Neurava Inc.

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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. 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. The recorded 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 conducted clinical testing of its arm wearable on epilepsy patients and completed a prototype of the full platform.

Market and 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 & Reimbursement Strategy:

Neurava is pursuing the 510(k) premarket notification pathway for a wearable device that monitors and alerts 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 device. This strategy was validated in a pre-submission meeting with FDA. We are currently developing our insurance reimbursement strategy using DME and/or CPT codes.

Key Milestones:

Description	Date/Year
Validate full system in both adult and children epilepsy patients	Q4 2023
Arm wearable 510(k) submission	Q4 2023
Full system 510(k) submission	Q2 2024
Go-to market	Q1 2025

Capitalization History:

Year	Grant, Funding Round, etc.	Description	Amount
2019-21	Pre-Seed	Pitch competitions and early convertible note	$87,500
2021	Seed – Convertible Note	Syndicate round led by Elevate Ventures, incl. strategic – 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	$1.345M

Fundraising:

Neurava is seeking the remaining $655K of its Series Seed round. The milestones associated with this round include validation of the full system in both adults and pediatric epilepsy patients and submit a 510(k) for the arm wearable.

Key Team Members:

Jay Shah, PhD (Co-Founder, CEO) 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 (Co-Founder, CTO) also 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 include Dr. George Richerson (Univ. of Iowa), Dr. Nobis (Vanderbilt Univ.), and Dr. Michael Privitera (Univ. of Cincinnati). They are leading experts in epilepsy and SUDEP and partners for our clinical studies.
UCB is a strategic investor who bring epilepsy related business experience to the team. They are global leaders in epilepsy as producers of the most commonly used anti-seizure medications.