July 22, 2024

Xingjuan (Jane) Chao
Chief Executive Officer
Ceribell, Inc.
360 N. Pastoria Avenue
Sunnyvale, CA 94085

Re: Ceribell, Inc.
Draft Registration Statement on Form S-1
Submitted June 24, 2024
CIK No. 0001861107

Dear Xingjuan (Jane) Chao:

We have reviewed your draft registration statement and have the following comments.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1 submitted June 24, 2024
Cover Page

1. We note your disclosure on page 52 that your principal stockholders and management own a significant percentage of your stock and will be able to exert significant control over matters subject to stockholder approval. Please revise your cover page to note the same, and to quantify the percentage of your stock that will be held by your principal stockholders and management upon completion of your offering. In addition, please tell us whether you expect to be deemed to be a "controlled company" under the relevant listing rules. If so, please disclose on you cover page and in your prospectus summary whether you intend to take advantage of the controlled company exemptions under the Nasdaq rules, and provide related risk factor disclosure.

Prospectus Summary
Overview, page 2

2. Where you discuss data or statistics about certain medical conditions and the medical industry in which you operate, please revise to provide the sources for your disclosures, or characterize the same as management's opinions or beliefs. For example, we note the following disclosures:

- "conventional EEG systems, which were designed over 100 years ago for the outpatient setting, are insufficient to meet the needs of critically ill acute care patients as they are unable to provide the speed of diagnosis and continuous monitoring necessary for optimal patient management;"

- EEG technicians "typically work limited hours, are staffed across multiple departments within the hospital, and face a national supply shortage," and "arrival at the bedside . . . is often delayed;"

- "it is estimated that up to 92% of all seizures in the intensive care unit are non-convulsive;"

"the overall mortality rate for status epilepticus is approximately 30%, with mortality increasing by 13% for each hour that the condition goes untreated;"

"patient response rates to first-line anti-seizure medication drop by approximately 30% for every hour medication is delayed from the onset of seizures;"

"episodes of confusion and disorientation affect more than seven million hospitalized patients in the United States annually" (page 86); and

"there is a nationwide shortage of neurologists, with demand estimated to exceed supply by almost 20% by 2025."

As a related matter, we note your disclosure on page 59 that "[i]n some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from sources which we paid for, sponsored, or conducted, unless otherwise expressly stated or the context otherwise requires." Please revise your filing throughout to clearly provide the specific sources for relevant data and to clearly indicate when data is derived from sources which you paid for, sponsored, or conducted.

3. You disclose that "the technological and operational limitations of conventional EEG systems have contributed to significant delays in seizure diagnosis and suboptimal patient care and clinical outcomes." Please clarify how patient care and clinical outcomes are measured, and provide support for your disclosure that current patient care and clinical outcomes are "suboptimal." As a related matter, you disclose that "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." Please disclose how Ceribell measures patient outcomes, and provide data supporting your disclosure that outcomes and hospital and payer economics are "improved."

4. You disclose here and throughout your filing that you estimate you have a total annual addressable market opportunity of approximately $2 billion in the U.S. acute care setting. Please revise your disclosure to provide the data and sources underlying your estimate of your annual addressable market, including how you arrived at "the approximately three million acute care patients in the United States" who you believe should be monitored with EEG each year due to high risk of seizures, and the average selling prices of the hardware and software components of your solution.

5. We note your disclosure in your risk factor summary that you have a limited operating history and have experienced periods of significant business changes in a short time. Please revise your overview to briefly discuss the operating history of the company, including details describing the "significant business changes in a short time."

Risk Factors
Business and Industry Risk Factors
We have a limited operating history . . ., page 12

6. We note your reference to your "significant growth." Please clarify the metric by which

you have experienced this growth. For example, disclose whether you have experienced growth in market shares, sales, revenues, or some other metric or combination of metrics.

We rely on third parties . . ., page 32

7. We note your disclosure that you utilize and depend upon independent investigators and collaborators, such as third-party researchers, medical institutions, and strategic partners, to conduct and support portions of your preclinical studies and clinical trials under agreements with you. In an appropriate place in your filing, please describe the material terms of these agreements.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Key Factors Affecting Our Results of Operations and Performance, page 68

8. We note your disclosure that as you seek to increase your account base, you expect that your revenue will increase due to resulting utilization and subscription revenue. Please clarify what is meant by utilization revenue, including whether product revenue and utilization revenue are interchangeable terms. As a related matter, you disclose on page 69 that your revenue will continue to fluctuate from quarter-to-quarter due to a variety of factors, including the potential success of your sales force in expanding adoption of the Ceribell System in new accounts and expanding the utilization of your system in existing accounts. To provide context for investors regarding your statements about revenue, for the periods presented in the filing, please disclose the percentage of your total revenue from new accounts compared to existing accounts.

Gross Profit and Gross Margin, page 69

9. Please revise your disclosure to discuss whether you expect gross margin to increase, decrease, or remain the same over the short-term and to briefly describe the factors that you expect to cause your gross margin to fluctuate.

