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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 13, 2025

CeriBell, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**333-281784**	**47-1785452**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
360 N. Pastoria Avenue Sunnyvale, California		**94085**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 800 436-0826

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 7.01 Regulation FD Disclosure.

Ceribell, Inc. is scheduled to present at the 2025 J.P. Morgan Annual Healthcare Conference on January 13, 2025. A copy of this presentation is attached as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed' for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Presentation Slides made available on January 13, 2025.
104	Cover Page Interactive Data File, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements 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 hereunto duly authorized.

CERIBELL, INC.

Date: January 13, 2025

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

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Corporate Presentation

January 2025

Forward Looking Statement

This presentation contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, about the Company and its industry. These statements and the outcomes of the events they describe involve substantial risks, uncertainties and potentially inaccurate assumptions, some of which cannot be predicted or quantified. All statements other than statements of historical facts contained in this presentation, including statements regarding the Company's strategy, financial guidance and projections, future results of operations and financial performance, future operations, projected costs, prospects, plans, objectives, expected products, market size, growth opportunities and competitive position, as well as assumptions relating to the foregoing, 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," "aims," "forecasts," "guidance" or "continue" or the negative of these words or other similar terms or expressions that concern the Company's expectations, strategy, plans, or intentions.

The Company cautions you that the foregoing list does not contain all of the forward-looking statements made in this presentation. You should not rely upon forward-looking statements as predictions of future events and future trends. The Company has based the forward-looking statements contained in this presentation primarily on its current expectations, estimates, forecasts, and projections about future events and trends that it believes may affect its business, financial condition, results of operations, and prospects. The Company cannot guarantee or ensure that the future results, performance, events, circumstances or any other outcome expressed, anticipated or reflected in the forward-looking statements will be achieved or occur in whole or in part. Actual results, events, or circumstances could differ materially from those described or assumed in the forward-looking statements. Moreover, the Company operates in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for the Company to predict all risks and uncertainties that could have an impact on the forward-looking statements in this presentation. This presentation contains estimates, projections, and other information concerning the Company's industry and its business, as well as data regarding market research, estimates, and forecasts prepared by its management or third parties. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties. These data and the industry in which it operates are subject to a high degree of uncertainty and risk due to a variety of factors which could cause results to differ materially from those expressed in these estimates, publications, and reports made by third parties or the Company.

Among the factors that could cause actual results to differ materially from past results and future plans and projected future results are the following: risks related to our limited operating history and history of net losses; our ability to successfully achieve substantial market acceptance and adoption of our products; competitive pressures; our ability to adapt our manufacturing and production capacities to evolving patterns of demand and customer trends; the manufacturing of a substantial number of our product components and their assembly in China; product defects and related liability; the complexity, timing, expense, and outcomes of clinical studies; our ability to obtain and maintain adequate coverage and reimbursement levels for our products; our ability to comply with changing laws and regulatory requirements and resulting costs; our dependence on a limited number of suppliers; and other risks and uncertainties, including those described under the heading "Risk Factors" in our Registration Statement on Form S-1, Quarterly Report on Form 10-Q, and other reports filed with the U.S. Securities and Exchange Commission ("SEC"). These filings, when made, are available on the Investor Relations section of our website at https://investors.ceribell.com/ and on the SEC's website at https://sec.gov/.

The forward-looking statements made in this presentation relate only to events as of the date on which the statements are made. The Company undertakes no obligation to update any forward-looking statements made in this presentation to reflect events or circumstances after the date of this presentation or to reflect new information or the occurrence of unanticipated events, except as required by law. The Company's forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments it may make. In addition, the results of studies referenced in this presentation concerning the Clarity algorithm apply only to the algorithm version that was in use at the time of the analysis and do not reflect subsequent algorithm updates. Most studies referenced in this presentation were conducted with small sample sizes and were not powered for statistical significance, did not control for other clinical variables, or have other design limitations (e.g., the studies may be retrospective and are not randomized controlled trials). In addition, some of the studies were sponsored, funded or supported by the Company or involved employees or consultants of the Company.

By attending or receiving this presentation, you acknowledge that you will be solely responsible for your own assessment of the market and the Company's market position and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of its business.

