UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended September 30, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-40439

NeuroOne Medical Technologies Corporation

(Exact name of Registrant as specified in its charter)

Delaware	**27-0863354**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
7599 Anagram Dr., Eden Prairie, MN	**55344**
(Address of principal executive offices)	(Zip Code)

952-426-1383

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**NMTC**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registration included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatement that required a recovery analysis of incentive-based compensation received by an of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of March 31, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of shares of the registrant's common stock held by non-affiliates of the registrant based upon the March 31, 2023 price at which the common equity was last sold was $24,807,523 million. The number of outstanding shares of the registrant's common stock as of December 13, 2023 was 23,962,847.

DOCUMENTS INCORPORATED BY REFERENCE

Parts of the Proxy Statement for the Registrant's 2024 Annual Meeting of Stockholders to be filed subsequently are incorporated by reference into Part III of this Annual Report on Form 10-K.

NeuroOne Medical Technologies Corporation

FORM 10-K

FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2023

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Unless the context requires otherwise, references in this Annual Report on Form 10-K (this "Annual Report" or "Report") to "we," "us," "the Company" and "our" refer to NeuroOne Medical Technologies Corporation (the "Company").

This Annual Report contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "target," "seek," "contemplate," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- the timing of and our ability to maintain regulatory clearance of our cortical strip and grid electrode technology;
- our ability to maintain regulatory clearance for our RF ablation system;
- our ability to successfully commercialize our technology in the United States;
- our ability to achieve or sustain profitability;
- our ability to raise additional capital and to fund our operations;
- our ability to access available, additional capital on terms acceptable to us at all or when needed;
- the clinical utility of our cortical strip, grid and depth electrode including technology under development;
- our ability to develop additional applications of our cortical strip, grid and depth electrode technology with the benefits we hope to offer as compared to existing technology, or at all;
- the results of our development and distribution relationship with Zimmer, Inc. ("Zimmer");
- the performance, productivity, reliability and regulatory compliance of our third party manufacturers of our cortical strip, grid electrode and depth electrode technology;
- our ability to develop future generations of our cortical strip, grid and depth electrode technology;
- our future development priorities;
- our ability to obtain reimbursement coverage for our cortical strip, grid and depth electrode technology;
- our expectations about the willingness of healthcare providers to recommend our cortical strip, grid and depth electrode technology to people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders;
- our future commercialization, marketing and manufacturing capabilities and strategy;
- our ability to comply with applicable regulatory requirements;
- our ability to maintain our intellectual property position;
- our expectations regarding international opportunities for commercializing our cortical strip, grid and depth electrode technology under including technology under development;

- our estimates regarding the size of, and future growth in, the market for our technology, including technology under development; and
- our estimates regarding our future expenses and needs for additional financing.

Forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. You should refer to the "Risk Factors" section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

These forward-looking statements speak only as of the date of this Annual Report. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the Securities and Exchange Commission (the "SEC") after the date of this Annual Report.

PART I

ITEM 1. BUSINESS

Overview

Corporate Overview of NeuroOne Medical Technologies Corporation

We were originally incorporated as Original Source Entertainment, Inc. under the laws of the State of Nevada on August 20, 2009. Prior to the closing of the Acquisition, as defined below, we completed a series of steps contemplated by a Plan of Conversion pursuant to which we, among other things, changed our name to NeuroOne Medical Technologies Corporation, increased our authorized number of shares of Common Stock from 45,000,000 to 100,000,000, increased our authorized number of shares of preferred stock from 5,000,000 to 10,000,000 and reincorporated in Delaware. On July 20, 2017, we acquired NeuroOne, Inc. (the "Acquisition"). Immediately following the closing of the Acquisition, the business of NeuroOne, Inc. became our sole focus.

Corporate Overview and History of NeuroOne, Inc.

NeuroOne, Inc. was incorporated under the laws of the State of Delaware on October 7, 2016. Its predecessor entity, NeuroOne LLC (the "LLC"), was formed on December 13, 2013 and operated as a limited liability company until it was merged with and into NeuroOne, Inc. on October 27, 2016, with NeuroOne, Inc. as the surviving entity (the "Merger"). As a result of the Merger, all of the properties, rights, privileges and powers of the LLC vested in NeuroOne, Inc., and all debts, liabilities and duties of the LLC became the debts, liabilities and duties of NeuroOne, Inc., except for the Exclusive Start-up Company License Agreement, dated as of October 1, 2014, as amended on February 22, 2017, March 30, 2019 and September 18, 2019 (the "Original WARF License"), with the Wisconsin Alumni Research Foundation ("WARF"), which was not legally transferred until May 2017. The purposes of the Merger were to: change the jurisdiction of incorporation from Minnesota to Delaware; change the ownership of the LLC's underlying assets; and convert from a limited liability company to a corporation. In December 2019, NeuroOne, Inc. was merged with and into the Company, with the Company remaining as the surviving entity.

We are a medical technology company focused on the development and commercialization of thin film electrode technology for continuous electroencephalogram ("cEEG") and stereoelectrocencephalography ("sEEG") recording, spinal cord stimulation, brain stimulation and ablation solutions for patients suffering from epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders. Additionally, we are investigating the potential applications of our technology associated with artificial intelligence. Members of our management team have held senior leadership positions at a number of medical technology and biopharmaceutical companies, including Boston Scientific, St. Jude Medical, Stryker Instruments, C.R. Bard, A-Med Systems, Nuwellis, Inc., formerly known as Sunshine Heart, Empi, Don-Joy and PMT.

We are developing our cortical sheet and depth electrode technology to provide solutions for diagnosis through cEEG recording and sEEG recording and treatment through spinal cord stimulation, brain stimulation and ablation, all in one product. A cEEG is a continuous recording of the electrical activity of the brain that identifies the location of irregular brain activity, which information is required for proper treatment. cEEG recording involves an invasive surgical procedure, referred to as a craniotomy. sEEG involves a less invasive procedure whereby doctors place electrodes in targeted brain areas by drilling small holes through the skull. Both methods of seizure diagnosis are used to identify areas of the brain where epileptic seizures originate in order to precisely locate the seizure source for therapeutic treatment if possible.

Deep brain stimulation, or DBS, therapies involve activating or inhibiting the brain with electricity that can be given directly by electrodes on the surface or implanted deeper in the brain via depth electrodes. Introduced in 1987, this procedure involves implanting a power source referred to as a neurostimulator, which sends electrical impulses through implanted depth electrodes, to specific targets in the brain for the treatment of disorders such as Parkinson's disease, essential tremor, dystonia, and chronic pain. Alzheimer's is another indication evaluating the effects of DBS. Unlike ablative technologies, the effects of DBS are reversible.

Radio frequency ("RF") ablation is a procedure that uses radiofrequency under the electrode contacts that is directed to the site of the brain tissue that is targeted for removal. The process involves delivering energy to the contacts, thereby heating them and destroying the brain tissue. The ablation does not remove the tissue. Rather, it is left in place and typically scar tissue forms in the place where the ablation occurs. This procedure is also known as brain lesioning as it causes irreversible lesions. In August 2021, the Company announced a strategic partnership with RBC Medical Innovations to develop a RF ablation generator. The following month, our OneRF ablation system was tested by representatives from Emory University in Atlanta Georgia in an animal study. During the second fiscal quarter of 2023, we successfully completed summative usability testing for OneRF with 15 neurosurgeons, and completed execution of internal device verification/validation protocols for the final OneRF ablation system.

Failed back surgery syndrome ("FBSS") is a condition that produces chronic lower back/leg pain due to one or more failed back surgeries. Typically, it is related to patients that suffer with pain after surgery of the lumbar spine for degenerative disc disease. Re-operations are usually not recommended for these patients due to low success rates. These patients experience greater levels of pain, a lower quality of life, varying levels of disability and higher rate of unemployment. Spinal cord stimulation works by placing one or more electrodes in a targeted area of the spine and then connected to an implantable pulse generator that sends electrical stimulation to the electrode to block the pain signals from reaching the brain. During the second fiscal quarter of 2023, we completed an initial animal implant of novel thin film paddle leads for spinal cord stimulation ("SCS"). The devices are intended for the treatment of patients with chronic back pain due to multiple failed back surgery syndrome, intractable low back, and leg pain. A percutaneous (through a needle) delivery system for paddle leads is also under development and has been successfully bench-tested. According to a 2020 *Market Insights* report, the total global addressable market for spinal cord stimulation is estimated to be greater than $3 billion.

Our cortical sheet electrode and depth electrode technology have been tested over the years by both WARF, the owners of our licensed patents, and Mayo Clinic located in Rochester, Minnesota, in both pre-clinical models as well as through an institutional review board ("IRB") approval at Mayo Clinic for clinical research. In December 2020, we announced the first human commercial use of our Evo cortical electrode in a procedure performed at the Mayo Clinic. Regarding our ablation electrode, the Cleveland Clinic and representatives from Emory University have performed testing in bench top models and pre-clinical (or animal testing) models. These pre-clinical tests have demonstrated that the technology is capable of recording, ablation and acute stimulation.

We received 510(k) FDA clearance for our Evo cortical technology in November 2019, in September 2021 we received FDA clearance to market our Evo sEEG electrode technology for temporary (less than 24 hours) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain, and in October 2022 we received FDA clearance to market our Evo sEEG 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.

We submitted a 510(k) application to the FDA for the OneRF ablation system in June 2023 and responded to FDA comments on November 6, 2023. On December 6, 2023, we received 510(k) FDA clearance to market the OneRF ablation system for creation of radiofrequency lesion in nervous tissue for functional neurosurgical procedures.

We intend to develop our Evo sEEG electrode technology for drug delivery applications in the next 12 months. This device is intended to deliver neurological drugs or gene therapy that are FDA approved or that are currently planned for clinical trials or in development to allow for monitoring, recording and stimulation and drug delivery for less than 30 days. In addition to having the capability of delivering a drug through the center lumen, it will also be able to record brain activity before, during, and after drug delivery.

Our Market Opportunity

Epilepsy Market

We expect to initially target the diagnosis and treatment of epilepsy. Epilepsy can be caused by a variety of conditions that affect a person's brain, some of which are: stroke, brain tumor, traumatic brain injury and central nervous system infections. According to the Centers for Disease Control and Prevention (the "CDC") and Citizens United for Research in Epilepsy ("CURE"), there are approximately 3,000,000 patients annually suffering with epilepsy in the United States, with an additional 200,000 diagnosed every year. The CDC and CURE also estimate that epilepsy costs

the United States $15.5 billion per year. Approximately 720,000 of these patients are not receptive to pharmaceutical treatment and therefore are appropriate for surgical treatment of this disorder. In addition to poor quality of life, epilepsy also is associated with fairly high mortality rates. Sudden Unexpected Death in Epilepsy has an annual incidence of 1.16/1000 in epilepsy patients. Despite the large market opportunity, it is estimated that there are only less than 5K epilepsy surgeries performed each year in the United States.[1]

These numbers represent an underpenetrated market due to the invasiveness of diagnostic procedures. After the diagnostic procedure, a second therapeutic procedure is required and at times even a third surgery if the seizures persist. We believe patients are unwilling to proceed due to the long diagnostic and treatment procedure times (one to four weeks in the hospital after a potential craniotomy for diagnosis). As detailed above, after the diagnosis is completed, if successful, the patient must undergo an additional procedure to have the affected area of brain tissue ablated or removed. The average cost for the diagnostic technology per procedure could be >$10,000, with ablation devices costing >$15,000. We believe our technology, once developed, will offer an all-in-one solution with diagnostic and therapeutic capabilities.

Many leading neurologists believe that the limits of today's current technologies are the reason the exact affected area of the brain causing epileptic seizures is not well-determined. We believe our technology, which has been developed to date by physicians at WARF and Mayo Clinic, will provide a number of advantages over the current commercially available technologies, including the following:

- Our proprietary thin film technology under development has a smaller footprint with many more electrodes.
- We expect that our technology will eventually be able to be implanted using a minimally invasive procedure utilizing a dime sized burr hole rather than a full craniotomy.
- Our technology may provide more accurate detection of irregular brain activity over currently available technology. In limited clinical testing, doctors at Mayo Clinic have documented pre-seizure activity (micro-seizures) during their clinical research with their patients using our cEEG technology.

We expect our technology can ablate through the electrodes as well as perform brain recording, monitoring and stimulation, allowing for diagnosis and treatment through the same product and in the same procedure.

Parkinson's Disease

The Parkinson's Disease Foundation estimates that as many as 1,000,000 patients in the United States live with Parkinson's disease with an additional 60,000 patients diagnosed per year. Over 10,000,000 patients worldwide are living with Parkinson's disease. There have not been any drugs introduced that have been effective at treating all patients with Parkinson's disease. The average onset is over 60 years old, but some people have been diagnosed as young as 40 years old. Parkinson's is a disorder of the central nervous system caused by loss of brain cells throughout various regions of the brain.

Today's primary treatment for Parkinson's disease involves medications that have not proven to be curative but rather ease symptoms. One of the potential treatments for Parkinson's patients is DBS. According to the Michael J. Fox Parkinson's Disease Research Foundation website, patients that seem to do best with DBS are those that have had the disease for at least four years and have benefited from taking medications prescribed to control the disease. In addition, DBS seems to help with reducing the issues with motor functions such as tremors, stiffness and slowness but not for balance issues.

Essential Tremors

Essential tremors are thought to be due to electrical irregularities in the brain that send abnormal signals to the muscles. It is a progressive condition that worsens over time and is linked to genetic disorders that typically appear in people who are over 40. Essential tremors usually occur alone and without any other neurological symptoms or

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1 Epilepsy surgery in the United States: Analysis of data from the National Association of Epilepsy Centers 2015 Epilepsy Research.

signs. The tremors usually occur when the hands are raised and primarily affect the hands. Muscles in the trunk, face and neck may also experience symptoms. Sometimes misdiagnosed as Parkinson's disease, essential tremors are an involuntary rhythmic shaking of the hands that is not present at rest. It is apparent during activities such as drinking, writing and eating. Symptoms can worsen due to stress, anxiety, smoking, caffeine, fatigue, etc. Genetics Home Reference estimates that as many as 10,000,000 people in the United States are affected by the disease. Treatments for the disease include medical therapy and DBS. DBS, which unlike other therapies, is reversible and programmable, helping to adjust the settings to maximize patient benefit. Similar to Parkinson's disease, the ability to detect this irregular brain activity before it causes a tremor is highly desirable.

Dystonia

Dystonia is a neurological condition recognized as a motion disorder that involves over activity of a variety of different muscles simultaneously that work against each other. It presents itself in a variety of symptoms but typically involves repetitive, patterned and often twisting involuntary muscle contractions resembling tremors. According to the Dystonia Medical Research Foundation, over 300,000 people are affected in the United States and Canada alone. Dystonia is the third most common problem seen in movement disorder clinics. Because it has many different manifestations, it is often misdiagnosed. In addition, similar to Parkinson's disease, there are no specific tests that can positively diagnose dystonia. A doctor typically will evaluate patient and family history, potentially do genetic testing, electroencephalogram ("EEG") testing, blood and urine tests. There are several treatment options (including medication and Botox) for patients depending on the type of dystonia. DBS may be also an alternative for certain patient sub-types.

Spinal Cord Stimulation

Chronic back pain is one of the most prevalent chronic conditions in the world. According to the CDC, "in 2016, an estimated 20.4% of U.S. adults had chronic pain and 8.0% of U.S. adults had high-impact chronic pain. Chronic pain has been linked to numerous physical and mental conditions and contributes to high health care costs and lost productivity". FBSS is one of leading causes for chronic lower back/leg pain due to one or more failed back surgeries. Typically, it is related to patients that suffer with pain after surgery of the lumbar spine for degenerative disc disease. Re-operations are usually not recommended for these patients due to low success rates. These patients experience greater levels of pain, a lower quality of life, varying levels of disability and higher rate of unemployment. Spinal cord stimulation works by placing an electrode(s) in a targeted area of the spine which is then connected to an implantable pulse generator that sends electrical stimulation to the electrode to block the pain signals from reaching the brain.

The back pain market includes the following indications: FBSS, Ischemic Limb Pain, and Complex Regional Pain Syndrome. Over half of this market is comprised of patients with FBSS. Studies have indicated a benefit for some patients suffering from chronic back and lower limb pain when they have been treated with electrical stimulation. Prior to the patient receiving an implant, they undergo a trial period that allows them to determine if they are receiving relief from the therapy while preventing a surgery to implant the pulse generator that provides the stimulation. If the trial period is successful, then the device is implanted in a follow-up procedure.

Artificial Intelligence

The brain consists of approximately 100 billion nerve cells, which are small wires that pass electrical signals to control all of its functions. There have been a number of successful clinical trials in which small metal wires, known as electrodes, are implanted in the brain to correct nerve damage using wireless communication between implanted wires to simulate functional nerve cells. In addition to correcting damaged nerve cells, certain scientists have theorized that if millions of wires could be implanted in the brain, these electrodes could present an opportunity to use artificial intelligence to create infrared sight, increase hearing or perfect memory recall. However, there currently is no commercially available manufacturing platform capable of making thousands of wires that can be placed within or on the brain and work reliably for the lifetime of a subject, and are soft enough to match the tissue of the brain, that avoid damage to the brain.

Limitations of Currently Available Therapies

There are a limited number of currently available products for diagnosis and treatment for people with neurological disorders such as epilepsy. Although the currently available systems provide diagnosis and treatment for patients, they have certain inherent limitations and shortcomings that we believe limit their use and validate the need for improved technology in the market. These limitations include:

- **Lengthy diagnostic times:** It takes several months for patients to go through the various phases of diagnostic methods, including imaging and non-invasive EEGs. If the source of seizures are still unknown, patients spend one to four weeks in the hospital after interventional diagnostic procedures (cortical and/or sEEG implants) waiting to have seizures that will allow doctors to determine where the seizures are occurring.

- **Lower Accuracy:** Historically, clinical electrode manufacturers primarily provided electrodes that sample brain tissue at approximately centimeter spatial scales. Advances in digital EEG acquisition have made recordings at sub-millimeter spatial scales possible, but high-spatial resolution EEG has been slow to impact clinical practice. Existing, higher spatial scales increase the potential for missing data that may be critical in the removal of brain tissue causing the irregular activity.

- **Need to perform a full craniotomy (invasiveness):** Currently available cortical electrode technology is typically placed after a craniotomy, which may require removing the top part of the cranium and is a very painful and invasive procedure. Procedural times for a craniotomy can be as high as eight hours. A variety of complications can occur when a full craniotomy is performed, including but not limited to: stroke, bleeding, infection, seizures, swelling of the brain (which may require a second craniotomy), nerve damage, which may cause muscle paralysis or weakness, cerebrospinal fluid leak, which may require repair, loss of mental functions and permanent brain damage with associated disabilities. The invasiveness, procedural times and possible surgical complications have limited the growth of surgical treatment of epilepsy.

- **Requirement for multiple devices for diagnostic and therapeutic procedures:** Today both interventional diagnostic and treatment procedures may require different device implants, surgeries and even hospitalizations for each procedure. This causes significant patient inconvenience, use of precious hospital resources and tremendous cost to the system.

- **Limited number of contacts on an electrode:** Paddle electrodes currently are available in a variety of sizes and number of contacts. Physicians increasingly want to explore greater number of contacts on the same electrode in order to be able to be more precise in stimulating targeted areas.

Our Solution

As a result of the inherent limitations and inconvenience of existing systems, we believe that there is a significant unmet need among people with neurological disorders for cortical strip, grid and depth electrodes that provide diagnostic capabilities through cEEG and sEEG recording in addition to therapeutic modalities, such as brain stimulation and ablation, offered as an all-in-one product. In comparison to currently available technologies, we are continuing to develop applications of our strip, grid and depth electrodes with the goal of providing the following expected advantages:

- **Reduced time for diagnosis and treatment:** By offering a minimally invasive procedure and developing an all-in-one solution, we expect our technology will reduce overall procedural times. While our pre-clinical and clinical experience to date is limited, our cortical grid technology has demonstrated the ability to provide high fidelity recordings that have allowed physicians to identify the affected brain tissue causing seizures. This may provide the potential for meaningful cost savings for hospitals and patients and improved quality of life for patients.

- **Improved accuracy of diagnostic technologies:** Because we believe our thin film technology is capable of recording at higher fidelity than current technologies used in EEG recording, we believe our technology may be able to more precisely determine the brain tissue causing seizures. In December 2020, we announced the first human commercial use of our Evo cortical electrode to perform recording, functional mapping, monitoring and stimulation of the brain. In the procedure, performed at the Mayo Clinic, our electrodes

were used to record evidence of pre-seizure activity, which may be critical in developing treatments to prevent the onset of seizures. Since then, several institutions around the country have successfully tried and adopted our devices for diagnostic procedures.

- **Implantation via minimally invasive procedure with fewer post-procedure complications:** We are currently developing approaches to deliver the electrodes by minimizing the invasiveness of the procedures. We expect that patients who have qualified for diagnostic or treatment procedures will be more accepting of a minimally-invasive procedure. Such procedures may potentially reduce the patient's pain, bleeding and other adverse events. For example, our cortical electrode technology is expected to also have fewer wires, also referred to as tails, exiting the patient's head, which can also reduce the potential for infections. Furthermore, the material we currently use in our cortical electrodes has shown in pre-clinical evaluations to cause less inflammation than current electrode substrates as it appears more compatible with brain tissue. As discussed under "Our Strategy" below, our technology has been and will be implanted via a full craniotomy until such time, if ever, as we are able to develop our minimally invasive procedure.

- **All-in-one diagnostic and therapeutic technology solution:** Due to the expected recording and treatment capabilities of some of our technology under development, we have received feedback from physicians that they will attempt to perform the diagnosis and treatment in a single procedure, thereby potentially eliminating the need for a second surgical procedure, reducing the likelihood of patient infection, risks associated with surgical procedures and minimizing the diagnostic, procedural and hospital costs. As discussed under "Our Strategy" below, our initial product offering offers diagnostic-only capabilities while we advance the development of our all-in-one approach. Currently, we are preparing a combination recording, stimulation and RF ablation technology that will perform both diagnostic and therapeutic functions for commercialization.

- **Percutaneous placement of spinal cord stimulation paddle electrodes with scalability options:** Due to the thin film nature of our electrode technology, we believe that it may allow for percutaneous placement of "paddle" (flat) shaped electrodes, thereby preventing the need to use more invasive surgical approaches to place the electrodes. Minimally invasive and percutaneously placed technologies have become almost a requirement for adoption with patients and physicians. In addition, our technology in the future offers the ability to increase the number of contacts on a film that traditionally offers fewer contacts. Increasing the number of contacts may allow for more precise stimulation in the spine, potentially improving the therapeutic outcomes.

Our Strategy

Our goal is to be the global leader in cEEG and sEEG recording, monitoring, deep brain stimulation and ablation, owning the procedure from diagnosis through treatment. The key elements of our strategy include:

- **Introduce cortical strip and grid electrodes for the diagnosis of epilepsy in United States:** In December 2019, we announced that we received FDA 510(k) clearance to market our thin film cortical electrode technology for temporary (less than 30 days) recording, monitoring, and stimulation on the surface of the brain. Our initial product offering has initially been and will be placed through traditional surgical means involving a craniotomy until such time, if any, that we launch our minimally invasive procedure. In July 2020, we entered into a development relationship with Zimmer, pursuant to which we granted Zimmer exclusive global rights to distribute the cortical strip and grid electrodes, and Zimmer will use commercially reasonable efforts to promote, market and sell the strip and grid electrodes. We believe, due to physician feedback, that our technology represents a major improvement over existing cortical electrodes for the recording of brain activity. We are initially targeting epilepsy as we believe this is a clinical area of great need and a market that is underserved with a quick path to commercialization. We believe the largest and quickest-to-market geography for our cortical strip and grid technology under development is the United States for a number of reasons, including the following: (i) many industry sources believe there is a large underserved U.S. market, (ii) healthy procedural reimbursement exist for centers and physicians, (iii) average selling prices are robust, and (iv) there is substantial physician enthusiasm for our technology under development. To date, several institutions around the country have successfully tried and adopted our cortical electrode technology for diagnostic procedures.

- **Launch depth electrodes for sEEG recording:** In September 2021, we announced that we received FDA 510(k) clearance to market our Evo sEEG electrode technology for temporary (less than 24 hours) use with recording, monitoring, and stimulation equipment for recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain. We filed for 510(k) clearance to expand the duration of use up to less than 30 days in November 2021. On October 20, 2022, the Company received an FDA clearance to market its Evo sEEG 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. Given the reluctance of patients to undergo epilepsy surgery due to its invasiveness, a number of epilepsy centers have adopted the use of depth electrodes, which are placed by drilling small holes into the patient's cranium, thereby avoiding a craniotomy. We believe our technology offers advantages compared to current depth electrode technology in the market and will also enable us to offer a therapeutic solution using this same technology in the future. As we continue to develop our technology, we plan to release further information about the expected advantages of our technology over currently available therapies.

- **Utilize these core technologies to develop all-in-one diagnostic and therapeutic solutions with the initial focus on a combination diagnostic and ablation electrode:** For many patients who currently undergo one surgical procedure for diagnosis, a second and different procedure or surgery is then required to treat the patient. There is strong physician/surgeon interest to be able to perform both the diagnostic and therapeutic procedure with the same implanted devices. We are developing our technology with the goal of being able to offer this benefit although there can be no assurance that we will be able to do so. We are pursuing cortical grid, strip and depth electrode technology that can record brain activity (diagnose) and also provide both acute and long term stimulation as well as depth electrode technology that can ablate brain tissue. The technology has demonstrated these functions in acute and short term animal models; however, additional development is required to offer a device that has long term therapeutic application. These long term therapeutic technologies are expected to require more robust regulatory approvals for the United States, ranging from a 510(k) to potential for pre-market approvals ("PMAs") with human clinical data. We will engage the FDA at the proper time to determine the most efficient regulatory path.

- **Develop percutaneous placed electrodes for spinal cord stimulation with scalable contact configurations:** Given that many surgically placed technologies have become less invasive due to patient and physician demands, we believe that our flexible thin film technology will allow for percutaneous placement of "paddle" shaped electrodes, thus potentially eliminating the need to make a more invasive surgical procedure. Spinal cord clinical literature over the years have shown that "paddle" electrodes (flat shaped) require less energy for stimulation (thus saving neurostimulator battery life) and may be associated with lower revision rates over time. Even then, "paddle" shaped electrodes are used less often due to the more invasive surgical procedure that is required for placement. But we hope to change that paradigm by creating "paddle" electrodes that can be implanted percutaneously (less invasively) through a "needle hole incision". By leveraging our existing FDA cleared cortical electrode and sEEG technology, we may also be able to offer the ability to improve precision of where the stimulation is delivered. NeuroOne's platform thin film technology has the capability to increase the number of contacts in a similar footprint that has fewer contacts.

- **Gain approval for other brain or motor related disorders such as Parkinson's with the therapeutic technologies developed for epilepsy:** While we are developing our technology for the diagnosis and treatment of epilepsy, we believe that our technology has strong application and utilization for other brain or motor related disorders such as Parkinson's disease, dystonia, essential tremors and facial pain as these diseases are currently treated with DBS if medications are not effective. As previously mentioned, we are actively evaluating the potential to offer electrodes that can be implanted for long term stimulation applications, but such use will require that we pursue additional approvals from the FDA and any international regulatory bodies where we seek to commercialize our technology.

- **Explore partnerships with other companies that leverage our core technology:** Given that 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, we believe there may be opportunities to establish mutually beneficial relationships. 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.

