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, 2021

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

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. ☐

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, 2021, 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, 2021 price at

which the common equity was last sold was $82.5 million. The number of outstanding shares of the registrant's common stock as of December 13, 2021 was 16,187,722.

NeuroOne Medical Technologies Corporation

FORM 10-K

FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2021

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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 obtain and maintain regulatory clearance of our cortical strip, grid and depth electrode technology;
- even if our cortical strip, grid electrode and depth electrode technology is approved for commercial sale, 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;
- the availability of additional capital on acceptable terms or at all as 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;
- the impact of the COVID-19 pandemic on our business;
- 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;

- the outcome of legal proceedings with PMT Corporation ("PMT");

- 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, 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 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 tremors, dystonia, and chronic pain. The effects of DBS as a potential treatment for Alzheimer's is also being evaluated by researchers. Unlike ablative technologies, the effects of DBS are reversible.

RF ablation is a procedure that uses radiofrequency under the electrode contacts which 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 radio frequency (RF) ablation generator. The following month, our RF ablation technology was tested by representatives from Emory University in Atlanta Georgia in an animal study. The product remains in development.

Our cortical sheet electrode and depth electrode technology has 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 has performed testing in bench top models and pre-clinical (or animal testing) modes. These pre-clinical tests have demonstrated that the technology is capable of recording, ablation and acute stimulation, although our ablation electrode technology remains in product development (meaning that additional testing will be needed prior to it being cleared for sale by the U.S. Food and Drug Administration (the "FDA")) for recording (or diagnostic) and therapeutic modalities.

We received 510(k) FDA clearance for our Evo cortical technology in November 2019, and 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.

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 16,000 craniotomies performed for epilepsy cases each year in the United States with 18,000 performed in Europe.[1] These numbers represent an underpenetrated market due to the invasiveness of a full craniotomy required just to perform the diagnostic procedure. 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 times (one to four weeks in the hospital with a craniotomy), infection rates and 50% rate of success in the diagnosis and treatment of the disorder. 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 removed. The average cost for the diagnostic technology per procedure is $10,000, with ablation devices costing $15,000 and brain stimulation devices costing $25,000 to $30,000. We believe our technology, once developed, will offer an all-in-one solution with diagnostic and therapeutic capabilities.

1 American Association of Neurological Surgeons National Neurosurgical Procedural Statistics 2012.

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 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 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. It is attributed to the loss of dopamine production in the brain, a messenger in the brain that allows for movement and coordination. There are no objective tests to diagnose Parkinson's disease, and misdiagnosis rates are still very high. Doctors look to find two or more signs to make a diagnosis, including balance problems, rigidity and tremors that occur during rest. In 2011, the FDA approved the first imaging device called a DaTscan that can capture images of the dopamine system in the brain. By itself, these scans cannot diagnose Parkinson's but can help confirm a doctor's diagnosis. Parkinson's disease is typically not fatal; however, complications caused by the symptoms of Parkinson's, such as difficulty swallowing causing food to travel to the lungs resulting in pulmonary issues or falls related to loss of balance, can be fatal.

Today's primary treatment for Parkinson's disease involves medications that have not proven to resolve symptoms but rather ease symptoms. Years ago, surgical procedures such as thalamotomy and pallidotomy targeted certain parts of the brain and involved destroying the tissue. More recently, these procedures have been replaced with DBS. A doctor evaluates the patient by reviewing the patient's symptoms and medications taken and administering detailed memory, thinking and imaging tests to determine if they are appropriate for 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. Doctors are evaluating treatment to other parts of the brain in an effort to address more symptoms to treat walking or balance issues. In addition, research is being conducted to provide stimulation when the symptoms return as opposed to all of the time.

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 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, weighting the limbs and DBS. Patients need to eliminate any medications they are taking that cause tremors as this can exacerbate the symptoms. For some patients, using wrist weights may ease symptoms allowing the patient to function. Other patients may also use relaxation techniques as stress can increase symptoms. Medical therapy is also used to treat patients' symptoms. Primidone is typically the first drug prescribed as it has had success in some situations for epilepsy. Botox is also used at times to control head tremors. When these fail, surgery is the next alternative. A surgical procedure used years ago created lesions in the ventral intermediate thalamus and was highly successful with treating essential tremors but is no longer commonly used due to increased risk of developing speech problems. The latest therapy is 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, EEG testing, blood and urine tests. There are also many treatment options for patients but depend on the type of dystonia. Botox and certain medications may be helpful or DBS may be used.

Spinal Cord Stimulation

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 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. Certain studies have indicated a benefit for these 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:** Patients spend one to four weeks in the hospital 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 placed through a craniotomy, which requires removing the top part of the cranium and is a very painful and invasive procedure. Procedural times for a craniotomy range from a minimum of four to 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 (CSF) 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 a surgical incision**: Currently, when patients have been implanted with paddle electrodes in the spinal area, a surgical incision has been required. A technology that allows for percutaneous placement is desirable.

- **Limited number of contacts on an electrode**: Paddle electrodes currently are available in a variety of sizes and number of contacts. Physicians want to explore adding a 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:** If we are successful in identifying brain activity more quickly, in 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 in hours versus weeks. This represents 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. We believe our technology may be able to improve outcomes compared to using other diagnostic technologies regardless of whether we are able to offer an all in one diagnostic and therapeutic solution.