Results of Operations, page 71

10. Revise to provide more substantial discussion of the underlying drivers of the increase in revenue from FY22 to FY23. For example, discuss what contributed to the increase in headband sales and quantify the impact that the increase in active account base and increase in adoption had on subscription revenue. See Item 303 of Regulation S-K and SEC Release No. 33-8350.

Business, page 82

11. We note your disclosure throughout the filing that the Ceribell System hardware is simple to use and can be applied by any non-specialized healthcare professional, and that EEG data captured by the recorder is interpreted by Clarity, which continuously monitors the patient's EEG signal and can support the clinician's real-time assessment of seizure activity. You also disclose that EEG data is interpreted and monitored by specialized neurologists. In an appropriate place in your filing, please clarify whether the need for a neurologist or other clinician to read the results of your Ceribell System, even in conjunction with Clarity, could impact the "real-time" assessment of the Ceribell System's data and the intended benefit of the Ceribell System to decrease delays in diagnosis and monitoring. In your discussion, please address any staffing shortages in the industry for clinicians.

Our Success Factors
Recurring, predictable and scalable revenue model with attractive gross margins, page 84

12. You disclose that "[w]e generate revenue primarily from two recurring sources the sale of our single use, disposable headbands and a monthly subscription fee for the use of our system." Please revise your description of business to more clearly describe your subscription model, including the cadence of subscription fees and the material terms of subscription agreements, including termination provisions. In addition, please clarify whether a customer can purchase your product without a subscription to your services.

Our Growth Strategies
Increase adoption of the Ceribell System in new accounts., page 85

13. You disclose that there are approximately 5,800 acute care facilities in the United States that you believe could benefit from your system, and as of March 31, 2024, you have successfully deployed your system to more than 450 active accounts. To provide context for investors, please clarify whether an acute care facility has one active account, or whether care facilities have multiple accounts. If the 450 active accounts are encompassed in less than 450 care facilities, please clarify this fact in your disclosure. In addition, please revise to describe the significance of the 5,800 acute care facilities for your growth plans, including how you identified that these facilities could benefit from your system and whether and to what extent you have targeted or plan to target these facilities to open accounts.

Drive utilization of the Ceribell System within our existing customer base, page 85

14. We note your disclosure that "[a]s we grow our customer base, we plan to drive utilization of our system within existing accounts by leveraging our CAMs to raise awareness of the prevalence of seizures in critically ill patients, train and educate clinicians and nurses, and assist our customers in developing diagnostic protocols consistent with medical society recommendations and guidelines. Since implementing this approach in July 2021, we have demonstrated success in meaningfully increasing utilization within our active accounts." Please clarify the significance of utilization to your active accounts, including a more detailed discussion of how an account can be active but under-utilizing your product or services. In addition, please describe how you measure a "meaningful" increase in utilization. Make conforming changes to your brief discussion of active accounts on page 68, where you disclose that "[w]e define active accounts as those with an active subscription or recent headband usage, which is typically considered to be six months."

Invest in further growing our base of clinical evidence., page 85

15. You disclose that "we are sponsoring and supporting studies to further validate the impact of our system on patient outcomes and to further 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." Please identify the studies, including the parties that will perform the studies, and

clarify that there is no
guarantee that these studies will be able to demonstrate your intended outcomes.

Market Overview, page 86

16. Please provide sources for the data included in your disclosures in this section, including your tables and other graphics. As a related matter, we note your references to Young, et al.; Payne, E.T., et al.; De Marchis, G.M., et al.; and Lowenstein, D. H., et al. Please clarify your references to these sources, including a brief description of the date, substance, and findings of these sources.

Our Addressable Market Opportunities in Seizures, page 89

17. You disclose that "[b]ased 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." Please identify the hospitals, the parameters of the referenced studies, and the data underlying your belief that the adoption of the Ceribell System will drive an increase in EEG testing volumes. In addition, please disclose whether you compensated these hospitals for their studies of the Ceribell System.

18. You disclose that you have received a CE Mark for the Ceribell System in Europe, and in the future you intend to pursue additional regulatory clearances in Europe and elsewhere outside of the United States. Please revise your disclosure to discuss your intended timing for pursuing additional regulatory clearances in Europe and to commercialize your product in Europe. Identify other areas outside of the United States where you are pursuing commercialization of your product, if known.

Other Potential Opportunities Beyond Seizures, page 90

19. You disclose that "[i]n September 2022, we received FDA Breakthrough Device Designation for the detection of delirium," and that you "have also initiated technical and clinical work to develop an algorithm that may allow for earlier triage of ischemic stroke." Please clarify whether and to what extent you have sought FDA approval for the use of your algorithm related to ischemic stroke.

20. As a related matter, we note your disclosure that based on the prevalence of delirium and ischemic stroke, you believe expansion of your indications could represent "an incremental, multi-billion-dollar market opportunity." Please provide the basis for management's belief that these conditions represent a "multi-billion dollar market opportunity," including further describing "prevalence" as it relates to this opportunity. Please also provide your intended timing for commercialization of your product and services related to these two indications, and the relevant steps you will need to accomplish before commercialization.