A Novel, AI-Powered Point-of-Care EEG Platform Designed to Optimize Care in the Acute Care Setting for Patients with Serious Neurological Conditions

Key Operating Highlights

>$2B
Total U.S.Estimated Annual Addressable Market

~$69M
Annual Run-Rate Revenue

46%
FY 2024 YTD YoY Revenue Growth

Significant
Potential Pipeline Market

504
Active Accounts

86%
FY 2024 YTD Gross Margin

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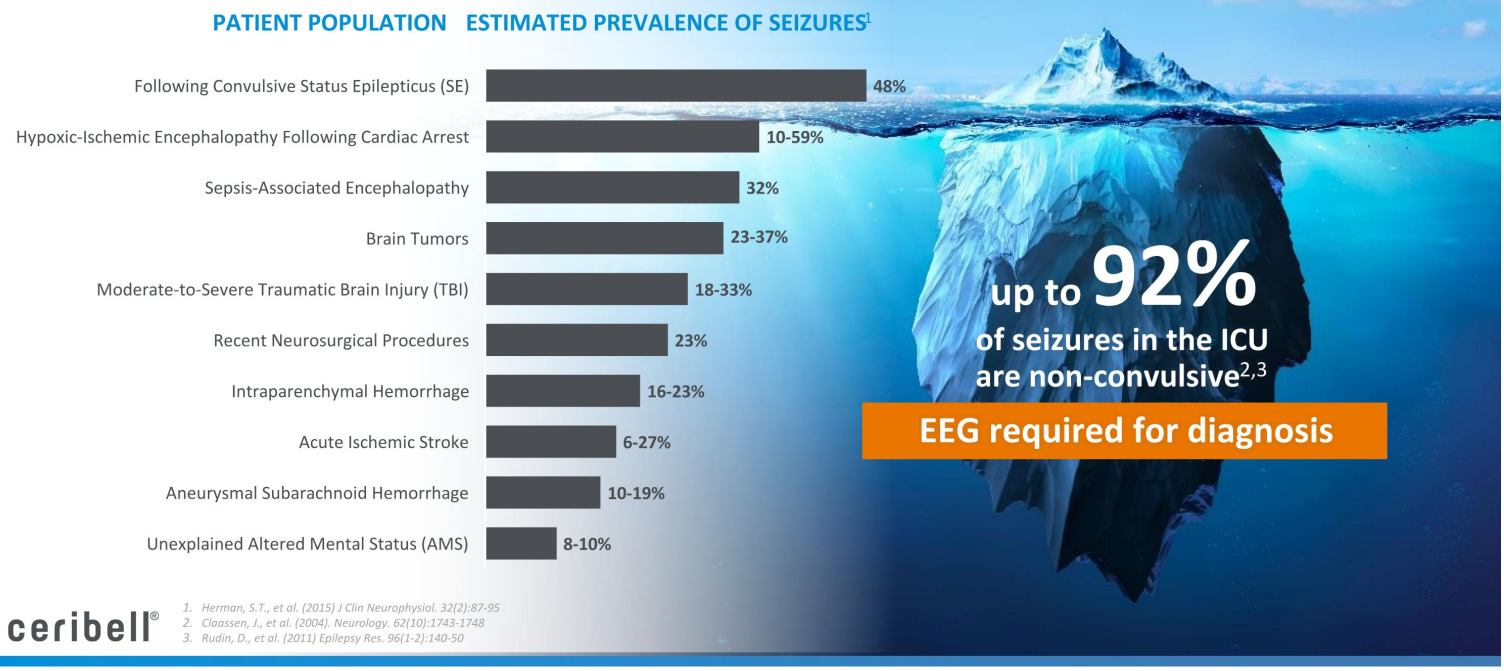
** Data as of September 30, 2024*

Seizures Are Highly Prevalent in Critically-Ill Patients, and Often Go Undiagnosed



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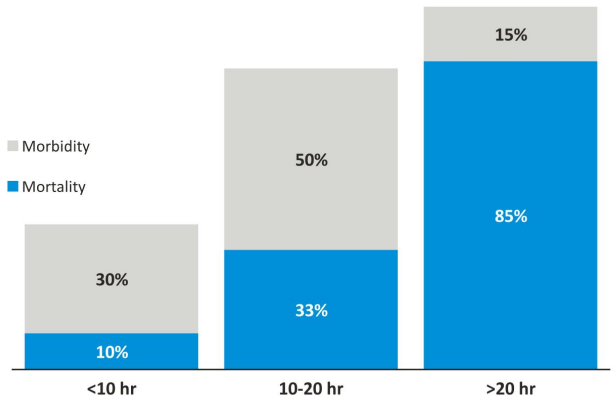
1. Herman, S.T., et al. (2015) J Clin Neurophysiol. 32(2):87-95
2. Claassen, J., et al. (2004). Neurology. 62(10):1743-1748
3. Rudin, D., et al. (2011) Epilepsy Res. 96(1-2):140-50