- **Implantation via minimally invasive procedure with fewer post-procedure complications:** We are currently developing an approach to deliver the cortical electrodes, including minimizing the invasiveness of the procedure. We expect that patients who have qualified for this therapy will be more accepting of a minimally-invasive procedure. Such a procedure would potentially reduce the patient's pain, bleeding and other adverse events associated with a full craniotomy. Our 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 high fidelity recording capabilities 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 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 developing a combination recording, stimulation and RF ablation technology that will perform both diagnostic and therapeutic functions.

- **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, thereby preventing the need to make surgical incisions 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 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.

- **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. This submission is pending FDA review. 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 and will enable us to offer a therapeutic solution using this 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:** Patients currently undergo one surgical procedure for diagnosis (either to have a cortical electrode placed via a craniotomy or depth electrodes placed via holes drilled into the skull) and, hopefully after the brain recordings successfully indicate where the affected brain tissue is located, a second procedure or surgery is then required to treat the patient. There is strong physician interest in being able to perform both the diagnostic and therapeutic procedure concurrently. 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 therapeutic technologies are expected to require more robust regulatory approvals for the United States, ranging from a 510(k) to 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, thus potentially eliminating the need to make a surgical incision. By leveraging our existing FDA cleared cortical electrode and sEEG technology, we may 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 planning 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.

- **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 up to 30 days. Our Evo sEEG electrode technology has received FDA 510(k) clearance from the FDA for use (less than 24 hours) 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. Further, as we announced in December 2020, 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.

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 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. This submission is pending FDA review. Zimmer has indicated its desire to distribute this product once we receive FDA 510(k) clearance to market for less than 30 days use and has placed initial stocking orders.

Depth electrode diagnostic and ablation devices	No design freeze. Pre-clinical testing, including benchtop and animal testing, has been conducted on early designs. Additional pre-clinical testing at the Cleveland Clinic was completed in the second calendar quarter of 2020. Pre-clinical (animal) testing was conducted in September 2021 with representatives from Emory University in Atlanta Georgia. 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 clinical testing planned prior to FDA clearance because predicates did not perform clinical testing.	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. We are planning a Pre-Submission (Q-Sub) to the FDA for the RF Ablation System, to review the feasibility of "Breakthrough" designation and to complete animal studies in the first calendar quarter of 2022. We anticipate filing a 510(k) submission in the fourth calendar quarter of 2022. We expect that we will need to demonstrate design verification, which we estimate will cost us $200,000 to complete, biocompatibility, which we estimate will require an investment of $100,000 to complete, and sterilization validation and adoption, which we estimate will require $25,000 to complete. We may also need to demonstrate electrical safety, which we estimate will cost us $60,000. It is estimated the RF generator will cost approximately $1.5 million to complete. Future testing requirements for regulatory clearance will continue to be evaluated as we develop the design and regulatory strategy for this product.
Spinal cord stim electrodes	No design freeze. We performed pre-clinical in-house bench top testing in August 2020 and are currently performing bench top testing at Carnegie Mellon University in Pittsburgh, Pennsylvania. In June 2021 we started bench top testing of prototypes to demonstrate chronic performance and longevity.	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 remains in progress and we expect to announce results of these studies in the first quarter of 2022. While this device remains in early development, we began conducting bench top durability testing in the second calendar quarter of 2021 and expect to announce results in the first quarter of 2022.	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 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 approximately $2,000,000, as well as demonstrate

biocompatibility, which we estimate will cost $150,000 to complete, and demonstrate sterilization validation and adoption, which we estimate will cost $35,000 to complete.

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 showed 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, 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.

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 the manufacturers we currently utilize have sufficient capacity to meet our requirements; however, see “Risk Factors—Risks Related to Our Business—The COVID-19 pandemic has adversely impacted, and may continue to impact, our business”. 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 $3.9 million and $2.1 million for the years ended September 30, 2021 and 2020, respectively.

Competition

In the market for Epilepsy diagnosis, our cortical strip, sheet 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. We believe there are additional companies pursuing thin film electrode technology for use in the brain although none are expected to be commercially available in 2022.

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 and sheet 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 the 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 the 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, 2021, 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 pending U.S. patent application filed by us and published in 2018 covering our applications and additional devices used during the diagnostic and therapeutic ablation and stimulation procedures, pending U.S. and European patent applications 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, three pending U.S. applications (and corresponding PCT applications) filed in 2020 and 2021 relating to minimally invasive electrodes, spinal cord stimulation devices, and additional electrode improvements and one additional pending U.S. application relating to devices with temperature sensors. The licensed issued patents expire between 2025 and 2030, subject to any patent extensions that may be available for such patents. If a patent or patents are issued on our pending patent applications, the resulting patents are projected to expire between 2038 and 2042.

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 sheet 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, 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 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 a registered U.S. trademark for the "EVO" trademark. The document(s) updating the owner's name were filed with the U.S. Trademark Office on November 30, 2021, with an effective date of December 30, 2019.

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 guidance) govern product design and development, pre-clinical and clinical testing, premarket clearance or approval, 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 and local quality regulations, 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 controls for labeling. However, most such devices are exempt from pre-market notification and adherence to the FDA's QSR. 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 or approval. 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, we believe our diagnostic strip, grid depth electrode and RF ablation technology will be 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. By statute, the FDA is required to complete its review of a 510(k) notification within 90 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 (Q-Sub) 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 adverse side effects;
- 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 defective 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, 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, 2021, we had 11 employees, all of whom are full-time, 6 of whom are engaged in research and development activities, and all of whom are located in the United States. As of September 30, 2021, we also retained the services of approximately 11 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 2021 fiscal year, we did not experience any turnover among our employees.