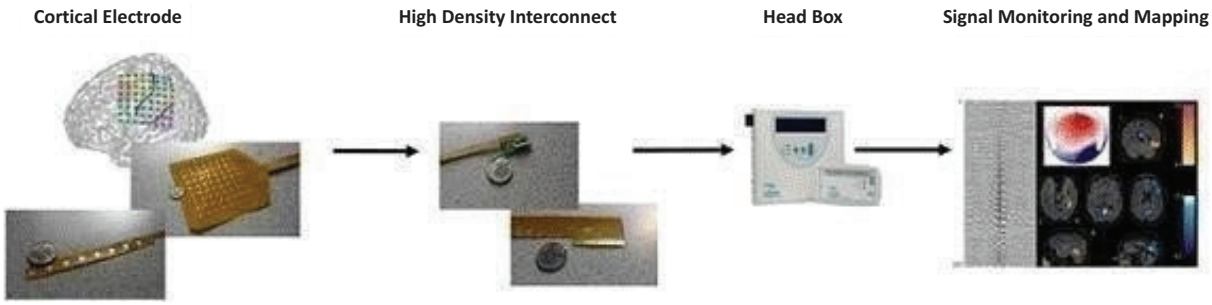
- **Partner with biotech, pharmaceutical or biopharma companies to provide a drug delivery sEEG electrode capable of delivering the therapy and recording before, during and after the therapy is delivered for up to 30 days.**
- **Investigate the potential applications associated with Artificial Intelligence:** We have been informed by some of our corporate advisors that the ability to offer scale-able electrode technology that can provide thousands of electrodes in the brain may be helpful in treating medical conditions that may benefit from using artificial intelligence. The Company has formed an advisory board that will provide guidance to the Company as we continue to explore the opportunities in this exciting field.

Our Technology

Epilepsy Mapping and Monitoring

Epileptic seizures occur when the neurons in the brain miscommunicate. This miscommunication typically results in involuntary muscle seizure activities and/or periods of perceptual disconnect where the individual appears frozen. Modern medical science has advanced the treatment of epileptic seizures by mapping the electrical communication activity of neurons and understanding their special orientation in the brain. This mapping is accomplished by access to the cranium (through a craniotomy) and placing conductive contacts on the brain directly. The craniotomy procedure is very invasive, traumatic to the surrounding tissue, results in high patient down time, and increases the risk of infection.

We seek to leverage scale-able technology and produce ultra-thin, or paper-thin electrodes that allow for high-resolution and high-definition recordings, which would improve mapping resolution and signal acquisition. If the Company is able to leverage scale-able technology, it would mean that our technology would be able to incorporate smaller electrodes and thereby increase the number of electrodes on a given surface area. We expect that this would increase the imaging resolution so that brain activity is displayed in greater definition. We also believe that the electrodes' unique thinness and flexibility will provide a less invasive approach to electrode placement. The electrodes would be able to be placed through a small quarter size hole instead of by an invasive full craniotomy procedure.



The images under "Cortical Electrode," from bottom to top, are images of our cortical electrode strip, our grid electrode, and the placement of the grid electrode on the brain, respectively. The images under "High Density Interconnect" are both images of our product that connects our electrodes to the head box, which is a piece of hardware that connects to electrodes to acquire, amplify, display, store and archive electrophysiological signals, and is integrated as part of our manufactured electrode product. The images under "Head Box" and "Signal Monitoring and Mapping" are images of the device which processes information received through the high density interconnect, and a sample output of data acquisition, respectively, neither of which is one of the Company's products.

Our technology consists of three primary types of cortical electrodes: grid electrodes, strip electrodes and dual-sided electrodes. These electrodes have a patented design that utilizes proprietary processing and materials technology, which we believe will allow the electrodes to have improved features over the current industry standard recording electrodes.

What sets our technology apart from others is the integration of state of the art design leveraging the latest in flexible printed circuit technology. We believe our patented designs will provide the surgeon a higher tactile perspective on electrode placement allowing for ultra-precise neuron recording. We expect the benefits of our electrode designs to include the ability to detect better defined margins between healthy tissue and resect-able tissue, less immune-response from the brain and surrounding tissue, better signal acquisition due to superior conformability of the electrode over the brain, improved flexibility that physicians have requested, which we expect will enable a minimally invasive approach and the electrodes unique thinness that is unmatched by current products being used.

The Future of Neurology Mapping with NeuroOne

We seek to develop superior "scale-able" technology for future product system iterations in higher density contact placement. This will open the doors to other brain related disease recording procedures by providing high fidelity, more accurate diagnostic capabilities and also the ability to provide an all-in-one therapy capable of diagnosis, ablation and/or stimulation. Beyond the brain, we believe our technology under development has applications in other neurological signal recording disease states related to voluntary or involuntary motor neuron abnormalities, understanding sensory neuro behavior (pain), limb prosthetics and degenerative muscle disease.

Clinical Development and Regulatory Pathway

Clinical Experience, Future Development and Clinical Trial Plans

Our Evo cortical electrode technology has received 510(k) clearance from the FDA for recording, monitoring, and stimulating brain tissue for less than 30 days on the surface of the brain. Our Evo sEEG electrode technology has received FDA 510(k) clearance from the FDA for use (less than 30 days) with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain. Our other products have not received any clearance for commercialization by any U.S. or foreign regulatory body. To date, the Company has performed a number of bench top (which includes feasibility testing) and pre-clinical tests (which include animal testing of device placement, ergonomics, performance, ease of use, and other tests required by FDA regulations). As described in "— Government Regulation" below, the Company will be required to perform additional testing of its technology in connection with seeking additional regulatory clearances or approvals.

We intend to expand our product offerings to include less invasive means and all-in-one solutions, thus providing both patients and physicians better options to treat epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders. While we expect to make modifications to our initial system, we believe that most of our future product development initiatives will involve unique and transformational next generation technology that should drive further appeal of our products with both physicians and patients.

We are utilizing a number of resources to develop these technologies. We license three critical patents from WARF that are the foundation of the technology and we are developing and intend to commercialize and benefit from the thin film technology know-how of Mayo Clinic doctors through our license and development agreement. WARF, Mayo Clinic (cortical electrodes) and Cleveland Clinic (sEEG electrodes) have been responsible for all pre-clinical studies of our technology under development to date. See "— WARF License" and "— Mayo Foundation for Medical Education and Research License and Development Agreement" below. We announced in December 2020 that Mayo Clinic doctors used our technology in the first human commercial application of our Evo cortical electrode technology to perform recording, functional mapping and stimulation of the brain on a human patient. And more recently, in July 2022, we announced the first clinical case using the Evo sEEG electrode was performed by Dr. Robert Gross at Emory University. Dr. Gross selected the Evo sEEG electrode for intraoperative brain mapping at the subsurface level of the brain.

Below we have summarized, for each component of our technology, the current stage of development or commercial production, the pre-clinical testing done to date by WARF, the Cleveland Clinic or Mayo Clinic on such component, if any, our plans for further testing or clinical trials and our expectations regarding the requirements for regulatory clearance or approval and timing of regulatory submissions.

Technology	Stage of Development and Pre-Clinical Testing to Date	Additional Expected Steps for Regulatory Clearance or Approval
Cortical strip and grid electrodes for the diagnosis of epilepsy	The Company has finalized the design for the product and there are no further expected changes to the device ("design freeze"). Pre-clinical testing and clinical testing on the final design has been conducted by Mayo Clinic and WARF (as described in "Mayo Clinic and University of Wisconsin-Madison Studies" below). The product is in commercial production.	The Company received FDA 510(k) clearance in the fourth calendar quarter of 2019. Commercial launch commenced utilizing Zimmer, our distribution partner.
Depth electrodes for recording (diagnostic) purposes	We have frozen this design and the product is in commercial production. No clinical testing was required in order to obtain FDA clearance.	The Company filed for FDA 510(k) marketing clearance for sEEG electrodes in May 2021 and received a 510(k) clearance from FDA for recording, monitoring and stimulation of brain tissue for less than 24 hours in September 2021. The Company filed for 510(k) clearance to expand the duration of use up to less than 30 days in November 2021. On October 20, 2022, the Company received an FDA clearance to market its Evo sEEG 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. Zimmer began distributing this product in May 2023.
Depth electrode diagnostic and ablation devices	The design phase was completed at the end of 2022, the verification phase was completed in June 2023, and the transfer to manufacturing phase began in July 2023. Pre-clinical testing, including benchtop and animal testing, has been conducted on final designs. Very early testing at the Cleveland Clinic was completed in the second calendar quarter of 2020. Pre-clinical (animal) feasibility testing was conducted in September 2021 with representatives from Emory University in Atlanta, Georgia. Additional pre-clinical animal testing of our final design was conducted at Emory University in April 2023 and invivo testing of our final design was conducted in May 2023.	The Company submitted a 510(k) application to the FDA for the OneRF ablation system in June 2023 and responded to FDA comments on November 6, 2023. The Company received 510(k) clearance from the FDA for creation of radiofrequency lesions in nervous tissue for functional neurosurgical procedures on December 6, 2023.

Technology	Stage of Development and Pre-Clinical Testing to Date	Additional Expected Steps for Regulatory Clearance or Approval
	The Company announced a partnership with RBC Medical Systems in August 2021 to develop an RF generator that will be used with the Company's diagnostic and ablation electrode. No animal or human clinical testing is anticipated for FDA submission since 510K predicate devices did not perform such clinical testing.	
Spinal cord stim electrodes	No design freeze. We performed pre-clinical in-house bench top testing in August 2020. In 2021/early 2022, we performed bench top testing of prototypes to demonstrate chronic performance and longevity. In 2023, we will continue to refine our chronic spinal cord electrode design based on SCS customer feedback and do additional pre-clinical bench and/or animal tests to further validate our value proposition.	This device is in early stages of development. Once the design is finalized, we will be required to conduct additional pre-clinical testing, which may include additional benchtop or animal testing for safety and performance. Additionally, the FDA may require that we conduct human clinical studies. No FDA feedback has been sought or received by us to date on the regulatory/clinical process that may be required for spinal cord stimulation indication, but we expect regulatory PMA approval will require a more robust clinical process, human clinical data for a PMA (implanted system), depending on proposed indications for use. Future pre-clinical and clinical testing requirements for regulatory submission will continue to be evaluated as we develop the design of this product.
Depth electrode chronic stimulation devices	No design freeze. Bench top testing were successfully performed in 2021 and early 2022. We announced the results of these studies in the first quarter of 2022. While this device remains in early development, we expect to work with clinicians to further refine our designs and continue testing in 2023.	Following a design freeze, we will be required to conduct additional pre-clinical testing, which may include additional benchtop or animal testing for safety and performance. Additionally, FDA-approved human clinical studies will most likely be required. No FDA feedback has been sought or received by us to date on the clinical process that will be required for chronic stimulation, but we expect regulatory approval for chronic stimulation may require a more robust clinical process, which could include a PMA with human clinical data. Because we have not yet met with the FDA, we cannot yet determine what clinical data and testing we will need to complete or what the testing will need to demonstrate. However, we believe, based on the experience of competitors for similar technology, that we will need to conduct clinical trials, which we estimate will require an investment of over $2,000,000.

Mayo Clinic and University of Wisconsin-Madison Studies

Our cortical technology for the diagnosis of epilepsy has been tested by doctors at Mayo Clinic in multiple pre-clinical tests conducted from 2012 to 2017. In pre-clinical models, doctors examined the biological impact on mammalian brains. Polyimide substrate electrodes (NeuroOne technology) were implanted on the pig's brain for one week alongside standard competitive electrodes. The tissue underneath the two types of electrodes was removed, fixed, stained, and examined for immunological responses. The results of a histological (evaluation of brain tissue under a microscope) analysis showed reduced immunological reaction to prolonged polyimide substrate implants (NeuroOne technology) compared to standard silicone substrate clinical electrodes. Electrophysiological recordings showed data obtained from polyimide electrodes which demonstrated the feasibility of high fidelity multi-scale electrophysiology while also displaying easier deployment of polyimide electrodes (NeuroOne technology) through minimally invasive burr holes.

Additionally, doctors implanted our polyimide thin film electrodes on five human patients who were undergoing surgery to remove brain tissue for drug resistant epilepsy. Electrophysiological recordings from the polyimide thin film technology displayed in each of these patients demonstrated micro-seizure activity due to the high fidelity multi-scale electrophysiology. In December 2020, we announced the first human commercial use of our Evo cortical electrode to perform recording, functional mapping and stimulation of the brain. In the procedure, performed at the Mayo Clinic, our electrodes were used to record evidence of pre-seizure activity which may be critical in developing treatments to prevent the onset of seizures.

Conclusions reached by the physicians at Mayo Clinic were that thin, flexible polyimide electrodes (NeuroOne technology) provided recordings similar to standard clinical electrodes with reduced immunological response. In addition, Mayo Clinic physicians observed that the flexibility of polyimide electrodes may reduce pain and swelling associated with implantation of the device, and the single wire exiting the skull may reduce infection risk. The ability to record micro-seizure and single neuron brain activity may also provide additional useful clinical data. Combined, these properties suggest that the replacement of current competitive silicone electrodes with polyimide substrate electrodes (NeuroOne technology) for recording brain activity for epilepsy could provide enhanced clinical value with reduced cost, reduced infection risk, and improved patient comfort.

In addition, our thin film cortical implant technology has been tested by researchers at the University of Wisconsin-Madison in multiple pre-clinical animal studies conducted from 2006 to 2016, which included mice, rats and primates. In these studies, our technology was able to record brain activity from different areas of the brain, was implanted in a minimally invasive fashion, electrically provided brain stimulation and tissue ablation, and had increased flexibility compared to existing commercially available technology, which allowed the grids to conform more easily to the brain surface (and may have reduced pain and swelling, compared to less flexible devices).

Sales and Marketing

Zimmer Development Agreement

Based on the size and maturity of the U.S. market and our initial commercial focus, on July 20, 2020, we entered into an exclusive development and distribution agreement (the "Development Agreement") with Zimmer, pursuant to which we granted Zimmer exclusive global rights to distribute NeuroOne's strip and grid cortical electrodes (the "Strip/Grid Products") and electrode cable assembly products (the "Electrode Cable Assembly Products"), including to approximately 188 Level 4 epilepsy centers. Additionally, we granted Zimmer the exclusive right and license to distribute certain depth electrodes developed by the Company ("SEEG Products", and together with the Strip/Grid Products and Electrode Cable Assembly Products, the "Products"). The parties have agreed to collaborate with respect to development activities under the Development Agreement through a joint development committee composed of an equal number of representatives of Zimmer and the Company.

Under the terms of the Development Agreement, we are responsible for all costs and expenses related to developing the Products, and Zimmer is responsible for all costs and expenses related to the commercialization of the Products. In addition to the Development Agreement, Zimmer and the Company have entered into a Manufacturing and Supply Agreement (the "MS Agreement") and a supplier quality agreement (the "Quality Agreement") with respect to the manufacturing and supply of the Products.

Except as otherwise provided in the Development Agreement, we are responsible for performing all development activities, including non-clinical and clinical studies directed at obtaining regulatory approval of each Product. Zimmer has agreed to use commercially reasonable efforts to promote, market and sell each Product following the "Product Availability Date" (as defined in the Development Agreement) for such Product.

Pursuant to the Development Agreement, Zimmer made an upfront payment of $2.0 million to the Company in August 2020.

In August 2022, we entered into an amendment to the Development Agreement with Zimmer that provided us with a $3.5 million accelerated payment relating to certain milestone events. In addition, Zimmer received a Warrant to purchase 350,000 shares of our Common Stock, with an exercise price of $3.00 per share.

The Development Agreement will expire on the tenth anniversary of the date of the first commercial sale of the last of the Products to achieve a first commercial sale, unless terminated earlier pursuant to its terms. Either party may terminate the Development Agreement (x) with written notice for the other party's material breach following a cure period or (y) if the other party becomes subject to certain insolvency proceedings. In addition, Zimmer may terminate the Development Agreement for any reason with 90 days' written notice, and we may terminate the Development Agreement if Zimmer acquires or directly or indirectly owns a controlling interest in certain competitors of the Company.

We will investigate markets outside of the U.S. with the assistance of Zimmer and formulate a plan to enter those markets with the support of Zimmer.

For more information regarding the Development Agreement, see "Management's Discussion and Analysis of Financial Condition and Results of Operations-Financial Overview-Collaborations Revenue" and "Note 7 — Zimmer Development Agreement" included in "Item 8 — Financial Statements and Supplementary Data" in this Report.

Reimbursement

Coverage in the United States

Reimbursement from private third-party healthcare payors and, to a lesser extent, Medicare will be an important element of our success. Although the Centers for Medicare and Medicaid Services ("CMS") and third-party payors have adopted coverage policies for our targeted indications, there is no guarantee this will continue at the same levels or at all in the future. Current Procedural Terminology, or CPT, is a medical code set that is used to report medical, surgical and diagnostic procedures and services to entities such as physicians, health insurance companies and accreditation organizations.

Applicable diagnostic CPT codes for mapping (diagnosing) the brain for diagnostic procedures are as follows:

- 61531 Subdural implantation of strip electrodes through one or more burr or trephine (saw) hole(s) for long-term seizure monitoring;
- 61533 Craniotomy with elevation of bone flap: for subdural implantation of an electrode array, for long term seizure monitoring;
- 61535 Craniotomy with elevation of bone flap; for removal of epidural or subdural electrode array, without excision of cerebral tissue (separate procedure); and
- 61760 Stereotactic implantation of depth electrodes into the cerebrum for long term seizure monitoring.

Regarding ICD-10 codes, the International Classification of Diseases, Tenth Edition (ICD-10) is a clinical cataloging system that went into effect for the U.S. healthcare industry on October 1, 2015, after a series of lengthy delays. Accounting for modern advances in clinical treatment and medical devices, ICD-10 codes offer many more classification options compared to those found in its predecessor, ICD-9. Within the healthcare industry, providers, coders, IT professionals, insurance carriers, government agencies and others use ICD codes to properly note diseases on health records, to track epidemiological trends and to assist in medical reimbursement decisions.

ICD-10 codes for epilepsy are as follows:

- G40.0 Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset;
- G40.1 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures;
- G40.2 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures;
- G40.3 Generalized idiopathic epilepsy and epileptic syndromes;
- G40.A Absence epileptic syndrome;
- G40.4 Other generalized epilepsy and epileptic syndromes;
- G40.50 Epileptic seizures related to external causes, not intractable;
- G40.80 Other epilepsy; and
- G40.82 Epileptic spasms.

We believe that many of the indications we are pursuing with our technologies are currently reimbursed on a widespread basis by Medicare, Medicaid and private insurance companies.

Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medical devices, and, as a result, their coverage policies may be restrictive, or they may not cover or provide adequate payment for our products. In order to obtain reimbursement arrangements, we may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. Our revenue may be limited by the continuing efforts of government and third-party payors to contain or reduce the costs of healthcare through various increasingly sophisticated means, such as requiring prospective reimbursement and second opinions, purchasing in groups, or redesigning benefits. Our future dependence on the commercial success of our technologies makes us particularly susceptible to any cost containment or reduction efforts. Accordingly, if government and other third-party payors do not provide adequate coverage and reimbursement for our products and the related insertion and removal procedures, our financial performance will be negatively impacted.

Manufacturing, Supply and Quality Assurance

We currently outsource the supply and manufacture of all components of our prototypes of our technology under development. We plan to continue with an outsourced manufacturing arrangement for the foreseeable future. Our third-party manufacturers are recognized in their field for their competency to manufacture the respective portions of our system and have quality systems established that meet FDA requirements. We believe at this time the manufacturers we currently utilize have sufficient capacity to meet our requirements. We believe that as we increase our demand in the future, our per-unit costs will decrease materially. We have also identified capable second source manufacturers and suppliers in the event of disruption from any of our primary vendors.

Our suppliers meet the latest ISO 13485 certification, which includes design control requirements. As a medical device developer, the facilities of our sterilization and other critical suppliers are subject to periodic inspection by the FDA and corresponding state and foreign agencies. We believe that our quality systems and those of our suppliers are robust and achieve high product quality. We plan to audit our suppliers periodically to ensure conformity with the specifications, policies and procedures for our devices.

Research and Development

Our research and development team, which includes our Director of Electrode Development, utilizes advice from leading experts in the neurotech field on our scientific advisory board and is focused on the development of thin film cortical grid and strip electrodes and depth electrodes for recording, ablation and chronic stimulation for brain related disorders as well as stimulation for spinal cord stimulation for back related pain. Our research and development expenses were $6.9 million and $4.9 million for the years ended September 30, 2023 and 2022, respectively.

Competition

In the market for Epilepsy diagnosis, our cortical strip, grid and depth electrode technology will likely compete with Integra Life Science's Integra Epilepsy Strip, Grid and depth electrodes, which provide a similar function to our diagnostic technologies. These products are well established in the marketplace and Integra has greater resources than us, which could allow them to innovate faster. Ad-Tech Medical Instrument Corporation's Epilepsy/LTM (subdural grid, strip and depth) electrodes, which have become the market leaders for diagnostic mapping in epilepsy, and PMT's Cortac Strips and grid electrodes and Depthalon depth electrodes are used for recording brain activity similar to other competitive technologies. In addition, Dixie Medical has launched a product line of depth electrodes and CorTec has launched a cortical electrode product line called AirRay. Today's success rates for seizure free post-operative conditions remain at 50%, which has limited patients' willingness to undergo the currently highly invasive surgical procedure. We will also compete against other companies in early stages of development of thin film technologies.

In the neuro-ablation market, we expect to compete with Medtronic's Visualase guided-laser ablation technology and Monteris Medical's NeuroBlate technology, which use MRI guided laser surgical ablation for use to ablate, necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers. Their website claims it is used for ablation in the brain for soft tissue and tumors. We believe there are other laser-based systems in development that will compete with these technologies.

In the neurostimulation market, we expect to compete with NeuroPace's RNS system approved for epilepsy, Medtronic's Activa system approved for Parkinson's disease, Boston Scientific Vercise (indicated for Parkinson's, dystonia and essential tremors), Abbott/St. Jude Medical's Infinity DBS system (approved for Parkinson's disease and essential tremors), Liva Nova/Cyberonic's VNS therapy intended for patients suffering with epilepsy.

Although we will face potential competition from many different sources, we believe that our technology, knowledge, experience and scientific resources will provide us with competitive advantages. For a discussion of the key competitive factors that we believe will impact the success of our cortical strip, grid electrodes under development, if successfully developed and approved, see "— Our Solution" above.

Many of the companies against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development.

WARF License

In January 2020, we entered into an Amended and Restated Exclusive Start-Up Company License Agreement, dated as of January 21, 2020, as amended on June 15, 2020 (the "WARF License") with WARF, which amended and restated in full the Original WARF License. Pursuant to the WARF License, WARF has granted to us an exclusive license to make, use and sell, in the United States only, products that employ certain licensed patents for a neural probe array or thin-film micro electrode array and method. We have agreed to pay WARF a royalty equal to a single-digit percentage of our product sales pursuant to the WARF License, with a minimum annual royalty payment of $50,000 for calendar year 2020, $100,000 for calendar year 2021 and $150,000 for calendar year 2022 and each calendar year thereafter that the WARF License is in effect. The minimum annual royalty payment for calendar year 2020 in the amount of $50,000 was paid in January 2021. If we or any of our sublicensees contest the validity of any licensed patent, the royalty rate will be doubled during the pendency of such contest and, if the contested patent is found to be valid and would be infringed by us if not for the WARF License, the royalty rate will be tripled for the remaining term of the WARF License.

WARF may terminate this license on 30 days' written notice, if we default on the payments of amounts due to WARF or fail to timely submit development reports, actively pursue our development plan or breach any other covenant in the WARF License and fail to remedy such default in 90 days or in the event of certain bankruptcy events involving us. WARF may also terminate the WARF License (i) on 90 days' notice if we had failed to have commercial sales of one

or more FDA-approved products under the WARF License by June 30, 2021 or (ii) if, after royalties earned on sales begin to be paid, such earned royalties cease for more than four calendar quarters. The first commercial sale occurred on December 7, 2020, prior to the June 30, 2021 deadline. The WARF License otherwise expires by its terms on the date that no valid claims on the patents licensed thereunder remain. We expect the latest expiration of a licensed patent to occur in 2030.

In addition, WARF reserves the right to grant non-profit research institutions and government agencies non-exclusive licenses to practice and use the inventions of the licensed patents for non-commercial research purposes, and we grant WARF a non-exclusive, sub licensable, royalty-free right and license for non-commercial research purposes to use improvements to the licensed patents. In the event that we discontinue use or commercialization of the licensed patents or improvements thereon, we must grant WARF an option to obtain a non-exclusive, sub-licensable, royalty-bearing license to use the improvements for commercial purposes.

See "Risk Factors — Risks Related to Our Business — We depend on intellectual property licensed from WARF for our technology, including our technology under development, and the termination of this license would harm our business" for additional information regarding the WARF License.

Mayo Foundation for Medical Education and Research License and Development Agreement

In May 2017, we entered into an Amended and Restated License and Development Agreement, dated as of May 25, 2017 (the "Mayo Development Agreement"), with Mayo Foundation for Medical Education and Research ("Mayo") to license worldwide (i) certain know how for the development and commercialization of products, methods and processes related to flexible circuit thin film technology for the recording of tissue and (ii) the products developed therefrom, and to partner with Mayo to assist the Company in the investigation, research application, development and improvement of such technology. Mayo has agreed to assist us by providing access to certain individuals at Mayo (the "Mayo Principal Investigators"), in developing our cortical thin film flexible circuit technology, including prototype development, animal testing, protocol development for human and animal use, abstract development and presentation and access to and license of any intellectual property that the Mayo Principal Investigators develop relating to the procedure.

We have agreed to pay Mayo a royalty equal to a single-digit percentage of our product sales pursuant to the Mayo Development Agreement. Mayo may purchase any developed products licensed under the Mayo Development Agreement at the best price offered by us to the end user in the prior year. The Mayo Development Agreement generally will expire in October 2034, unless the Mayo know-how and improvements under the Mayo Development Agreement remain in use, and the Mayo Development Agreement may be terminated by Mayo for cause or under certain circumstances.

For additional information regarding the Mayo Development Agreement, see "Risk Factors — Risks Related to Our Business — We depend on our partnership with Mayo to license certain know how for the development and commercialization of our technology. Termination of this partnership would harm our business, and even if this partnership continues, it may not be successful."

Intellectual Property

Protection of our intellectual property is a strategic priority for our business. We rely on a combination of patents, trademarks, copyrights, and trade secrets as well as nondisclosure and assignment of invention agreements, material transfer agreements, confidentiality agreements and other measures to protect our intellectual property and other proprietary rights.

Patents

As of September 30, 2023, our patent estate consists of three issued United States patents licensed from WARF covering a neural probe array and thin-film micro electrode array and method, a U.S. patent issued in October 2022 and a pending European patent application filed by us and published in 2020 relating to improved neural depth electrodes, a pending U.S. patent application filed by us and published in 2020 relating to agent-delivering neural electrodes in which a Notice of Allowance was issued in August 2023 (along with a second pending U.S. patent application filed in 2023 relating to the same technology), pending U.S. and European patent applications published in 2020 relating to minimally invasive electrodes (with a Notice of Allowance issued in September 2023 in the

U.S. application), pending U.S. and European patent applications published in 2021 relating to spinal cord stimulation systems and devices (with a Notice of Allowance issued in October 2023 in the U.S. application), pending U.S. and European patent applications published in 2022 relating to methods of making electrode probes, a pending U.S. patent application (and corresponding PCT application) published in 2023 relating to devices having temperature sensors, a pending U.S. patent application (and corresponding PCT application) filed in 2023 relating to deformable spinal cord stimulation devices, a pending U.S. patent application (and corresponding PCT application) filed in 2023 relating to spinal cord stimulation device implantation methods, and a pending U.S. patent application (and corresponding PCT application) filed in 2023 relating to ablation probe and temperature sensing device systems. The licensed issued patents expire between 2025 and 2030, subject to any patent extensions that may be available for such patents. The issued patent owned by NeuroOne expires in 2041. If a patent or patents are issued on our additional pending patent applications, the resulting patents are projected to expire between 2038 and 2043.