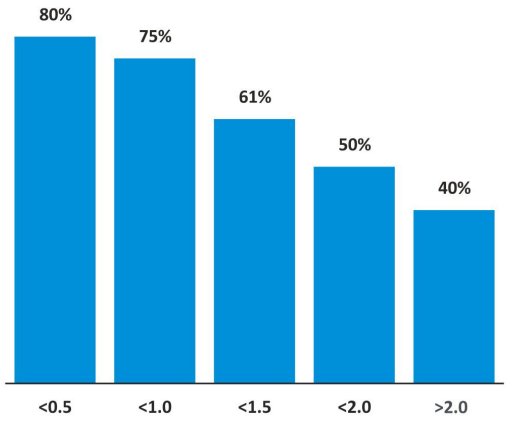
"Time is Brain"

STATUS EPILEPTICUS ALL-CAUSE MORBIDITY & MORTALITY RATE[1]



DURATION OF SEIZURE

PATIENT RESPONSE RATE TO FIRST-LINE TREATMENT[2]



TREATMENT DELAY (hrs)

1. Young, G. B., et al. (1996). Neurology, 47(1), 83–89.
2. Lowenstein, D. H., et al. (1993). Neurology, 43(3 Pt 1), 483–488

Medical Society Guidelines Recommend Timely EEG to Detect and Manage Seizures Across Different Disease States

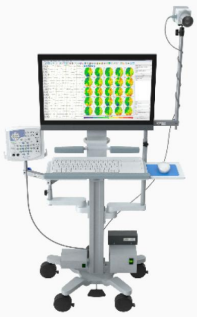
2012	NEUROCRITICAL CARE SOCIETY	Recommends continuous **EEG** monitoring **within 15-60 minutes** of the **onset of seizure** for treatment of **status epilepticus.**[1]
2020	American **Heart** Association	"Recommend **promptly performing and interpreting EEG** for the diagnosis of seizures in **all comatose** patients after the return of spontaneous circulation (ROSC)" from **cardiac arrests.**[2]
2021	American **Stroke** Association	"**EEG** [is recommended] for a change in mental status or depressed mental status out of proportion to the **[ischemic] stroke.**"[3]
2023	American **Stroke** Association	"Monitoring with continuous EEG can detect nonconvulsive seizures, especially in **[aneurysmal subarachnoid hemorrhage] patients** with depressed consciousness or fluctuating neurological examination."[4]

1. Brophy, G., et al. (2012) Neurocrit Care. 17(1):3-23
2. Panchal, et al. (2020) Circulation 149(16):S366-S468
3. Green, T.L., et al. (2021) Stroke 52(5):e179-e197
4. Hoh, B.L., et al. (2023) Stroke 54(7): e314-e370

Overview of Conventional EEG and its Limitations in the Acute Care Setting

Overview of EEG

An EEG is a non-invasive tool used to measure and display electrical activity in the brain



*Designed for the use in the **outpatient setting**, primarily for managing epilepsy patients*

Conventional EEG systems were not designed for the acute care setting

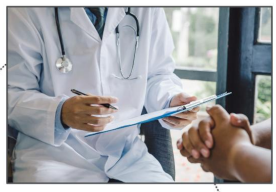
Hardware & Access Challenges

- Requires EEG Technician
- Long Set-Up Process
- Large & Cumbersome Equipment

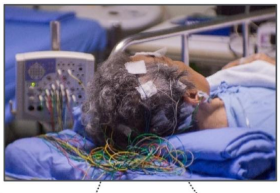
Interpretation Challenges

- Requires Interpretation by a Specially-Trained Neurologist
- Continuous Monitoring Rarely Performed in Practice

Clinical Reality: Conventional EEG is Not Suited for the Acute Care Setting and Leads to Long Delays



1 Seizure Suspicion / EEG Order



2 EEG Arrival & Set-Up

3 EEG Interpretation

Hours or Days[1,2,3]

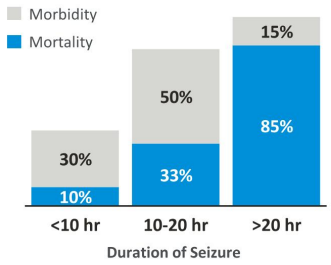
Continuous Review of EEG Records is Rare[4]