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.n1mtc.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;
- the COVID-19 pandemic has adversely impacted and will likely continue to adversely impact our business, including through component shortages, including of our primary component, polyimide film, due to supply chain shortages attributed to COVID related issues, supply chain disruptions, including related to staffing availability, and delays in product availability and delivery, impacts on pre-clinical and clinical trials and regulatory clearances/approvals;

- 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;

- 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, 2021, we had an accumulated deficit of $40.8 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, 2020. 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, successfully complete all required steps for regulatory clearance to expand the use of our depth electrodes for sEEG recording in the U.S. for up to 30 days, 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, 2021, we have generated limited in 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 and our former independent registered public accounting firm included explanatory paragraphs in the reports on our financial statements as of and for the years ended September 30, 2021 and 2020, respectively, noting the existence of substantial doubt about our ability to continue as a going concern. At September 30, 2021, we had $6.9 million in cash deposits. Our existing cash and cash equivalents 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.

The COVID-19 pandemic has adversely impacted, and may continue to impact, our business.

Since the beginning of the COVID-19 pandemic, governments, public institutions, and other organizations have taken and are continuing to take certain preventative or protective measures to combat the transmission of the virus, including implementation of travel restrictions or bans, vaccination mandates, closures of non-essential businesses, limitations of public gatherings, other social distancing and shelter-in-place measures, and delays or cancellations of elective surgeries. The Company, our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time due to shutdowns or other regulatory requirements that may be requested or mandated by state and federal governmental authorities.

We have experienced, and will likely continue to experience, disruptions that could negatively or severely impact our business and planned clinical trials, including:

- delays or difficulties in conducting pre-clinical and clinical trials;
- interruption in global manufacturing and shipping, including testing equipment and personal protective equipment used at our facilities;
- material shortages for manufacturing, including those the Company is currently experiencing related to its primary component, polyimide film, due to supply chain shortages attributed to COVID related issues;
- delays in timelines for product availability and delivery from vendors, including related to staffing shortages, both generally and due to employee illness, and due to increases in demand from other larger or more longstanding customers of our suppliers placing large orders due to concerns with supply chain disruption and the impact of COVID-19;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the way in which clinical trials are conducted and may result in unexpected costs; and
- delay in the timing of interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19.

In addition, COVID-19 could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. COVID-19 illness could also impact members of our Board and its ability to hold meetings.

As the COVID-19 pandemic continues to adversely affect our operating and financial results, it may also have the effect of heightening many of the other risks described in the risk factors in this Report. Further, the COVID-19 pandemic may also affect our operating and financial results in a manner that is not presently known to us or that we currently do not expect to present significant risks to our operations or financial results, particularly if the COVID-19 pandemic and its associated impacts reoccur in successive waves in the coming months.

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 in connection with the COVID-19 pandemic;
- 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 for less than 24 hours use, which have each received 510(k) clearance from the FDA. If we are unable to successfully develop, and receive regulatory approval for our sEEG electrode for use up to 30 days or our other products under development, or if we experience significant delays in doing so, our business will be harmed.

Two 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 for up to 30 days, and our Evo sEEG electrode technology has received 510(k) clearance from the FDA for use (less than 24 hours) with recording, monitoring, and stimulation equipment for recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain. Our submission to the FDA seeking 510(k) for use of our Evo sEEG electrode technology for up to 30 days is pending. 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 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;

- the COVID-19 pandemic may cause delays and disruptions in the supply chain, clinical trials, clinical development, and regulatory approval process; 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, including, but not limited to, the COVID-19 pandemic. 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 approval for 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.

If we are unable to expand our sales and marketing infrastructure, and execute other steps necessary to penetrate market opportunities and produce our products, we may not be successful in commercializing our cortical strip, grid electrode and depth electrode technology in the United States.

We are an early stage development company with limited resources, and have not generated significant revenues to date. To achieve commercial success and generate sufficient revenue in the United States for our cortical strip, grid electrode and depth electrode technology, we will need to further expand our sales and marketing infrastructure to drive adoption of our products, which will include a team of educators that will train healthcare providers and people with brain related disorders on the benefits and use of our cortical strip, grid electrode and depth electrode technology. There is significant competition for sales personnel experienced in relevant medical device sales. We expect that we will face significant challenges as we recruit and subsequently grow our sales and marketing infrastructure. If we are unable to attract and retain sufficient, and skilled, sales and marketing representatives, our sales could be adversely affected. If one of our sales or marketing representatives were to depart and be retained by one of our competitors, they could help competitors solicit business from customers, which could further harm our sales. In addition, if our sales and marketing representatives or educators fail to achieve their objectives or if we are not able to recruit and retain a network of educators, we may not be able to successfully train healthcare providers on the use of our cortical strip, grid electrode and depth electrode technology, which could delay new sales and harm our reputation.