Our patent applications may not result in issued patents, and any patents that have been issued or may be issued in the future may not protect the commercially important aspects of our technology. Furthermore, the validity and enforceability of our issued patents may be challenged by third parties and our patents could be invalidated or modified by the issuing governmental authority. Third parties may independently develop technology that is not covered by our patents that is similar to, or competes with, our technology. In addition, our intellectual property may be infringed or misappropriated by third parties, particularly in foreign countries where the laws and governmental authorities may not protect our proprietary rights as effectively as those in the United States.

The medical device industry in general, and the recording, ablation and neurostimulation sector of this industry in particular, are characterized by the existence of a large number of patents and frequent litigation based on assertions of patent infringement. We are aware of numerous patents issued to third parties that may relate to the technology used in our business, including the design and manufacture of electrodes and pulse generators, as well as methods for device placement. Each of these patents contains multiple claims, any one of which may be independently asserted against us. The owners of these patents may assert that the manufacture, use, sale or offer for sale of our cortical strip and grid electrodes infringe one or more claims of their patents. Furthermore, there may be additional patents issued to third parties of which we are presently unaware that may relate to aspects of our technology that such third parties could assert against us and materially and adversely affect our business. In addition, because patent applications can take many years to issue, there may be patent applications that are currently pending and unknown to us, which may later result in issued patents that third parties could assert against us and materially and adversely affect our business.

Any adverse determination in litigations or post grant trial proceedings at the Patent Office relating to intellectual property to which we are or may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties, and could result in the cancellation and/or invalidation of our intellectual property. Furthermore, if a court finds that we have willfully infringed a third party's intellectual property, we could be required to pay treble damages and/or attorney fees for the prevailing party, in addition to other penalties. Although intellectual property disputes in the medical device area are often settled through licensing or similar arrangements, costs associated with such arrangements can be substantial and often require ongoing royalty payments. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement; if we are able to redesign our products to avoid infringement, we may not receive FDA approval in a timely manner. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which could have a significant adverse impact on our business.

Trademarks

We have registered U.S. trademarks for the trademarks "NEUROONE" and "EVO". We have a pending U.S. trademark application for the trademark OneRF. We also have registered trademarks in the United Kingdom and the European Union for the trademark OneRF.

Trade Secrets

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect such intellectual property and proprietary information by generally requiring our employees, consultants, contractors, scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements upon the commencement of their employment or engagement as the case may

be. Our agreements with our employees prohibit them from providing us with any intellectual property or proprietary information of third parties. We also generally require confidentiality agreements or material transfer agreements with third parties that receive or have access to our confidential information, data or other materials. Notwithstanding the foregoing, there can be no assurance that our employees and third parties that have access to our confidential proprietary information will abide by the terms of their agreements. Despite the measures that we take to protect our intellectual property and confidential information, unauthorized third parties may copy aspects of our products or obtain and use our proprietary information.

Government Regulation

Our cortical strip, grid and depth electrodes are medical devices subject to extensive and ongoing regulation by the FDA and the U.S. CMS. Regulations cover virtually every critical aspect of a medical device company's business operations, including research activities, product development, quality, manufacturing, supplier management and risk management, contracting, reimbursement, medical communications, and sales and marketing. In the United States, the Federal Food, Drug and Cosmetic Act ("FDCA"), and the implementing regulations of the FDA (specifically, 21 Code of Regulations (21 CFR Parts 801 — labeling, 803 — medical device reporting, 807 — registration and listing, subpart E premarket notification 510k, 812 — investigational device exemption, 814 — premarket approval and 820 — quality system regulation) and applicable FDA issued guidance's govern product design and development, pre-clinical and clinical testing, premarket clearance or approval, risk management, product manufacturing, quality systems, import and export, product labeling, product storage, recalls and field safety corrective actions, advertising and promotion, product sales and distribution, and post-market clinical surveillance. Our business is subject to federal, state, local and harmonized standards, such as ISO 13485, ISO 14971, and FDA's Quality System Regulation ("QSR") contained in 21 CFR Part 820.

Regulatory Framework in the United States

Device classification

The FDA characterizes medical devices into one of three classes, Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification under 510(k); most Class II devices require Premarket Notification under 510(k); and most Class III devices require Premarket Approval.

Class I devices are subject to general controls including labeling. However, most such devices are exempt from pre-market notification. If a device is exempted from any of the general controls, such exemption is stated in the classification regulation for that device. This pertains to manufacturers' methods and documentation of the design, testing, production, control quality assurance, labeling, packaging, sterilization, storage and shipping of products. Class II devices are subject to the same general controls but may be subject to special controls such as performance standards, post-market surveillance, FDA guidance, or particularized labeling, and may also require clinical testing prior to clearance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, including devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Premarket Approval is required for most Class III devices.

Some Class I and Class II devices are exempted by regulation from the pre-market notification requirement under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, but must meet the requirement of compliance with substantially all of the QSR. However, a pre-market approval ("PMA application") is required for devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, or those that are "not substantially equivalent" either to a device previously cleared through the 510(k) process or to a "preamendment" Class III device in commercial distribution before May 28, 1976 when PMA applications were not required. The PMA approval process is more comprehensive than the 510(k) clearance process and typically takes multiple years to complete.

Based on FDA classifications, our diagnostic cortical strip, grid and depth electrode and RF ablation technology are categorized by the FDA as Class II devices that do not require clinical testing and can be filed as a 510(k), similar to existing competitive technology. The Company expects that indications for treating epilepsy, Parkinson's and other patients suffering from motor related neurological deficiencies via a permanent implant for chronic treatment will require a PMA process to commercially distribute in the United States.

The 510(k) clearance process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use, indications for use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. The FDA goal is to complete its review of a 510(k) notification within 90 calendar days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the De Novo process. The De Novo request provides a marketing pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. De Novo classification is a risk-based classification process. The De Novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a Pre-submission for De Novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a De Novo device application and potentially a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file based on adherence to FDA guidance on changes to an existing 510(k) device. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a De Novo or PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin its review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be safe, effective, reliable or accurate to the FDA's satisfaction;
- the data from pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If an FDA evaluation of a PMA application is favorable, the FDA will either issue an approval letter, or approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of a device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel.

Clinical Trials

Clinical trials are typically required to support a PMA application and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an Investigational Device Exemption ("IDE"), to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. The FDA's approval of an IDE allows clinical testing to go forward, but it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. Clinical trials must be entered into the clinical trials registry at clinicaltrials.gov.

The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients, sponsor (NeuroOne) or study sites do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience unanticipated adverse event;
- the data safety monitoring board determines the study should be placed on hold;
- patients die during a clinical trial, even though their death may not be related to the products that are part of our trial;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- the sponsor (NeuroOne) or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- third-party clinical investigators have significant financial interests related to the sponsor (NeuroOne) or the study that the FDA deems to make the study results unreliable, or the company or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

Other Regulatory Requirements

Even after a device receives clearance or approval and is placed in commercial distribution, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, risk management, production control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations that prohibit the promotion of products for uncleared, unapproved or "off-label" uses, and impose other restrictions on labeling, advertising and promotion;
- MDR regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- voluntary and mandatory device recalls to address problems when a device is mislabeled or does not meet specifications and could be a risk to health; and

- corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health.

Also, the FDA may require us to conduct post-market surveillance studies or establish and maintain a system for tracking our products through the chain of distribution to the patient level. The FDA enforces regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors.

Failure to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies. These may include any of the following sanctions or consequences:

- warning letters or untitled letters that require corrective action;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving or refusal to approve future products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA clearance or approval;
- product recall or seizure; interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

Our contract manufacturers, specification developers and some suppliers of components or device accessories, also are required to manufacture our products in compliance with current good manufacturing practice requirements set forth in the QSR. The QSR requires a quality system for the design, risk management, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes that any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down such manufacturing operations, require a recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees.

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and Similar Foreign and State Laws and Regulations Affecting the Transmission, Security and Privacy of Health Information

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as service providers of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from HIPAA and each other in significant ways and may not have the same effect.

Fraud and Abuse Laws

In addition to FDA restrictions, there are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

Federal Anti-Kickback and Self-Referral Laws

The federal Anti-Kickback Statute (the "Anti-Kickback Statute") prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at less than its fair market value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a review of all its relevant facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of (or purchases, or recommendations related to) federal healthcare covered business, the Anti-Kickback Statute has been implicated and potentially violated.

The penalties for violating the Anti-Kickback Statute include imprisonment for up to five years, fines of up to $25,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the Anti-Kickback Statute, some of which do not have the same exceptions and apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs. Further, the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act ("ACA"). Specifically, as noted above, under the Anti-Kickback Statute, the government must prove the defendant acted "knowingly" to prove a violation occurred. The ACA added a provision to clarify that with respect to violations of the Anti-Kickback Statute, "a person need not have actual knowledge" of the statute or specific intent to commit a violation of the statute. This change effectively overturns case law interpretations that set a higher standard under which prosecutors had to prove the specific intent to violate the law. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (the "False Claims Act").

We plan to provide the initial training to providers and patients necessary for appropriate use of our technology either through our own educators or by contracting with outside educators that have completed an appropriate training course. Outside educators are reimbursed for their services at fair market value.

Noncompliance with the Anti-Kickback Statute could result in our exclusion from Medicare, Medicaid or other governmental programs, restrictions on our ability to operate in certain jurisdictions, and civil and criminal penalties.

The federal Physician Self-Referral Prohibition, commonly known as the "Stark Law," prohibits a physician from ordering "designated health services," including durable medical equipment, for Medicare and Medicaid patients from entities with which the physician (or an immediate family member) has a "financial relationship." Financial relationships include both compensation arrangements and investment and ownership interests. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. We believe that we have structured our provider arrangements to comply with current Stark Law requirements.

Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Additionally, as some of these laws are still evolving, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers with respect to patient training. We cannot predict the final form that these regulations will take or the effect that the final regulations will have on us. As a result, our provider and training arrangements may ultimately be found to be not in compliance with applicable federal law.

False Claims Act

The False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the False Claims Act have made it easier for private parties to bring "qui tam" whistleblower lawsuits against companies under the False Claims Act. Penalties include fines ranging from $5,500 to $11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

There are other federal anti-fraud laws that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Additionally, HIPAA established two federal crimes related to making false statements in relation to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

Civil Monetary Penalties Law

In addition to the Anti-Kickback Statute and the False Claims Act, the federal government has the authority to seek civil monetary penalties, or CMPs, assessments, and exclusion against an individual or entity based on a wide variety of prohibited conduct. For example, the Civil Monetary Penalties Law authorizes the imposition of substantial CMPs against an entity that engages in activities including, but not limited to: (1) knowingly presenting or causing to be presented, a claim for services not provided as claimed or which is otherwise false or fraudulent in any way; (2) knowingly giving or causing to be given false or misleading information reasonably expected to influence the decision to discharge a patient; (3) offering or giving remuneration to any beneficiary of a federal health care program likely to influence the receipt of reimbursable items or services; (4) arranging for reimbursable services with an entity which is excluded from participation from a federal health care program; (5) knowingly or willfully soliciting or receiving remuneration for a referral of a federal health care program beneficiary; or (6) using a payment intended for a federal health care program beneficiary for another use. The government is authorized to seek different amounts of CMPs and assessments based on underlying violation. For false or fraudulent claims, the government may seek a penalty of up to $10,000 for each item or service improperly claimed, and an assessment of up to three times the amount improperly claimed. For kickback violations, the government may seek a penalty of up to $50,000 for each improper act and damages of up to three times the amount of remuneration at issue.

State Fraud and Abuse Provisions

Many states have also adopted some form of anti-kickback and anti-referral laws and a false claims act. We believe that we are in conformance to such laws. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Physician Payment Sunshine Act

Transparency laws regarding payments or other items of value provided to healthcare providers and teaching hospitals may also impact our business practices. The federal Physician Payment Sunshine Act requires most medical device manufacturers to report annually to the Secretary of Human Health Services financial arrangements, payments, or other transfers of value made by that entity to physicians and teaching hospitals. The payment information is made publicly available in a searchable format on a CMS website. Over the next several years, we will need to dedicate significant resources to establish and maintain systems and processes in order to comply with these regulations. Failure to comply with the reporting requirements can result in significant civil monetary penalties. Similar laws have been enacted or are under consideration in foreign jurisdictions.

Human Capital

As of September 30, 2023, we had 16 employees, all of whom are full-time, eight of whom are engaged in research and development activities, and all of whom are located in the United States. As of September 30, 2023, we also retained the services of approximately 9 regular consultants. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good. During our 2023 fiscal year, we had one employee resign.

Corporate Information

Our principal executive offices are located at 7599 Anagram Drive, Eden Prairie, Minnesota 55344, and our telephone number is 952-426-1383. Our website address is *www.nmtc1.com* Information on our website is not part of this Annual Report.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

The risk factors summarized and detailed below could materially harm our business, operating results and financial condition, impair our future prospects and cause the price of our common stock to decline. These are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

- we have incurred significant operating losses since inception and cannot assure you that we will ever achieve or sustain profitability;
- our ability to continue our operations requires that we raise additional capital and our operations could be curtailed if we are unable to obtain the additional funding as or when needed;
- we will need to raise substantial additional funds in the future, and these funds may not be available on acceptable terms or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, scale back or cease some or all operations;
- medical device development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product;
- changes in the configuration of our cortical strip, grid electrode and depth electrode technology under development may result in additional costs or delay;
- if we are unable to successfully develop, receive regulatory clearance/approval for and commercialize our technology and other products under development, or if we experience significant delays in doing so, our business will be harmed;
- failure to secure or retain coverage or adequate reimbursement for our cortical strip, grid electrode and depth electrode technology or future versions thereof, including the implantation procedures, by third-party payors could adversely affect our business, financial condition and operating results;

- if our competitors are better able to develop and market products for the diagnosis and treatment of epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders that are safer, more effective, less costly, easier to use or otherwise more attractive than our cortical strip, grid electrode and depth electrode technology, our business will be adversely impacted;
- the size and future growth in the market for our cortical strip, grid electrode and depth electrode technology under development has not been established with precision and may be smaller than we estimate, possibly materially;
- we depend on intellectual property licensed from WARF for our technology under development, and the termination of this license would harm our business;
- we depend on our partnership with Mayo to license certain know how for the development and commercialization of our technology. Termination of this partnership would harm our business, and even if this partnership continues, it may not be successful;
- even if we have our cortical strip, grid electrode and depth electrode technology approved for commercial sale, if we are unable to expand our sales and marketing infrastructure, we may not be successful in commercializing our cortical strip, grid electrode and depth electrode technology in the United States;
- we contract with third parties for the manufacture of our cortical strip, grid electrode and depth electrode technology under development and expect to continue to do so for clinical trials and commercialization. Risks associated with the manufacturing of our products could reduce our gross margins and negatively affect our operating results;
- if we or our third-party suppliers or manufacturers fail to comply with the FDA's good manufacturing practice regulations, this could impair our ability to market our products in a cost-effective and timely manner;
- potential complications from our cortical strip, grid electrode and depth electrode technology that are currently unknown may come to light;
- if there are significant disruptions in our information technology systems, our business, financial condition and operating results could be adversely affected;
- we have entered into, and may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues;
- our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel;
- we have been the victim of a cyber-related crime and our controls may not be successful in avoiding further cyber-related crimes in the future;
- our ability to protect our intellectual property and proprietary technology is uncertain;
- we may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors;
- our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer;
- the price of our Common Stock might fluctuate significantly, and you could lose all or part of your investment; and
- we intend to issue more shares to raise capital, which will result in substantial dilution.

Risks Related to Our Business

We have incurred significant operating losses since inception and cannot assure you that we will ever achieve or sustain profitability.

We have incurred losses since inception, and as of September 30, 2023, we had an accumulated deficit of $62.7 million primarily as a result of expenses incurred in connection with our operations and from our research and development programs. We expect to continue to incur significant expenses and increasing operating costs resulting in net losses for the foreseeable future, and management has raised substantial doubt about our ability to continue as a going concern. There was also substantial doubt about the Company's ability to continue as a going concern as of and for the year ended September 30, 2022. To date, we have financed our operations primarily through debt and equity financings, and our primary activities have been limited to, and our limited resources have been dedicated to, performing business and financial planning, raising capital, recruiting personnel, negotiating with business partners and the licensors of our intellectual property and conducting development activities.

To implement our business strategy we need to, among other things, develop an all-in-one diagnostic and therapeutic solution, successfully complete the necessary testing and clinical trials required for regulatory approval of our technology for ablation and stimulation therapies, gain approval for other brain or motor related disorders such as Parkinson's with the therapeutic technologies developed for epilepsy, convince physicians and patients that our technology, if approved, represents an improvement over existing diagnostic or treatment options, hire direct experienced sales representatives to market our technology, and engage in beneficial partnerships that can leverage our core technology. We have never been profitable and do not expect to be profitable in the foreseeable future. We expect our expenses to increase significantly as we pursue our objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, and we expect to continue incurring significant expenses and operating losses over the next several years. Our prior losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Any additional operating losses may have an adverse effect on our stockholders' equity, and we cannot assure you that we will ever be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our Company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain regulatory approvals or continue our operations.

We have a limited operating history, making it difficult for you to evaluate our business and your investment.

We are an early-stage medical technology company developing comprehensive neuromodulation cEEG and sEEG monitoring, ablation, and brain stimulation solutions to diagnose and treat patients with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders. Our operations are subject to all of the risks inherent in the establishment of a new business enterprise, including but not limited to the absence of an operating history, lack of fully-developed or commercialized products, insufficient capital, expected substantial and continual losses for the foreseeable future, limited experience in dealing with regulatory issues, lack of manufacturing and marketing experience, need to rely on third parties for the development and commercialization of our proposed products, a competitive environment characterized by well-established and well-capitalized competitors and reliance on key personnel.

From our inception through September 30, 2023, we have generated limited revenue from the commercial sales of our products. Because we have generated very limited revenues from commercialization, our operations to date have been principally financed through public and private offerings of our Common Stock and convertible debt and exercises of options and warrants.

Investors are subject to all the risks incident to the creation and development of a new business and each investor should be prepared to withstand a complete loss of his, her or its investment. Furthermore, the accompanying financial statements have been prepared assuming that we will continue as a going concern. However, the factors included above raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our Company has limited experience in medical device development and may not be able to successfully develop any device or therapy. Our ability to become profitable depends primarily on: our ability to further develop our cortical strip, grid electrode and depth electrode technology, our successful completion of all necessary pre-clinical testing and clinical trials on such technology, our ability to obtain clearance or approval for such technology and successfully commercialize such technology, our ongoing research and development efforts, the timing and cost of clinical trials, our ability to identify personnel with the necessary skill sets or enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, regulatory affairs, sales, marketing and distribution and our ability to obtain and maintain necessary intellectual property rights to such technology. Our limited experience in medical device development may make it more difficult for us to complete these tasks.

Even if we successfully develop and market such technology, we may not generate sufficient or sustainable revenue to achieve or sustain profitability, which could cause us to cease operations and cause you to lose all of your investment.

Our ability to continue our operations requires that we raise additional capital and our operations could be curtailed if we are unable to obtain the additional funding as or when needed.

Our independent registered public accounting firm included an explanatory paragraph in the report on our financial statements as of and for the years ended September 30, 2023 and 2022, respectively, noting the existence of substantial doubt about our ability to continue as a going concern. At September 30, 2023, we had cash and cash equivalents in the aggregate of approximately $5.3 million. Our existing cash, cash equivalents and short-term investments will not be sufficient to fund our operating expenses. To continue to fund operations, we will need to secure additional funding. We may obtain additional financing in the future through the issuance of our Common Stock, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all.

Adverse global economic conditions could have a negative effect on our business, results of operations and financial condition and liquidity.

A general slowdown in the global economy, including a recession, or in a particular region or industry, an increase in trade tensions with U.S. trading partners, inflation or a tightening of the credit markets could negatively impact our business, financial condition and liquidity. Adverse global economic conditions have from time to time caused or exacerbated significant slowdowns in the industries and markets in which we operate, which have adversely affected our business and results of operations. Macroeconomic weakness and uncertainty also make it more difficult for us to accurately forecast revenue, gross margin and expenses, and may make it more difficult to raise or refinance debt.

Worldwide economic and social instability could adversely affect our revenue, financial condition, or results of operations.

Generally, worldwide economic conditions remain uncertain, particularly due to the effects of the conflict between Russia and Ukraine and potentially between Israel and Hamas, disruptions in the banking system and financial markets, lingering COVID-19 pandemic, increased inflation and rising interest rates. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected the Company's access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, the Company's future cost of equity or debt capital and access to the capital markets could be adversely affected. Our vendors and development partners may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all. In addition, adverse economic conditions, such as recent supply chain disruptions and labor shortages and persistent inflation, have affected, and may continue to adversely affect our suppliers' ability to provide our manufacturers with materials and components, which may negatively impact our business. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities.

We will need to raise substantial additional funds in the future, and these funds may not be available on acceptable terms or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, scale back or cease some or all operations.

The continued growth of our business, including the development, regulatory approval and commercialization of our cortical strip, grid electrode and depth electrode technology, will significantly increase our expenses going forward. As a result, we will be required to seek substantial additional funds in the future. Our future capital requirements will depend on many factors, including:

- the cost of further developing our cortical strip, grid electrode and depth electrode technology;
- obtaining and maintaining regulatory clearance or approval for our cortical strip, grid electrode and depth electrode technology;
- the costs associated with commercializing our cortical strip, grid electrode and depth electrode technology;
- any change in our development priorities;
- the revenue generated by sales of our cortical strip, grid electrode and depth electrode technology;
- the costs associated with expanding our sales and marketing infrastructure for commercialization of our cortical strip grid electrode and depth electrode technology;
- any change in our plans regarding the manner in which we choose to commercialize any approved product in the United States;
- the cost of ongoing compliance with regulatory requirements;
- expenses we incur in connection with potential litigation or governmental investigations;
- expenses and costs we incur in connection with changes in the economy and regulatory process;
- the costs to develop additional intellectual property;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

As a result of these and other factors, we do not know whether and the extent to which we may be required to raise additional capital. We may in the future seek additional capital from public or private offerings of our capital stock, borrowings under credit lines or other sources.

We may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise additional capital could compromise our ability to execute on our business plan, and we may be forced to liquidate our assets. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

If we issue additional equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies or grant licenses on terms that are not favorable to us.

Changes in the configuration of our cortical strip, grid electrode and depth electrode technology under development may result in additional costs or delay.

As products are developed through pre-clinical testing and clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and configuration, are altered along the way in an effort to optimize processes and results. Any changes we make carry the risk that they will

not achieve the intended objectives. Any of these changes could cause our products to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered device. Such changes may also require additional testing, regulatory notification or regulatory approval. This could delay completion of pre-clinical testing or clinical trials, increase costs, delay approval of our future products and jeopardize our ability to commence sales and generate revenue.

We have two products, our cortical strip and grid electrodes and our sEEG electrode technology, which have each received 510(k) clearance from the FDA. If we are unable to successfully develop, and receive regulatory clearance/approval for our other products under development, or if we experience significant delays in doing so, our business will be harmed.

Three of our products have received 510(k) clearance from the FDA. Our Evo cortical electrode technology has received 510(k) clearance from the FDA for recording, monitoring, and stimulating brain tissue on the surface of the brain for less than 30 days, and our Evo sEEG electrode technology has received 510(k) clearance from the FDA for use (less than 30 days) with recording, monitoring, and stimulation equipment for recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain. Our OneRF ablation system has received 510(k) clearance from the FDA for creation of radiofrequency lesions in nervous tissue for functional neurosurgical procedures. None of our other products have received clearance or approval for commercial sale. Our ability to generate revenue from our developed products, if any, will depend heavily on their successful development and regulatory approval.

Before obtaining marketing clearance or approval from regulatory authorities for the sale of our cortical strip, grid electrode and depth electrode technology under development in the United States for certain indications, we must complete all pre-clinical testing, clinical trials and other regulatory requirements necessitated by the FDA and demonstrate the performance and safety of our technology. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Further, the outcomes of completed clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain marketing clearance or approval. We have limited resources to complete the expensive process of medical device development, pre-clinical testing and clinical trials, putting us at a disadvantage, particularly compared to some of our larger and established competitors, and we may not have sufficient resources to commercialize our products under development in a timely fashion, if ever.

We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our products, including:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the failure to successfully complete pre-clinical testing requirements required by the FDA;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts with third parties or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;
- clinical trials of our cortical strip, grid electrode and depth electrode technology may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our development programs;
- the number of people with brain related disorders required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or people may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our products may have unanticipated adverse events, undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors conducting the clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- regulators may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our products may be greater than we anticipate;
- the supply or quality of our products or other materials necessary to conduct clinical trials of our products may be insufficient or inadequate; and
- delays from our suppliers and manufacturers could impact clinical trial completion and impact revenue.

If we are required to conduct additional clinical trials or other testing of our cortical strip, grid electrode and depth electrode technology under development beyond those that we contemplate, if we are unable to successfully complete clinical trials, if the results of these trials or tests are not favorable or if there are safety concerns, we may:

- not obtain marketing approval at all;
- be delayed in obtaining marketing approval for our cortical strip, grid electrode and depth electrode technology under development in a jurisdiction;
- be subject to additional post-marketing testing requirements; or
- have our cortical strip, grid electrode and depth electrode technology removed from the market after obtaining marketing approval.

Our development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could allow our competitors to bring innovative products to market before we do and impair our ability to successfully commercialize our products.

Even if we obtain regulatory clearance and/or approval for all of our products, we will remain subject to extensive regulatory scrutiny and compliance obligations.

Both before and after a product is commercially released, we will have ongoing responsibilities under FDA regulations. We will also be subject to periodic inspections by the FDA and comparable foreign authorities to determine compliance with regulatory requirements, such as the Quality System Regulation, or QSR, of the FDA, medical device reporting regulations and regulations regarding notification, corrections, and recalls. These inspections can result in observations or reports, warning letters or other similar notices or forms of enforcement action. If the FDA concludes that we are not in compliance with applicable laws or regulations, or that any of our products are ineffective or pose an unreasonable health risk, it could ban these products, suspend or cancel our marketing authorizations, impose "stop-sale" and "stop-import" orders, detain or seize adulterated or misbranded products, order a recall, repair, replacement, correction or refund of such products, or require us to notify health providers and others that the products present unreasonable risks of substantial harm to the public health. Discovery of previously unknown problems with our product's design or manufacture may result in restrictions on use, restrictions placed on us or our suppliers, or withdrawal of an existing regulatory clearance. The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, assess civil or criminal penalties against our officers, employees or us, or recommend criminal prosecution of our Company. Adverse regulatory action may restrict us from effectively marketing and selling our products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our business, financial condition, and operating results.