1. Gururangan, K., et al. (2016) Clinical Neurophysiology. 127(10):3335-3340. Maximum time from EEG order to arrival and set-up
2. Vespa, P., et al. (2020) Crit Care Med. 48(9):1249-1257. Median time from EEG order to arrival and set-up
3. Quigg, M. et al. (2001) J Clin Neurophysiol. 18(2):162 165. Range of time from request to interpretation.
4. Gavvala, J., et al. (2014) Epilepsia. 55(11):1864-1871

Delayed Access to EEG Leaves Clinicians with a Difficult Choice

Wait, Treat, or Transfer?

Wait For EEG[1]



Treat Empirically Before EEG

Potentially:

- Unnecessary Intubation and/or Medication
- Increased Length of Stay
- Against Guidelines[2,3,4]

Transfer to Better Equipped Hospital

- Delays in Treatment
- Increased Costs

1. Young, G.B., et al. (1996). Neurology, 47(1):83-89
2. Perman S.M., et al. (2023) Circulation 149(5):e254-e273
3. Morgenstern, L. B., et al (2010) Stroke. 41(9):2108-29
4. Hoh, B.L., et al. (2023) Stroke 54(7): e314-e370

Status Epilepticus Compared to Other Serious Conditions in the Acute Care Setting

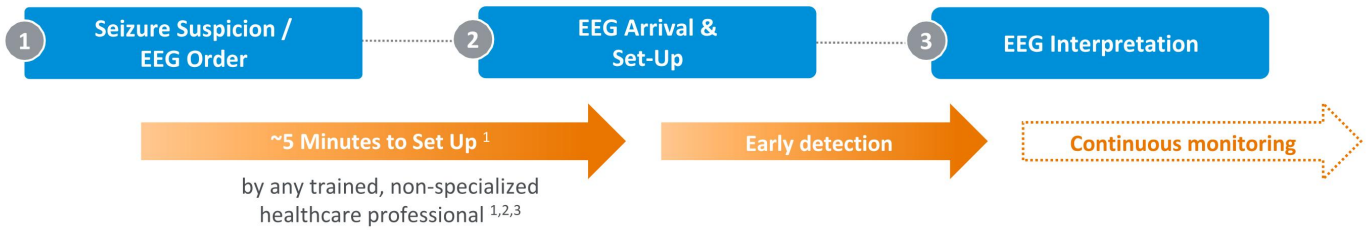
	Sepsis	In-Hospital Stroke	Cardiac Arrest	Status Epilepticus
In-Hospital Mortality Rate	16% [1]	6-10% [2-4*]	63% [5]	18-30% [6 7**]
Average Age	67 [8]	65 [9*]	63 [10]	40 [11]
Hospital Protocol	✓	✓	✓	✗ [12]

* Estimated/computed amounts
**All-cause mortality

1. Agency for Healthcare Research and Quality, Statistical Brief #122, October 2011
2. Hammond, et al. (2020) Stroke. 51:2131–2138.
3. Ovbiagele, B., et al. (2010) Stroke. 41(8):1748-1754
4. Salah, H. M., et al. (2022) Am Heart J. 243:103-109
5. Martin S. S., et al .(2024) Circulation. 149:e347–e913
6. Bogli, S.Y., et al. (2023) Epilepsia. 64:2409-2420
7. Shneker et al. (2003) Neurology. 61 (8) 1066-1073
8. Rhee, C., et al. (2017) JAMA. 318(13):1241-1249
9. Neves, G., et al. (2022) eNeurologicalSci. 26: 1000392
10. Khosla, S., et al. (2022) Circulation. 146:A257
11. Dham, B., et al. (2014) Neurocrit Care. 20, 476-483
12. Based on management's experience

Ceribell EEG System: Suspicion to Diagnosis in Minutes, Enabling Earlier & More Accurate Treatment