As we increase our sales and marketing expenditures with respect to our cortical strip, grid electrode and depth electrode technology under development, if approved, or future versions thereof, we will need to hire, train, retain and motivate skilled sales and marketing representatives with significant industry-specific knowledge in various areas. Our success will depend largely on the competitive landscape for our products and the ability of our sales personnel to obtain access to healthcare providers and persuade those healthcare providers to recommend our cortical strip, grid electrode and depth electrode technology. Recently hired sales representatives require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. In addition, the expansion of our sales and marketing personnel will place significant burdens on our management team.

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. As a result, our financial condition and operating results will be highly dependent on the ability of our sales representatives to adequately promote, market and sell our cortical strip, grid electrode and depth electrode technology and the ability of our educators to train healthcare providers on the use of our cortical strip, grid electrode and depth electrode technology. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our existing or planned products, or enhance the strength of our brand, either of which could impair our projected sales growth and have an adverse impact on our business.

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;

- launching commercial sales of our cortical strip, grid electrode and depth electrode technology, if approved for marketing;

- market acceptance of our cortical strip, grid electrode and depth electrode technology, if approved, 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, including, but not limited to, events related to 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 following approval.

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. In addition, as a result of the COVID-19 pandemic, our access to these professionals has been limited at times, and travel restrictions, shutdowns and similar measures have impacted our ability to maintain these relationships, thereby affecting our ability to develop, gain regulatory clearance or approval and market 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 disordersin 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 disordersof 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 under development, if approved, 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 disorderscan 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.

The 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 disordersthat 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.

Additionally, the Mayo Clinic is conducting testing of its own minimally invasive cortical electrode delivery device. In the event the Mayo Clinic completes development of its own device prior to us, we may forego completing development of our device and we may be unable to enter into any arrangement with Mayo Clinic relating to its device. If we are unable to pursue the development of a minimally invasive cortical electrode device, this may delay our ability to become profitable and we could be forced to terminate our operations.

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 under development 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 under development, including the number of people with epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorderswho 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 sublicenses 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 arising in connection with the COVID-19 pandemic. 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.

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 do not currently have insurance to cover such losses or expenses and, once we obtain such insurance, it may not 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.

See "—The COVID-19 pandemic has adversely impacted, and may continue to impact, our business" above.

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.

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. Neither the Product Availability Date nor the Acceptance of all Deliverables for SEEG Products under the Development Plan (which are key milestones for payments under the Development Agreement) has occurred. In September 2021, the Company received 510(k) clearance from the FDA to market its 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. FDA clearance is one condition of the Product Availability Date. However, the Company does not intend to deliver saleable product to Zimmer if and until it receives regulatory clearance to expand the use of its Evo sEEG Electrode technology for up to 30 days, at which point the Company and Zimmer intend to commence negotiations regarding payments by Zimmer under the Development Agreement notwithstanding the deadlines under the Development Agreement for the Product Availability Date and the Acceptance of all Deliverables for SEEG Products. Accordingly, the amount of the SEEG Exclusivity Maintenance Fee and the Interim Fee Bonus that we may receive under the Development Agreement will depend on the outcome of such negotiations, and we cannot guarantee any particular outcome.

Moreover, 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.

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 on 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.

We are currently subject to litigation with the former employer of a current employee of NeuroOne, which is described in more detail under “Note 4—Commitments and Contingencies” included in “Item 8 — Financial Statements and Supplementary Data” in this Annual Report.

Even if we successfully defend against these claims, litigation could result in substantial costs place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. 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;

- 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; and

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 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. 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. 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.

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, 2021, we had outstanding warrants to purchase an aggregate of 7,503,808 shares of Common Stock at a weighted average exercise price of $6.06 per share, and options to purchase an aggregate of 1,122,560 shares of Common Stock at a weighted average exercise price of $5.89 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—Historical 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.

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.

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.

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 tax laws in the U.S. and any other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could materially adversely affect our business, our results of operations, and our effective tax rate. For example, on December 22, 2017, the U.S. enacted the Tax Act, which contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, and the recent change in administration and control of Congress in the U.S. may result in additional U.S. tax law changes that could have a material impact on our future effective tax rate. Notwithstanding the reduction in the corporate income tax rate under the Tax Act, guidance on tax reform continues to be released and such guidance may adversely affect our business and financial condition. It is also unknown if and to what extent various states will conform to the Tax Act or any future tax reform legislation. The impact of the tax reform implemented under the Tax Act and any future tax reform legislation on holders of our Common Stock is likewise uncertain and could be adverse. We urge you to consult with your legal and tax advisors with respect to this legislation and the potential tax consequences of investing in our Common Stock. The decrease in the corporate tax rate resulted in changes in the valuation of our deferred tax assets and liabilities.

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 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, including, but not limited to, changes related to the COVID-19 pandemic. 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, the Company is subject to litigation and claims arising in the ordinary course of business.