In addition, even though we have obtained FDA clearance to market two of our products, and even if we obtain the proper regulatory approval or clearance to market any additional products under development, the FDA has the power to require us to conduct post-market surveillance studies, which are designed to identify adverse events, device malfunctions or complaints from patients implanted with the device during a specified period after the commencement of commercial use in the U.S. The FDA may also require us to conduct post-approval studies to further monitor the safety and/or effectiveness of our products. Failure to conduct required surveillance or studies in a timely manner could result in the revocation of the approved PMA product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

We may not be successful in commercializing our cortical strip, grid electrode and depth electrode.

We anticipate that we will derive nearly all of our U.S. revenue from the sales of our cortical strip, grid electrode and depth electrode technology or future versions thereof.

Moreover, we expect the revenue opportunity for additional uses of our technology to be greater than the technology and uses that have currently been cleared by the FDA, and so we believe our ability to generate significant revenue in the future will be dependent upon the receipt of additional FDA clearances.

Our revenue will be dependent, in part, upon the size of the markets in which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of people we target is not as significant as we estimate or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

The success of any products that we develop will depend on several factors, including:

- receipt of timely commercialization approvals from applicable regulatory authorities;
- our ability to procure and maintain suppliers and manufacturers of the components of our current cortical strip, grid electrode and depth electrode technology and future versions;
- market acceptance of our cortical strip, grid electrode and depth electrode technology by people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders, the medical community and third-party payors;
- our success in educating healthcare providers and people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders about the benefits, administration and use of our cortical strip, grid electrode and depth electrode technology and future versions;
- the prevalence and severity of adverse events and public health emergencies such as the COVID-19 pandemic;
- the perceived advantages, cost, safety, convenience and accuracy of alternative therapies;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our cortical strip, grid electrode and depth electrode technology and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including current good manufacturing practices; and
- obtaining and maintaining a continued acceptable performance and safety profile of our cortical strip, grid electrode and depth electrode technology.

The continuing development and commercialization of our products depends upon us maintaining strong relationships with academic and healthcare institutions and professionals.

If we fail to maintain our strong working relationships with healthcare and academic institutions and their professionals such as the Mayo Clinic, the Cleveland Clinic and Emory University, many of our products may not be developed and marketed in line with the needs and expectations of the professionals who use and support our products, which could cause a decline in our earnings and profitability. The development, marketing and sales of many of our products depends on our maintaining working relationships with healthcare institutions and professionals. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. If we are unable to maintain strong relationships with these institutions and professionals, the development and marketing of our products could suffer, which could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

Our success depends on our ability to continue to develop, commercialize and gain market acceptance for our cortical strip, grid electrode and depth electrode technology.

Our current business strategy is highly dependent on developing and commercially launching our cortical strip, grid electrode and depth electrode technology, and achieving and maintaining market acceptance. In order for us to sell cortical strip, grid electrode and depth electrode technology to people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders, we must convince them, their caregivers and healthcare providers that cortical strip, grid electrode and depth electrode technology is an attractive alternative to competitive products for neuromodulation cEEG and sEEG recording, ablation, and brain stimulation. Market acceptance and adoption of our cortical strip, grid electrode and depth electrode technology depend on educating people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders, as well as their caregivers and healthcare providers, and other perceived benefits of our cortical strip, grid electrode and depth electrode technology as compared to competitive products. We may face challenges convincing physicians, many of whom have extensive experience with competitors' products and established relationships with other companies, to appreciate the benefits of our cortical strip, grid electrode and depth electrode technology and, in particular, our ability to successfully diagnose and treat epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders in a way that is superior to and differentiated from currently available technology, and adopt it for treatment of their patients.

Achieving and maintaining market acceptance of cortical strip, grid electrode and depth electrode technology could be negatively impacted by many factors, including:

- the failure of our cortical strip, grid electrode and depth electrode technology to achieve wide acceptance among people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders, their caregivers, healthcare providers, third-party payors and key opinion leaders in the community;
- lack of evidence supporting the performance criteria or other perceived benefits of our cortical strip, grid electrode and depth electrode technology over competitive products or other currently available technology;
- perceived risks associated with the use of our cortical strip, grid electrode and depth electrode technology or similar products or technologies generally;
- the introduction of competitive products and the rate of acceptance of those products as compared to our cortical strip, grid electrode and depth electrode technology;
- adverse results of clinical trials relating to our cortical strip, grid electrode and depth electrode technology or similar competitive products; and
- loss of regulatory clearance or approval for our cortical strip, grid electrode and depth electrode technology, adverse publicity or other adverse events including any product liability lawsuits.

In addition, our cortical strip, grid electrode and depth electrode technology may be perceived by people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders, their caregivers or healthcare providers to be more complicated or less effective than current technology, and people may be unwilling to change their current regimens.

Moreover, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement. Accordingly, healthcare providers may not recommend our cortical strip, grid electrode and depth electrode technology until, if ever, there is sufficient evidence to convince them to alter the treatment methods they typically recommend, such as receiving recommendations from prominent healthcare providers or other key opinion leaders in the community.

If we are not successful in convincing people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders of the benefits of our cortical strip, grid electrode and depth electrode technology, or if we are unable to achieve the support of caregivers and healthcare

providers or widespread market acceptance for our cortical strip, grid electrode and depth electrode technology, then our sales potential, strategic objectives and profitability could be negatively impacted, which would adversely affect our business, financial condition and operating results.

Failure to secure or retain coverage or adequate reimbursement for our cortical strip, grid electrode and depth electrode technology or future versions thereof, including the implantation procedures, by third-party payors could adversely affect our business, financial condition and operating results.

We plan to derive nearly all of our revenue from sales of our cortical strip, grid electrode and depth electrode technology, in the United States and expect to do so for the next several years. We anticipate a substantial portion of the purchase price of our cortical strip, grid electrode and depth electrode technology will be paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Patients who receive treatment for their medical conditions and their healthcare providers generally rely on third-party payors to reimburse all or part of the costs associated with their medical treatment, including healthcare providers' services. Coverage and adequate reimbursement from third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, and commercial payors, is critical to new product acceptance. Future sales of our cortical strip, grid electrode and depth electrode technology will be limited unless people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders can rely on third-party payors to pay for all or part of the cost to purchase our cortical strip, grid electrode and depth electrode technology. Access to adequate coverage and reimbursement for our cortical strip, grid electrode and depth electrode technology by third-party payors is essential to the acceptance of our products by people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders.

In the United States, a third-party payor's decision to provide coverage for our products does not imply that an adequate reimbursement rate will be obtained. Further, one third-party payor's decision to cover our products does not assure that other payors will also provide coverage for the products or will provide coverage at an adequate reimbursement rate. Healthcare providers may choose not to order a product unless third-party payors pay a substantial portion of the product. Within and outside the United States, reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans. These third-party payors determine whether to provide coverage and reimbursement for specific products and procedures. Coverage determinations and reimbursement levels of both our products and the healthcare provider's performance of the insertion and removal procedures are critical to the commercial success of our product, and if we are not able to secure positive coverage determinations and reimbursement levels for our products or the insertion and removal procedures, our business would be materially adversely affected.

In addition, there may be significant delays in obtaining reimbursement, and coverage may be more limited than the purposes for which the product is cleared by the FDA or other foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States.

Because there is generally no separate reimbursement for medical devices and other supplies used in such procedures, including our cortical strip, grid electrode and depth electrode technology, and because we believe that our cortical strip, grid electrode and depth electrode technology, if approved, would be adequately described by existing DRG and ICD-9 codes for epilepsy surgery, some of our target customers may be unwilling to adopt our cortical strip, grid electrode and depth electrode technology over more established or lower cost therapeutic alternatives already available or subsequently become available. Further, any decline in the amount payors are willing to reimburse our customers for procedures using our cortical strip, grid electrode and depth electrode technology could make it difficult for new customers to adopt our cortical strip, grid electrode and depth electrode technology and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business.

Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained.

If sufficient coverage and reimbursement is not available for our any product we develop, in the United States, the demand for our products and our revenues will be adversely affected.

Reimbursement by Medicare is highly regulated and subject to change.

Medicare program is administered by the Centers for Medicare and Medicaid Services, or CMS, which imposes extensive and detailed requirements on medical services providers, including, but not limited to, rules that govern how we structure our relationships with physicians, and how and where we provide our solutions. Our failure to comply with applicable Medicare rules could result in discontinuing the ability for physicians to receive reimbursement as they will likely utilize our cortical strip, grid electrode and depth electrode technology under the Medicare payment program, civil monetary penalties, and/or criminal penalties, any of which could have a material adverse effect on our business and revenues.

If our competitors are better able to develop and market products for the diagnosis and treatment of epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders that are safer, more effective, less costly, easier to use or otherwise more attractive than our cortical strip, grid electrode and depth electrode technology, our business will be adversely impacted.

The medical device industry is highly competitive and subject to technological change. Our success depends, in part, upon our ability to establish a competitive position in the market for the diagnosis and treatment of epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders by securing broad market acceptance of our cortical strip, grid electrode and depth electrode technology. Any product we develop that achieves regulatory clearance or approval will have to compete for market acceptance and market share. We believe that the primary competitive factors of our cortical strip, grid electrode and depth electrode technology will be: reduced infections, ability to record additional brain activity, minimally invasive surgical procedure, ease of use and cost effectiveness. We face significant competition in the United States and internationally, which we believe will intensify. For example, our major competitors are: (i) in the market for diagnosis, PMT, Ad-Tec Medical and Integra Lifesciences, (ii) in the market for neuro-ablation, Medtronic and Monteris Medical and (iii) in the market for neurostimulation, Medtronic, Boston Scientific, NeuroPace Biotronik and Abbott. Each of the foregoing competitors has systems approved in the United States and certain foreign jurisdictions and has been established for several years. We face a particular challenge overcoming the long-standing practices by some physicians of using the existing technology of our larger, more established competitors. Physicians may be reluctant to try new products from a source with which they are less familiar. If these physicians do not try to subsequently adopt our product, then we may never achieve profitability and such failure to adopt our product could have a material adverse effect on our business, financial condition and operating results.

In addition to facing competition from major competitors and potentially our development partner, we may also face competition from other emerging competitors or smaller companies with active development programs that may emerge in the future.

Many of the companies developing or marketing competing products enjoy several advantages over us, including:

- more experienced sales forces;
- greater name recognition;
- more established sales and marketing programs and distribution networks;
- earlier regulatory clearance or approval in the United States or foreign jurisdictions;

- long established relationships with physicians and hospitals;
- significant patent portfolios, including issued U.S. and foreign patents and pending patent applications, as well as the resources to enforce patents against us or any of our third-party suppliers and distributors;
- the ability to acquire and integrate our competitors and/or their technology;
- demonstrated ability to develop product enhancements and new product offerings;
- established history of product reliability, safety and durability;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives;
- greater financial and human resources for product development, sales, and marketing; and
- greater experience in and resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval for products and marketing approved products.

Our competitors may develop and patent processes or products earlier than us, obtain patents that may apply to us at any time, obtain regulatory clearance or approvals for competing products more rapidly than us or develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. Furthermore, the frequent introduction by competitors of products that are, or claim to be, superior to our products may create market confusion that may make it difficult to differentiate the benefits of our products over competitive products. In addition, the entry of multiple new products may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of any product we may develop and commercialize. We also face fierce competition in recruiting and retaining qualified sales, scientific, and management personnel, establishing clinical trial sites and enrolling patients in clinical studies. If our competitors are more successful than us in these matters, our business may be harmed.

The size and future growth in the market for our cortical strip, grid electrode and depth electrode technology has not been established with precision and may be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market, our sales growth may be adversely affected.

Our estimates of the size and future growth in the market for our cortical strip, grid electrode and depth electrode technology, including the number of people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders who may benefit from and be amenable to using cortical strip, grid electrode and depth electrode technology for diagnosis and treatment, is based on a number of internal and third-party studies, reports and estimates. In addition, our internal estimates are based in large part on current treatment patterns by healthcare providers using current generation technology and our belief is that the incidence of epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders in the United States and worldwide is increasing. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for cortical strip, grid electrode and depth electrode technology, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. The actual incidence of brain related disorders, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. As a result, our estimates of the size and future growth in the market for cortical strip, grid electrode and depth electrode technology may prove to be incorrect. If the actual number of people with brain related disorders who would benefit from cortical strip, grid electrode and depth electrode technology and the size and future growth in the market for cortical strip, grid electrode and depth electrode technology is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business.

We depend on intellectual property licensed from WARF for our technology, including our technology under development, and the termination of this license would harm our business.

WARF has granted us the WARF License, to make, use and sell, in the United States only, products that employ certain licensed patents for a neural probe array or thin-film micro electrode array and method. See "Business — WARF License" for additional information regarding our license agreement with WARF.

WARF may terminate this license in the event that we default on the payments of amounts due to WARF or fail to timely submit development reports, actively pursue our development plan or breach any other covenant in the WARF License and fail to remedy such default in 90 days or in the event of certain bankruptcy events involving us. WARF may also terminate this license if, after royalties earned on sales begin to be paid, such earned royalties cease for more than four calendar quarters. The WARF License otherwise expires by its terms on the date that no valid claims on the patents licensed thereunder remain.

Disputes may arise between us and WARF regarding intellectual property subject to this agreement, including with respect to: the scope of rights granted under the WARF License and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of WARF that is not subject to the WARF License; the amount and timing of milestones and royalty payments; the rights of WARF under the license; our right to sublicense; and the ownership of inventions and know-how resulting from the WARF License. For example, if we or any of our sublicensees for any reason contest the validity of any patent licensed under the WARF License, the royalty rate will be doubled during the pendency of such contest and, if the contested patent is found to be valid and would be infringed by us if not for the WARF License, the royalty rate will be tripled for the remaining term of the WARF License.

Any disputes with WARF may prevent or impair our ability to maintain our current licensing arrangement. We depend on the intellectual property licensed from WARF to develop our cortical strip, grid electrode and depth electrode technology. The original license agreement entered into with WARF in 2014 required that we meet certain milestones and make certain payments to WARF. We failed to do so and were in default under the original license agreement. Furthermore, the LLC was not able to transfer the rights and obligations under the 2014 WARF Agreement to us at the time of the Merger without the consent of WARF. As a result, in February 2017, we signed an amendment to the WARF License which, among other things, modified and removed certain previous milestones and provided WARF's consent to such transfer. Because of this past breach, WARF may be less likely to waive future defaults or breaches or further amend the WARF License in the future, to the extent we request any waiver or amendment. See "Note 4 — Commitments and Contingencies" included in "Item 8 — Financial Statements and Supplementary Data" in this Report.

Termination of our license could result in the loss of significant rights and would harm our ability to further develop our cortical strip, grid electrode and depth electrode technology. In addition, WARF reserves the right to grant non-profit research institutions and government agencies non-exclusive licenses to practice and use the inventions of the licensed patents for non-commercial research purposes, and we grant WARF a non-exclusive, sub-licensable, royalty-free right and license for non-commercial research purposes to use improvements to the licensed patents. In the event that we discontinue use or commercialization of the licensed patents or improvements thereon, we must grant WARF an option to obtain a non-exclusive, sub-licensable royalty-bearing license to use the improvements for commercial purposes. Such rights, if exercised by WARF, could harm our ability to develop and commercialize our cortical strip, grid electrode and depth electrode technology.

We depend on our partnership with Mayo to license certain know how for the development and commercialization of our technology. Termination of this partnership would harm our business, and even if this partnership continues, it may not be successful.

We have entered into the Mayo Development Agreement to (i) exclusively license worldwide certain Mayo improvements for the development and commercialization of products, methods and processes related to flexible circuit technology for the recording and stimulation of tissue and (ii) license, on a non-exclusive basis, worldwide Mayo thin film electrode technology know-how for the development and commercialization of products, methods and processes related to flexible circuit technology for the recording and stimulation of tissue. Mayo has agreed to assist the Company by providing access to the Mayo Principal Investigators in developing a minimally invasive device/delivery system and procedure for a minimally invasive approach for the implantation of any flexible circuit technology developed by the Company, including prototype development, animal testing, protocol development for human and animal use, abstract development and presentation and access to and license of any intellectual property that the Mayo Principal Investigators develop relating to the procedure. See "Business-Mayo Foundation for Medical Education and Research License and Development Agreement" for additional information regarding our agreement with Mayo.

The Mayo Development Agreement generally will expire in October 2034, unless the Mayo know-how and improvements under the Mayo Development Agreement remain in use, and the Mayo Development Agreement may be terminated by Mayo for cause or under certain circumstances. Mayo and the Company may not be successful in their efforts to develop any product, method, process, device, delivery system or minimally invasive approach by such expiration date or termination, if at all. If no such minimally invasive device or delivery system and procedure for minimally invasive approach is developed, the Company may never receive regulatory approval of its cortical strip, grid electrode and depth electrode technology under development or the market may never accept such technology, if approved.

Disputes may arise between us and Mayo regarding intellectual property subject to the Mayo Development Agreement or other matters, including with respect to: the scope of rights granted under the agreement and other interpretation-related issues; the amount and timing of payments; the rights and obligations of Mayo under the license agreement; and the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by Mayo and us.

Any disputes with Mayo may prevent or impair our ability to maintain our current arrangement. We depend on the intellectual property licensed from and development assistance from Mayo to develop our cortical strip, grid electrode and depth electrode technology. We cannot assure you that we will be able to continue to comply with the Mayo Development Agreement. In fact, the original license and development agreement entered into with Mayo in 2014 required that, upon the Merger with the LLC, we make certain payments and issue shares of Common Stock to Mayo, which we failed to do at such time. We signed the Mayo Development Agreement in May 2017, which, among other things, modified or removed certain provisions of the original agreement, including those we breached. In addition, pursuant to the Mayo Development Agreement signed in May 2017, we agreed to pay Mayo a cash payment of approximately $92,000 on the earlier of September 30, 2017 or the date we raise a minimum amount of financing. We did not make this payment by September 30, 2017 and breached this provision of the Mayo Development Agreement. Mayo granted us an extension of this deadline to December 31, 2017, and we made this payment within such extended deadline. Because of our past breach, Mayo may be less likely to waive future defaults or breaches or further amend the Mayo Development Agreement in the future, to the extent we request any waiver or amendment. Termination of the Mayo Development Agreement could result in the loss of significant rights and would harm our ability to further develop our technology.

We depend on a limited number of third-party suppliers for the components of our cortical strip, grid electrode and depth electrode technology, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of materials, could harm our business.

We rely on third-party suppliers to supply and manufacture the components of our cortical strip, grid electrode and depth electrode technology. For our business strategy to be successful, our suppliers must be able to provide us with components in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Future increases in sales of our cortical strip and sheet electrode technology, if approved, whether expected or unanticipated, could strain the ability of our suppliers to deliver an increasingly large supply of components and our cortical strip, grid electrode and depth electrode technology in a manner that meets these various requirements.

We use a small number of suppliers of components for our products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. We may not have long-term supply agreements with our suppliers and, in many cases, we may make our purchases on a purchase order basis. Our ability to purchase adequate quantities of components or our products may be limited and we may not be able to convince suppliers to make components and products available to us. Additionally, our suppliers may encounter problems that limit their ability to supply components or manufacture products for us, including financial difficulties, damage to their manufacturing equipment or facilities, product discontinuations, or complications due to worldwide economic and social instability. As a result, there is a risk that certain components could be discontinued and no longer available to us. We may be required to make significant "last time" purchases of component inventory that is being discontinued by the supplier to ensure supply continuity. If we fail to obtain sufficient quantities of high quality components to meet demand for our products in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and regulatory requirements, we may not be able to quickly engage additional or replacement suppliers for some of our critical components. Failure of any supplier to deliver components at the level our business requires could disrupt the manufacturing of our products and, if approved, limit our ability to meet our sales commitments, which could harm our reputation and adversely affect our business.

We may not procure volumes sufficient to receive favorable pricing, which could impact our gross margins if we are unable to pass along price differences to our customers. Recent global economic cost inflation trends could unfavorably impact pricing from our suppliers.

Furthermore, vandalism, terrorism or a natural or other disaster, such as an earthquake, fire or flood, could damage or destroy equipment, our inventory of component supplies or finished products, cause substantial delays in development or our operations, result in the loss of key information, and cause us to incur additional expenses. We maintain Liability insurance and Property Casualty insurance, but it may not be adequate to fully cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our or our suppliers' facilities could harm our business, financial condition and operating results.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other regulatory agencies, and the failure of any supplier to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, and termination of distribution, product seizures or civil penalties. It could also require us to cease using the components, seek alternative components or technologies and modify our products to incorporate alternative components or technologies, which could result in a requirement to seek additional regulatory approvals. Any disruption of this nature or increased expenses could harm our development, approval or commercialization efforts and adversely affect our operating results.

We contract with third parties for the manufacture of our cortical strip, grid electrode and depth electrode technology, including our under development and expect to continue to do so for clinical trials and commercialization. Risks associated with the manufacturing of our products could reduce our gross margins and negatively affect our operating results.

We currently rely, and expect to continue to rely, on third parties for the manufacture of our cortical strip, grid electrode and depth electrode technology. Therefore, our business strategy depends on our third-party manufacturers' ability to manufacture our cortical strip, grid electrode and depth electrode technology and future generations thereof in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. To date, we have only manufactured small quantities of our cortical electrodes. As a result, we currently have limited data and experience regarding the quality, reliability and timeliness of our third-party manufacturers.

We are subject to numerous risks relating to the manufacturing capabilities of our third-party manufacturers, including:

- quality or reliability defects;
- inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- failure to increase production to meet demand;
- inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;
- difficulty identifying and qualifying alternative manufacturers in a timely manner;
- inability to manufacture product components cost-effectively;
- inability to establish agreements with future third-party manufacturers or to do so on acceptable terms;
- potential damage to or destruction of our manufacturers' equipment or facilities;
- failure to complete sterilization on time or in compliance with the required regulatory standards;
- transportation and import and export risk;
- delays in analytical results or failure of analytical techniques that we will depend on for quality control and release of products;

- natural disasters, labor disputes, financial distress, raw material availability, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturers or suppliers; or
- latent defects that may become apparent after products have been released and that may result in a recall of such products.

These risks are likely to be exacerbated by our limited experience with our cortical strip, grid electrode and depth electrode technology and its manufacturing process. As demand for our products increases, our third-party suppliers will need to invest additional resources to purchase components, hire and train employees, and enhance their manufacturing processes. If our manufacturers fail to increase production capacity efficiently, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, manufacturing any future versions of our cortical strip, grid electrode and depth electrode technology may require the modification of production lines, the identification of new manufacturers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make any future versions of our cortical strip, grid electrode and depth electrode technology commercially viable.

Potential complications from our cortical strip, grid electrode and depth electrode technology that are currently unknown may come to light.

Based on our industry experience and the experience of the physicians that use products similar to our cortical strip, grid electrode and depth electrode technology, complications from use of our cortical strip, grid electrode and depth electrode technology may include post-operative hemorrhage, infection, brain inflammation, brain tissue necrosis, inability to accurately localize the epileptogenic focus (the area of the cerebral cortex responsible for causing epileptic seizures), neurologic deficit (abnormal function of a body area due to weaker function of the brain, spinal cord, muscles or nerves, such as abnormal reflexes, inability to speak and decreased sensation) and extra axial fluid collections (fluid that occurs in the brain after surgery). If these or unanticipated complications or side-effects result from the use of our cortical strip, grid electrode and depth electrode technology, our product development may be delayed, we may not be able to obtain regulatory clearance or approval for certain products, we could be subject to liability and, even for cleared/approved products, our technology would not be widely adopted. We cannot assure you that use, even for a limited time, would not result in unanticipated complications, even after the device is removed.

Undetected errors or defects in our cortical strip, grid electrode and depth electrode technology under development or future versions thereof could harm our reputation, decrease the market acceptance of our cortical strip, grid electrode and depth electrode technology or expose us to product liability claims adversely affecting our financial condition and results of operations or liquidity.

Our cortical strip, grid electrode and depth electrode technology may contain undetected errors or defects. As a result, we may be subject to warranty and liability claims for damages related to errors or defects in such products. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our cortical strip, grid electrode and depth electrode technology could harm our business and operating results. This risk exists even if a device is cleared or approved for commercial sale and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products are designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our cortical strip, grid electrode and depth electrode technology or future versions thereof could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability lawsuits. Our clinical and commercial product liability insurance coverage may not be sufficient to cover claims that may be made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost, or in sufficient amounts or scope, to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management team and other resources, and adversely impact or eliminate the prospects for commercialization of the product candidate, or sale of the product, which that is the subject of any such claim.

The sale and use of our cortical strip, grid electrode and depth electrode technology or future versions thereof could lead to the filing of product liability claims if someone were to allege that our cortical strip, grid electrode and depth electrode technology or one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm

our business or financial condition. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our cortical strip, grid electrode and depth electrode technology;
- decreased demand;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards or settlements to patients or other claimants; or
- loss of revenue.

Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, could cause us to incur substantial costs, delay our product development efforts, place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation, increase our product liability insurance rates, once we obtain such insurance, or prevent us from securing such insurance coverage in the future and adversely affect our ability to attract and retain customers, if approved, any of which could harm our business, financial condition and operating results.

We currently maintain commercial product liability insurance with an aggregate limit of $5,000,000. We cannot be assured that such insurance would adequately protect our assets from the financial impact of defending a product liability claim because these policies typically have substantial deductibles. Product liability claims in excess of applicable insurance coverage would negatively impact our business, financial condition and operating results. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all.

We depend on sophisticated information technology systems, and any breach or disruption affecting these systems could adversely affect our business, financial condition and operating results.

The efficient operation of our business depends on our information technology systems, which we use to manage product development tasks, research and development data and accounting and financial functions. In the future, we may rely on our information technology systems for inventory management and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods, other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures.

In addition, our data management application and a variety of our software systems are hosted by third-party service providers whose security and information technology systems are subject to similar risks. If our, or our third-party service provider's, security systems are breached or fail, unauthorized persons may be able to obtain access to sensitive data.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability. The failure of our or our service providers' information technology systems or our transmitter's software to perform as we anticipate or our failure to effectively implement new information technology systems could disrupt our entire operation, adversely affect our products, or result in delays in our product development, clinical trial or commercialization efforts, increased overhead costs and damage our reputation. Any of these results could negatively affect our business, financial condition and operating results.

Zimmer has exclusive global rights to distribute our strip and grid cortical electrodes and electrode cable assembly products. Zimmer's failure to timely develop or commercialize these products would have a material adverse effect on our business and operating results. Further, our inability to agree with Zimmer on dates of completion for product development, regulatory clearance and commercialization milestones on which various fee payments to the Company are based under the Zimmer Development Agreement could have a material adverse impact on our financial and operating results.

The Company granted Zimmer an exclusive global right to distribute our strip and grid cortical electrodes and electrode cable assembly products. Additionally, we granted Zimmer the exclusive right and license to distribute certain depth electrodes developed by the Company. The collaboration with Zimmer may not be successful due to several factors, including the following:

- Zimmer may not be able to obtain from us or manufacture our products in a timely or cost-effective manner;
- Zimmer may not timely perform its obligations under the Zimmer Development Agreement;
- Zimmer may fail to effectively commercialize our products; or
- contractual disputes or other disagreements between us and Zimmer, including those regarding the development, manufacture, and commercialization of our products, interpretation of the Zimmer Development Agreement, and ownership of proprietary rights.

Any of the foregoing could adversely impact the likelihood and timing of any payments we are eligible to receive under the Zimmer Development Agreement. The Company is reliant on Zimmer to drive the commercialization and sales of our products. If Zimmer does not perform its obligations under the Zimmer Development Agreement, we may be forced to incur material expenses to build a sales organization and infrastructure to market our products which sales would be substantially delayed and could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

We have entered into, and may enter into additional collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop products and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

We have been the victim of a cyber-related crime and our controls may not be successful in avoiding further cyber-related crimes in the future.

