NEURAVA

Company Overview

SUDEP (sudden unexpected death) is a terrible risk faced by 65M epilepsy patients globally and 3.5M Americans. There is no device currently available to monitor for this risk nor identify patients at highest risk of SUDEP. Building on over a decade of epilepsy research and following our discovery of a potential mechanism of action behind SUDEP, Neurava is developing novel wearables on the arm and neck for nighttime monitoring and alerting of seizures, cardiorespiratory dysfunctions and SUDEP risk in epilepsy patients. Letters of support from key opinion leaders inform that this data will enable physicians to expedite formulation of treatment plans and to triage and further assess patients with the highest individual SUDEP risk. Neurava has completed a clinical study of its arm wearable and is currently conducting clinical testing of its full platform on people with epilepsy.

Market & Commercialization Strategy

Employing a bottom-up approach, the total available market consisting of 3.5M Americans with epilepsy is $8.1B. The serviceable available market consisting of 1.2M refractory patients is $2.8B. Neurava plans to enter the market by targeting the approximate 221,000 refractory patients waiting to enter an epilepsy monitoring unit (EMU) annually, giving a target market of $512M. Once a neurologist determines that an epilepsy patient needs to go to an EMU, we will sell our device to these patients through physician prescriptions. Our wearables will cost $1600. A smartphone app grants access to a patient database for $1/day, in addition to $1/day for replaceable adhesive patches. Neurava's platform technology can also be scaled to patients at risk of sudden infant death syndrome and sleep apnea.

Technical & Competitive Advantage

Currently, there are no devices on the market that specifically monitor SUDEP risk. Epilepsy patients instead use seizure monitoring devices like those by Empatica, NightWatch, and Neureka. However, seizure-based detection devices remain limited in their ability to mitigate SUDEP risk since they do not monitor for the cardiorespiratory dysfunctions leading up to SUDEP. By detecting cardiorespiratory dysfunctions in addition to seizures, our wearables can help mitigate the risk of SUDEP within the entire epilepsy community.

Regulatory Strategy & Intellectual Property

Neurava is pursuing the 510(k) premarket notification pathway for their wearables to monitor and alert for seizures and cardiorespiratory dysfunctions. Once approved, Neurava will apply for a breakthrough device designation for SUDEP risk monitoring and expand indications of its 510(k) approved devices. This strategy was validated in a pre-submission meeting with FDA. Neurava has secured an exclusive license to a patent portfolio consisting of three patents from Purdue. This portfolio provides a variety of coverages, including for a multi-modal wearable seizure sensor system (arm wearable). Neurava also converted and filed a non-provisional patent application (Neurava owned) for the neck wearable.

Key Milestones

Objective	Milestone	Date/Year
Clinical	Validate full system in both adult and children epilepsy patients	Q4 2024
Regulatory	Arm wearable 510(k) submission	Q3 2024
Regulatory	Neck wearable 510(k) submission	Q2 2025
Commercialization	Go-to market	Q1 2026

Capitalization History

Year	Grant, Funding Round	Description	Amount
2019-21	Pre-Seed	Pitch competitions and early convertible note	$87,500
2021	Seed – Convertible Note	Syndicate round led by Elevate Ventures, including strategic investor UCB	$656,250
2022-23	Series Seed – Equity	Syndicate round led by Life Science Angels with follow-on investments from all major previous investors, incl. UCB	$2.26M
2023	Cash Prize	Grand Prize Finalist – MedTech Innovator 2023 Program	$25,000

Use of Proceeds

The milestones of the Series Seed equity round include validation of the full system in both adults and pediatric epilepsy patients and a 510(k) submission to FDA for the arm wearable. Prior to Series A, Neurava plans to raise more capital to submit a 510(k) to FDA for the neck wearable.

Key Team Members

Jay Shah, PhD | CEO, Co-Founder

Jay has over 5 years of experience in medical device development. He previously worked at Cyberonics (now LivaNova) and a medical device startup on product development & clinical trial management/execution.

Vivek Ganesh, PhD | CTO, Co-Founder

Vivek has over 5 years of experience in medical device development. He previously worked at a startup designing medical equipment and at Apple designing new features of the Apple Watch.

Clinical Advisors

Dr. George Richerson, MD, PhD (Univ. of Iowa), Dr. William Nobis, MD, PhD (Vanderbilt Univ.), Dr. Samden Lhatoo, MD, FRCP (UT Health – Houston), and Dr. Michael Privitera, MD (Univ. of Cincinnati). They are leading experts in epilepsy and SUDEP and are partners for Neurava's clinical studies.

UCB Biopharma

UCB is a strategic investor who brings epilepsy related business experience to the team. They are global leaders in epilepsy as producers of many important anti-seizure medications.

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