On March 29, 2018, the Company was served with a complaint filed by PMT Corporation ("PMT"), the former employer of Mark Christianson, a current Company employee and Wade Fredrickson, a now former Company employee. The complaint added the Company, NeuroOne, Inc. and Mr. Christianson to its existing lawsuit against Mr. Fredrickson in the Fourth Judicial District Court of the State of Minnesota. In the lawsuit, PMT claims by virtue of their work for the Company and their prior work during employment with PMT, Mr. Fredrickson and Mr. Christianson breached their non-competition, non-solicitation and non-disclosure obligations, breached their fiduciary duty obligations, were unjustly enriched, engaged in unfair competition, engaged in a civil conspiracy, tortiously interfered with PMT's contracts and prospective economic advantage, and breached a covenant of good faith and fair dealing. The complaint purported to attach Mr. Fredrickson's noncompete agreement as Exhibit A. Against Mr. Fredrickson, PMT also alleged that he intentionally or negligently spoliated evidence, made negligent or fraudulent misrepresentations, misappropriated trade secrets in violation of Minnesota law, and committed the tort of conversion and statutory civil theft. Against the Company and NeuroOne, Inc., PMT alleged that the Company and NeuroOne, Inc. were unjustly enriched and engaged in unfair competition. PMT asked the Court to impose a constructive trust over the shares held by Mr. Fredrickson and Mr. Christianson and to award compensatory damages, equitable relief, punitive damages, attorneys' fees, costs and interest.

On April 18, 2018, Mr. Christianson, the Company and NeuroOne, Inc. filed a motion for dismissal, which was heard by the Court on October 11, 2018. The motion for dismissal stated that: the contract claims against Mr. Christianson fail because his agreement was not supported by consideration; the Minnesota Uniform Trade Secrets Act preempts plaintiff's claims for unfair competition, civil conspiracy and unjust enrichment; plaintiff fails to state a claim regarding alleged breach of the duties of loyalty and good faith/fair dealing; plaintiff cannot legally obtain a constructive trust; plaintiff has insufficiently pled its tortious interference claims; and Plaintiff has not stated a claim for unfair competition. On January 7, 2019, the judge granted the motion for dismissal with respect to PMT's claim for breach of the duty of good faith and fair dealing, and denied the motion for dismissal with respect to the other claims presented.

In April 2019, PMT served the Company, NeuroOne, Inc. and Christianson with a proposed Second Amended Complaint, which included new claims against the Company and NeuroOne, Inc for tortious interference with contract and tortious interference with prospective business advantage and punitive damages against the Company, NeuroOne Inc. and Christianson. On June 28, 2019, the Company presented evidence indicating that PMT had participated in a fraud on the Court and sought an Order that PMT had waived the attorney client privilege.

On July 16, 2019, the defendants served PMT with a joint notice of motion for sanctions seeking a variety of sanctions for litigation misconduct including, but not limited to, dismissal of the case and an award of attorneys' fees. The Company, NeuroOne Inc and Mr. Christianson further moved for summary judgment on all remaining claims asserted against them as well as for leave to assert counterclaims against PMT for abuse of process. Following hearings on the dispositive motions and defendants' sanctions motion, the district court granted the Company's motion for sanctions on April 29, 2020. Additionally, the district court granted the Company's motion for summary judgment in part with respect to the counts for Christianson's breach of non-confidentiality agreement, and denied the Company's motion for summary judgment on all other counts.

On August 24, 2020, defendants moved the Court to amend their counterclaims for abuse of process against PMT to add a claim for punitive damages with respect to its conduct pertaining to the Fredrickson noncompete. On October 12, 2020 the Court awarded NeuroOne, Inc. $185,000 in Rule 11 sanctions and Fredrickson $145,000 in Rule 11 sanctions with respect to PMT's misconduct relating to the Fredrickson noncompete. PMT and its former litigation counsel, Barnes & Thornburg, were jointly and severally liable for these awards, which were paid on December 11, 2020 and have been recognized in other income in the statements of operations. The Court granted NeuroOne, Inc.'s motion to amend to permit its assertion of the right to assert a punitive damages claim against PMT associated with fighting the allegations relating to the Fredrickson noncompete.

On May 27, 2021 PMT moved for summary judgment on defendants' claims for abuse of process and punitive damages, and on August 5, 2021, the district court granted PMT's motion to dismiss the abuse of process and punitive damage claims.

Trial has been postponed from December 2021 to August of 2022. The Company intends to continue to defend itself vigorously and to continue to aggressively prosecute its affirmative counterclaim against PMT. The outcome of any claim against the Company by PMT was not estimable as of the issuance of the financial statements included herein.

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 6, 2021, there were 119 record holders of our Common Stock. The transfer agent and registrar for our Common Stock is Action Stock Transfer Corporation.

Recent Sales of Unregistered Equity Securities

All sales of unregistered equity securities have previously been disclosed in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

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. References in this discussion to "series" or "notes" refer to all of our outstanding notes as of the relevant date of the item being discussed. References in this discussion to "convertible promissory notes" refer to all of our outstanding convertible promissory notes as of the relevant date of the item being discussed.

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) 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.

Prior to FDA approval or clearance of certain of our products, our primary activities were limited to, and our limited resources were dedicated to, performing business and financial planning, raising capital, recruiting personnel, negotiating with business partners and the licensors of our intellectual property and conducting research and development activities. In November 2019, our Evo cortical technology ("cEEG") received 510(k) clearance from the FDA for recording, monitoring, and stimulating brain tissue for up to 30 days, and in September 2021, we received FDA clearance for 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. Our submission to the FDA seeking 510(k) for use of our Evo sEEG electrode technology for up to 30 days is pending.

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 are targeting the third calendar quarter of 2022 for completion of such hardware. We also completed an animal feasibility study at Emory University in September 2021. Next, we plan to submit a Pre-Submission(Q-Sub) to the FDA for the RF ablation system and to review the feasibility of "Breakthrough" designation, complete additional animal studies through the first half of calendar 2022, and submit an application for FDA 510(k) clearance in the fourth calendar quarter of 2022. Our other products are still under development.