In January 2023, we were the victim of a business email compromise fraud which resulted in our incurring a loss of approximately $0.1 million. We have worked with law enforcement authorities and the banks involved in the wire transfer to pursue recovery of the $0.1 million, but at this time we do not expect that we will be able to recover such funds. Enhancements have been made to our controls relating to electronic payments by or for us that we believe will reduce our risk of becoming a victim of future frauds related to our payments, including by wire transfers. However, cyber-related criminal activities continue to evolve and increase in sophistication, frequency and severity. As a result, the control enhancements that have been made, and any additional enhancements that may be made in the future, to our controls may not be successful in avoiding our becoming a victim to further cyber-related crimes.

Risks Related to our Intellectual Property

Our ability to protect our intellectual property and proprietary technology is uncertain.

The medical device market in which we operate is largely technology driven. We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our intellectual property and proprietary technologies. We continue to review new technological developments in order to make decisions about what additional filings would be the most appropriate for us. We also plan to seek patent protection for our proprietary technology in select countries internationally. If we fail to timely file a patent application in any jurisdiction, we may be precluded from doing so at a later date. Furthermore, we cannot assure you that any patent application will be approved in a timely manner or at all. The rights granted to us under our patents, and the rights we are seeking to have granted in our pending patent applications, may not be meaningful or provide us with any commercial advantage. In addition, those rights could be opposed, contested or circumvented by our competitors, or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Even if we are successful in receiving patent protection for certain products and processes, our competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available.

We rely on our trademarks and trade names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. For example, we have a registered U.S. trademark for the "EVO" trademark. We cannot assure you that our trademark applications will be approved in a timely manner or at all. Third parties also may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We also rely on trade secrets, know-how and technology, which are not protectable by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary

information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in the related or resulting know-how and inventions. If any of our trade secrets, know-how or other technologies not protected by a patent were to be disclosed to or independently developed by a competitor, our business, financial condition and results of operations could be materially adversely affected.

If a competitor infringes upon one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult and time-consuming. Patent law relating to the scope of claims in the industry in which we operate is subject to rapid change and constant evolution and, consequently, patent positions in our industry can be uncertain. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may harm our business, financial condition and operating results.

There is limited market awareness of our technology, and we may not be able to establish or strengthen our brand.

There is currently limited market awareness of our technology. We believe that establishing and strengthening our brand is critical to achieving widespread acceptance of our cortical strip, grid electrode and depth electrode technology. Promoting and positioning our brand, and increasing market awareness of our technology, will depend largely on the success of our marketing efforts and our ability to provide physicians with a reliable product for successful treatment of brain-related disorders. Additionally, we believe the quality and reliability of our product is critical to building physician support in the United States, and any negative publicity regarding the quality or reliability of our cortical strip, grid electrode and depth electrode technology could significantly damage our reputation in the market. Further, given the established nature of our competitors, it is likely that our future marketing efforts will require us to incur significant additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our cortical strip, grid electrode and depth electrode technology may not be accepted by physicians, which would adversely affect our business, results of operations and financial condition.

We could become subject to patent litigation that could be costly, result in the diversion of management's time and efforts, stop our development and commercialization measures or require us to pay damages.

Our success will depend in part on not infringing the patents or violating the other proprietary rights of third-parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

In the future, we could receive communications from various industry participants alleging our infringement of their intellectual property rights. Any potential intellectual property litigation could force us to do one or more of the following:

- stop selling our products or using technology that contains the allegedly infringing intellectual property;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing;

- redesign those products that contain the allegedly infringing intellectual property; or
- attempt to obtain a license to the relevant intellectual property from third-parties, which may not be available on reasonable terms or at all, and if available, may be non-exclusive, thereby giving our competitors access to the same technology.

Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the neurostimulation market increases, the possibility of intellectual property infringement claims against us increases.

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Some of our current or future employees may have previously been employed at other medical device companies, including those that are our direct competitors or could potentially be our direct competitors. We may be subject to claims that we, or our employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we may in the future be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims.

There can be no assurance that this type of litigation will not occur, and any future litigation or the threat thereof may adversely affect our ability to hire additional employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our cortical strip, grid electrode and depth electrode technology or future versions thereof, which could have an adverse effect on our business, financial condition and operating results.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make devices that are the same as or similar to our cortical strip, grid electrode and depth electrode technology but that are not covered by the claims of the patents that we own;
- we or any collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- we might enforce our patent rights or defend a challenge to our issued patents or pending application, putting the patents and patent applications at risk of being invalidated or interpreted narrowly;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and
- we may not develop additional proprietary technologies that are patentable.

Risks Related to our Legal and Regulatory Environment

Our products and operations are subject to extensive governmental regulation, and any adverse regulatory action may materially adversely affect our financial condition and business operations.

Our medical devices and technologies and business activities, including marketing, manufacturing, sales and development processes, are subject to regulation by the FDA, U.S. Department of Justice, Health and Human Services — Office of Inspector General, and other federal and state, governmental authorities. These governmental authorities enforce laws and regulations that are meant to assure product safety and effectiveness, including the regulation of, among other things:

- product design and development;
- pre-clinical studies and clinical trials;
- product safety;
- establishment registration and product listing;
- labeling, content and language of instructions for use and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance or approval;
- servicing and post-market surveillance;
- record-keeping procedures;
- product import and export;
- advertising and promotion; and
- recalls and field safety corrective actions.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated revenues.

Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the regulatory agency or other regulators to grant future clearances or approvals, and the suspension or withdrawal of existing approvals by such regulatory agencies. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and operating results.

A recall of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us.

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Our third-party suppliers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our third-party distributors, if any, could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to produce our products in a cost-effective and timely manner.

Further, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product

malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

We are subject to additional federal, state and foreign laws and regulations relating to our healthcare business; our failure to comply with those laws could have an adverse impact on our business.

Although we will not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from government health insurance programs or other third-party payors for our cortical strip, grid electrode and depth electrode technology, we are subject to healthcare fraud and abuse regulation and enforcement by federal, state and foreign governments, which could adversely impact our business. Healthcare fraud and abuse and health information privacy and security laws potentially applicable to our operations include, but are not limited to:

- the Anti-Kickback Statute, which will apply to our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare or Medicaid programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;

- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;

- HIPAA, and its implementing regulations, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations, also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information;

- federal "sunshine" requirements imposed by the ACA on device manufacturers regarding any "transfer of value" made or distributed to physicians and teaching hospitals. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. Manufacturers must submit reports by the 90th day of each subsequent calendar year;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require device manufacturers to report information

related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

The risk of our being found in violation of these laws and regulations is increased by the fact that the scope and enforcement of these laws is uncertain, many of them have not been fully interpreted by the regulatory authorities or the courts, their provisions are open to a variety of interpretations, or they vary country by country. We are unable to predict what additional federal, state or foreign legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal, state or foreign governments may (i) impose additional restrictions or adopt interpretations of existing laws that could have a material adverse effect on us or (ii) challenge our current or future activities under these laws. Any of these challenges could impact our reputation, business, financial condition and operating results.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement of profits, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any federal, state or foreign regulatory review to which we may become subject, regardless of the outcome, would be costly and time-consuming.

For example, to enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has recently increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time and resource consuming and can divert management's attention from our core business. Additionally, if we settle an investigation with law enforcement or other regulatory agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

We may be liable if the FDA or another regulatory agency concludes that we have engaged in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off-label use of our products. Healthcare providers may use our products, if approved, off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties. Although we intend to train our marketing and direct sales force to not promote our products for uses outside of their cleared uses and our policy will be to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

Legislative or regulatory healthcare reforms may have a material adverse effect on our business, financial condition, results or operations and cash flows.

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our products would harm our business, financial condition and operating results.

While one often stated goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. For example, the ACA and Health Care and Education Affordability Reconciliation Act of 2010 were enacted into law in the U.S. in March 2010. Certain provisions of this law, including comparative effectiveness research, pilot programs to evaluate alternative payment methodologies and other changes to the payment systems, have started changing the way healthcare is delivered, reimbursed and funded. While the extent to which it has affected our business is not clear, these changes, over the long-term, may adversely affect our business and results of operations. The current U.S. administration may attempt to reverse some of the previous administration's changes to the ACA, particularly related to healthcare coverage for the uninsured, and is further expected to introduce more ambitious healthcare legislation, which could include what is commonly referred to as a "public option" or changes to Medicare age requirements. If passed, this legislation would lead to increased coverage levels and utilization of services; however, at this point, the impact of any such changes is unclear because specific changes have not been enacted or implemented.

We cannot predict whether any additional healthcare reform proposals will be adopted or how such proposals may impact our business and operations. However, any changes that lower reimbursements for either our products or procedures using our products, reduce medical procedure volumes, increase cost containment pressures on us or others in the healthcare sector, or impose additional or heightened regulatory requirements could adversely affect our business and results of operations.

Risks Related to our Common Stock

The price of our Common Stock might fluctuate significantly, and you could lose all or part of your investment.

Volatility in the market price of our Common Stock may prevent you from being able to sell your shares of our Common Stock at or above the price you paid for your shares. The trading price of our Common Stock may be volatile and subject to wide price fluctuations in response to various factors, including:

- actual or anticipated fluctuations in our quarterly financial and operating results;
- our progress toward developing our cortical strip and sheet electrode technology;
- the commencement, enrollment and results of our future clinical trials;
- adverse results from, delays in or termination of our clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts, if any;
- perceptions about the market acceptance of our products and the recognition of our brand;
- adverse publicity about our products or industry in general;
- overall performance of the equity markets;
- introduction of products, or announcements of significant contracts, licenses or acquisitions, by us or our competitors;
- legislative, political or regulatory developments;
- additions or departures of key personnel;
- threatened or actual litigation and government investigations;
- third-party promotional activities, which are subject to ongoing regulatory obligations;

- sale of shares of our Common Stock by us or members of our management; and
- general economic conditions.

These and other factors might cause the market price of our Common Stock to fluctuate substantially, which may negatively affect the liquidity of our Common Stock. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. The changes frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our Common Stock could fluctuate based upon factors that have little or nothing to do with our Company, and these fluctuations could materially reduce our share price.

Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in substantial costs, divert our management's attention and resources, and harm our business, operating results and financial condition.

Any failure to maintain an effective system of internal controls over our financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our stock.

We are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("SOX") and management is required to report annually on our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Although we prepare our financial statements in accordance with accounting principles generally accepted in the United States, our internal accounting controls may not meet all standards applicable to companies with publicly traded securities. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of SOX until the date we have a public float of $75 million or greater.

If we fail to maintain effective internal controls and procedures for financial reporting, it could result in material misstatements in the annual or interim financial statements that would not be prevented or detected in a timely manner. In that case, we could become subject to regulatory sanction or investigation. Further, these outcomes could damage investor confidence in the accuracy and reliability of our financial statements. Our management has concluded that our internal controls over financial reporting were, and continue to be, effective as of September 30, 2023. However, we identified material weaknesses in our internal control over financial reporting in 2018, and we cannot assure you that material weaknesses or significant deficiencies will not occur in the future and that we will be able to remediate such weaknesses or deficiencies in a timely manner, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

We intend to issue more shares to raise capital, which will result in substantial dilution.

Our certificate of incorporation authorizes the issuance of a maximum of 100,000,000 shares of Common Stock and 10,000,000 shares of preferred stock. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources. Any additional financings effected by us may result in the issuance of additional securities without stockholder approval and the substantial dilution in the percentage of Common Stock held by our then existing stockholders. Moreover, the Common Stock issued in any such transaction may be valued on an arbitrary or non-arm's-length basis by our management, resulting in an additional reduction in the percentage of Common Stock held by our current stockholders. Our Board has the power to issue any or all of such authorized but unissued shares without stockholder approval. To the extent that additional shares of Common Stock are issued, dilution to the interests of our stockholders will occur and the rights of the holder of Common Stock might be materially and adversely affected.

As of September 30, 2023, we had outstanding warrants to purchase an aggregate of 6,202,426 shares of Common Stock at a weighted average exercise price of $5.92 per share, and options to purchase an aggregate of 1,708,427 shares of Common Stock at a weighted average exercise price of $4.34 per share. For a description of our outstanding warrants and information about the number of shares of Common Stock for which they are exercisable, see "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Capital Resources." To the extent these outstanding options or warrants are exercised, there will be further dilution to holders of our Common Stock.

Anti-takeover provisions in the Company's certificate of incorporation and bylaws may prevent or frustrate attempts by stockholders to change the Board or current management and could make a third-party acquisition of the Company difficult.

The Company's certificate of incorporation and bylaws contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. For example, our certificate of incorporation permits the Board without stockholder approval to issue up to 10,000,000 shares of preferred stock and to fix the designation, power, preferences, and rights of those shares. Furthermore, our Board has the ability to increase the size of the Board and fill the newly created vacancies without stockholder approval. These provisions could limit the price that investors might be willing to pay in the future for shares of the Common Stock.

We are a smaller reporting company, and the reduced reporting requirements applicable to smaller reporting companies may make our Common Stock less attractive to investors.

We are a "smaller reporting company" as defined in Section 12 of the Exchange Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies such as, reduced disclosure obligations regarding executive compensation in our annual and periodic reports and proxy statements and stockholder approval of any golden parachute payments not previously approved. We will remain a "smaller reporting company" as long as (i) our public float remains less than $250 million or (ii) our annual revenues are less than $100 million and we either have no public float, or our public float is less than $700 million. Public float is measured as of the last business day of our most recently-completed second fiscal quarter, and annual revenues are as of the most recently completed fiscal year for which audited financial statements are available. We cannot predict if investors will find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Accordingly, you may have to sell some or all of your shares of our Common Stock in order to generate cash flow from your investment. You may not receive a gain on your investment when you sell shares and you may lose the entire amount of the investment.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our Common Stock will be influenced by the research and reports that securities or industry analysts publish about us and our business. Securities or industry analysts may elect not to provide coverage of our Common Stock, and such lack of coverage may adversely affect the market price of our Common Stock. In the event we do not secure additional securities or industry analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more securities or industry analysts downgrade our stock or issue other unfavorable commentary or research. If one or more securities or industry analysts ceases coverage of our Company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we fail to comply with the continued listing standards of the Nasdaq Capital Market, our Common Stock could be delisted. If it is delisted, our Common Stock and the liquidity of our Common Stock would be impacted.

The continued listing of our Common Stock on Nasdaq is contingent on NeuroOne's continued compliance with a number of listing standards. There is no assurance that NeuroOne will remain in compliance with these standards. Delisting from Nasdaq would adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our securities and negatively affect the value and liquidity of our Common Stock. Delisting also could limit our strategic alternatives and attractiveness to potential counterparties and have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities. Moreover, NeuroOne committed in connection with the sale of securities to use commercially reasonable efforts to maintain the listing of its Common Stock during such time that certain warrants are outstanding.

Our Common Stock has been, and may in the future be subject to the "penny stock" rules of the SEC, which makes transactions in our stock cumbersome and may reduce the value of an investment in our stock.

The SEC has adopted regulations which generally define a "penny stock" as an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The SEC's penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's agreement to the transaction. If our Common Stock is subject to the "penny stock" rules, these rules may restrict the ability of brokers-dealers to sell our Common Stock and may affect the ability of investors to sell their shares, until our Common Stock no longer is considered a penny stock.

There can be no assurance that we will be able to comply with Nasdaq's continued listing standards, a failure of which could result in a de-listing of our common stock.

There is no assurance that we will continue to comply with the applicable Nasdaq listing standards. In order to maintain the listing of our common stock on Nasdaq, Nasdaq requires that the trading price of a company's listed stock on Nasdaq remain above one dollar in order for such stock to remain listed. If a listed stock trades below one dollar for more than 30 consecutive trading days, then it is subject to delisting from Nasdaq. In addition, to maintain a listing on Nasdaq, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, and certain corporate governance requirements. If we are unable to satisfy these requirements or standards, we could be subject to delisting, which would have a negative effect on the price of our common stock and warrants and would impair your ability to sell or purchase our common stock and warrants when you wish to do so. In the event of a delisting, we would expect to take actions to restore our compliance with the listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock and/or warrants to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the minimum bid price requirement, or prevent future non-compliance with the listing requirements.

Risks Related to the Acquisition

We may be subject to unknown risks as a result of our completed Acquisition by Original Source Entertainment, Inc.

Original Source Entertainment, Inc., which was renamed NeuroOne Medical Technologies Corporation in connection with the Acquisition, was formed to license songs to the television and movie industry and has generated very little revenues. Prior to the Acquisition, its operations have been primarily limited to organizational, start-up, and capital formation activities, with no employees other than the former officers. In connection with the Acquisition, the liabilities existing in Original Source Entertainment, Inc. at the time of the Acquisition were cancelled or paid by a related party, as required by the Merger Agreement with NeuroOne, Inc. and OSOK Acquisition Company (the "Merger Agreement"). Despite this requirement and the representations and warranties of Original Source Entertainment, Inc. in the Merger

Agreement, there may be unknown liabilities, or liabilities that were known but believed to be immaterial, related to the business of Original Source Entertainment, Inc. that may become material liabilities we are subject to in the future. If we are subject to material liabilities as a result of the conduct of Original Source Entertainment, Inc., we may have limited recourse for such liabilities, which could have a material impact on our business and stock price.

Additional risks may exist since we were engaged in a transaction that can be generally characterized as a "reverse merger" with a shell company. Securities analysts of major brokerage firms may not provide coverage of the Company since there is little incentive to brokerage firms to recommend the purchase of the Common Stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings.

General Risk Factors

Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our business, results of operations, financial condition and cash flows.

We are subject to income and other non-income-based taxes and tariffs in the U.S., and our operations, plans and results are affected by tax and other initiatives. The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, the U.S. Treasury Department, and state/local taxing authorities. The tax laws in the U.S. could change on a prospective or retroactive basis, and any such changes could materially adversely affect our business, our results of operations, our effective tax rate, and holders of our common stock. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders', tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, results of operations, tax provision, cash tax liability, and effective tax rate. For example, in August 2022, the Inflation Reduction Act of 2022 ("IRA") was enacted into law. The IRA includes a 15% corporate alternative minimum tax and a 1% excise tax on share repurchases.

We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

We are also subject to regular reviews, examinations, and audits by the Internal Revenue Service and other taxing authorities with respect to our taxes. Although we believe our tax estimates are reasonable, if a taxing authority disagrees with the positions we have taken, we could face additional tax liability, including interest and penalties. There can be no assurance that payment of such additional amounts upon final adjudication of any disputes will not have a material impact on our results of operations and financial position.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to complete acquisitions, or the failure to integrate them with our existing business, could harm our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. The success of our strategy relating to future acquisitions, investments or alliances will depend on a number of factors, including our ability to:

- identify suitable opportunities for acquisition, investment or alliance, if at all;
- manage acquisition, investment or alliance opportunities within our capital capacity and prioritize those investments to execute on our strategy;
- manage our due diligence process to uncover potential issues and liabilities with targets;
- finance any future acquisition, investment or alliance on terms acceptable to us, if at all;
- complete acquisitions, investments or alliances in a timely manner on terms that are satisfactory to us, if at all;

- successfully integrate and operate acquired businesses;
- successfully identify and retain key target employees;
- comply with applicable laws and regulations;
- protect intellectual property and to prevail in litigation related to newly acquired technologies;
- assimilate the acquired products or technologies;
- maintain uniform standards, procedures, controls and policies;
- anticipate costs associated with acquisitions;
- avoid the diversion of management's attention from our existing business;
- manage risks associated with entering new markets in which we have limited or no experience; and
- manage legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our officers and advisory board members. Although we have an employment agreement with our Chief Executive Officer, David Rosa, he (and each of our other key employees) may terminate his employment with us at any time and will continue to be able to do so. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous medical device companies for similar personnel, many of which have greater financial and other resources dedicated to attracting and retaining personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Prolonged negative economic conditions could adversely affect us, our customers and third-party partners, manufactures or suppliers, if any, which could harm our financial condition.

We are subject to the risks arising from adverse changes in general economic and market conditions. Uncertainty about future economic conditions could negatively impact our existing and potential customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, and cause delays or other problems with key suppliers.

Healthcare spending in the United States has been, and is expected to continue to be, under significant pressure and there are many initiatives to reduce healthcare costs. As a result, we believe that some insurers are scrutinizing insurance claims more rigorously and delaying or denying coverage and reimbursement more often. Because the sale, if approved, of our cortical strip, grid electrode and depth electrode technology under development will generally depend on the availability of third-party coverage and reimbursement, any delay or decline in coverage and reimbursement will adversely affect our sales.

We have incurred, and may continue to incur increased costs and demands upon management as a result of being a public company.

As a public company in the United States, we incur significant legal, accounting and other costs. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the stock exchange on which we may list our Common Stock, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board, on committees of our Board or as members of senior management.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We currently lease office space in Eden Prairie, Minnesota and Los Gatos, California to accommodate our finance and administrative functions as well as laboratory space accommodating our research and development operations. We believe that our existing facilities are adequate for our immediate needs and can accommodate our anticipated growth. We believe that, should it be needed, additional space can be leased to accommodate any future growth.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock commenced trading on the Nasdaq Capital Market on May 26, 2021 under the ticker symbol "NMTC." Previously, our Common Stock was traded on the OTC Markets quotation system on the OTCQB administered by the Financial Industry Regulatory Authority under the symbol "NMTC" since December 19, 2017. Prior to December 19, 2017, our Common Stock had been quoted on the OTC Pink Sheets under the symbol "OSOK" from November 2012 to August 4, 2017 and under the symbol "NMTC" from August 4, 2017 to December 19, 2017.

Stockholders

On December 13, 2023, there were 103 record holders of our Common Stock. The transfer agent and registrar for our Common Stock is Equiniti Trust Company.

Share Repurchases

During the three months ended September 30, 2023, we repurchased 8,382 common shares surrendered by employees to satisfy income tax withholding obligations of employees in connection with the administration of employee share-based compensation plans. The following table summarizes the share repurchase activity:

Purchase period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number of shares that may yet be purchased under the plans or programs
July 1 – July 31, 2023	2,794	$ 1.20	—	—
August 1 – August 31, 2023	2,794	$ 1.02	—	—
September 1 – September 30, 2023	2,794	$ 0.85	—	—

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and results of operations of NeuroOne together with our financial statements and the related notes included elsewhere in this Report.

Overview

We are a medical technology company focused on the development and commercialization of thin film electrode technology for continuous electroencephalogram ("cEEG") and stereoelectrocencephalography ("sEEG"), spinal cord stimulation, brain stimulation, drug delivery and ablation solutions for patients suffering from epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders. We are also developing the capability to use our sEEG electrode technology to deliver drugs or gene therapy while being able to record brain activity before, during, and after delivery. Additionally, we are investigating the potential applications of our technology associated with artificial intelligence.

In November 2019, our Evo cortical electrode technology received 510(k) clearance from the FDA for recording, monitoring, and stimulating brain tissue for up to 30 days, and in October 2022, we received FDA clearance for our Evo sEEG 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.

We completed feasibility bench top testing with a new design of our diagnostic and ablation depth electrode in the first calendar quarter of 2021 and signed a contract with RBC Medical Innovations to develop hardware for the system in the third calendar quarter of 2021. We completed design verification of such hardware early in the second calendar quarter of 2023. We also completed an animal feasibility study at Emory University in September 2021. We completed additional animal studies early in the second quarter of calendar 2023 and received 510(k) clearance in December 2023 for creation of radiofrequency lesions in nervous tissue for functional neurosurgical procedures. Our other products are still under development.

We commenced commercial sales of cEEG strip/grid and electrode cable assembly products beginning in the first quarter of fiscal year 2021. We sold, on a limited application basis for design verification, sEEG depth electrode products for non-human use beginning in late fiscal year 2021, and we commenced commercial sales of our sEEG depth electrode products in late calendar 2022. Our other products are still under development.

We have incurred losses since inception. As of September 30, 2023, we had an accumulated deficit of $62.7 million, primarily as a result of expenses incurred in connection with our research and development, selling, general and administrative expenses associated with our operations and interest expense, fair value adjustments and loss on extinguishments related to our debt, offset in part by collaborations and product revenues.

Prior to FDA clearance of certain of our products, our main sources of cash, cash equivalents and short-term investments were proceeds from the issuances of notes, common stock, warrants and unsecured loans. See "Liquidity and Capital Resources — Capital Resources" below. While we have begun to generate revenue from the sale of products based on our cEEG and sEEG technology and through milestone and other payments from our current collaboration with Zimmer, we expect to continue to incur significant expenses and increasing operating and net losses for the foreseeable future until and unless we generate a higher level of revenue from commercial sales, and we will need to obtain substantial additional funding in connection with our continuing operations through public or private equity or debt financings, through collaborations or partnerships with other companies or other sources.

We may be unable to raise additional funds when needed on favorable terms or at all. Our failure to raise such capital as and when needed would have a negative impact on our financial condition and our ability to develop and commercialize our cortical strip, grid electrode and depth electrode technology and future products and our ability to pursue our business strategy. See "Liquidity and Capital Resources — Liquidity Outlook" below.

Recent Developments and Upcoming Milestones

Corporate Updates

Appointment of COO

On November 14, 2023, we announced the appointment of Christopher R. Volker as the Chief Operating Officer of the Company, effective on November 10, 2023.

sEEG Commercial Launch

In May 2023, we announced the commercial launch of the Evo® sEEG electrode product line in the United States with exclusive distribution partner Zimmer Biomet. We have fulfilled eight shipments of sEEG product to Zimmer Biomet in preparation for launch and completed initial training on the sEEG product line to Zimmer Biomet sales personnel.

The first clinical case using the Evo® sEEG electrode in robotic neurosurgery was performed by Dr. William Bingaman at the Cleveland Clinic. The procedure was the first to utilize NeuroOne's Evo sEEG electrode with Zimmer Biomet's ROSA One® Brain, a robotic platform that assists surgeons in planning and performing complex yet minimally invasive neurosurgical procedures.

OneRF Ablation

During the second fiscal quarter of 2023, we successfully completed summative usability testing for OneRF with 15 neurosurgeons, and completed execution of internal device verification/validation protocols for the final OneRF ablation system. We submitted a 510(k) application to the FDA for the OneRF ablation system in June 2023, submitted responses to FDA comments on November 6, 2023 and received 510(k) clearance on December 6, 2023.

Spinal Cord Stimulation Program

During the second fiscal quarter of 2023, we completed an initial animal implant of novel thin film paddle leads for spinal cord stimulation (SCS). The devices are intended for the treatment of patients with chronic back pain due to multiple failed back surgery syndrome, intractable low back, and leg pain. A percutaneous (through a needle) delivery system for paddle leads is also under development and has been successfully bench-tested.

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the conflicts between Russia and Ukraine and the Middle East, disruptions in the banking system and financial markets, lingering effects of the COVID-19 pandemic and increased inflation. The general economic and capital market conditions both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms or at all. If economic conditions decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

The COVID-19 pandemic that began in late 2019 introduced significant volatility to the global economy, disrupted supply chains and had a widespread adverse effect on the financial markets. Additionally, our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the conflicts in Ukraine and the Middle East, disruptions in the banking system and financial markets, and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates.

Financial Overview

Product Revenue

Our product revenue was derived from the sale of our Strip/Grid Products, depth electrodes ("sEEG Products") and electrode cable assembly products ("Electrode Cable Assembly Products") based on Evo cortical electrode technology. We anticipate that we will generate additional revenue from the sale of products based on Evo cortical electrode technology.

