



DIVISION OF
CORPORATION FINANCE

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

August 23, 2024

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

Re: Ceribell, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted August 5, 2024
CIK No. 0001861107

Dear Xingjuan (Jane) Chao:

We have reviewed your amended 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. Unless we note otherwise, any references to prior comments are to comments in our July 22, 2024, letter.

Amendment No. 1 to Draft Registration Statement on Form S-1 submitted August 5, 2024

Prospectus Summary

Overview, page 1

1. We note your response to comment 3 and your revised disclosure on page 94, but your revisions are not completely responsive to our comment. Please revise your prospectus summary to disclose how patient care and clinical outcomes are measured. Footnote disclosure or cross-references may be appropriate.

Market Opportunity, page 3

2. We note your revisions in response to comment 4, including your amended disclosure on page 95. Please revise your prospectus summary to briefly describe the basis for your

estimate of your addressable market opportunity. A cross reference or footnote disclosure may be appropriate. Also, your response indicates that the company does not believe "the average selling prices of the hardware and software components of its solution is information that is material to an understanding of the Company's estimate of its total annual addressable market opportunity, in the context of the other details included in Amendment No. 1. The Company has determined the average selling price for the hardware and software components of its solution in light of the value of its solution, competitive benefits, market dynamics, customer demand, competitive pressures and other relevant factors." Please further explain why the average selling prices of hardware and software components of the company's product are not material to an understanding of the company's total annual addressable market opportunity, given that the market opportunity of \$2 billion appears to be tied to your ability to sell your hardware and software at a certain average price.

Risk Factors

We rely on third parties . . . , page 32

3. We note your revisions in response to prior comment 7. To the extent that any of these collaboration agreements are material, please identify the relevant agreement and include a description of the material terms of each of these agreements in your filing, including rights and obligations, financial terms including amounts paid to date, aggregate milestone amounts to be paid or received, the royalty range and term, as applicable, term, and termination provisions. Please also file these agreements as exhibits.

Use of Proceeds, page 61

4. We note your disclosure that you "currently intend to use the net proceeds from this offering to fund sales and marketing efforts, fund research and product development activities, conduct or sponsor clinical studies, and for general corporate purposes, including working capital, operating expenses, and capital expenditures." Please revise to clarify the approximate amount of your net proceeds for each of the principal purposes listed in your disclosure, if known. Please also clarify the products for which you intend to "conduct or sponsor clinical studies," and the stage of development you expect to reach with proceeds from the offering.

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

Liquidity and Capital Resources

Sources of Liquidity, page 80

5. Please revise your disclosure in this section to provide additional detail about the material terms of the relevant loans, including, as discussed in your revised disclosure on page F-23, that the SVB Loan carries a variable per-annum interest rate at the Prime Rate 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%, and that 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. In addition, please disclose that the Revolving Facility includes additional fees of \$300,000 million that are payable regardless of whether any amounts are drawn. As a related matter, we note your disclosure on page F-23 that "[u]pon execution of the VLSA, the Company paid to the

Lenders \$245,000 and issued warrants to purchase 106,263 shares of the Company's Series C-1 Preferred Stock at a price of \$4.47 per share ('Initial Warrants')." Please revise your disclosure here to include a discussion of these terms.

Business

Invest in further growing our base of clinical evidence, page 91

6. We note your revisions and response to prior comment 15, but we are not persuaded by your response. Please revise to identify the studies you are sponsoring and supporting, including the parties that will perform the studies, the trial design, and primary end points of the studies.

Other Potential Opportunities Beyond Seizures, page 95

7. We note your revised disclosure in response to comments 19, 20, and 25, including that you have not yet applied for marketing authorization from the FDA for the use of the Ceribell System relating to delirium or ischemic stroke, and that prior to commercialization within these indications, you would need to apply for and obtain the required marketing authorizations. Please revise to clearly disclose when you expect to apply for marketing authorizations from the FDA, that you have no intended timeline for commercialization of the services related to these two indications, and that there is no guarantee you will obtain the required authorizations. Please also clarify how you determined, based on the average selling price of your headband, that expansion of your indications could represent an incremental, multi-billion-dollar market opportunity, given that your headbands have not been used for these indications and that you have no timeline for commercialization of your Ceribell System relating to these indications. Finally, provide a brief description of the ongoing research and active clinical studies, if any, related to these two indications. In this regard, we note your disclosure on page 118.

Our Addressable Market Opportunity in Seizures, page 95

8. We note your response to comment 18. Please revise to state, as you do in your response, that you do not have specific, intended timing at this stage of development: (i) for pursuing additional regulatory clearances in Europe, or (ii) to commercialize your product in Europe.

Our Clinical Results and Economic Evidence, page 101

9. We note your footnote disclosure on page 117 including "Study was supported, sponsored, or funded by Ceribell." Please clarify the difference between supported, sponsored, or funded, and clarify which of the studies noted in the table are included in each category.

Intellectual Property, page 120

10. We note your revisions in response to prior comment 27; however, these revisions do not appear to be completely responsive to our comment. Please revise your intellectual property disclosure to clearly describe in tabular form, 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.

Underwriting

Directed Share Program, page 165

11. We note your disclosure here and throughout the prospectus regarding your directed share program. Please revise your prospectus to clarify, where appropriate:

- whether the participating employees in the directed share program include any directors, officers, business associates, and related persons;
- the "certain minimum requirements" for the directed share program; and
- the risks associated with the participants of the directed share program not being subject to a 180-day lock-up restriction.

In addition, please expand your disclosure to address the process that prospective participants will follow to participate in the program, the manner by which you will communicate with prospective participants about the program, when and how you will determine the allocation for the program, whether such allocation will change depending on the interest level of potential participants, and any other material features of the program.

Financial Statements

Note 2. Summary of Significant Accounting Policies, page F-8

12. You disclose that you provide product warranties at page 117. Please revise to provide all required disclosures under ASC 460-10-50 related to product warranties, where applicable.

Please contact Li Xiao at 202-551-4391 or Kristin Lochhead at 202-551-3664 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.