

PathMaker Neurosystems Inc.

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www.pmneuro.com



Industry: Medtech

- Lead product: First non-invasive neuromodulation device for treatment of stroke patients with muscle spasticity
- Second product: First disease-modifying neuromodulation device to slow ALS

Management Team

- Nader Yaghoubi, MD, PhD
Co-Founder and CEO
- Jerry Jennings, BSEE
Chief Technology Officer
- Jake Maslow, JD
Executive VP and Chief IP Officer
- Sheila Hemeon-Heyer, JD
VP Regulatory and Clinical Affairs



Board of Directors

- Hooman Hakami, BBA
Chairman, Board of Directors;
Formerly President of Medtronic Diabetes
- Terri Bresenham, MS
Formerly Chief Innovation Officer,
GE Healthcare
- John Donoghue, Ph.D.
Formerly Founding Director,
Wyss Center for Neuroengineering



Scientific Advisory Board

- Zaghoul Ahmed, PhD
Scientific Founder; Chairman, Dept. of
Physical Therapy, CUNY/CSI
- Jean-Charles Lamy, PhD
Research Associate, ICM
- Emilio Bizzi, MD, PhD
Institute Professor, MIT
- Bechir Jarraya, MD, PhD
Neurosurgeon, Foch Hospital
- Ole Isaacson, MD, PhD

Intellectual Property

- MyoRegulator platform under patent protection in 38 countries
- 5 registered trademarks
- Freedom-to-operate (FTO) confirmed

Funding to Date

- \$7.8M in non-dilutive capital and \$2.4M in seed/investor funding raised to date

Key Risks Retired to Date

- Clinical feasibility
- EU pivotal clinical trial
- R&D & product development
- IP

Fundraising Objective

- \$20M Series B equity financing for commercial launch of first product in US
- Use of funds: FDA approval, US commercialization, US pivotal trial completion

Contacts:

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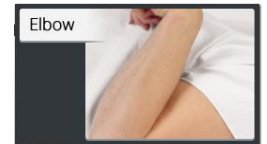
Executive Summary:

- PathMaker Neurosystems is a near-commercial stage neuromodulation company developing breakthrough non-invasive devices for the treatment of patients with serious neurological disorders. We are initially focused on stroke and ALS (amyotrophic lateral sclerosis, Lou Gehrig's disease). FDA clearance and start of product sales is anticipated in 2025.
- Our first product, MyoRegulator[®], is the first non-invasive neuromodulation device for treatment of muscle spasticity found in stroke patients. MyoRegulator is a microprocessor-controlled device that uses PathMaker's patent-protected DoubleStim[®] technology to deliver synchronized stimulation at two sites along the neural axis via two pairs of disposable skin-surface electrodes. Through precisely sequenced and targeted multi-site stimulation directed at the spinal outflow and peripheral nerve leading to affected muscles, our proprietary approach modulates neural activity to suppress hyperexcitable spinal neurons involved in dysfunction.
- The MyoRegulator platform for hyperexcitability suppression is now being applied to ALS to slow/stop disease progression. We have a robust pre-clinical data package that establishes POC to apply our approach to ALS, have recently won two major prizes in ALS field, and have recently launched our first clinical trial in ALS with funding and support from a leading neuromuscular disease foundation.

Market Opportunity/Unmet Need:

- Over 19 million people live with stroke-related disabilities in the US, EU5 and Japan, and over 1.7 million new stroke cases occur every year in these territories. About 33% of stroke patients develop spasticity, resulting in over 600,000 new post-stroke spasticity patients/year, in addition to over 6 million existing patients with post-stroke spasticity.
- Spasticity is a state of painful muscle contraction characterized by decreased motor function and stiffness. Affecting upper or lower limbs, it restricts performance and lowers quality of life.
- There are very few treatment options for patients with spasticity. Spasticity is now typically treated with repeated intramuscular injections of botulinum toxin (Botox[®] or Dysport[®]) every 3 to 4 months. These drugs are bacterial neurotoxins, which have been associated with serious adverse events including difficulty swallowing, respiratory compromise, generalized muscle weakness, hypersensitivity and pain, together with declining efficacy after repeated administrations. Botulinum toxin for spasticity is already a >\$1.0 billion annual market. Our neuromodulation-based approach represents a novel treatment modality, and is expected to be synergistic with botulinum toxin and other existing drugs.
- The MyRegulator device is a safe, non-invasive, painless and cost-effective therapy. It represents the first non-invasive, portable neuromodulation device for treating spasticity, and there is nothing comparable to MyoRegulator either on the market or under development.
- We expect our non-invasive device to provide a novel treatment alternative for patients who are unable/unwilling to be injected with botulinum neurotoxin, have failed therapy or have stopped responding to neurotoxin injections. For payors and healthcare systems, it will save significant money.

Upper limb spasticity post-stroke



Products, Pipeline & Competitive Advantage:

- MyoRegulator is the only neuromodulation device to offer stroke patients a breakthrough solution with clear benefits over conventional treatments. MyoRegulator is being shown at major medical conferences and clinicians are quite excited in anticipation of market clearance. EU pivotal trial was recently successfully concluded with a positive readout showing efficacy.
- MyoRegulator is designated by FDA as a "breakthrough" medical device which is on the De Novo regulatory pathway, and clinical trials are considered by FDA as Non-Significant Risk (NSR). Regulatory clearance (FDA) is expected in 2025, followed by EU CE Mark.
- Product revenues begin in 2025 with US commercial launch of MyoRegulator via direct sales, with a device plus disposables model.
- We have determined at the molecular level the mechanisms by which our technology works. We published the first direct link between spasticity and overexpression of a specific neuronal co-transporter (NKCC1) found on spinal cord neurons which is responsible for maintaining chloride gradient (Mekhael 2019). We found that our treatment suppresses NKCC1 levels and reduces neuronal hyperexcitability and spasticity, and molecular studies have been extended into ALS models.
- We expect our neuronal hyperexcitability suppression platform to be a game-changer for motor neuron diseases such as ALS. We have completed fundamental pre-clinical studies showing robust effects, and launched our first clinical trial in ALS in September 2023, supported by foundation funding.

Commercial MyoRegulator[®] system



Recent Milestones & Achievements:

- \$4.9M NIH grant awarded in February 2018 to support MyoRegulator development in US
- PathMaker was awarded France's top prize for Innovation across technology sectors in July 2019
- \$371K NIH grant awarded in September 2021 to apply our technology to ALS
- Awarded the \$250K CERF Medical Electronics Prize in ALS in February 2022
- Awarded \$600K funding in Jan 2023 by Muscular Dystrophy Association (MDA) to launch ALS trial
- One of five companies in MA selected in June 2023 by MassVentures for \$200K of START funding
- Positive readout on EU pivotal trial of MyoRegulator in post-stroke spasticity, with paper pending