In November 2019, we received FDA 510(k) clearance for our cortical strip electrode for temporary (less than 30 days) recording, monitoring, and stimulation on the surface of the brain. In October 2022, we received FDA 510(k) clearance for our Evo sEEG 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.

Product Gross Profit (Loss)

Product gross profit (loss) represents our product revenue less our cost of product revenue. Our cost of product revenue consists of the manufacturing and materials costs incurred by our third-party contract manufacturer in connection with our Strip/Grid Products, sEEG Products and outside supplier materials costs of producing the Electrode Cable Assembly Products. In addition, cost of product revenue includes royalty fees incurred in connection with our license agreements.

Collaborations Revenue

On July 20, 2020, we entered into an exclusive development and distribution agreement (the "Zimmer Development Agreement") with Zimmer, pursuant to which we granted Zimmer exclusive global rights to distribute the Strip/Grid Products and electrode cable assembly products (the "Electrode Cable Assembly Products"). Additionally, we granted Zimmer the exclusive right and license to distribute certain depth electrodes developed by the Company ("sEEG Products", and together with the Strip/Grid Products and Electrode Cable Assembly Products, the "Products"). The parties have agreed to collaborate with respect to development activities under the Zimmer Development Agreement through a joint development committee composed of an equal number of representatives of Zimmer and the Company.

Under the terms of the Zimmer Development Agreement, we are responsible for all costs and expenses related to developing the Products, and Zimmer is responsible for all costs and expenses related to the commercialization of the Products. In addition to the Zimmer Development Agreement, Zimmer and the Company have entered into an MS Agreement and a Quality Agreement with respect to the manufacturing and supply of the Products.

Except as otherwise provided in the Zimmer Development Agreement, we are responsible for performing all development activities, including non-clinical and clinical studies directed at obtaining regulatory approval of each Product. Zimmer has agreed to use commercially reasonable efforts to promote, market and sell each Product following the "Product Availability Date" (as defined in the Zimmer Development Agreement) for such Product.

Pursuant to the Zimmer Development Agreement, Zimmer made an upfront initial exclusivity fee payment of $2.0 million (the "Initial Exclusivity Fee") to the Company in fiscal year 2020. In addition, on August 2, 2022, we entered into a Third Amendment to the Zimmer Development Agreement (the "Amendment") with Zimmer. Pursuant to the terms and conditions of the Amendment, Zimmer made a $3.5 million payment to us in August 2022. In consideration of the mutual covenants and agreements contained in the Zimmer Development Agreement, certain fee and milestone payment provisions in the Zimmer Development Agreement were replaced with the following below:

- $1.5 million for the sEEG exclusivity maintenance fee; and
- $2.0 million for satisfaction of each of the milestone events related to the design of sEEG Products set forth in the Zimmer Development Agreement, even though the satisfaction was after the deadlines originally identified.

In addition, in connection with the Amendment, we issued to Zimmer a warrant to purchase common stock (the "2022 Zimmer Warrant"). The 2022 Zimmer Warrant is exercisable for up to an aggregate of 350,000 shares of our Common Stock. The 2022 Zimmer Warrant has an exercise price of $3.00 per share, will be exercisable commencing six months from the issuance date, and will expire on August 2, 2027.

The Zimmer Development Agreement will expire on the tenth anniversary of the date of the first commercial sale of the last Products to achieve a first commercial sale (the "Zimmer Term"), unless terminated earlier pursuant to its terms. Either party may terminate the Zimmer Development Agreement (x) with written notice for the other party's material breach following a cure period or (y) if the other party becomes subject to certain insolvency proceedings. In addition, Zimmer may terminate the Zimmer Development Agreement for any reason with 90 days' written notice, and the Company may terminate the Zimmer Development Agreement if Zimmer acquires or directly or indirectly owns a controlling interest in certain competitors of the Company. The license rights granted to Zimmer under the Zimmer Development Agreement shall be exclusive from the effective date of the Amendment until the end of the Zimmer Term.

All payments attributed to the Initial Exclusivity Fee, the sEEG exclusivity maintenance fee and sEEG design milestone payment are non-refundable.

The Zimmer Development Agreement and Amendment were accounted for under the provisions of Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers ("ASC 606").* In accordance with the provisions under ASC 606, we identified five performance obligations under the Zimmer Development Agreement and Amendment: (1) our obligation to grant Zimmer access to our intellectual property; (2) completion of sEEG Product development; (3) completion of Strip/Grid Product development; (4) the provision of sEEG exclusivity maintenance; and (5) sEEG design modifications as requested by Zimmer. All performance obligations under the Zimmer Development Agreement and Amendment were met as of December 31, 2022.

In October 2022, we received 510(k) clearance from the FDA for our Evo sEEG 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. Accordingly, we recognized revenue in the amount of $1.5 million during the year ended September 30, 2023 related to the completion of the sEEG exclusivity maintenance milestone. During the year ended September 30, 2022, we recognized revenue in the amount of $1.9 million related to sEEG Product development.

The achievement of the level of sales required to earn royalty payments from Zimmer is uncertain.

For further discussion about the determination of collaborations revenue, product revenue and cost of product revenue, and for a discussion of milestones and royalty payments under the Zimmer Development Agreement, see "— Liquidity and Capital Resources — Liquidity Outlook" below and see "Note 7 — Zimmer Development Agreement" included in our financial statements included in "Item 8 — Financial Statements and Supplementary Data" in this Report.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel-related costs including stock-based compensation for personnel in functions not directly associated with research and development activities. Other significant costs include legal and litigation costs relating to corporate matters, intellectual property costs, professional fees for consultants assisting with financial and administrative matters, and sales and marketing in connection with the commercial sale of cEEG strip/grid, sEEG depth electrode and electrode cable assembly products. We anticipate that our selling, general and administrative expenses will increase in the future to support our continued research and development activities, further commercialization of our cortical strip and grid technology, and our depth electrode technology, and the increased costs of operating as a public company. These increases will include increased costs related to the hiring of additional personnel and fees for legal and professional services, as well as other public company related costs.

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities in developing our cortical strip and grid electrode and depth electrode technology. Research and development expenses include compensation and benefits for research and development employees including stock-based compensation, overhead expenses, cost of laboratory supplies, clinical trial and related clinical manufacturing expenses, costs related to regulatory operations, fees paid to consultants and other outside expenses. Research and development costs are expensed as incurred and costs incurred by third parties are expensed as the contracted work is performed. Lastly, de minimis income from the sale of prototype products and related materials are offset against research and development expenses.

We expect our research and development expenses to significantly increase over the next several years as we develop our cortical strip and grid electrode and depth electrode technology and conduct preclinical testing and clinical trials and will depend on the duration, costs and timing to complete our preclinical programs and clinical trials.

Other Income, net

Other income, net primarily consists of interest income related to our cash, cash equivalents, investment income or loss from short-term investments and other income or expense outside of normal operating activity relating to legal settlements, sales of non-commercial supplies and other items as applicable.

Results of Operations

Comparison of the Fiscal Years Ended September 30, 2023 and 2022

The following table sets forth our results of operations for the fiscal years ended September 30, 2023 and 2022.

	For the years ended September 30,		
	2023	2022	Period to Period Change
Product revenue	$ 1,952,441	$ 171,169	$ 1,781.272
Cost of product revenue	1,495,924	241,963	1,253,961
Product gross profit (loss)	456,517	(70,794)	527,311
Collaborations revenue	1,455,188	1,948,872	(493,684)
Operating expenses:			
Selling, general and administrative	6.926,269	6,979,416	(53,147)
Research and development	6,940,686	4,929,427	2,011,259
Total operating expenses	13,866,955	11,908,843	1,958,112
Loss from operations	(11,955,250)	(10,030,765)	(1,924,485)
Other income, net	95,759	31,152	64,607
Loss before income taxes	(11,859,491)	(9,999,613)	(1,859,878)
Provision for income taxes	—	—	—
Net loss	$ (11,859,491)	$ (9,999,613)	$ (1,859,878)

Product Revenue and Product Gross Profit (Loss)

Product revenue and product gross profit were $2.0 million and $0.5 million, respectively, during the year ended September 30, 2023. Product revenue and product gross loss were $0.2 million and $0.1 million, respectively, during the year ended September 30, 2022. The increase in gross profit during the current period was largely due to the higher sales volume that exceeded fixed royalty and other overhead costs in the current year resulting in a positive gross margin of 23.4% for the first time in our history. Product revenue consisted of Strip/Grid Products, sEEG Products and Electrode Cable Assembly Products sales. The increase in product revenue of $1.8 million year over was attributed primarily to the sale of our sEEG Products that followed the FDA 510(k) clearance in October 2022 for our Evo sEEG electrode technology for temporary (less than 30 days) use. Cost of product revenue consisted of the manufacturing and materials costs incurred by our third-party contract manufacturer in connection with our Strip/Grid Products, sEEG Products and outside supplier materials costs in connection with the Electrode Cable Assembly Products. In addition, cost of product revenue included royalty fees incurred of approximately $0.2 million and $0.1 million in connection with our license agreements during the years ended September 30, 2023 and 2022, respectively.

Collaborations Revenue

Collaborations revenue was $1.5 million and $1.9 million during the years ended September 30, 2023 and 2022, respectively. Revenue during the periods presented were derived from the Zimmer Development Agreement and Amendment and represented the portion of our performance obligations that were met in connection with the upfront initial development fee and payments associated with the Amendment.

Selling, general and administrative expenses

Selling, general and administrative expenses were $6.9 million and $7.0 million for the years ended September 30, 2023 and 2022, respectively. The negligible change period over period was composed primarily due to an increase in payroll related costs of approximately $0.3 million offset by a reduction in professional service and marketing related costs of $0.4 million.

Research and development expenses

Research and development expenses were $6.9 million for the year ended September 30, 2023, compared to $4.9 million for the year ended September 30, 2022. The $2.0 million increase during fiscal 2023 over the comparable prior year period was attributed to supporting development activities, which primarily included salary-related expenses and costs related to consulting services, materials and supplies associated with the development of future sEEG product applications and other products utilizing new technologies.

Other Income, net

Other income, net during the year ended September 30, 2023 related to interest income attributed to our cash, cash equivalents and short-term investments in the amount of $0.2 million, while outstanding, which was partially offset by an exploit loss of $94,000 and a loss on disposal of equipment in the amount of $32,000.

Other income, net during the year ended September 30, 2022 consisted principally of interest income attributed to our cash, cash equivalents and short-term investments, while outstanding.

Liquidity and Capital Resources

Overview

As of September 30, 2023, our principal source of liquidity consisted of cash and cash equivalents in the aggregate of approximately $5.3 million. While we began to generate revenue in fiscal year 2021 from commercial sales and through milestone and other payments under our collaboration with Zimmer, we expect to continue to incur significant expenses and increasing operating and net losses for the foreseeable future until and unless we generate an adequate level of revenue from commercial sales to cover expenses. Our most significant cash requirements relate to the funding of our ongoing product development and commercialization operations and our royalty obligations under our intellectual property licenses with the Wisconsin Alumni Research Foundation ("WARF") and the Mayo Foundation for Medical Education and Research ("Mayo"). Our additional material cash needs include commitments under operating leases and other administrative services. See "Funding Requirements" below for more information. We anticipate that our expenses will increase substantially as we develop and commercialize our cortical strip, grid electrode and depth electrode technology and pursue pre-clinical and clinical trials, seek regulatory approvals, manufacture products, establish our own sales, marketing and distribution infrastructure to commercialize our ablation electrode technology, hire additional staff, add operational, financial and management systems and continue to operate as a public company.

Capital Resources

Our sources of cash, cash equivalents and short-term investments to date have been limited to collaboration and product revenues, along with proceeds from the issuances of notes with warrants, common stock with and without warrants and unsecured loans with the terms of our financings described below.

July 2023 Public Offering

On July 24, 2023, we entered into an underwriting agreement with The Benchmark Company, LLC, as underwriter ("Benchmark"), relating to the issuance and sale of 5,250,000 shares of our common stock, par value $0.001 per share, at a price to the public of $1.00 per share (the "July 2023 Public Offering"). In addition, under the terms of the July 2023 Public Offering, we granted Benchmark an option, exercisable for 30 days, to purchase up to an additional 787,500 shares of common stock on the same terms ("the Overallotment Option"). The July 2023 Public Offering closed on July 27, 2023, and we completed the sale and issuance of an aggregate of 6,037,500 shares of our common stock, including the exercise in full of the Overallotment Option.

The net proceeds to us from the July 2023 Public Offering were approximately $5.2 million after deducting underwriting discounts and other offering expenses payable by the Company. We intend to use the net proceeds from this offering to: (i) support the commercial launch of the EVO sEEG electrode with Zimmer Biomet, (ii) support the FDA submission for the OneRF ablation system, and (iii) complete the design of a novel drug delivery electrode, among other general corporate purposes.

At-The-Market Offering

On December 21, 2022, we entered into a Capital on Demand™ Sales Agreement ("Sales Agreement") with JonesTrading Institutional Services LLC ("JonesTrading") to create an at-the-market offering program ("ATM") under which we may offer and sell shares having an aggregate offering price of up to $14.5 million. JonesTrading is entitled to a commission at a fixed commission rate equal to up to 3% of the gross proceeds. Through September 30, 2023, we have issued 1,439,677 shares of common stock under the ATM for gross proceeds in the amount of $2.6 million. We incurred issuance costs in connection with the ATM in the amount of $0.2 million through September 30, 2023. On July 24, 2023, we decreased the amount of common stock that can be sold pursuant to the Sales Agreement, such that we were offering up to an aggregate of $2.6 million of our common stock for sale under the Sales Agreement, including the shares of common stock previously sold. On December 1, 2023, we increased the amount of common stock that can be sold pursuant to the Sales Agreement, such that we are offering up to an aggregate of $4.8 million of our common stock for sale under the Sales Agreement, including the shares of common stock previously sold.

October 2021 Underwritten Public Offering

On October 13, 2021, we entered into an underwriting agreement relating to the issuance and sale of 3,750,000 shares of our common stock at a price to the public of $3.20 per share (the "October 2021 Underwritten Public Offering"). In addition, under the terms of the underwriting agreement, we granted the underwriter an option, exercisable for 30 days, to purchase up to an additional 562,500 shares of common stock on the same terms. The base offering closed on October 15, 2021, and the sale of 422,057 shares of common stock subject to the underwriter's overallotment option closed on November 15, 2021. The gross proceeds from this offering were approximately $13.4 million prior to deducting underwriting discounts and other offering expenses payable by us.

Funding Requirements

As noted above, certain of our cash requirements relate to the funding of our ongoing product development and commercialization operations and our milestone and royalty obligations under our intellectual property licenses with WARF and Mayo. See "Item 1 — Business — Clinical Development and Regulatory Pathway — Clinical Experience, Future Development and Clinical Trial Plans" in this Report for a discussion of design, development, pre-clinical and clinical activities that we may conduct in the future, including expected cash expenditures required for some of those activities, to the extent we are able to estimate such costs.

On January 21, 2020, we entered into an Amended and Restated License Agreement (the "WARF License") with WARF, which amended and restated in full our prior license agreement with WARF, dated October 1, 2014 (the "Original WARF License"). Under the WARF License, we have agreed to pay WARF a royalty equal to a single-digit percentage of our product sales pursuant to the WARF License, with a minimum annual royalty payment of $50,000 for 2020, $100,000 for 2021 and $150,000 for 2022 and each calendar year thereafter that the WARF License is in effect. If we or any of our sublicensees contest the validity of any licensed patent, the royalty rate will be doubled during the pendency of such contest and, if the contested patent is found to be valid and would be infringed by us if not for the WARF License, the royalty rate will be tripled for the remaining term of the WARF License.

Under the Amended and Restated License and Development Agreement with Mayo (the "Mayo Development Agreement"), we have agreed to pay Mayo a royalty equal to a single-digit percentage of our product sales pursuant to the Mayo Development Agreement. Refer to "Note 4 — Commitments and Contingencies" included in our financial statements included in "Item 8 — Financial Statements and Supplementary Data" in this Report for more information about the WARF License and the Mayo Development Agreement.

Our other cash requirements within the next twelve months include accounts payable, accrued expenses, purchase commitments and other current liabilities. Our other cash requirements greater than twelve months from various contractual obligations and commitments include operating leases and contracted services. Refer to "Note 4 — Commitments and Contingencies" included in our financial statements included in "Item 8 — Financial Statements and Supplementary Data" in this Report for further detail of our lease obligations and the timing of expected future payments. Contracted services include agreements with third-party service providers for clinical research, product development, manufacturing, supplies, payroll services, equipment maintenance services, and audits for periods up to fiscal year 2025.

We expect to satisfy our short-term and long-term obligations through cash on hand and, until we generate an adequate level of revenue from commercial sales to cover expenses, if ever, from future equity and debt financings.

Liquidity Outlook

For a discussion of potential fee payments under the Zimmer Development Agreement, see "Note 7 — Zimmer Development Agreement" included in our financial statements included in "Item 8 — Financial Statements and Supplementary Data" in this Report. Even though we have received regulatory clearance to expand the use of our Evo sEEG electrode technology for up to 30 days, commercial sales of the sEEG electrodes are expected to take some time to be a significant source of liquidity. Zimmer has exclusive global rights to distribute our strip and grid cortical electrodes, depth electrodes and electrode cable assembly products. Zimmer's failure to timely develop or commercialize these products would have a material adverse effect on our business and operating results.

At September 30, 2023, we had cash and cash equivalents in the aggregate of approximately $5.3 million. Management has noted the existence of substantial doubt about our ability to continue as a going concern. Additionally, our independent registered public accounting firm included an explanatory paragraph in the report on our financial statements as of and for the years ended September 30, 2023 and 2022, respectively, noting the existence of substantial doubt about our ability to continue as a going concern. Our existing cash and cash equivalents may not be sufficient to fund our operating expenses through at least twelve months from the date of this filing. To continue to fund operations, we will need to secure additional funding through public or private equity or debt financings, through collaborations or partnerships with other companies or other sources. We may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise capital when needed could compromise our ability to execute on our business plan. If we are unable to raise additional funds, or if our anticipated operating results are not achieved, we believe planned expenditures may need to be reduced in order to extend the time period that existing resources can fund our operations. If we are unable to obtain the necessary capital, it may have a material adverse effect on our operations and the development of our technology, or we may have to cease operations altogether.

The development and commercialization of our cortical strip, grid electrode and depth electrode technology is subject to numerous uncertainties, and we could use our cash and cash equivalent resources sooner than we expect. Additionally, the process of developing medical devices is costly, and the timing of progress in pre-clinical tests and clinical trials is uncertain. Our ability to successfully transition to profitability will be dependent upon achieving further regulatory approvals and achieving a level of product sales adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Cash Flows

The following is a summary of cash flows for each of the periods set forth below.

	For the Years Ended September 30,	
	2023	**2022**
Net cash used in operating activities	$ (12,886,874)	$ (7,519,534)
Net cash provided by (used in) investing activities	2,649,964	(3,244,765)
Net cash provided by financing activities	7,399,074	12,023,282
Net (decrease) increase in cash	$ (2,837,836)	$ 1,258,983

Net cash used in operating activities

Net cash used in operating activities was $12.9 million for the year ended September 30, 2023, which consisted of a net loss of $11.9 million partially offset by non-cash stock-based compensation, depreciation, amortization related to intangible assets and short term investment premiums and discounts, operating lease expense and loss on disposal of fixed assets, totaling approximately $1.4 million in the aggregate. The net change in our net operating assets and liabilities associated with fluctuations in our operating activities resulted in a cash use of approximately $2.4 million. The net cash use stemming from the change in operating assets and liabilities was primarily attributable to both a decrease in deferred revenue in connection with the completion of the remaining milestone performance obligation under the Zimmer Development Agreement and to an increase in inventory purchases, attributed to the timing of payments. Partially offsetting the net cash operating use during the period was a decrease in our accounts receivable, prepaid expenses and by an increase in our accrued expenses, on a net basis, resulting from timing of payments and fluctuations in our operations.

Net cash used in operating activities was $7.5 million for the year ended September 30, 2022, which consisted of a net loss of $10.0 million partially offset primarily by stock-based compensation, depreciation, amortization related to intangible assets and to short-term investment discounts and premiums, non-cash lease expense and non-cash consideration associated with the Zimmer Development Agreement, totaling approximately $1.3 million in the aggregate. The net change in our net operating assets and liabilities associated with fluctuations in our operating activities resulted in a cash source of approximately $1.2 million. The year on year change in operating assets and liabilities was primarily attributable to a net increase in accounts payable, accrued expenses and deferred revenue, offset partially by increases in inventory purchases and prepaid expenses.

Net cash provided by (used in) investing activities

Net cash provided by investing activities was $2.6 million for the year ended September 30, 2023 and consisted of maturities of short-term investments in the amount of $4.5 million, offset by purchases of short term investments of $1.5 million, consisting of treasury and corporate notes. The balance of activity during the period consisted of outlays for purchases of property and equipment in the amount $0.4 million offset slightly by net proceeds associated with the disposal of equipment.

Net cash used by investing activities for the year ended September 30, 2022 was $3.2 million and consisted of purchases of short-term investments consisting of treasury and corporate notes of approximately $3.5 million and outlays for purchases of property and equipment of $0.3 million which were partially offset by maturities of short-term investments in the amount of $0.5 million.

Net cash provided by financing activities

Net cash provided by financing activities was $7.4 million for the year ended September 30, 2023, which consisted of net proceeds from the July 2023 Public Offering of $5.2 million and from the ATM of $2.3 million, offset partially by repurchases of common stock for the payment of employee taxes in the amount of $0.1 million.

Net cash provided by financing activities was $12.0 million for the year ended September 30, 2022, which consisted of net proceeds from the October 2021 Underwritten Public Offering.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles. These accounting principles require us to make estimates and judgments that can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenue and expense during the periods presented. We believe that the estimates and judgments upon which we rely are reasonably based upon information available to us at the time that we make these estimates and judgments. To the extent that there are material differences between these estimates and actual results, our financial results will be affected. The accounting policies that reflect our more significant estimates and judgments and which we believe are the most critical to aid in fully understanding and evaluating our reported financial results are described in "Note 3 — Summary of Significant Accounting Policies" to our financial statements included in "Item 8 — Financial Statements and Supplementary Data" in this Report.

Of these policies, the following are considered critical to an understanding of our financial statements included in "Item 8 — Financial Statements and Supplementary Data" in this Report that require the application of the most subjective and the most complex judgments:

Revenues:

For discussion about the determination of collaborations revenue, product revenue and cost of product revenue, see "Note 7 — Zimmer Development Agreement" included in "Item 8 — Financial Statements and Supplementary Data" in this Report. To date, we have not had, nor expect to have in the future, significant variable consideration adjustments related to product revenue, such as chargebacks, sales allowances and sales returns.

Stock-based Compensation

For discussions about the application of grant date fair value associated with our stock-based compensation, see "Note 8 — Stock-Based Compensation" included in "Item 8 — Financial Statements and Supplementary Data" in this Report.

Income Tax Assets and Liabilities

Income tax assets and liabilities include income tax valuation allowances. For additional information, see "Note 11 — Income Taxes" included in "Item 8 — Financial Statements and Supplementary Data" in this Report.

Contingencies

We are subject to numerous contingencies arising in the ordinary course of business, including legal contingencies. For additional information, see "Note 4 — Commitments and Contingencies" included in "Item 8 — Financial Statements and Supplementary Data" in this Report.

Recent Accounting Pronouncements

See "Note 3 — Summary of Significant Accounting Policies" included in "Item 8 — Financial Statements and Supplementary Data" in this Report regarding the impact of certain recent accounting pronouncements on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the board of directors of NeuroOne Medical Technologies Corporation:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of NeuroOne Medical Technologies Corporation (the "Company") as of September 30, 2023 and 2022, the related statements of operations, changes in stockholders' equity, and cash flows, for each of the two years in the period ended September 30, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2023 and 2022, and the results of the Company's operations and cash flows for each of the two years in the period ended September 30, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 of the financial statements, the Company had recurring losses from operations and an accumulated deficit, expects to incur losses for the foreseeable future and requires additional working capital. These are the reasons that raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not contain any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2021.

Minneapolis, Minnesota
December 15, 2023

NeuroOne Medical Technologies Corporation
Balance Sheets

	As of September 30,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 5,322,493	$ 8,160,329
Short-term investments	—	2,981,010
Accounts receivable	—	33,237
Inventory	1,726,686	704,538
Prepaid expenses	263,746	296,649
Total current assets	7,312,925	12,175,763
Intangible assets, net	89,577	111,892
Right-of-use asset	169,059	181,355
Property and equipment, net	525,753	353,599
Total assets	$ 8,097,314	$ 12,822,609
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 685,104	$ 927,662
Accrued expenses and other liabilities	1,107,522	715,839
Deferred revenue	—	1,455,188
Total current liabilities	1,792,626	3,098,689
Operating lease liability, long term	55,284	119,556
Total liabilities	1,847,910	3,218,245
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized as of September 30, 2023 and 2022; no shares issued or outstanding as of September 30, 2023 and 2022	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized as of September 30, 2023 and 2022; 23,928,945 and 16,216,540 shares issued and outstanding as of September 30, 2023 and 2022, respectively	23,929	16,217
Additional paid-in capital	68,911,778	60,414,959
Accumulated deficit	(62,686,303)	(50,826,812)
Total stockholders' equity	6,249,404	9,604,364
Total liabilities and stockholders' equity	$ 8,097,314	$ 12,822,609

See accompanying notes to financial statements

NeuroOne Medical Technologies Corporation
Statements of Operations

	Years ended September 30,	
	2023	**2022**
Product revenue	$ 1,952,441	$ 171,169
Cost of product revenue	1,495,924	241,963
Product gross profit (loss)	456,517	(70,794)
Collaborations revenue	1,455,188	1,948,872
Operating expenses:		
Selling, general and administrative	6,926,269	6,979,416
Research and development	6,940,686	4,929,427
Total operating expenses	13,866,955	11,908,843
Loss from operations	(11,955,250)	(10,030,765)
Other income, net	95,759	31,152
Loss before income taxes	(11,859,491)	(9,999,613)
Provision for income taxes	—	—
Net loss	$ (11,859,491)	$ (9,999,613)
Net loss per share:		
Basic and diluted	$ (0.65)	$ (0.63)
Number of shares used in per share calculations:		
Basic and diluted	18,121,108	15,998,567

See accompanying notes to financial statements

NeuroOne Medical Technologies Corporation
Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at September 30, 2021	12,010,019	$ 12,010	$ 47,369,090	$ (40,827,199)	$ 6,553,901
Issuance of common stock in connection with public offering	4,172,057	4,172	13,346,410	—	13,350,582
Issuance cost in connection with public offering	—	—	(1,352,280)	—	(1,352,280)
Issuance of warrants in connection with Zimmer development agreement	—	—	104,562	—	104,562
Stock-based compensation	—	—	947,212	—	947,212
Issuance of common stock upon vesting of restricted stock units	34,464	35	(35)	—	—
Net loss	—	—	—	(9,999,613)	(9,999,613)
Balance at September 30, 2022	16,216,540	16,217	60,414,959	(50,826,812)	9,604,364
Issuance of common stock in connection with public offering	6,037,500	6,038	6,031,462	—	6,037,500
Issuance of common stock in connection with at-the-market offering program	1,439,677	1,440	2,551,216	—	2,552,656
Issuance cost in connection with common stock issuances	—	—	(1,071,663)	—	(1,071,663)
Stock-based compensation	—	—	1,105,457	—	1,105,457
Issuance of common stock upon vesting of restricted stock units	314,485	313	(313)	—	—
Share repurchases for the payment of employee taxes	(79,257)	(79)	(119,340)	—	(119,419)
Net loss				(11,859,491)	(11,859,491)
Balance at September 30, 2023	23,928,945	$ 23,929	$ 68,911,778	$ (62,686,303)	$ 6,249,404

See accompanying notes to financial statements

NeuroOne Medical Technologies Corporation
Statements of Cash Flows

	Years ended September 30,	
	2023	**2022**
Operating activities		
Net loss	$ (11,859,491)	$ (9,999,613)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	199,266	118,620
Stock-based compensation	1,105,457	947,212
Loss on disposal of fixed assets	32,143	—
Amortization of discounts and premiums on short-term investments	(45,571)	(11,471)
Non-cash lease expense	109,832	107,593
Issuance of warrants in connection with Zimmer contract amendment	—	104,562
Change in assets and liabilities:		
Accounts receivable	33,237	15,099
Inventory	(1,022,148)	(606,251)
Prepaid expenses and other assets	32,903	(145,540)
Accounts payable	(247,189)	515,438
Accrued expenses, deferred revenue, operating lease and other liabilities	(1,225,313)	1,434,817
Net cash used in operating activities	(12,886,874)	(7,519,534)
Investing activities		
Purchases of short-term investments	(1,473,419)	(3,469,539)
Maturities of short-term investments	4,500,000	500,000
Proceeds from the disposal of fixed assets	7,500	—
Purchases of property and equipment	(384,117)	(275,226)
Net cash provided by (used in) investing activities	2,649,964	(3,244,765)
Financing activities		
Proceeds from issuance of common stock in connection with public offerings and at-the-market offering program	8,590,156	13,350,582
Issuance costs in connection with common stock issuances	(1,071,663)	(1,327,300)
Share repurchases for the payment of employee taxes	(119,419)	—
Net cash provided by financing activities	7,399,074	12,023,282
Net (decrease) increase in cash and cash equivalents	(2,837,836)	1,258,983
Cash and cash equivalents at beginning of year	8,160,329	6,901,346
Cash and cash equivalents at end of year	$ 5,322,493	$ 8,160,329
Supplemental non-cash financing and investing transactions:		
Unpaid purchases of property and equipment	$ 4,631	$ —
Modification of right-of-use asset and associated lease liability	$ 97,536	$ —
Reclass of deferred offering costs to additional paid-in capital in connection with public offering	$ —	$ 24,980

See accompanying notes to financial statements

NOTE 1 — Organization and Nature of Operations

NeuroOne Medical Technologies Corporation (the "Company" or "NeuroOne"), a Delaware corporation, is a medical technology company focused on the development and commercialization of thin film electrode for continuous electroencephalogram ("cEEG") and stereoelectrocencephalography ("sEEG") recording, monitoring, ablation, drug delivery and brain stimulation solutions to diagnose and treat patients with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders.