The ceribell® System



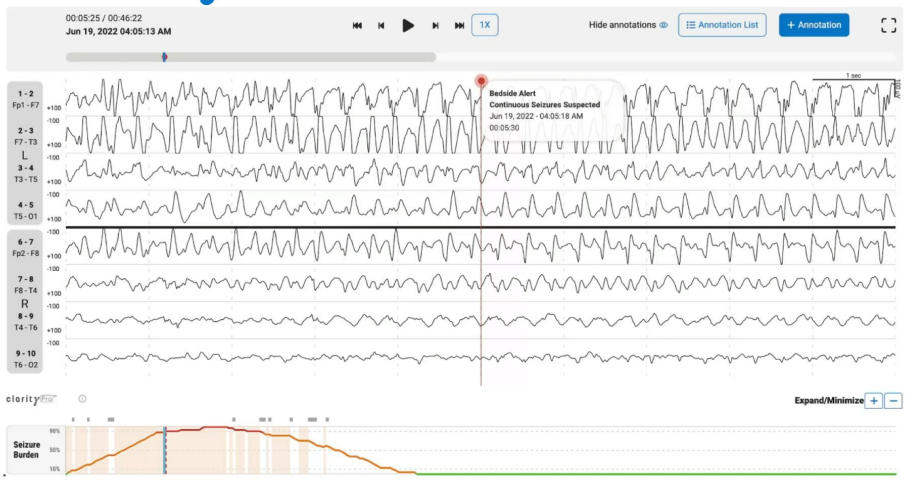
1. Yazbeck et al. (2019) Journal of Neuroscience Nursing
2. Hobbs et al. (2018) Neurocritical Care
3. Eberhard et al. (2023) Clinical Nursing Focus

The ceribell® System

Combining highly portable, simple-to-use and rapidly deployable hardware and AI-powered algorithms

Clarity: Our Proprietary AI-Powered Seizure Detection Algorithm

clarity™



✓ Provides seizure burden to facilitate EEG reading for neurologists

✓ Bed-side Alerts

✓ Real-time feedback on response to medication

Ceribell Supports Precise Patient Care for SE: Expediting Diagnosis and Continuously Monitoring

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SAFER-EEG Clinical Study: ICU Patient Outcomes at Sites w/ Conventional EEG and Ceribell[1]

Outcome	convEEG (N = 62)	Ceribell (N = 62)*	Δ Delta	P- Value
Median ICU LOS	8.0 Days	3.9 days	**4.1 days** **Ceribell patients had much shorter ICU LOS**	P = 0.003
mRS[2] greater than or equal to 4 at discharge	76%	58%	**18%** **More patients from the Ceribell cohort had better neurological outcomes****	p = 0.047
Median door-to-EEG time (hours)	25.3	5.9	**19.4 hours** **Faster door-to-EEG time for POC-EEG**	p < 0.0001

Study Overview: The Seizure Assessment and Forecasting with Efficient Rapid-EEG (SAFER-EEG) study is a multisite retrospective study of adult patients who received EEG during hospital stay. Most centers had 24/7 conventional EEG with technician onsite or on-call.

Study Sites Included In This Sub-Analysis:

- Yale University
- Mass General
- University of New Mexico

*The cohorts were matched 1:1 with propensity scores to have equivalent age, admission scores, diagnosis group and seizure suspicion
**Using mRS greater than or equal to 4 at discharge as an indicator of functional disability. Results with Ceribell vs. conventional EEG.

1. Desai, M., et al. (2024) Neurocrit Care.
2. The Modified Rankin Scale (mRS) is a 6-point disability scale with possible scores ranging from 0 to 5. 0 is healthy and 5 is severe disability. A separate category of 6 is usually added for patients who expire.

Validated Cost Savings

35+ Peer-Reviewed Publications & 75+ Abstracts

Reduced
Over-administration of
Anti-Seizure Medication (ASM)[1]

40%
changed diagnostic suspicion and 20% changed treatment decisions[5]

43%
of patients with reduced ASM[7] + 51% potential reduction in intubation and parenteral ASM[3]

53%
changed clinical management and expedited disposition for 21% of patients[6]

Reduced
Length of Stay (LOS)
in the ICU and Hospital

4.1 days
ICU LOS reduction[7]

Trend of
3 days
hospital LOS reduction[2]

Potential
0.4 days
ICU LOS reduction[3]

1.2 days
hospital LOS reduction[3]

Reduced
Patient Transfers[4]

94%
of transfers that would have been made avoided[8]

100%
of non-seizure patients retained[9]

