Magnetic Stimulator of the Facial Nerve: An Emergency Treatment for Stroke

Created in 2023 to acquire the distressed assets of Nervive Inc.

Management Team:

Jeffrey Lietzke, MA, JD
Chief Executive Officer

Stephanie Harrington, MS
Chief Clinical, RA/QA Officer

Emilio Sacristan, PhD
Chief Scientific Officer

Milestones Achieved to Date

- Preclinical testing: over 200 tests in various animal models
- Clinical system prototype complete. FDA IDE granted
- First in human tests in healthy volunteers
- Clinical trial in vasospasm patients
- HUD designation approved by FDA for the treatment of vasospasm
- 4 Patent families granted in US, Europe and China.
- Ongoing Early Feasibility Clinical Trial for treatment of stroke in ER - Cleveland Clinic and MetroHealth Hospitals

Seed Funding Sought 2024
US$6M working capital .

Funding Sought 2026
US$12-15M Series A

Use of 2024 seed funds:

- Complete comercial product development, Ramp up production
- Complete early feasibility trial for stroke clinical trials.
- Complete pilot study for migraine.
- Marketing and product launch for Vasospasm.
- Begin Feasibility trial for stroke (40-60 patients)

Contact:

Francisco Lozano Martínez
flozano@newgenesis.cl

Raúl Vázquez Cassani
rvazquez@newgenesis.cl

Save Brain Now™

Vacere Medical is developing a simple, safe, and non-invasive emergency treatment for stroke and other cerebro-vascular conditions, that significantly improves blood-flow to the brain at the earliest opportunity.

Product Description

The Magnetic Stimulator applies rapid magnetic pulses to the facial nerve on both sides of the face for 2 minutes, triggering widespread and long-lasting vasodilation of the cerebral arteries. The result is as much as a two-fold increase in cerebral blood flow. Because it is easy to use, non invasive, and safe, even if applied to patients with brain hemorrhage, it can be administered earlier than other therapies, saving brain, and also improving the efficacy of standard-of-care therapies such as clot-busting drug (tPA) or endovascular clot retrieval. Magnetic stimulation has also shown to be effective in reversing cerebral artery vasospasm, making it a much needed life-saving tool for the neuro-ICU.

Unmet Clinical Needs

Stroke is the most common cause of disability and the second most common cause of death. In the U.S., nearly 800,000 cases of stroke occur each year, costing approximately $37 billion in healthcare expenditures. In Europe, there are 1.1 million cases of stroke each year costing at least $22 billion in healthcare expenditures. Worldwide, there are more than 16.9 million cases of stroke annually of which 5.7 million prove fatal. For ischemic stroke, standard-of-care therapies aimed at restoring blood flow are only effective in a short time window before brain damage becomes irreversible. These therapies can only be administered after brain imaging can confirm the diagnosis. As a result, for most patients, by the time diagnosis is confirmed, the treatment window has passed. Less than 5% of patients with ischemic stroke are treated with tPa, and less than 1% of patients receive an endovascular procedure. There is a clear need for a therapy that is easy and safe to apply without requiring a brain scan first. A therapy that can be applied at the earliest opportunity, in the emergency department or an ambulance. Magnetic Stimulator meets this need and could become as ubiquitous as a cardiac defibrillator.

Cerebral artery vasospasm is a stroke-like condition that is caused by a constriction of the arterial wall, reducing blood flow to the brain. It is a serious complication that manifests several days after a subarachnoid hemorrhage or traumatic brain injury in patients that are recovering in a neuro-ICU. It has a very high mortality and no standard therapy that has proven to be effective. This is a small market, but one where the need is clear and desperate. In a pilot study in the Mexican National Institute of Neurology and Neurosurgery, the Magnetic Stimulator was effective in reversing vasospasm in 6 out of 6 patients after a single 2 minute stimulation, and all of them survived. The FDA has already approved a Humanitarian Use Device designation for the Magnetic Stimulator to treat vasospasm.

Market Strategy

Vacere intends to commercially launch the CEREFAST system for 3 distinct clinical applications:

- **Vasospasm:** treatment in the neuro-ICU, under a Humanitarian Device Exemption by the end of 2025.
- **Ischemic Stroke:** treatment in the Emergency Department, under a 510K de novo by 2029.
- **Migraine:** Preventive repeated treatments in the neurologist´s office, under a 510K by 2027. A clinical trial to be completed in 2026 (Pilot in 2025).