorities.

Persons Covered and Administration of Policy

The Insider Trading Compliance Policy and Procedures (this "Policy") applies to all officers, directors, employees, contractors, consultants and other contingent workers of the Company ("Covered Persons"). For purposes of this Policy, "officers" refer to those individuals who meet the definition of "officer" under Section 16 of the Securities Exchange Act of 1934 (as amended, the "Exchange Act"). Individuals subject to this Policy are responsible for ensuring that members of their household and close family members also comply with this Policy. In addition this Policy applies to any entities controlled by individuals subject to the Policy, including any corporations, limited liability companies, partnerships, or trusts. Transactions by these entities should be treated as if they were for the individual's own account.

Questions regarding the Policy should be directed to the General Counsel or his or her designee (the "Compliance Officer"), who is responsible for the administration of this Policy, or his or her designee.

Policy Statement

No Covered Person shall purchase or sell any type of security while in possession of material nonpublic information relating to the security or the issuer of such security in breach of a duty of trust or confidence, whether the issuer of such security is the Company or any other company. In addition, if a Covered Person is in possession of material nonpublic information about other publicly-traded companies, such as suppliers, customers, competitors, or potential acquisition targets, the Covered Person may not trade in such other companies' securities until the information becomes public or is no longer material. Further, no Covered Person shall purchase or sell any security of any other company, including another company in the Company's industry, while in possession of material nonpublic information if such information is obtained in the course of the Covered Person's employment or service with the Company.

In addition, Covered Persons shall not directly or indirectly communicate material nonpublic information to anyone outside the Company (except in accordance with the Company's policies regarding confidential information) or to anyone within the Company other than on a "need-to-know" basis.

*"*Securities*"* includes stocks, bonds, notes, debentures, options, warrants, equity, and other convertible securities, as well as derivative instruments.

*"*Purchase*"* and *"*sale*"* are defined broadly under the federal securities law. *"*Purchase*"* includes not only the actual purchase of a security, but also any contract to purchase or otherwise acquire a security. *"*Sale*"* includes not only the actual sale of a security, but also any contract to sell or otherwise dispose of a security. These definitions extend to a broad range of transactions, including conventional cash-for-stock

transactions, conversions, the exercise of stock options, transfers, gifts, and acquisitions and exercises of warrants or puts, calls, pledging and margin loans, or other derivative securities.

The laws and regulations concerning insider trading are complex, and Covered Persons are encouraged to seek guidance from the Compliance Officer prior to considering a transaction in Company securities.

Restricted Trading Periods

No director, officer, or employee (as well as any individual or entity covered by this Policy by virtue of their relationship to such director, officer, or employee) shall purchase or sell any security of the Company during the period beginning on the 15th calendar day of the last month of any fiscal quarter of the Company and ending after completion of the second full trading day after the public release of earnings data for such fiscal quarter or during any other trading suspension period declared by the Company (each such period, a "restricted trading period"). A "trading day" is a day on which U.S. national stock exchanges are open for trading. If, for example, the Company were to make an announcement on Monday *prior* to 9:30 a.m. Eastern Time, then the restricted trading period would terminate *after* the close of trading on Tuesday. If an announcement were made on Monday after 9:30 a.m. Eastern Time, then the restricted trading period would terminate after the close of trading on Wednesday. If you have any question as to whether information is publicly available, please direct an inquiry to the Compliance Officer.

These prohibitions do not apply to:

- purchases of the Company's securities from the Company, or sales of the Company's securities to the Company;
  - exercises of stock options or other equity awards or the surrender of shares to the Company in payment of the exercise price or in satisfaction of any tax withholding obligations in a manner permitted by the applicable equity award agreement, or vesting of equity-based awards, in each case, that do not involve a market sale of the Company's securities (the "cashless exercise" of a Company stock option or other equity award through a broker does involve a market sale of the Company's securities, and therefore would not qualify under this exception);
- *bona fide* gifts of the Company's securities, unless the individual making the gift knows, or is reckless in not knowing, the recipient intends to sell the securities while the donor is in possession of material nonpublic information about the Company; or
- purchases or sales of the Company's securities made pursuant to a plan adopted to comply with the Exchange Act Rule 10b5-1 ("Rule 10b5-1").