1. Wright, N., et al. (2021) EMJ. 38(12):923-926
2. Eberhard, E., et al. (2023) J Neurosci Nurs. 55(5):157-163
3. Ney, J.P., et al. (2021) J Med Econ. 24(1):318-327
4. Madill et al. (2022) Epileptic Disord 24 (3): 507-516
5. Vespa, P., et al. (2020) Crit Care Med. 48(9):1249-1257
6. Wright, N., et al. (2021). EMJ. 38(12):923-926
7. Desai et al. (2024). Critical Care Medicine. 52(1):p S268, 589
8. Madill, E.S., et al. (2022) Epileptic Disorders. 24(3):507-516
9. Ward, J., et al. (2023) Front. Digit. Health. 5(1)

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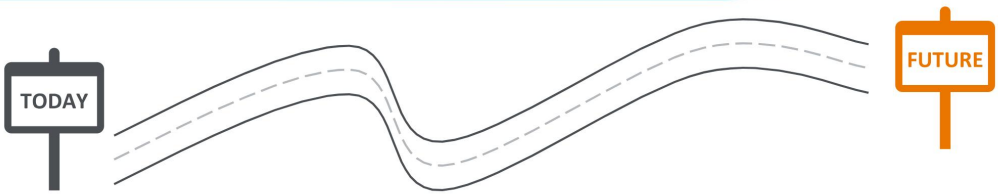
High Barriers To Entry



IP Portfolio	▪ 13 issued US patents	▪ 12 US patents pending
Database and AI Know-How	▪ Large acute care EEG database (800,000 hours)[1] enabled by our hardware ▪ Detailed labeling by epileptologists ▪ EEG signal processing and algorithm knowhow	▪ Indication extension beyond seizure, including stroke and delirium
Sticky Customer Base	▪ Established and supportive clinician base ▪ Workflow integration across multiple departments ▪ IT Integration	▪ Electronic Health Record integration

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Patent portfolio as of June 30, 2024
1. As of June 30, 2024

Business Model: Two Sources of Recurring Revenue

~25% SaaS
(monthly subscription)[1]
~$5,000 list price

~75% Disposable
(fee per Headband)[1]
~$800 list price

clarity™ +  + 

AI Algorithm
SaaS

Recorder
Capital

Portal
SaaS

Single Use Headband
Disposable

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1. From Q1 2022 to Q2 2024

Advantages of Ceribell's Business Model

1 Highly Sticky Business Model

- ✓ Low attrition rate
- ✓ Consistent reorders
- ✓ Strong competitive position and high barriers to entry

2 Bifurcated Sales Force Driving Growth and Retention

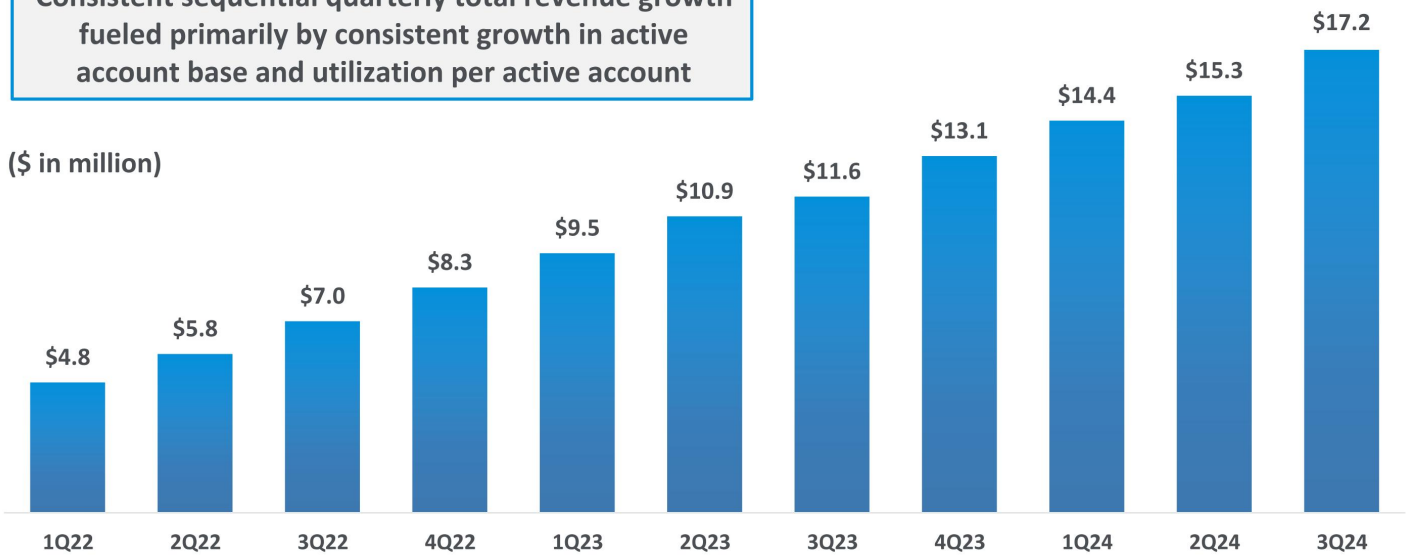
- ✓ Territory Managers focusing on new account acquisition and onboarding
- ✓ Clinical Account Managers focusing on increasing utilization