Reading Services, page 94

21. Please address the following issues related to your remote reading services:

- Please expand your discussion to provide more detail describing how your remote EEG interpretation services function in your business operations. For example, please clarify whether a significant portion of your customer base relies on these remote interpretation services. In this regard, we note your disclosure

that you believe this
product offering will help service a "subset" of your customer population where
neurology infrastructure is insufficient. Please also disclose any restrictions that
might impact these remote interpretation services, such as any hours-of-service
restrictions or differences in timing of the interpretations as opposed to non-
remote interpretations. We note the time restrictions from conventional EEG
technicians mentioned on page 1 and throughout the prospectus.

We note your disclosure that you have entered into agreements with two
teleneurology providers to offer remote EEG interpretation services to customers.
Please disclose the material terms of the agreements with two teleneurology
providers, and file the agreements in accordance with Item 601(b)(10) of Regulation
S-K or tell us why you believe you are not required to do so

Our Clinical Results and Economic Evidence, page 95

22. Where you reference studies supporting certain conclusions about Ceribell here and
throughout your filing, please identify the specific study supporting this determination.
For example only, we note the following disclosures:

"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;"

"One study presented in a peer-reviewed publication and three abstracts reporting on
different datasets and different iterations of Clarity have shown that the algorithm
detected nonconvulsive status epilepticus with 87% to 100% sensitivity, 93% to 98%
specificity, and 99% to 100% negative predictive value;" and

"Studies reported in publications and abstracts have shown meaningfully shorter time
to EEG setup (i.e., time from EEG order to EEG acquisition) and time to
interpretation or diagnosis with the Ceribell System. For example, a multicenter study
of ICUs in five major U.S. hospitals found that it took a median of five minutes to set
up a Ceribell EEG, while conventional EEGs took 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)."

The list of examples above is not exclusive, and you should make conforming changes
throughout your filing including, but not limited to, your prospectus summary
and description of your business.

23. In your table beginning on page 97, please clearly list the parties who conducted each
identified study, the number of patients studied, if not already disclosed, and any adverse
events. In this regard, we note your disclosure on page 28 that 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. In addition, where you note that there were "limitations" to the study, please
briefly describe these limitations.

24. We note references to the DECIDE study in your table on page 97. Please revise your filing to expand your discussion of the details of this study, including:

- Date(s) of trials and location;
- Identity of trial sponsor(s);
- Trial design;
- The number of patients enrolled and the criteria for participation in the study;
- Specific clinical endpoints established by the trial protocol;
- Observational metrics utilized and the actual results observed; and
- Comparisons to standard of care.

Please include a brief discussion of the importance and use of statistical significance in clinical trial analytics. With respect to any additional "clinical studies" and "third-party initiated trials" referenced throughout your filing, including the "clinical studies or

investigations on the Ceribell System [that] have produced . . . negative or inconclusive results," please provide the information above, or tell us why you do not include a discussion of the relevant studies in your filing.

Research and Development, page 102

25. You disclose that "[o]ur delirium and ischemic stroke algorithms remain under development, with ongoing research and active clinical studies." In an appropriate place in your filing, please identify the clinical studies and relevant parameters.

Manufacturing and Supply, page 103

26. You disclose that you depend on two key suppliers for the manufacturing, primary assembly, and inspection of your headband. To the extent that you are dependent on these or any other suppliers, provide appropriate summary information about any agreements with such suppliers, and file these agreements as exhibits to your registration statement. See Item 601(b)(10) of S-K. Please also identify these suppliers in your filing, consistent with Item 101(h)(4)(v) of Regulation S-K.

Intellectual Property, page 104

27. Please revise your intellectual property disclosure to clearly describe, for each material patent or group of patents or pending patent applications: (i) the specific products, product groups, and technologies to which such patents relate, (ii) whether the patents are owned or licensed, (iii) the type of patent protection, (iv) patent expiration dates, and (v) jurisdiction. In this regard, it may be useful to provide this disclosure in tabular form.

Certain Relationships and Related-party Transactions

Parvizi Consulting Agreement, page 133

28. Please revise your disclosure to clarify whether the Parvizi Consulting Agreement will survive this offering, and if so, please describe the material terms of the agreement moving forward. Please also file the agreement as an exhibit to your registration statement, or tell us why you believe you are not required to do so.

Principal Stockholders, page 134

29. Please disclose the natural persons with voting and dispositive control

of Entities
affiliated with The Rise Fund Clearthought L.P., Entities affiliated with u.life fund, and
Optimas Capital Partners Fund LP.
General

30. Please revise your disclosure to clarify the meaning of any significant scientific or technical terms or acronyms the first time they are used in the prospectus in order to provide context for such terms and better ensure that lay readers will understand the disclosure. For example, please define epileptiform and encephalopathic.
31. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Please contact Kristin Lochhead at 202-551-3664 or Li Xiao at 202-551-4391 if you have questions regarding comments on the financial statements and related matters. Please contact Nicholas O'Leary at 202-551-4451 or Katherine Bagley at 202-551-2545 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and Services

cc: Kathleen M. Wells, Esq.