Exceptions to the restricted trading period policy may be approved by (a) the Compliance Officer (b) the Chief Financial Officer, if the Compliance Officer is not available or in the case of an exception for the Compliance Officer, or (c) the Board of Directors, in the case of exceptions for directors).

The Compliance Officer may recommend that directors, officers, employees, or others suspend trading in Company securities because of developments that have not yet been disclosed to the public. Subject to the exceptions noted above, all of those individuals affected should not trade in the Company's securities while the suspension is in effect, and should not disclose to others that the Company has suspended trading.

Preclearance of Trades by Directors, Officers, and Certain Employees

All transactions in the Company's securities by directors, officers, and employees listed on Schedule I (each, a "Preclearance Person") must be precleared by the Compliance Officer or the Chief Financial Officer for transactions by the Compliance Officer. Preclearance does not constitute legal advice that a proposed transaction complies with the law.

A request for preclearance must be in writing, should be made at least two business days in advance of the proposed transaction, and should include the identity of the Preclearance Person, a description of the proposed transaction, the proposed date of the transaction, and the number of shares or other securities involved. In addition, the Preclearance Person must execute a certification that he or she is not aware of material nonpublic information about the Company. The Compliance Officer, or the Chief Financial Officer for transactions by the Compliance Officer, shall have sole discretion to decide whether to clear any contemplated transaction. All transactions that are precleared must take effect within five business days of receipt of the preclearance. A precleared transaction (or any portion of a precleared transaction) that has not been effected during the five business day period must be submitted for preclearance determination again prior to execution. Notwithstanding prior receipt of preclearance, if the Preclearance Person becomes aware of material nonpublic information or becomes subject to a restricted trading period before the transaction is effected, the transaction may not be completed. Transactions under a previously established Rule 10b5-1 Trading Plan that has been preapproved in accordance with this Policy are not subject to further preclearance.

None of the Company, the Compliance Officer, or the Company's other employees will have any liability for any delay in reviewing, or refusal of, a request for preclearance.

Notwithstanding the foregoing, this pre-clearance policy does not apply to venture capital firms or institutional investors, and the related transactions in the Company's equity securities by such entities, that may be affiliated with a director of the Company or that a director may be deemed to have beneficial ownership of by virtue of such affiliation.

Material Nonpublic Information

Information is considered "material" if there is a substantial likelihood that a reasonable investor would consider it important in making a decision to buy, sell, or hold a security, or if the information is likely to have a significant effect on the market price of the security. Material information can be positive or negative and can relate to virtually any aspect of a company's business or to any type of security, debt, or equity. Also, information that something is likely to happen in the future—or even just that it may happen—could be deemed material.

Examples of material information include (but are not limited to) information about:

- corporate earnings or earnings forecasts;
- possible mergers, acquisitions, tender offers, or dispositions;
- major new products or product developments;
- important business developments, such as developments regarding strategic transactions;
- management or control changes;
- significant financing developments including pending public sales or offerings of debt or equity securities;

- defaults on borrowings;
- bankruptcies;
- cybersecurity or data security incidents; and
- significant litigation or regulatory actions.

Information is "nonpublic" if it is not available to the general public. In order for information to be considered "public," it must be widely disseminated in a manner that makes it generally available to investors in a Regulation FD-compliant method, such as through a press release, a filing with the U.S. Securities and Exchange Commission (the "SEC") or a Regulation FD- compliant conference call. The Compliance Officer shall have sole discretion to decide whether information is public for purposes of this Policy.

The circulation of rumors, even if accurate and reported in the media, does not constitute public dissemination. In addition, even after a public announcement, a reasonable period of time may need to lapse in order for the market to react to the information. Generally, the passage of two full trading days following release of the information to the public is a reasonable waiting period before such information is deemed to be public.

Post-Termination Transactions

If an individual is in possession of material nonpublic information when the individual's service terminates, the individual may not trade in the Company's securities until that information has become public or is no longer material.

Prohibited Transactions

The Company has determined that there is a heightened legal risk and the appearance of improper or inappropriate conduct if persons subject to this Policy engage in certain types of transactions. Therefore, Covered Persons shall comply with the following policies with respect to certain transactions in the Company's securities.