3 Recurring Revenue

- ✓ SaaS pricing model + razor/razorblade model
- ✓ Predictable revenue model
- ✓ High gross margin

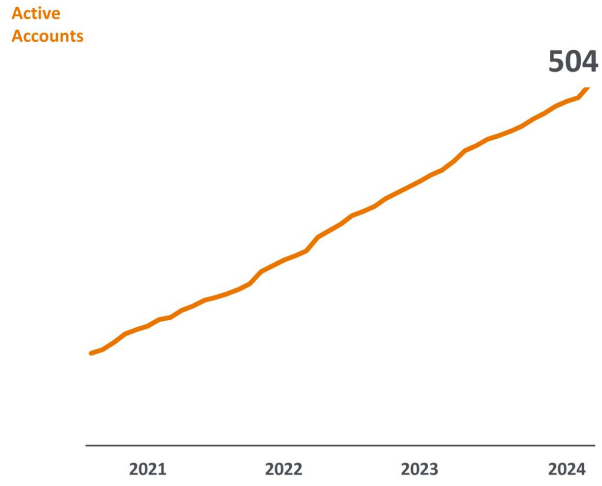
Rapid Commercial Expansion & Projectable Business Model

Consistent sequential quarterly total revenue growth fueled primarily by consistent growth in active account base and utilization per active account

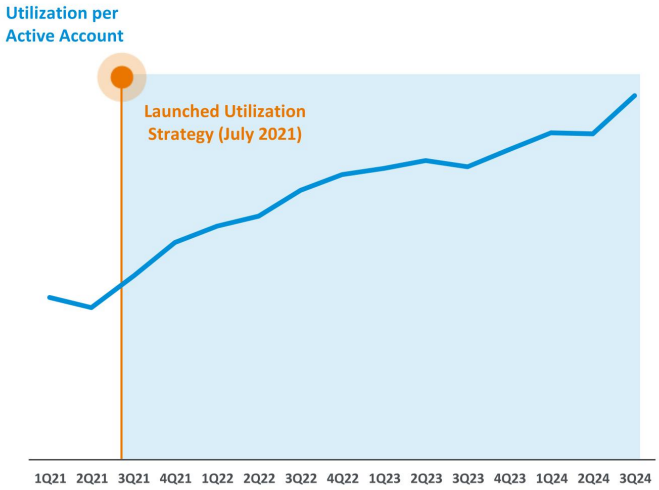


Key Growth Drivers: Increase Active Account Base & Drive Utilization

Continued Momentum on Account Acquisition



Significant Acceleration in Same Store Growth



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* As of September 30, 2024

Significant, Highly Under-penetrated Total Addressable Market

~3 Million Patients[1]

Ceribell-Relevant Patient Populations

- History of Prior Seizure; No Return to Baseline
- Cardiac Arrest after ROSC
- Subarachnoid Hemorrhage
- Intracerebral Hemorrhage
- Ischemic Stroke
- Brain Tumor
- Moderate / Severe TBI
- Sepsis with Encephalopathy
- Unexplained Persistent AMS / Coma
- Stroke Mimics

+

~6,000 Hospitals[2]

Ceribell-Relevant Facilities

- Short Term Acute Care Hospitals
- Critical Access Hospitals
- Freestanding EDs
- VA Hospitals (~200)

>$2 Billion Estimated Total U.S. Annual Addressable Market Opportunity

1. *Internal analysis of National Inpatient Sample and National Emergency Department Sample data*
2. *Per Definitive Healthcare*

