

NeuroOne Medical Technologies Corporation
Nasdaq: NMTC

January 2022

Dear fellow shareholders,

In fiscal 2022 we made terrific strides in advancing our game-changing cortical, strip, grid and sEEG electrode technology for broad diagnostic and therapeutic applications. Today, NeuroOne provides a full line of electrode technology to address an estimated worldwide market of \$100 million for patients requiring diagnostic brain mapping procedures. Our focus remains on patients suffering from epilepsy, chronic back pain, and Parkinson's disease.

NeuroOne's robust product suite has recently expanded beyond our first disruptive product introduction, the Evo[®] Cortical Electrode, to include our second FDA 510(k) cleared product, the Evo[®] sEEG Depth Electrode system, which is ready for commercial launch in the current calendar quarter. During 2022 we also made substantial development progress with our first combination system which includes both diagnostic and ablation capabilities.

The purpose of this letter is to share with you fiscal year 2022 and subsequent key highlights along with multiple exciting catalysts for NeuroOne in fiscal 2023.

Fiscal Year 2022 and Subsequent Highlights

- **Clearly our most exciting and important accomplishment as a company to date was receiving U.S. Food and Drug Administration (FDA) 510(k) clearance for our Evo[®] sEEG product portfolio.**

FDA 510(k) clearance enables us to market the Evo sEEG (stereoelectroencephalography) Electrode technology for temporary (less than 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain. With this milestone, the full diagnostic functionality of our EVO sEEG System is complete.

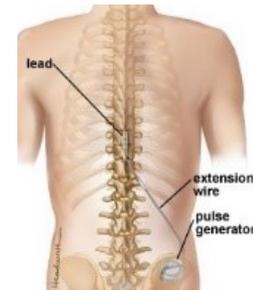


- **The first commercial order of Evo sEEG Electrodes for temporary (less than 30 days) use was shipped to Zimmer Biomet, another major achievement for our Company.** Our manufacturing ramp and commercialization strategies are in place for near-term market introduction in collaboration with our distribution and development partner Zimmer Biomet (NYSE: ZBH).

- **Significant progress was made in the development of our OneRF™ therapeutic ablation electrode system.** Milestones completed include *i)* testing of hardware and software prototypes for the accompanying RF generator, *ii)* the design and testing of the OneRF system accessories, and *iii)* a second successful animal feasibility study at the Mayo Clinic. Designed to both record brain activity and ablate nervous tissue using the same electrode, our system offers the potential for a safer and less expensive combination electrode, intended to improve patient outcomes, reduce procedures and overall treatment cost. This system will potentially be our first therapeutic device, representing the next major phase in our Company's development.



- **We completed initial testing and advanced the development of electrodes for chronic stimulation and recording.** Our initial target is the spinal cord stimulation market, a \$3 billion market in the U.S. alone. We are designing our devices to utilize percutaneous delivery systems (non-surgical placements) that require less battery energy and expanded tissue coverage as compared to standard electrodes placed percutaneously¹. Since our electrodes are intended to be implanted for long-term use, they



have advanced insulation against fluid permeation and greater durability than devices intended for less than 30 days use. Prominent key opinion leaders joined our new Physician Advisory Board to help guide our development of both the electrode and device delivery system(s).

- **We increased our financial runway and maintain capital resources to support upcoming commercial and development catalysts.** In August 2022 we received an accelerated \$3.5 million payment from Zimmer Biomet related to certain milestone events, as part of an amendment to our distribution and development agreement. Earlier in fiscal year 2022 we completed a public offering, raising gross proceeds of \$13.4 million.
- **Additional partners were qualified for manufacturing.** With an expanded supply chain, we are well-equipped to meet increased product demand with the market launch of the Evo sEEG.
- **We bolstered our management team by hiring key positions in Research and Development and Quality Control.** Our leadership team holds deep expertise in thin film electrode technology research and development, marketing, finance, quality control, regulatory affairs, and business development. The Company also benefits from a world-class board of directors and esteemed scientific and physician advisory boards.

¹ North RB, Kidd DH, Olin JC, Sieracki JM. Spinal cord stimulation electrode design: prospective, randomized, controlled trial comparing percutaneous and laminectomy electrodes-part I: technical outcomes. *Neurosurgery*. Aug 2002;51(2):381-9; discussion 389-90.

- **NeuroOne joined the University of Minnesota in a National Institutes of Health (NIH) grant submission.** NIH funding would support our joint development of a chronic cortical electrode capable of both recording and stimulation. We believe this device will provide new opportunities for clinical studies in many areas, including chronic pain, substance use disorder, depression, obsessive compulsive disorder, and other mental health conditions.
- **Our corporate and scientific teams presented and promoted NeuroOne at numerous high-profile events in the U.S. and overseas.** Our data was presented to the scientific community at the Neuroelectronic Interfaces Gordon Research Conference, Congress of Neurological Surgeons, Society for Neuroscience, and American Epilepsy Society meetings. We exhibited our Evo electrode product family with Zimmer Biomet at the Congress of Neurological Surgeons annual meeting and the American Epilepsy Society annual meeting. The Evo sEEG implantation accuracy study was featured in a podium presentation at the Biennial Meeting of the World Society for Stereotactic & Functional Neurosurgery, held in South Korea. Our full team participated in a Nasdaq Stock Market Closing Bell ceremony to celebrate our Evo sEEG FDA 510(k) clearance milestone.

Fiscal Year 2023 Potential Catalysts

- **Commercial launch of Evo sEEG Electrodes.** We expect to begin the commercial launch of our Evo sEEG electrodes with Zimmer Biomet in the first calendar quarter of 2023. We have already shipped the first commercial order and will continue to build up inventory to meet product forecasts and additional orders in house.
- **Continuing ablation electrode development.** OneRF is on track for submission of a 510(k) application to the FDA in the second quarter of calendar year 2023.
- **Continuing spinal cord stimulation (SCS) electrode development.** In 2023, we will continue to refine our chronic spinal cord electrode design based on customer feedback and conduct additional pre-clinical bench and/or animal tests to further validate our value proposition.
- **Exploration of additional partnerships.** We believe there may be opportunities to establish mutually beneficial relationships with companies that could leverage our core technology. Our technology enables, complements, and/or competes with a number of companies that are in the market or attempting to enter the market with diagnostic or therapeutic technologies to treat brain related disorders. In addition, our technology may have application in cardiovascular, orthopedic, and pain related indications that could benefit from a high-fidelity thin film electrode product that can provide stimulation and/or ablation therapies.
- **Exploration of new indications.** As mentioned previously, we are excited about working with the University of Minnesota to develop an electrode that could be used as part of a closed loop cortical system that has the potential to provide both recording and therapeutic stimulation for multiple indications, one of which includes mental health conditions, an exciting market that is exploring more effective treatments in addition to pharmacological care.

- In closing, the NeuroOne team made great progress in fiscal 2022 on multiple fronts including commercialization, product development, and financing. We are in a strong position to continue executing meaningful advances in electrode technology for a variety of neurological applications.

On behalf of our Board of Directors and employees, we thank you for your continued support of NeuroOne and wish you and your family a wonderful 2023.

Sincerely,

Dave Rosa
President and CEO
NeuroOne Medical Technologies Corporation



The entire NeuroOne team was thrilled to ring the Nasdaq Closing Bell on November 22, 2022, to celebrate the milestone achievement for the Evo® thin film electrode platform.

“Caution: Federal law restricts this device to sale by or on the order of a physician.”