Short Sales

Short sales of the Company's securities are prohibited by this Policy. Short sales of the Company's securities, or sales of shares that the insider does not own at the time of sale, or sales of shares against which the insider does not deliver the shares within 20 days after the sale, evidence an expectation on the part of the seller that the securities will decline in value, and, therefore, signal to the market that the seller has low confidence in the Company or its short-term prospects. In addition, Section 16(c) of the Exchange Act prohibits Section 16 reporting persons (i.e., directors, officers, and the Company's 10% stockholders) from making short sales of the Company's equity securities.

Options

Transactions in puts, calls, or other derivative securities involving the Company's equity securities, on an exchange, on an over-the-counter market, or in any other organized market, are prohibited by this Policy. A transaction in options is, in effect, a bet on the short-term movement of the Company's stock and, therefore, creates the appearance that a Covered Person is trading based on material nonpublic information. Transactions in options, whether traded on an exchange, on an over-the-counter market, or any other

organized market, also may focus a Covered Person's attention on short-term performance at the expense of the Company's long- term objectives.

Hedging Transactions

Hedging transactions involving the Company's securities, such as prepaid variable forward contracts, equity swaps, collars, and exchange funds, or other transactions that hedge or offset, or are designed to hedge or offset, any decrease in the market value of the Company's equity securities, are prohibited by this Policy. Such transactions allow the Covered Person to continue to own the covered securities, but without the full risks and rewards of ownership. When that occurs, the Covered Person may no longer have the same objectives as the Company's other stockholders.

Margin Accounts and Pledging

Individuals are prohibited from pledging Company securities as collateral for a loan, purchasing Company securities on margin (i.e., borrowing money to purchase the securities), or placing Company securities in a margin account. This prohibition does not apply to cashless exercises of stock options under the Company's equity plans, nor to situations approved in advance by the Compliance Officer.

Partnership Distributions

Nothing in this Policy is intended to limit the ability of an investment fund, venture capital partnership, or other similar entity with which a director is affiliated to distribute Company securities to its partners, members, or other similar persons. It is the responsibility of each affected director and the affiliated entity, in consultation with their own counsel (as appropriate), to determine the timing of any distributions, based on all relevant facts and circumstances, and applicable securities laws.

Rule 10b5-1 Trading Plans

The trading restrictions set forth in this Policy, other than those transactions described under "Prohibited Transactions," do not apply to transactions under a previously established contract, plan, or instruction to trade in the Company's securities entered into in accordance with Rule 10b5-1 (a "Trading Plan") that:

- has been submitted to and preapproved by the Compliance Officer;
- includes a "Cooling Off Period" for
  - Section 16 reporting persons that extends to the later of 90 days after adoption or modification of a Trading Plan or two business days after filing the Form 10-K or Form 10-Q covering the fiscal quarter in which the Trading Plan was adopted, up to a maximum of 120 days; and
  - employees and any other persons, other than the Company, that extends 30 days after adoption or modification of a Trading Plan;
- for Section 16 reporting persons, includes a representation in the Trading Plan that the Section 16 reporting person is (1) not aware of any material nonpublic information about the Company or its securities; and (2) adopting the Trading Plan in good faith and not as part of a plan or scheme to evade Rule 10b-5;

- has been entered into in good faith at a time when the individual was not in possession of material nonpublic information about the Company and not otherwise in a restricted trading period, and the person who entered into the Trading Plan has acted in good faith with respect to the Trading Plan;

- either (1) specifies the amounts, prices, and dates of all transactions under the Trading Plan; or (2) provides a written formula, algorithm, or computer program for determining the amount, price, and date of the transactions, and (3) prohibits the individual from exercising any subsequent influence over the transactions; and

- complies with all other applicable requirements of Rule 10b5-1.

The Compliance Officer may impose such other conditions on the implementation and operation of the Trading Plan as the Compliance Officer deems necessary or advisable. Individuals may not adopt more than one Trading Plan at a time except under the limited circumstances permitted by Rule 10b5-1 and subject to preapproval by the Compliance Officer.

An individual may only modify a Trading Plan outside of a restricted trading period and, in any event, when the individual does not possess material nonpublic information. Modifications to and terminations of a Trading Plan are subject to preapproval by the Compliance Officer and modifications of a Trading Plan that change the amount, price, or timing of the purchase or sale of the securities underlying a Trading Plan will trigger a new Cooling-Off Period.