Ceribell Growth Strategies

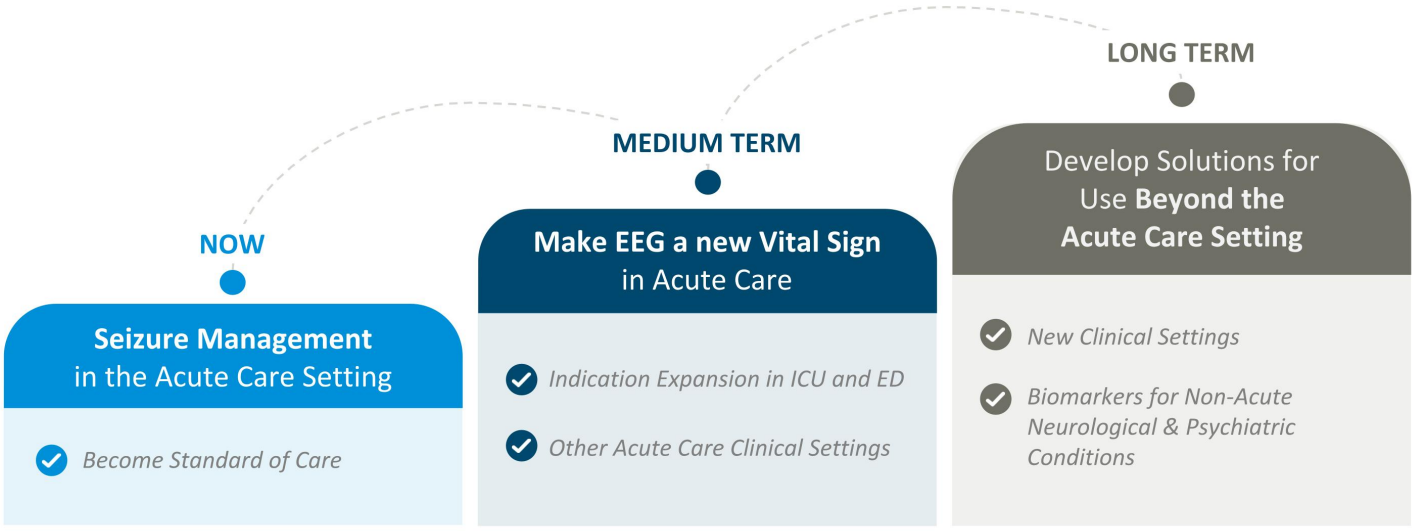
1. **Increase Adoption** of the Ceribell System in New Accounts
2. **Drive Utilization** of the Ceribell System within Existing Customer Base
3. Continue to **Drive Awareness** of Seizures in the Acute Care Setting
4. Invest in **Growing our Base of Clinical Evidence** further
5. Continue to **Improve and Innovate** the Ceribell System for Use in Seizures

Core US Acute Care Seizure Opportunity

6. Pursue **Adjacent and International Markets**
7. Expand into **New Indications and Clinical Use Cases** Beyond Seizures

Upside / Growth Opportunities

Ceribell's Long-Term Vision: Building an EEG Platform for Various Indications and Settings



>$2BN CURRENT US TAM

SIGNIFICANT POTENTIAL, INCREMENTAL MARKET OPPORTUNITIES

2025 Areas of Focus

NOW

Seizure Management in the Acute Care Setting

Commercial

- Expand active account base and drive utilization to further advance market leadership
- Further penetrate VA opportunity following receipt of Authority to Operate from the Department of Veterans Affairs in late 2024

Regulatory

- Secure FDA 510(k) clearance for **pediatric** Clarity algorithm
  510(k) submitted in late 2024
- Prepare for submission of FDA application for **neonate** Clarity algorithm

MEDIUM TERM

Make EEG a new Vital Sign in Acute Care

Regulatory

- Submit FDA application for **Delirium** indication
  FDA Breakthrough Designation received

Product Development

- Continue to improve existing product & user experience
- Advance longer-range R&D pipeline programs including ischemic stroke and second-gen hardware

Ceribell Investment Highlights

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1. Unique **platform technology** representing a paradigm shift in brain monitoring in the acute care setting
2. Compelling **clinical and economic benefits** for key stakeholders, with support from robust body of clinical and real-world evidence
3. Large **>$2B estimated addressable market** opportunity with a significant unmet need
4. **Recurring, predictable, and scalable revenue model** with attractive gross margins
5. **Strong value proposition and first mover advantage** protected by comprehensive IP portfolio, data science and AI expertise, and strong customer support
6. **Established reimbursement** further enhanced by additional New Technology Add-on Payment (NTAP)[1]
7. **Experienced leadership team** with deep industry and subject matter expertise

1. Until October 2026


ceribell®