The Company received 510(k) clearance from the United States ("U.S.") Food and Drug Administration ("FDA") for its Evo cortical electrode technology in November 2019 and in October 2022, the Company received 510(k) clearance from the FDA for its Evo sEEG 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.

The Company is based in Eden Prairie, Minnesota.

Global Economic Conditions

Generally, worldwide economic conditions remain uncertain, particularly due to the conflicts between Russia and Ukraine and in the Middle East, disruptions in the banking system and financial markets, lingering effects of the COVID-19 pandemic and increased inflation. The general economic and capital market conditions both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected the Company's access to capital and increased the cost of capital. The capital and credit markets may not be available to support future capital raising activity on favorable terms or at all. If economic conditions continue to decline, the Company's future cost of equity or debt capital and access to the capital markets could be adversely affected.

The COVID-19 pandemic that began in late 2019 introduced significant volatility to the global economy, disrupted supply chains and had a widespread adverse effect on the financial markets. Additionally, the Company's operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, the conflicts in Ukraine and the Middle East, disruptions in the banking system and financial markets, and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, have led to higher inflation, which has led to an increase in costs and has caused changes in fiscal and monetary policy, including increased interest rates.

NOTE 2 — Going Concern

The accompanying financial statements have been prepared on the basis that the Company will continue as a going concern. The Company has incurred losses since inception, negative cash flows from operations, and an accumulated deficit of $62.7 million as of September 30, 2023. To date, the Company's revenues have not been sufficient to cover its full operating costs, and as such, has been dependent on funding operations through the issuance of debt and sale of equity securities. With the July 2023 public offering, the Company has adequate liquidity to fund its operations through March 31, 2024. The raising of additional funds is not solely within the control of the Company. These factors raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this condition. If the Company is unable to raise additional funds, or the Company's anticipated operating results are not achieved, management believes planned expenditures may need to be reduced in order to extend the time period that existing resources can fund the Company's operations. The Company intends to fund ongoing activities by utilizing its current cash and cash equivalents on hand, from product and collaborations revenue and by raising additional capital through equity or debt financings. If management is unable to obtain the necessary capital, it may have a material adverse effect on the operations of the Company and the development of its technology, or the Company may have to cease operations altogether.

NOTE 3 — Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting standards generally accepted in the United States of America ("U.S. GAAP").

Management's Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and are evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer. The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is the business of development and commercialization of products related to comprehensive neuromodulation cEEG and sEEG recording, monitoring, ablation, and brain stimulation solutions. Accordingly, the Company has a single reporting segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original contractual maturity on date of purchase of less than or equal to three months to be classified and presented as cash equivalents on the Balance Sheets. Cash equivalents are stated at cost, which approximates fair value. The Company's cash and cash equivalents may include demand deposit accounts with large financial institutions, institutional money market funds, U.S. Treasury securities, and corporate notes and bonds. The Company monitors the creditworthiness of the financial institutions, institutional money market funds, and corporations in which the Company invests its surplus funds. The Company has experienced no credit losses from its cash and cash equivalent investments.

Short-Term Investments

The Company has periodically invested its excess cash in U.S. Treasury securities and highly rated corporate securities. The Company has held these investments to maturity. Securities with original maturity dates of more than three months were reported as held-to-maturity investments and were recorded at amortized cost, which approximated fair value due to the negligible risk of changes in value due to interest rates. All investments held as September 30, 2022 had contractual maturities of less than one year. There were no short-term investments outstanding as of September 30, 2023. The amortized cost and estimated fair values of the Company's investments as of September 30, 2022 were as follows:

	September 30, 2022			
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Fair Value
Short-term:				
U.S. treasury and corporate notes	$ 2,981,010	$ —	$ 2,870	$ 2,978,140
Total	$ 2,981,010	$ —	$ 2,870	$ 2,978,140

NOTE 3 — Summary of Significant Accounting Policies (cont.)

Revenue Recognition

The Company entered into a development and distribution agreement which has current and future revenue recognition implications. See "Note 7 — Zimmer Development Agreement."

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in Account Standards Codification ("ASC") Topic 606 ("ASC 606"). Performance obligations may include license rights, development services, and services associated with regulatory submission and approval processes. Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations are either completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

Product Revenue

Revenues from product sales are recognized when control of the promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. At the inception of each customer contract, performance obligations are identified and the total transaction price is allocated to the performance obligations.

Cost of Product Revenue

Cost of product revenue consists of the manufacturing and materials costs incurred by the Company's third-party contract manufacturer in connection with the Company's strip and grid cortical electrodes (the "Strip/Grid Products"), depth electrodes ("sEEG Products) and outside supplier materials costs in connection with the electrode cable assembly products ("Electrode Cable Assembly Products"). In addition, cost of product revenue includes royalty fees incurred in connection with the Company's license agreements.

Collaborations Revenue

As part of the accounting for collaboration arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. The Company allocates the total transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

NOTE 3 — Summary of Significant Accounting Policies (cont.)

Milestone payments: At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission) is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until those approvals are received. When the Company's assessment of probability of achievement changes and variable consideration becomes probable, any additional estimated consideration is allocated to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation and recorded in collaborations revenues based upon when the customer obtains control of each element.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Fair Value of Financial Instruments

The Company's accounting for fair value measurements of assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring or nonrecurring basis adheres to the Financial Accounting Standards Board ("FASB") fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are as follows:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the Company at the measurement date.
- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

As of September 30, 2023 and 2022, the fair values of cash, cash equivalents, short-term investments, accounts receivable, inventory, prepaids and other assets, accounts payable and accrued expenses and other liabilities approximated their carrying values because of the short-term nature of these assets or liabilities.

There were no transfers between fair value hierarchy levels during the years ended September 30, 2023 and 2022.

Intellectual Property

The Company has entered into two licensing agreements with major research institutions, which allow for access to certain patented technology and know-how. Payments under those agreements are capitalized and amortized to selling, general and administrative expense over the expected useful life of the acquired technology.

Property and Equipment

Property and equipment is recorded at cost and reduced by accumulated depreciation. Depreciation expense is recognized over the estimated useful lives of the assets using the straight-line method. The estimated useful life for equipment and furniture ranges from three to seven years and three years for software. Tangible assets acquired for research and development activities and that have alternative use are capitalized over the useful life of the acquired asset. Estimated useful lives are periodically reviewed, and, when appropriate, changes are made prospectively.

NOTE 3 — Summary of Significant Accounting Policies (cont.)

Software purchased for internal use consists primarily of amounts paid for perpetual licenses to third-party software providers and installation costs. When certain events or changes in operating conditions occur, asset lives may be adjusted and an impairment assessment may be performed on the recoverability of the carrying amounts. Maintenance and repairs are charged directly to expense as incurred.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist of licensed intellectual property, property and equipment and right-of-use assets for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. The Company assesses the recoverability of long-lived assets by determining whether or not the carrying value of such assets will be recovered through undiscounted expected future cash flows. If the asset is considered to be impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset.

Allowances for Doubtful Accounts

The Company records a provision for doubtful accounts, when appropriate, based on historical experience and a detailed assessment of the collectability of its accounts receivable. In estimating the allowance for doubtful accounts, the Company considers, among other factors, the aging of the accounts receivable, its historical write-offs, the credit worthiness of each customer, and general economic conditions. Account balances are charged off against the allowance when the Company believes that it is probable that the receivable will not be recovered. Actual write-offs may be in excess of the Company's estimated allowance.

Inventory

Inventory is stated at the lower of cost (using the first-in, first-out "FIFO" method) or net realizable value. The Company calculates inventory valuation adjustments for excess and obsolete inventory, when appropriate, based on current inventory levels, movement, expected useful lives, and estimated future demand of the products and spare parts. The Company's inventory is currently comprised of Strip/Grid Products, sEEG and electrode cable assembly work-in-process and finished good product. The Strip/Grid Products and sEEG Products are produced by a third-party contract manufacturer and the Electrode Cable Assembly Products are obtained from outside suppliers. No inventory valuation allowance was required during the periods presented.

Research and Development Costs

Research and development costs are charged to expense as incurred. Research and development expenses may include costs incurred in performing research and development activities, including clinical trial costs, manufacturing costs for both clinical and pre-clinical materials as well as other contracted services, license fees, and other external costs. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC 730, *Research and Development*.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel-related costs including stock-based compensation for personnel in functions not directly associated with research and development activities. Other significant costs include legal and litigation costs relating to corporate matters, intellectual property costs, professional fees for consultants assisting with regulatory, clinical, product development, financial matters and sales and marketing in connection with the commercial sales of the Company's products.

NOTE 3 — Summary of Significant Accounting Policies (cont.)

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of ASC 718, *Compensation — Stock Compensation* ("ASC 718"). Accordingly, compensation costs related to equity instruments granted are recognized at the grant-date fair value over the requisite service period. The Company records forfeitures when they occur. Stock-based compensation arrangements to non-employees are accounted for in accordance with the applicable provisions of ASC 718.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

Net Loss Per Share

Basic loss per share of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period.

Diluted earnings or loss per share of common stock is computed similarly to basic earnings or loss per share except the weighted average shares outstanding are increased to include additional shares from the assumed exercise of any common stock equivalents, if dilutive. The Company's warrants, stock options, and restricted stock units while outstanding are considered common stock equivalents for this purpose. Diluted earnings or loss per share of common stock is computed utilizing the treasury method for the warrants, stock options and restricted stock units. No incremental common stock equivalents were included in calculating diluted loss per share because such inclusion would be anti-dilutive given the net loss reported for the years ended September 30, 2023 and 2022.

The following potential common shares were not considered in the computation of diluted net loss per share as their effect would have been anti-dilutive for the years ended September 30:

	2023	2022
Warrants	6,202,426	7,103,344
Stock options	1,708,427	1,239,915
Restricted stock units	393,370	414,430
Unissued vested restricted stock units	—	7,316

Recent Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update ("ASU") 2016-13, "*Financial Instruments — Credit Losses"*. The ASU sets forth a "current expected credit loss" ("CECL") model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, with early adoption permitted. The FASB issued the final ASU to delay adoption for smaller reporting companies to fiscal years beginning after December 15, 2022. The Company adopted the guidance on October 1, 2023. The Company does not expect that the adoption of this ASU will have a material impact on its financial statements.

NOTE 3 — Summary of Significant Accounting Policies (cont.)

In August 2020, the FASB issued ASU 2020-06*, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, this ASU modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in this ASU are effective for smaller reporting companies as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU 2020-06 effective October 1, 2022 and the ASU did not have a material impact to its financial statements.

NOTE 4 — Commitments and Contingencies

WARF License Agreement

The Company has entered into an exclusive start-up company license agreement with the Wisconsin Alumni Research Foundation ("WARF") for WARF's neural probe array and thin film micro electrode technology (the "WARF Agreement"). The Company entered into an Amended and Restated Exclusive Start-up Company License Agreement (the "WARF License") with WARF on January 21, 2020, which amended and restated in full the prior license agreement between WARF and NeuroOne, LLC, a predecessor of the Company, dated October 1, 2014, as amended on February 22, 2017, March 30, 2019 and September 18, 2019.

The WARF License grants to the Company an exclusive license to make, use and sell, in the United States only, products that employ certain licensed patents for a neural probe array or thin-film micro electrode array and method. The Company agreed to pay WARF a royalty equal to a single-digit percentage of our product sales pursuant to the WARF License, with a minimum annual royalty payment of $50,000 for 2020, $100,000 for 2021 and $150,000 for 2022 and each calendar year thereafter that the WARF License is in effect. If the Company or any of its sublicensees contest the validity of any licensed patent, the royalty rate will be doubled during the pendency of such contest and, if the contested patent is found to be valid and would be infringed by the Company if not for the WARF License, the royalty rate will be tripled for the remaining term of the WARF License.

WARF may terminate the WARF License on 30 days' written notice if we default on the payments of amounts due to WARF or fail to timely submit development reports, actively pursue our development plan or breach any other covenant in the WARF License and fail to remedy such default in 90 days or in the event of certain bankruptcy events involving us. WARF may also terminate the WARF License (i) on 90 days' notice if we had failed to have commercial sales of one or more FDA-approved products under the WARF License by June 30, 2021 or (ii) if, after royalties earned on sales begin to be paid, such earned royalties cease for more than four calendar quarters. The first commercial sale occurred on December 7, 2020, prior to the June 30, 2021 deadline. The WARF License otherwise expires by its terms on the date that no valid claims on the patents licensed thereunder remain. The Company expects the latest expiration of a licensed patent to occur in 2030. During the years ended September 30, 2023 and 2022, $150,000 and $137,500 in royalty fees were incurred related to the WARF License, respectively, and were reflected as a component of cost of product revenue.

Mayo Agreement

The Company has an exclusive license and development agreement with the Mayo Foundation for Medical Education and Research ("Mayo") related to certain intellectual property and development services for thin film micro electrode technology ("Mayo Agreement"). If the Company is successful in obtaining regulatory approval, the Company is to pay royalties to Mayo based on a percentage of net sales of products of the licensed technology

NOTE 4 — Commitments and Contingencies (cont.)

through the term of the Mayo Agreement, set to expire May 25, 2037. During the years ended September 30, 2023 and 2022, $7,486 and $4,861 in royalty fees were incurred, respectively, and were reflected as a component of cost of product revenue.

Facility Leases

Headquarters Lease

On October 7, 2019, the Company entered into a non-cancellable lease agreement (the "Lease") with certain landlords (together, the "Landlord") pursuant to which the Company has agreed to lease office space located at 7599 Anagram Drive, Eden Prairie, Minnesota (the "Premises"). The Company took possession of the Premises on November 1, 2019, with the term of the Lease ending 65 months after such date, unless terminated earlier (the "Lease Term"). The initial base rent for the Premises is $6,410 per month for the first 17 months, increasing to $7,076 per month by the end of the Lease Term. In addition, as long as the Company is not in default under the Lease, the Company shall be entitled to an abatement of its base rent for the first 5 months. In addition, the Company will pay its pro rata share of the Landlord's annual operating expenses associated with the Premises, calculated as set forth in the Lease of which the Company is entitled to an abatement of these operating expense for the first 3 months.

Los Gatos Lease

On July 1, 2021, the Company entered into a non-cancellable facility lease (the "Los Gatos Lease"), pursuant to which the Company agreed to rent office space for its research and development operations located at 718 University Avenue, Suite #111, Los Gatos, California. The facility space under the Los Gatos Lease is approximately 1,162 square feet. The Company took possession of the office space on July 2, 2021. The initial monthly rent under the Los Gatos Lease was approximately $4,241. On November 4, 2022, the Los Gatos Lease was extended for an additional two years to December 31, 2024. The rent under the extended Los Gatos Lease ranges from $4,453 to $4,632 per month beginning on January 1, 2023.

During the years ended September 30, 2023 and 2022, rent expense associated with the facility leases amounted to $171,633 and $170,501, respectively.

Supplemental cash flow information related to the operating lease was as follows:

	For the Years Ended September 30,	
	2023	2022
Cash paid for amounts included in the measurement of lease liability:		
Operating cash flows from operating leases	$ 134,632	$ 130,727
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 97,536	$ —

Supplemental balance sheet information related to the operating lease was as follows:

	As of September 30,	
	2023	2022
Right-of-use assets	$ 169,059	$ 181,355
Lease liability	$ 184,400	$ 202,895
Weighted average remaining lease term (years)	1.4	2.4
Weighted average discount rate	7.8%	6.9%

NOTE 4 — Commitments and Contingencies (cont.)

Maturity of the lease liability was as follows:

Calendar Year	As of September 30, 2023
2023 (period from October 1, 2023 to December 31, 2023)	$ 34,070
2024	139,969
2025	21,227
Total lease payments	195,266
Less imputed interest	(10,866)
Total	184,400
Short-term portion	(129,116)
Long-term portion	$ 55,284

NOTE 5 — Supplemental Balance Sheet Information

Inventory

Inventory consisted of the following:

	As of September 30,	
	2023	2022
Component inventory	$ 1,202,778	$ 400,063
Work-in-process	343,597	230,507
Finished goods	180,311	73,968
Total	$ 1,726,686	$ 704,538

Intangibles

Intangible assets roll forward is as follows:

	Useful Life	
Net Intangibles, September 30, 2021	12 – 13 years	$ 134,207
Less: amortization		(22,315)
Net Intangibles, September 30, 2022		111,892
Less: amortization		(22,315)
Net Intangibles, September 30, 2023		$ 89,577

The Company anticipates amortization expense of approximately $22,000 per year for fiscal year 2024 through 2027 based upon the two current license agreements.

NOTE 5 — Supplemental Balance Sheet Information (cont.)

Property and Equipment

Property and equipment, net held for use by category are presented in the following table:

	As of September 30,	
	2023	2022
Equipment and furniture	$ 860,737	$ 538,061
Software	—	1,895
Total property and equipment	860,737	539,956
Less accumulated depreciation	(334,984)	(186,357)
Property and equipment, net	$ 525,753	$ 353,599

Depreciation expense was $176,951 and $96,305 for the years ended September 30, 2023 and 2022, respectively. Equipment with a net book value of $39,643 was disposed by the Company resulting in net proceeds of $7,500.

NOTE 6 — Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following

	As of September 30,	
	2023	2022
Accrued payroll	$ 874,382	$ 521,368
Operating lease liability, short term	129,116	83,339
Royalty fees	104,024	111,132
Total	$ 1,107,522	$ 715,839

NOTE 7 — Zimmer Development Agreement

On July 20, 2020, the Company entered into an exclusive development and distribution agreement (the "Development Agreement") with Zimmer, Inc. ("Zimmer"), pursuant to which the Company granted Zimmer exclusive global rights to distribute the Strip/Grid Products and electrode cable assembly products (the "Electrode Cable Assembly Products"). Additionally, the Company granted Zimmer the exclusive right and license to distribute certain depth electrodes developed by the Company ("SEEG Products", and together with the Strip/Grid Products and Electrode Cable Assembly Products, the "Products"). The parties have agreed to collaborate with respect to development activities under the Development Agreement through a joint development committee composed of an equal number of representatives of Zimmer and the Company.

Under the terms of the Development Agreement, the Company is responsible for all costs and expenses related to developing the Products, and Zimmer is responsible for all costs and expenses related to the commercialization of the Products. In addition to the Development Agreement, Zimmer and the Company have entered into a Manufacturing and Supply Agreement and a supplier quality agreement with respect to the manufacturing and supply of the Products.

Except as otherwise provided in the Development Agreement, the Company is responsible for performing all development activities, including non-clinical and clinical studies directed at obtaining regulatory approval of each Product. Zimmer has agreed to use commercially reasonable efforts to promote, market and sell each Product following the "Product Availability Date" (as defined in the Development Agreement) for such Product.

Pursuant to the Development Agreement, Zimmer made an upfront initial exclusivity fee payment of $2.0 million (the "Initial Exclusivity Fee") to the Company in fiscal year 2020.

NOTE 7 — Zimmer Development Agreement (cont.)

On August 2, 2022, the Company entered into a Third Amendment to Exclusive Development and Distribution Agreement (the "Amendment") with Zimmer. Pursuant to the terms and conditions of the Amendment, Zimmer made a $3.5 million payment to the Company. In consideration of the mutual covenants and agreements contained in the Development Agreement, the fee and milestone payment provisions in the Development Agreement were replaced with the following below:

- $1.5 million for the sEEG Exclusivity Maintenance Fee; and
- $2.0 million for satisfaction of each of the milestone events related to the design of sEEG products set forth in the Development Agreement even though the satisfaction was after the deadlines originally identified.

In addition, in connection with the Amendment, the Company issued Zimmer a warrant to purchase common stock (the "2022 Zimmer Warrant"). The 2022 Zimmer Warrant is exercisable for up to an aggregate of 350,000 shares of the Company's common stock. The 2022 Zimmer Warrant has an exercise price of $3.00 per share, will be exercisable commencing six months from the issuance date, and will expire on August 2, 2027. The fair value of the 2022 Zimmer Warrant of $0.1 million was based on the Black-Scholes pricing model. Input assumptions used were as follows: a risk-free interest rate of 2.9%; expected volatility of 53.5%; expected life of 5 years; expected dividend yield of 0%; and the underlying fair market of the common stock. The 2022 Zimmer Warrant was classified in stockholders' equity as the number of shares were fixed and determinable, no cash settlement was required and no other provisions precluded equity treatment.

The Development Agreement will expire on the tenth anniversary of the date of the first commercial sale of the last Products to achieve a first commercial sale (the "Term"), unless terminated earlier pursuant to its terms. Either party may terminate the Development Agreement (x) with written notice for the other party's material breach following a cure period or (y) if the other party becomes subject to certain insolvency proceedings. In addition, Zimmer may terminate the Development Agreement for any reason with 90 days' written notice, and the Company may terminate the Development Agreement if Zimmer acquires or directly or indirectly owns a controlling interest in certain competitors of the Company. The license rights granted to Zimmer under the Strip/Grid Distribution License and sEEG Distribution License shall be exclusive from the Effective Date of the Amendment until the end of the Term.

The Development Agreement and Amendment were accounted for under the provisions of ASC 606. In accordance with the provisions under ASC 606, the Company identified five performance obligations under the Development Agreement and Amendment: (1) the Company's obligation to grant Zimmer access to its intellectual property; (2) completion SEEG Product development; (3) completion of Strip/Grid Product development; (4) the provision of sEEG exclusivity maintenance; and (5) completion of sEEG design modifications as requested by Zimmer. All performance obligations under the Development Agreement and Amendment, outside of the sEEG exclusivity maintenance obligation, were met by September 30, 2022. The remaining performance obligation in deferred revenue as of September 30, 2022 attributed to sEEG exclusivity maintenance was completed in first quarter of fiscal year 2023.

The aggregate transaction price associated with the Development Agreement and Amendment was $5.4 million comprising the Initial Exclusivity Fee of $2.0 million and the $3.5 million payment under the Amendment, less the fair value 2022 Zimmer Warrant of $0.1 million. The transaction price was allocated between performance obligations based on their relative standalone selling prices. The Company used a market based valuation approach and an expected cost plus margin approach with regard to estimating the standalone selling price for the performance obligations. The Company recognized revenue in the amount of $1,455,188 and $1,948,872 during the years ended September 30, 2023 and 2022, respectively, in connection with the Development Agreement and Amendment.

NOTE 7 — Zimmer Development Agreement (cont.)

A reconciliation of the closing balance of deferred revenue related to the Development Agreement and Amendment is as follows as of September 30, 2023 and 2022:

Deferred Revenue	
Balance as of September 30, 2021	$ 8,622
Zimmer agreement amendment related to sEEG exclusivity maintenance	3,395,438
Revenue recognized	(1,948,872)
Balance as of September 30, 2022	1,455,188
Revenue recognized	(1,455,188)
Balance as of September 30, 2023	$ —

Product Revenue

Product revenue is related to its Strip/Grid Products, sEEG Products and Electrode Cable Assembly Products. Product revenue recognized during the years ended September 30, 2023 and 2022 was $1,952,441 and $171,169, respectively.

Advertising Expense

Advertising expense is charged to selling, general and administrative expenses during the period that it is incurred. Total advertising expense amounted to $173,430 and $270,612 for the years ended September 30, 2023 and 2022, respectively.

NOTE 8 — Stock-Based Compensation

During the years ended September 30, 2023 and 2022, stock-based expense related to the stock options, restricted stock units and stock awards was included in selling, general and administrative and research and development costs as follows in the accompanying statements of operations:

	2023	2022
Selling, general and administrative	$ 905,108	$ 780,818
Research and development	200,349	166,394
Total stock-based compensation expense	$ 1,105,457	$ 947,212

The Company's 2017 Equity Incentive Plan ("2017 Plan") provides for the issuance of restricted shares and stock options to employees, directors, and consultants of the Company. Effective October 1, 2021, no shares were available for issuance under the 2016 Equity Incentive Plan.

Inducement Plan

In addition to the Company's 2017 Plan, the Company adopted the NeuroOne Medical Technologies Corporation 2021 Inducement Plan (the "Inducement Plan") on October 4, 2021, pursuant to which the Company reserved 420,350 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The Inducement Plan was approved by the Company's board of directors without stockholder approval in accordance with such rule. On November 9, 2023, the Company's board of directors adopted the First Amendment to the Company's Inducement Plan, increasing the aggregate number of shares of common stock that may be issued pursuant to equity incentive awards under the Inducement Plan by 150,000 shares for a total of 570,350 shares of common stock that may be issued pursuant to equity incentive awards under the Inducement Plan.