The Company reserves the right to publicly disclose, announce, or respond to inquiries from the media regarding the adoption, modification, or termination of a Trading Plan and non- Rule 10b5-1 trading arrangements, or the execution of transactions made under a Trading Plan. The Company also reserves the right from time to time to suspend, discontinue, or otherwise prohibit transactions under a Trading Plan if the Compliance Officer or the Board of Directors, in his, her, or its discretion, determines that such suspension, discontinuation, or other prohibition is in the best interests of the Company.

Compliance of a Trading Plan with the terms of Rule 10b5-1 and the execution of transactions pursuant to the Trading Plan are the sole responsibility of the person initiating the Trading Plan, and none of the Company, the Compliance Officer, or the Company's other employees assumes any liability for any delay in reviewing and/or refusing to approve a Trading Plan submitted for approval, nor the legality or consequences relating to a person entering into, informing the Company of, or trading under, a Trading Plan.

Interpretation, Amendment, and Implementation of this Policy

The Compliance Officer shall have the authority to interpret and update this Policy and all related policies and procedures. In particular, such interpretations and updates of this Policy, as authorized by the Compliance Officer, may include amendments to or departures from the terms of this Policy, to the extent consistent with the general purpose of this Policy and applicable securities laws.

Actions taken by the Company, the Compliance Officer, or any other Company personnel do not constitute legal advice, nor do they insulate you from the consequences of noncompliance with this Policy or with securities laws.

Certification of Compliance

All directors, officers, employees, and others subject to this Policy may be asked periodically to certify their compliance with the terms and provisions of this Policy.

Schedule I

Individuals Subject to Preclearance Requirement

Directors and officers of the Company and their assistants

Members of the Company's executive leadership team and their assistants

Employees involved in the preparation of financial statements, as determined by the Controller Senior members of the Finance, Legal, Investor Relations and Communications teams
Other employees with access to material nonpublic information, as determined by the General Counsel

Close family members or others living in the same household as any of the above, and family members whose transactions in Company securities are directed by, or are subject to the influence or control of, the individuals listed above, and any entities that the individuals listed above influence or control

Consultants, contractors and other contingent workers performing any of the above functions

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-282603) of CeriBell, Inc. of our report dated February 25, 2025 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 25, 2025

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 Annual Report on Form 10-K 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: February 25, 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 Annual Report on Form 10-K 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: February 25, 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 Annual Report of CeriBell, Inc. (the "Company") on Form 10-K for the period ending December 31, 2024 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: February 25, 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 Annual Report of CeriBell, Inc. (the "Company") on Form 10-K for the period ending December 31, 2024 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: February 25, 2025

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

CERBELL, INC.

POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

CeriBell, Inc., a Delaware corporation (the "***Company***"), has adopted this Policy for Recovery of Erroneously Awarded Compensation (the "***Policy***"), effective as of the date of effectiveness of the Company's Registration Statement on Form S-1 to be filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended, in connection with the Company's initial public offering of its common stock (the "***Effective Date***"). Capitalized terms used in this Policy but not otherwise defined in the text of this Policy are defined in Section 11.

1. Persons Subject to Policy

This Policy shall apply to current and former Officers of the Company. Each Officer shall be required to sign an acknowledgement pursuant to which such Officer will agree to be bound by the terms of, and comply with, this Policy; however, any Officer's failure to sign any such acknowledgement shall not negate the application of this Policy to the Officer.

2. Compensation Subject to Policy

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is "received" shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is "received" in the Company's fiscal period during which the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs prior to or after the end of that period.

3. Recovery of Compensation

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee has determined that recovery from the relevant Officer would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any Officer's right to voluntarily terminate employment for "good reason," or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

4. Manner of Recovery; Limitation on Duplicative Recovery

The Committee shall, in its sole discretion, determine the manner of recovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation by the Company or an affiliate of the Company of Incentive-Based Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy of the Erroneously Awarded Compensation, and, to the extent permitted by law, an offset of the Erroneously Awarded Compensation against other compensation payable by the Company

or an affiliate of the Company to such person. Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such Erroneously Awarded Compensation may be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person.