We have incurred losses since inception. As of September 30, 2021, we had an accumulated deficit of $40.8 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 approval of certain of our products, our main source of cash was proceeds from the issuances of notes, common stock, warrants and unsecured loans. See "—Liquidity and Capital Resources—Historical Capital Resources" below. While we have begun to generate revenue from the sale of products based on our cEEG technology beginning in the first quarter of fiscal 2021 and through milestone 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—Funding Requirements and Outlook" below.

Recent Developments

October 2021 Underwritten Public Offering

On October 13, 2021, we 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 our common stock, par value $0.001 per share, at a price to the public of $3.20 per share. 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. We intend to use the net proceeds from this offering for working capital and general corporate purposes.

Change of Independent Registered Public Accounting Firm for Fiscal 2021

On June 18, 2021, the Audit Committee of the Board (i) engaged Baker Tilly US, LLP ("Baker Tilly") to serve as the Company's independent registered public accounting firm for the Company's fiscal year ending September 30, 2021, and (ii) determined to dismiss BDO USA, LLP ("BDO"), the Company's independent registered public accounting firm for the year ending September 30, 2020.

2021 Shelf Registration

On June 4, 2021, NeuroOne filed a Form S-3 shelf registration statement under the Securities Act, which was declared effective by the SEC on June 14, 2021 (the "2021 Shelf"). Under the 2021 Shelf, the Company may offer and sell, from time to time in its sole discretion, securities having an aggregate offering price of up to $150 million, subject to the limitations of Form S-3.

Nasdaq Capital Market

The Company's common stock commenced trading on The Nasdaq Capital Market on May 26, 2021 under the ticker symbol "NMTC." Previously, the Company's common stock was traded on the OTC Markets quotation system on the OTCQB.

Reverse Stock Split

Effective after the close of business on March 31, 2021, the Company completed a 1-for-3 reverse stock split of its common stock. All share and per share amounts in this Report have been reflected on a post-split basis.

COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic. As a result of the COVID-19 pandemic, the Company has experienced, and will likely continue to experience, delays and disruptions in our pre-clinical and clinical trials, as well as interruptions in our manufacturing, supply chain, shipping and research and development operations. For example:

- development of our technology was delayed in fiscal year 2021 due to interruptions in global manufacturing and shipping as a result of the COVID-19 pandemic, including as one of our key manufacturing partners and one of the Company's suppliers had staffing issues leading to delays in the Company's development builds and delays in shipping product;

- the Company's own staff has been impacted by infections and mandatory quarantines;

- the Company is currently experiencing product shortages of its primary component, polyimide film, due to supply chain shortages attributed to COVID related issues;

- the Company is experiencing delays in timelines for product availability and delivery from vendors, including related to staffing shortages, both generally and due to employee illness, and due to increases in demand from other larger or more longstanding customers of our suppliers placing large orders due to concerns with supply chain disruption and the impact of COVID-19.

The Company's plans for further testing or clinical trials may be further impacted by the continuing effects of COVID-19. The global outbreak of COVID-19 continues to rapidly evolve. In April 2020, given the impact of COVID-19 on the Company, the Company applied for and received loan funding of $83,333 under the Paycheck Protection Program, which was forgiven by the U.S. Small Business Administration on June 9, 2021.

The extent to which the COVID-19 pandemic may further impact our business and pre-clinical and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the effect of the pandemic on our suppliers and distributors and the global supply chain, the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease. The COVID-19 pandemic may also continue to impact our business as a result of employee illness, school closures, and other community response measures.

The COVID-19 pandemic may also impact our ability to secure additional financing. Although the Company cannot estimate the length or gravity of the impact of the COVID-19 outbreak at this time, if the pandemic continues, it may have a material adverse effect on the Company's results of future operations, financial position, and liquidity in for fiscal year 2022 and beyond.

See "Risk Factors—Risks Related to Our Business—The COVID-19 pandemic has adversely impacted, and may continue to impact, our business."

Financial Overview

Product Revenue

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

We have 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 and 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, but we do not expect to generate any revenue from the sale of our other products until we develop and obtain all required regulatory approvals or clearances for and commercialize depth electrode technology. If we fail to complete the development of the depth electrode technology, or any other product candidate we may pursue in the future, in a timely manner, or fail to obtain regulatory approvals or clearances, we may never be able to generate revenue from product sales sufficient to sustain operations.

Product Gross Loss

Product gross 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 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, the Company entered into the Development Agreement with 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 (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, 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.