Evergreen provision

Under the 2017 Plan, the shares reserved automatically increase on January 1st of each year, for a period of not more than ten years from the date the 2017 Plan is approved by the stockholders of the Company, commencing on January 1, 2019 and ending on (and including) January 1, 2027, to an amount equal to 13% of the fully-diluted shares outstanding

NOTE 8 — Stock-Based Compensation (cont.)

as of December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board of Directors may act prior to January 1st of a given year to provide that there will be no January 1st increase in the share reserve for such year or that the increase in the share reserve for such year will be a lesser number of shares of common stock than would otherwise occur pursuant to the preceding sentence. "Fully Diluted Shares" as of a date means an amount equal to the number of shares of common stock (i) outstanding and (ii) issuable upon exercise, conversion or settlement of outstanding awards under the 2017 Plan and any other outstanding options, warrants or other securities of the Company that are (directly or indirectly) convertible or exchangeable into or exercisable for shares of common stock, in each case as of the close of business of the Company on December 31 of the preceding calendar year. On January 1, 2023 and 2022, 129,479 and 1,614,538 shares were added to the 2017 Plan, respectively, as a result of the evergreen provision.

Stock Options

During the years ended September 30, 2023 and 2022, 459,512 and 152,690 stock options were granted to employees, directors and consultants, respectively, with a weighted average grant date fair value of $0.88 and $0.76 per share, respectively. The options granted have vesting periods ranging from being immediate to four years. All options expire ten years from the date of grant. The total expense for the years ended September 30, 2023 and 2022 related to the stock options was $632,315 and $582,329, respectively. The following table summarizes the Company's stock option plan activity for the years ended September 30, 2023 and 2022 as follows:

	Number of Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value[1]
Outstanding at September 30, 2021	1,122,560	$ 5.89	8.8	$ 127,339
Granted	152,690	$ 1.50	—	—
Exercised	—	$ —	—	—
Forfeited/Cancelled	(35,335)	$ 4.14	—	—
Outstanding at September 30, 2022	1,239,915	$ 5.40	8.0	$ 89,295
Granted	469,512	$ 1.55	—	—
Exercised	—	$ —	—	—
Forfeited/Cancelled	(1,000)	$ 3.78	—	—
Outstanding at September 30, 2023	1,708,427	$ 4.34	7.69	$ 20,064
Vested and expected to vest at September 30, 2023	1,708,427	$ 4.34	7.69	$ 20,064
Vested and exercisable at September 30, 2023	1,120,768	$ 5.08	7.12	$ 20,064

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of our common stock as of September 30, 2023 and 2022 of $0.89 and $1.69 per share, respectively. As of September 30, 2023 and 2022, 1,682,912 and 1,125,710 outstanding options, respectively, had no intrinsic value.

The weighted-average assumptions used in the Black-Scholes option-pricing model are as follows for the stock options granted during the years ended September 30:

	2023	2022
Expected stock price volatility	57.4%	53.5%
Expected life of options (years)	5.8	5.6
Expected dividend yield	0%	0%
Risk free interest rate	3.7%	2.3%

During the years ended September 30, 2023 and 2022, 337,753 and 327,615 stock options vested, respectively. No options were exercised during the years ended September 30, 2023 and 2022.

NOTE 8 — Stock-Based Compensation (cont.)

Restricted Stock Units

A summary of restricted stock unit ("RSU") activity is as follows for the years ended September 30, 2023 and 2022:

	Number of Shares
Non-vested at September 30, 2021	11,384
Granted	443,670
Vested	(40,624)
Non-vested at September 30, 2022	414,430
Granted	310,728
Vested	(331,788)
Non-vested at September 30, 2023	393,370

During the years ended September 30, 2023 and 2022, 310,728 and 443,670 RSUs were granted to members of the Company's board of directors and employees that vest over a period ranging from a one year to three year period, with a grant date fair value of $1.60 and $1.91 per unit, respectively. During the years ended September 30, 2023 and 2022, 331,788 and 40,624 RSUs vested, respectively. The total expense for the years ended September 30, 2023 and 2022 related to the RSU's was $473,142 and $364,883, respectively. No RSUs were forfeited during the years ended September 30, 2023 and 2022.

General

As of September 30, 2023, 1,137,983 shares were available for future issuance on a combined basis under the 2017 Plan and the Inducement Plan. Unrecognized stock-based compensation was $1,474,119 as of September 30, 2023. The unrecognized share-based expense is expected to be recognized over a weighted average period of 1.8 years.

NOTE 9 — Stockholders' Equity

July 2023 Public Offering

On July 24, 2023, the Company entered into an underwriting agreement with The Benchmark Company, LLC, as underwriter ("Benchmark"), relating to the issuance and sale of 5,250,000 shares of the Company's common stock, par value $0.001 per share, at a price to the public of $1.00 per share (the "July 2023 Public Offering"). In addition, under the terms of the July 2023 Public Offering, the Company granted Benchmark an option, exercisable for 30 days, to purchase up to an additional 787,500 shares of common stock on the same terms ("the Overallotment Option"). The July 2023 Public Offering closed on July 27, 2023, and the Company completed the sale and issuance of an aggregate of 6,037,500 shares of its common stock, including the exercise in full of the Overallotment Option.

The net proceeds to the Company from the July 2023 Public Offering were approximately $5.2 million after deducting underwriting discounts and other offering expenses payable by the Company. The Company intends to use the net proceeds from this offering to: (i) support the commercial launch of the EVO sEEG electrode with Zimmer Biomet, (ii) support the FDA submission for the OneRF ablation system and (iii) complete the design of a novel drug delivery electrode, among other general corporate purposes.

At-The-Market Offering

On December 21, 2022, the Company entered into a Capital on Demand™ Sales Agreement ("Sales Agreement") with JonesTrading Institutional Services LLC ("JonesTrading") to create an at-the-market offering program ("ATM") under which the Company may offer and sell shares having an aggregate offering price of up to $14.5 million. JonesTrading is entitled to a commission at a fixed commission rate equal to up to 3% of the gross proceeds. As of September 30, 2023, 1,439,677 shares of common stock were issued for gross proceeds of $2,552,656 under the ATM, and issuance costs in the amount of $234,725 have been incurred in connection with the ATM. On July 24, 2023, we decreased

NOTE 9 — Stockholders' Equity (cont.)

the amount of common stock that can be sold pursuant to the Sales Agreement, such that we were offering up to an aggregate of $2,560,000 of our common stock for sale under the Sales Agreement, including the shares of common stock previously sold.

2021 Public Offering

On October 13, 2021, the Company, entered into an underwriting agreement (the "Underwriting Agreement") with Craig-Hallum Capital Group LLC, as underwriter (the "Underwriter"), relating to the issuance and sale of 3,750,000 shares of the Company's common stock at a price to the public of $3.20 per share. In addition, under the terms of the Underwriting Agreement, the Company granted the Underwriter an option, exercisable for 30 days, to purchase up to an additional 562,500 shares of common stock on the same terms. The base offering closed on October 15, 2021, and the sale of 422,057 shares of common stock subject to the Underwriter's overallotment option closed on November 15, 2021.

The gross proceeds to the Company from this offering were approximately $13.4 million prior to deducting underwriting discounts and other offering expenses payable by the Company in the amount of approximately $1.4 million in the aggregate.

Warrant Activity and Summary

The following table summarizes warrant activity during the years ended September 30, 2023 and 2022:

	Warrants	Exercise Price Per Warrant	Weighted Average Exercise Price	Weighted Average Term (years)
Outstanding and exercisable at September 30, 2021	7,503,808	$ 5.25 – 9.00	$ 6.06	3.23
Issued	350,000	$ 3.00	$ 3.00	4.84
Exercised	—	$ —	$ —	—
Reverse split adjustment correction	(100)	$ —	$ —	—
Expired	(750,364)	$ 5.40	$ 5.40	—
Outstanding and exercisable at September 30, 2022	7,103,344	$ 3.00 – 9.00	$ 5.98	2.68
Issued	—	$ —	$ —	—
Exercised	—	$ —	$ —	—
Expired	(900,918)	$ 5.61 – 9.00	$ 6.38	—
Outstanding at September 30, 2023	6,202,426	$ 3.00 – 9.00	$ 5.92	2.00
Outstanding and exercisable at September 30, 2023	6,202,426	$ 3.00 – 900	$ 5.92	2.00

The following table summarizes information about warrants outstanding at September 30, 2023:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual life (Years)	Number Exercisable at September 30, 2023
$ 3.00	350,000	3.84	350,000
$ 5.25	4,166,682	2.29	4,166,682
$ 5.61	220,855	4.75	220,855
$ 6.00	45,171	0.75	45,171
$ 7.50	279,727	0.41	279,727
$ 8.25	62,906	0.75	62,906
$ 9.00	1,077,085	0.25	1,077,085
Total	6,202,426		6,202,426

NOTE 10 — Concentrations

Revenue

One customer accounts for all of the Company's product and collaborations revenue.

Supplier concentration

One contract manufacturer produces all of the Company's Strip/Grid Products and sEEG Products and another supplier was responsible for the development of the Company's OneRF Ablation system.

NOTE 11 — Income Taxes

The effective tax rate for the Company for the years ended September 30, 2023 and 2022 was zero percent. A reconciliation of income tax computed at the statutory federal income tax rate to the provision (benefit) for income taxes included in the accompanying statements of operations for the years ended September 30 is as follows:

	2023	2022
Income tax benefit at federal statutory rate	(21.0)%	(21.0)%
State income tax, net of federal benefit	(7.7)	(7.7)
Research credits	(1.7)	(3.0)
Stock-based compensation and other	0.8	0.7
Valuation allowance	29.6	31.0
Effective tax rate	—%	—%

Significant components of the Company's deferred tax assets and liabilities are summarized in the tables below as of September 30:

	2023	2022
Deferred tax assets:		
Federal and state operating loss carryforwards	$ 11,657,158	$ 10,164,679
Acquired intangibles	28,352	26,447
Accruals and other	63,301	70,399
Research and development capitalization	1,780,649	—
Research and development credit carryforwards	1,314,487	1,107,559
Stock-based compensation	788,790	688,998
Total deferred tax assets	15,632,737	12,058,082
Deferred tax liabilities:		
Fixed assets and other	(204,829)	(140,538)
Total deferred tax liabilities	(204,829)	(140,538)
Valuation allowance	(15,427,908)	(11,917,544)
Net deferred tax assets	$ —	$ —

As of September 30, 2023 and 2022, the Company had gross deferred tax assets of approximately $15,633,000 and $12,058,000, respectively. Realization of the deferred assets is primarily dependent upon future taxable income, if any, the amount and timing of which are uncertain. The Company has had significant pre-tax losses since its inception. The Company has not yet generated revenues from sales to the level of becoming profitable. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance of approximately $15,428,000 and $11,918,000 as of September 30, 2023 and 2022, respectively. Net deferred tax assets will continue to require a valuation allowance until the Company can demonstrate their realizability through sustained profitability or another source of income.

NOTE 11 — Income Taxes (cont.)

As of September 30, 2023 and 2022, the Company's federal net operating loss carryforwards were approximately $40,571,000 and $35,408,000, respectively. The Company had federal research credit carryforwards as of September 30, 2023 and 2022 of approximately $1,074,000 and $759,000, respectively. The federal net operating loss incurred prior to January 1, 2018 and tax credit carryforwards will begin to expire in 2036 if not utilized. Federal net operating losses incurred after December 31, 2017 will not expire. As of September 30, 2023 and 2022, the Company had state net operating loss carryforwards of approximately $40,522,000 and $35,249,000, respectively. The Company had state research credit carryforwards of approximately $598,000 and $441,000 as of September 30, 2023 and 2022, respectively. The state net operating loss carryforwards will begin to expire in 2031, if not utilized, and the state research credit carryforwards will begin to expire in 2032 if not utilized.

Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. Generally, in addition to certain entity reorganizations, the limitation applies when one or more "5-percent shareholders" increase their ownership, in the aggregate, by more than 50 percentage points over a 36-month testing period or beginning the day after the most recent ownership change, if shorter. The annual limitation may result in the expiration of net operating losses and credits before utilization.

In accordance with ASC 740, Income Taxes ("ASC 740"), specifically related to uncertain tax positions, a Company is required to use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. A reconciliation of the beginning and ending amounts of unrecognized tax positions for the years ended September 30 is as follows:

	2023	2022
Unrecognized tax positions, beginning of year	$ —	$ —
Gross increase, current period tax positions	231,968	—
Unrecognized tax positions, end of year	$ 231,968	$ —

If recognized, none of the unrecognized tax positions would impact the Company's income tax benefit or effective tax rate as long as the Company's net deferred tax assets remain subject to a full valuation allowance. The Company does not expect any significant increases or decreases to the Company's unrecognized tax positions within the next 12 months.

In accordance with this guidance, the Company has adopted a policy under which, if required to be recognized in the future, interest related to the underpayment of income taxes will be classified as a component of interest expense and any related penalties will be classified in operating expenses in the accompanying statements of operations.

The Company has tax filing obligations in the following jurisdictions: U.S. federal, Minnesota and California. The income tax returns since inception as a corporation in 2016 are subject to examination by the federal and state taxing authorities.

NOTE 12 — Defined Contribution Plan

The Company has a 401(k) defined contribution plan (the "401K Plan") for all employees over age 21. Employees can defer up to 100% of their compensation through payroll withholdings into the 401K Plan subject to federal law limits. The Company may match 100% of deferrals up to 3% of one's contributions. The Company's matching contributions to employee deferrals are discretionary. The Company may also make discretionary profit sharing contributions under the 401K Plan in the future, but it has not done so through September 30, 2023.

Employee contributions and any employer matching contributions made to satisfy certain non-discrimination tests required by the Internal Revenue Code are 100% vested upon contribution. Discretionary employer matches to employee deferrals vest over a six year period beginning on the second anniversary of an employee's date of hire. Discretionary profit sharing contributions vest over a five year period beginning on the first anniversary of an employee's date of hire. The amount of contributions made by the Company under the 401K Plan during the years ended September 30, 2023 and 2022 was nil and $30,697, respectively.

NOTE 13 — Subsequent Events

First Amendment to 2021 Inducement Plan

On November 9, 2023, the Company's board of directors adopted the First Amendment to the Company's Inducement Plan, increasing the aggregate number of shares of common stock that may be issued pursuant to equity incentive awards under the Inducement Plan by 150,000 shares for a total of 570,350 shares.

At-The-Market Offering

On December 1, 2023, the Company increased the amount of common stock that can be sold pursuant to the Sales Agreement with JonesTrading, such that we are offering up to an aggregate of $4.8 million of common stock for sale under the Sales Agreement, including the shares of common stock previously sold.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) which are controls and other procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

As of September 30, 2023, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2023.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and Board of Directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our management, including our Chief Executive Officer and Chief Financial Officer, recognizes that our internal control over financial reporting cannot prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management, with the participation of the Chief Executive Officer and Chief Financial Officer, assessed our internal control over financial reporting as of September 30, 2023, the end of our fiscal year. Management based its assessment on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, management has concluded that the Company's internal control over financial reporting was effective as of September 30, 2023.

Exemption from Attestation Report of Independent Registered Public Accounting Firm

This Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to the rules of the SEC that permit us to provide only Management's report because we are a non-accelerated filer.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the captions "Executive Compensation", "Proposal No. 1 — Election of Class I Director," and "Executive Officers," and "Board and Committee Information."

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the captions "Executive Compensation" (excluding the information under the subheading "Pay versus Performance") and "Proposal No. 1 — Election of Class I Director — Non-Employee Director Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation — Securities Authorized for Issuance under Equity Compensation Plan."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by Item 13 is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the captions "Certain Relationships and Related-Party Transactions" and "Board and Committee Information."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference to the sections of the 2024 Proxy Statement under the caption "Proposal No. 2 — Ratification of Independent Registered Public Accounting Firm."

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report:

(1) Financial Statements: The financial statements filed as part of this Annual Report are listed in Part II, Item 8.

(2) Financial Statement Schedules:

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes thereto.

(3) Exhibits: The exhibits incorporated by reference or filed as part of this Annual Report are listed in the Index to Exhibits below.

Exhibit No.	Document
2.1***	Agreement and Plan of Merger and Reorganization by and among NeuroOne Medical Technologies Corporation, OSOK Acquisition Company and NeuroOne, Inc. dated as of July 20, 2017 (incorporated by reference to Exhibit 2.1 on the Registrant's Current Report on Form 8-K filed on July 20, 2017)
2.2	Plan of Conversion of NeuroOne Medical Technologies Corporation dated June 20, 2017 (incorporated by reference to Exhibit 2.1 on the Registrant's Current Report on Form 8-K filed on June 29, 2017)
3.1	Certificate of Incorporation of NeuroOne Medical Technologies Corporation (incorporated by reference to Exhibit 3.4 on the Registrant's Current Report on Form 8-K filed on June, 29, 2017)
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of NeuroOne Medical Technologies Corporation (incorporated by reference to Exhibit 3.1 on the Registrant's Current Report on Form 8-K filed on March 31, 2021)
3.3	Bylaws of NeuroOne Medical Technologies Corporation (incorporated by reference to Exhibit 3.5 on the Registrant's Current Report on Form 8-K filed on June 29, 2017)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 on the Registrant's Current Report on Form 8-K filed on July 20, 2017)
4.2	Description of Securities (incorporated by reference to Exhibit 4.2 on the Registrant's Annual Report on Form 10-K filed on December 20, 2019)
10.1#	Amended and Restated Exclusive Start-up Company License Agreement effective January 21, 2020 by and between NeuroOne Medical Technologies Corporation and Wisconsin Alumni Research Foundation (incorporated by reference to Exhibit 10.1 on the Registrant's Current Report on Form 8-K filed on January 24, 2020)
10.2##	Mayo Foundation for Medical Education and Research Amended and Restated License and Development Agreement by and between Mayo Foundation for Medical Education and Research, and NeuroOne LLC dated as of May 25, 2017 (incorporated by reference to Exhibit 10.3 on the Registrant's Current Report on Form 8-K filed on July 20, 2017)
10.3+	2016 Equity Incentive Plan of NeuroOne, Inc. (incorporated by reference to Exhibit 10.11 on the Registrant's Current Report on Form 8-K filed on July 20, 2017)
10.3.1+	Form of Stock Option Award Agreement pursuant to 2016 Equity Incentive Plan of NeuroOne, Inc. (incorporated by reference to Exhibit 10.12 on the Registrant's Current Report on Form 8-K filed on July 20, 2017)
10.4+	2017 Equity Incentive Plan of the Company (incorporated by reference to Appendix G to Schedule 14C filed on April 20, 2017)
10.4.1+	NeuroOne Medical Technologies Corporation 2017 Equity Incentive Plan Option Agreement (incorporated by reference to Exhibit 10.15 on the Registrant's Current Report on Form 8-K filed on July 20, 2017)
10.4.2+	NeuroOne Medical Technologies Corporation 2017 Equity Incentive Plan Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.16 on the Registrant's Current Report on Form 8-K filed on July 20, 2017)
10.5+	NeuroOne Medical Technologies Corporation 2021 Inducement Plan (incorporated by reference to Exhibit 10.1 on the Registrant's Current Report on Form 8-K filed on October 4, 2021)

Exhibit No.	Document
10.5.1+	NeuroOne Medical Technologies Corporation 2021 Inducement Plan Form of Option Grant Agreement (incorporated by reference to Exhibit 10.2 on the Registrant's Current Report on Form 8-K filed on October 4, 2021)
10.6+	Offer Letter to Mark Christianson from NeuroOne, Inc. dated December 1, 2016 (incorporated by reference to Exhibit 10.18 on the Registrant's Current Report on Form 8-K filed on July 20, 2017)
10.7+	Form of Indemnification Agreement with the Company's Officers and Directors (incorporated by reference to Exhibit E to Appendix B to Schedule 14C filed on April 20, 2017)
10.8+	Employment Agreement by and between NeuroOne Medical Technologies Corporation and David A. Rosa dated August 4, 2017 (incorporated by reference to Exhibit 10.1 on the Registrant's Current Report on Form 8-K filed on August 7, 2017)
10.9+	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.40 on the Registrant's Annual Report on Form 10-K filed April 16, 2018)
10.10	Form of Warrant (incorporated by reference to Exhibit 4.1 on the Registrant's Current Report on Form 8-K filed July 13, 2018)
10.11	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 on the Registrant's Current Report on Form 8-K filed July 13, 2018)
10.12+	Employee Proprietary Information, Inventions, Assignment and Non-Competition Agreement. (incorporated by reference to Exhibit 10.52 on the Registrant's Annual Report on Form 10-KT filed on December 12, 2018)
10.13	Form of Warrant (incorporated by reference to Exhibit 4.1 on the Registrant's Current Report on Form 8-K filed on January 4, 2019)
10.14	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 on the Registrant's Current Report on Form 8-K filed on January 4, 2019)
10.15+	Offer Letter between Steve Mertens and NeuroOne Medical Technologies Corporation, effective April 1, 2019 (incorporated by reference to Exhibit 10.2 on the Registrant's Quarterly Report on Form 10-Q filed on May 10, 2019)
10.16	Form of Conversion Warrant (incorporated by reference to Exhibit 4.2 on the Registrant's Current Report on Form 8-K filed on March 6, 2019)
10.15	Form of Paulson Placement Agent Warrant (incorporated by reference to Exhibit 4.2 on the Registrant's Current Report on Form 8-K filed on July 5, 2019)
10.17	Form of HRA Placement Agent Warrant (incorporated by reference to Exhibit 4.3 on the Registrant's Current Report on Form 8-K filed on July 5, 2019)
10.18	Lease Agreement dated October 7, 2019, by and among NeuroOne Medical Technologies Corporation and Biynah Cleveland, LLC, BIP Cleveland, LLC, and Edenvale Investors (incorporated by reference to Exhibit 10.1 on the Registrant's Current Report on Form 8-K filed on October 11, 2019)
10.19	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 on the Registrant's Current Report on Form 8-K filed on October 29, 2019)
10.20	Form of Broker Warrant (incorporated by reference to Exhibit 4.1 on the Registrant's Current Report on Form 8-K filed on January 24, 2020)
10.21	Form of Warrant (incorporated by reference to Exhibit 4.2 on the Registrant's Current Report on Form 8-K filed on May 1, 2020)
10.22	Exclusive Development and Distribution Agreement dated as of July 20, 2020 by and between the Company and Zimmer, Inc. (incorporated by reference to Exhibit 10.1 on the Registrant's Current Report on Form 8-K filed on July 22, 2020)
10.22.1	Amendment to Exclusive Development and Distribution Agreement by and between the Company and Zimmer, Inc. dated January 6, 2021 (incorporated by reference to Exhibit 10.39 on the Registrant's Annual Report on Form 10-K filed on December 15, 2021)
10.22.2	Second Amendment to Exclusive Development and Distribution Agreement by and between the Company and Zimmer, Inc. dated June 28, 2022 (incorporated by reference to Exhibit 10.1 on the Registrant's Quarterly Report on Form 10-Q filed on August 11, 2022)
10.22.3	Third Amendment to Exclusive Development and Distribution Agreement by and between the Company and Zimmer, Inc. dated August 2, 2022 (incorporated by reference to Exhibit 10.2 on the Registrant's Quarterly Report on Form 10-Q filed on August 11, 2022)
10.23+	Employment Offer Letter, dated as of January 1, 2021, by and between Ron McClurg and the Company (incorporated by reference to Exhibit 10.1 on the Registrant's Current Report on Form 8-K filed on January 7, 2021)

Exhibit No.	Document
10.24	Form of Warrant (incorporated by reference to Exhibit 4.1 on the Registrant's Current Report on Form 8-K filed on January 15, 2021)
10.25	Form of Common Stock and Warrant Purchase Agreement (incorporated by reference to Exhibit 10.1 on the Registrant's Current Report on Form 8-K filed on January 15, 2021)
10.26	Underwriting Agreement, dated October 13, 2021, between NeuroOne Medical Technologies Corporation and Craig-Hallum Capital Group LLC (incorporated by reference to Exhibit 1.1 on the Registrant's Current Report on Form 8-K filed on October 14, 2021)
10.27	Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 on the Registrant's Quarterly Report on Form 10-Q filed on August 11, 2022)
10.28	Capital on Demand™ Sales Agreement, dated December 21, 2022 between NeuroOne Medical Technologies Corporation and JonesTrading Institutional Services LLC (incorporated by reference to Exhibit 1.1 on the Registrant's Annual Report on Form 10-K filed on December 22, 2022)
10.29	Underwriting Agreement, dated July 24, 2023, between NeuroOne Medical Technologies Corporation and The Benchmark Company, LLC (incorporated by reference to Exhibit 1.1 on the Registrant's Current Report on Form 8-K filed on July 27, 2023)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of Baker Tilly US, LLP
31.1*	Certification of Principal Executive Officer Pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1*	NeuroOne Medical Technologies Corporation Policy for the Recovery of Erroneously Awarded Compensation
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104.1	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Indicates filed herewith.

** Indicates furnished herewith.

*** Pursuant to Item 601(b)(2) of Regulation S-K, the Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the Agreement and Plan of Merger to the Securities and Exchange Commission upon request.

Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request. Certain portions of the exhibits that are not material have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. Copies of the unredacted exhibits will be furnished to the SEC upon request.

Portions of this exhibit have been omitted pursuant to a request for confidential treatment and have been separately filed with the Securities and Exchange Commission.

\+ Indicates management contract or compensatory plan.

(b) The exhibits listed in Item 15(a)(3) are hereby filed with this Annual Report.

(c) None.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 15, 2023

NEUROONE MEDICAL TECHNOLOGIES CORPORATION

By: /s/ DAVID ROSA
David Rosa
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ DAVID ROSA David Rosa	Chief Executive Officer and Director (Principal Executive Officer)	December 15, 2023
/s/ RONALD MCCLURG Ronald McClurg	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 15, 2023
/s/ PAUL BUCKMAN Paul Buckman	Chairman of the Board of Directors	December 15, 2023
/s/ EDWARD ANDRLE Edward Andrle	Member of the Board of Directors	December 15, 2023
/s/ JEFFREY MATHIESEN Jeffrey Mathiesen	Member of the Board of Directors	December 15, 2023

Exhibit 31.1

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a), AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002**

I, David Rosa, certify that:

1. I have reviewed the annual report on Form 10-K for the year ended September 30, 2023 (the "report") of NeuroOne Medical Technologies Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 15, 2023

/s/ David Rosa
Name: David Rosa
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a), AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Ronald McClurg, certify that:

1. I have reviewed the annual report on Form 10-K for the year ended September 30, 2023 (the "report") of NeuroOne Medical Technologies Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 15, 2023

/s/ Ronald McClurg
Name: Ronald McClurg
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER,
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002***

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code, David Rosa, Chief Executive Officer of NeuroOne Medical Technologies Corporation (the "Company") hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended September 30, 2023 (the "Report") to which this Certification is attached as Exhibit 32.1 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

/s/ David Rosa
David Rosa
Chief Executive Officer
(Principal Executive Officer)

Dated: December 15, 2023

* This certification accompanies the report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NeuroOne Medical Technologies Corporation under the Securities Act of 1933, as amended, or the Exchange Act made before or after the date of the report, irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER,
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002***

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code, Ronald McClurg, Chief Financial Officer of NeuroOne Medical Technologies Corporation (the "Company") hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended September 30, 2023 (the "Report") to which this Certification is attached as Exhibit 32.2 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

/s/ Ronald McClurg
Ronald McClurg
Chief Financial Officer
(Principal Financial Officer)

Dated: December 15, 2023

* This certification accompanies the report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NeuroOne Medical Technologies Corporation under the Securities Act of 1933, as amended, or the Exchange Act made before or after the date of the report, irrespective of any general incorporation language contained in such filing.