5. Administration

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Board of Directors of the Company (the "***Board***") may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the "Committee" shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, equityholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

6. Interpretation

This Policy will be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the extent necessary to ensure it is consistent therewith.

7. No Indemnification; No Personal Liability

Notwithstanding the terms of any insurance policy or any contractual arrangement with any Officer that may provide or be interpreted to the contrary, the Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person's potential obligations under this Policy. No member of the Committee or the Board shall have any personal liability to any person as a result of actions taken under this Policy and each member of the Committee and the Board will be fully indemnified by the Company to the fullest extent available under applicable law and the Company's governing documents with respect to any actions taken under this Policy. The foregoing sentence will not limit any other rights to indemnification of the members of the Board under applicable law and the Company's governing documents.

8. Application; Enforceability

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any other clawback, recoupment, forfeiture or similar policies or provisions of the Company or its affiliates, including any such policies or

provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (the "***Other Recovery Arrangements***"). The remedy specified in this Policy shall not be exclusive and shall be in addition to every other right or remedy at law or in equity that may be available to the Company or an affiliate of the Company.

9. Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10. Amendment and Termination

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association and will be limited to the extent that any provision of the Applicable Rules is no longer in effect or applicable to the Company.

11. Definitions

"***Applicable Rules***" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company's securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company's securities are listed, in each case, as amended from time to time.

"***Committee***" means the committee of the Board responsible for executive compensation decisions comprised solely of independent directors (as determined under the Applicable Rules), or in the absence of such a committee, a majority of the independent directors serving on the Board.

"***Erroneously Awarded Compensation***" means the amount of Incentive-Based Compensation received by a current or former Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules. For Incentive-Based Compensation based on total stockholder return or stock price, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the Restatement, Erroneously Awarded Compensation is the Committee's reasonable estimate of the effect of the Restatement on the total stockholder return or stock price upon which the Incentive-Based Compensation was received, consistent with any documentation of the determination of such reasonable estimate provided by the Company to the applicable listing exchange or association.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Financial Reporting Measure***" means any measure determined and presented in

accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including GAAP, IFRS and non- GAAP/IFRS financial measures, as well as stock or share price and total equityholder return.

"***GAAP***" means United States generally accepted accounting principles.

"***IFRS***" means international financial reporting standards as adopted by the International Accounting Standards Board.

"***Impracticable***" means that (a) the direct costs paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company has
(i) made reasonable attempts to recover the Erroneously Awarded Compensation, (ii) documented such attempt(s), and (iii) provided such documentation to the relevant listing exchange or association, (b) to the extent permitted by the Applicable Rules, the recovery would violate the Company's home country laws pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such violation, and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. § 401(a)(13) or 26 U.S.C. § 411(a) and the regulations thereunder.

"***Incentive-Based Compensation***" means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after beginning service as an Officer; (b) who served as an Officer at any time during the performance period for that compensation; (c) while the Company has a class of its securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

"***Officer***" means each person who serves as an executive officer of the Company, as defined in Rule 10D-1(d) under the Exchange Act.

"***Restatement***" means an accounting restatement to correct the Company's material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Three-Year Period***" means, with respect to a Restatement, the three completed fiscal years immediately preceding the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such Restatement, or, if earlier, the date on which a court, regulator or other legally authorized body directs the Company to prepare such Restatement. The "Three-Year Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.

ACKNOWLEDGMENT AND CONSENT TO
CERBELL, INC. POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

The undersigned has received a copy of the Policy for Recovery of Erroneously Awarded Compensation (the "Policy") adopted by CeriBell, Inc. (the "Company").

For good and valuable consideration, the receipt of which is acknowledged, the undersigned hereby agrees, to the extent that the Policy is authorized and required by Applicable Rules (as defined in the Policy), that: (i) the undersigned is and shall be bound by and subject to the terms of the Policy; (ii) compensation received by the undersigned may be subject to reduction, cancellation, forfeiture and/or recoupment to the extent necessary to comply with the Policy, notwithstanding any other agreement to the contrary; (iii) the undersigned is not entitled to indemnification in connection with any enforcement of the Policy to the extent required by the Applicable Rules; and (iv) the undersigned expressly waives any rights to such indemnification under the Company's organizational documents or otherwise.

Date Signature

Name

Title

BR15678C-0425-10K