Except where Zimmer timely delivers a Design Modification Notice under the Development Agreement, if one or more of the events set forth below occurs on or before the deadline indicated for such event and the Product Availability Date (as defined in the Development Agreement) for the SEEG Products occurs on or before June 30, 2021, then the Company shall receive the additional amount indicated for such event as part of the SEEG Exclusivity Maintenance Fee:

- Design freeze for the SEEG Products by December 15, 2020 - $500,000
- Acceptance of all Deliverables for SEEG Products under the Development Plan (as defined in the Development Agreement) by April 30, 2021 - $500,000

If Zimmer timely delivers a Design Modification Notice to the Company under the Development Agreement, and one or more of the events set forth below occurs on or before the deadline indicated for such event and the Product Availability Date for the SEEG Products occurs on or before June 30, 2021, then the Company shall receive the additional amount indicated for such event as part of the SEEG Exclusivity Maintenance Fee:

- Acceptance of all Deliverables for SEEG Products under the Development Plan other than the Modified Connector by April 30, 2021 - $500,000
- Acceptance of all Deliverables for SEEG Products under the Development Plan, including the Modified Connector by September 30, 2021 - $500,000

For purposes of the Development Agreement, each of the foregoing events shall have occurred only if the Company has demonstrated the achievement of the event to Zimmer's reasonable satisfaction. Notwithstanding the foregoing, the events in Sections 6.1(c)(ii), (iii) and (iv) of the Development Agreement shall not be deemed to be met if FDA Approval for the SEEG Products is not received prior to the applicable deadline.

Zimmer has delivered a Design Modification Notice. The design freeze for the SEEG Products occurred by December 15, 2020. In September 2021, the Company received 510(k) clearance from the FDA to market its 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. FDA clearance is one condition of the Product Availability Date under the Development Agreement. However, the Company does not intend to deliver saleable product to Zimmer unless and until it receives regulatory clearance to expand the use of its Evo sEEG Electrode technology for up to 30 days, at which point the Company and Zimmer intend to commence negotiations regarding payments of applicable amounts above, notwithstanding the deadlines for the Product Availability Date and the Acceptance of all Deliverables for SEEG Products.

In addition to the Initial Exclusivity Fee and Interim Fee Bonus, in order to maintain the exclusivity of the SEEG Distribution License, Zimmer must pay the SEEG Exclusivity Maintenance Fee to the Company, on or prior to the SEEG Exclusivity Confirmation Date, in immediately available funds as follows:

- if the Product Availability Date for the SEEG Products occurs on or before June 30, 2021, then $3,000,000, plus the amount of any Interim Fee Bonuses earned pursuant to Section 6.1(c), including any such Interim Fee Bonus earned after June 30, 2021 pursuant to Section 6.1(c)(iv) following the delivery of a Design Modification Notice;

- if the Product Availability Date for the SEEG Products occurs after June 30, 2021, but on or before September 30, 2021, then $3,000,000, plus if Zimmer timely issues a Design A-9 Modification Notice, any Interim Fee Bonus earned pursuant to Section 6.1(c)(iv);

- if the Product Availability Date for the SEEG Products occurs after September 30, 2021, but on or before December 31, 2021, then $2,500,000; and

- if the Product Availability Date for the SEEG Products occurs after December 31, 2021, then $1,500,000.

As noted above, upon receipt (if any) of regulatory clearance to expand the use of its Evo sEEG Electrode technology for up to 30 days, the Company and Zimmer intend to commence negotiations regarding the applicable SEEG Exclusivity Maintenance Fee amount, notwithstanding the above deadlines for the Product Availability Date. Notwithstanding any other provision of the Development Agreement, if the Product Availability Date for the SEEG Products has not occurred on or before June 30, 2022, Zimmer shall have the right to terminate the SEEG Distribution License by delivering written notice to the Company to that effect and, upon delivery of such notice, Zimmer shall be relieved of all of its obligations hereunder with respect to SEEG Products, including any obligation to pay the SEEG Exclusivity Maintenance Fee or to purchase, market, distribute or sell any SEEG Products. The Initial Exclusivity Fee and the SEEG Exclusivity Maintenance Fee (including any Interim Fee Bonus(es)), once paid, are non-refundable.

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 the Company may terminate the Development Agreement if Zimmer acquires or directly or indirectly owns a controlling interest in certain competitors of the Company.

At inception of the Zimmer Development Agreement through September 30, 2021, the Company has identified the following three performance obligations under the Zimmer Development Agreement: (1) the Company obligation to grant Zimmer access to its intellectual property; (2) complete SEEG Product development; and (3) complete Strip/Grid Product development. Accordingly, the Company recognized revenue in the amount of $64,812 and $1,926,566 during the years ended September 30, 2021 and 2020, respectively, related to the development of the Products completed during the periods in connection with the Initial Exclusivity Fee payment.

In August 2021, we received initial stocking orders from Zimmer for SEEG electrodes.

The achievement of future milestones or level of sales required to earn royalty payments from Zimmer is uncertain.

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 fees relating to corporate matters, intellectual property costs, professional fees for consultants assisting with regulatory, clinical, product development, financial matters, and beginning in the first quarter of fiscal year 2021, sales and marketing in connection with the commercial sale of our Strip/Grid Products and Electrode Cable Assembly Products. We anticipate that our general and administrative expenses will significantly increase in the future to support our continued research and development activities, further commercialization of our cortical strip technology, commercial sales of our sEEG electrode technology, and the increased costs of operating as a public company. These expense 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 developing our cortical strip, grid electrode and depth electrode technology, 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 continue to develop our cortical strip, 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.

Interest Expense

Interest expense primarily consists of interest costs related to our 2019 Paulson Notes and 2020 Paulson Notes, as defined below.

Net valuation change of instruments measured at fair value

The net valuation change of instruments measured at fair value includes the change in fair value of the 2019 Paulson Notes and 2020 Paulson Notes.

Loss on notes extinguishment

Loss on note extinguishment includes the loss associated with debt instrument modifications and conversions accounted for as debt extinguishments.

Other Income

Other income consists of proceeds derived from activity outside of normal operating activity, including legal settlements, the forgiveness of the paycheck protection program loan and interest income.

Results of Operations

Comparison of the Fiscal Years Ended September 30, 2021 and 2020

The following table sets forth our results of operations for the fiscal years ended September 30, 2021 and 2020.

	For the year ended September 30,		
	2021	2020	Period to Period Change
Product revenue	$ 178,146	$ —	$ 178,146
Cost of product revenue	275,895	—	275,895
Product gross loss	(97,749)	—	(97,749)
Collaborations revenue	64,812	1,926,566	(1,861,754)
Operating expenses:			
Selling, general and administrative	6,260,266	4,753,036	1,507,230
Research and development	3,925,008	2,075,791	1,849,217
Total operating expenses	10,185,274	6,828,827	3,356,447
Loss from operations	(10,218,211)	(4,902,261)	(5,315,950)
Interest expense	(3,053)	(7,524,581)	7,521,528
Net valuation change of instruments measured at fair value	1,974	804,529	(802,555)
Loss on note extinguishment	—	(2,017,847)	2,017,847
Other income	271,122	—	271,122
Net loss	$ (9,948,168)	$(13,640,160)	$ 3,691,992

Product Revenue and Product Gross Loss

Product revenue and product gross loss were $0.2 million and $(0.1) million, respectively, during the year ended September 30, 2021. The product revenue consisted of the sale of Strip/Grid Products and Electrode Cable Assembly Products. 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 and outside supplier materials costs in connection with the Electrode Cable Assembly Products. In addition, cost of product revenue included royalty fees incurred, including the royalty fees to WARF and Mayo of $0.1 million in connection with our license agreements. There was no product revenue or product gross loss recognized during the comparable prior year period.

Collaborations Revenue

Collaborations revenue was $65,000 and $1.9 million for the years ended September 30, 2021 and 2020, respectively. Revenue during the period was derived from the Development Agreement and represented the portion of the upfront initial development fee payment eligible for revenue recognition during the respective periods ended September 30, 2021 and 2020.

Selling, general and administrative expenses

Selling, general and administrative expenses were $6.3 million for the year ended September 30, 2021, compared to $4.8 million for the year ended September 30, 2020. The increase of $1.5 million was primarily due to an increase in sales and marketing costs of $0.8 million, payroll related costs of $0.3 million, board and public company costs of $0.3 million, insurance costs of $0.2 million and outside professional support and other costs of $0.2 million, offset partially by a reduction in litigation support costs of $0.2 million and stock-based compensation of $0.1 million.

Research and development expenses

Research and development expenses were $3.9 million for the year ended September 30, 2021, compared to $2.1 million for the year ended September 30, 2020. The increase during fiscal 2021 over the comparable prior year period was due to an increase in supporting development activities largely attributed to our Evo sEEG electrode technology, which primarily included salary-related expenses and other costs of consulting services, materials and supplies.

Interest expense

Interest expense for the year ended September 30, 2021 and 2020 was $3,000 and $7.5 million, respectively. The decrease year over year is attributed to the full conversion of the 2019 Paulson Notes and 2020 Paulson Notes by early fiscal year 2021. Interest expense during the year ended September 30, 2021 was $3,000 and consisted of issuance costs in connection with our 2019 Paulson Notes described further below. Interest expense in fiscal year 2020 related to the 2019 Paulson Notes and 2020 Paulson Notes and was comprised of issuance costs of $1.9 million and day-one interest at issuance of $5.6 million representing the amount by which fair value exceeded note proceeds. Interest on principal in connection with the 2019 Paulson Notes and 2020 Paulson Notes is included in the *net valuation change of instruments measured at fair value* line item.

Net valuation change of instruments measured at fair value

The net valuation change of instruments measured at fair value for the years ended September 30, 2021 and 2020 was a benefit of $(2,000) and $(0.8) million, respectively. The change was due to accrued interest on the 2019 Paulson Notes and 2020 Paulson Notes, while outstanding, and due to fluctuations in our common stock fair value, the number of potential shares of common stock issuable upon conversion of the 2019 Paulson Notes and 2020 Paulson Notes during the respective periods.

Loss on note extinguishment

Non-cash loss on note extinguishment for the year ended September 30, 2020 was $2.0 million. The 2019 Paulson notes as described further below were amended on April 24, 2020 to principally add a 40% discount to the optional conversion feature and to extend the maturity date by six months. The April 2020 amendment was accounted for as a note extinguishment given the significant modification made to the optional conversion feature. There were no note extinguishments during the year ended September 30, 2021.

Other Income

Other income during the year ended September 30, 2021 consisted principally of proceeds received in connection with the PMT Corporation litigation in the amount of $0.2 million and from the forgiveness of the paycheck protection program loan in the amount of $0.1 million. We did not have other income during the comparable prior year period.

Liquidity and Capital Resources

Historical Capital Resources

As of September 30, 2021, our principal source of liquidity consisted of cash deposits of $6.9 million. Subsequent to September 30, 2021, we received gross proceeds of $13.4 million in the aggregate from the issuance and sale of common stock in the October 2021 underwritten public offering described below. While we began to generate revenue from commercial sales during the first quarter of fiscal year 2021 and through milestone 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 an adequate level of revenue from commercial sales to cover expenses.

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 cortical strip, grid electrode and depth electrode technology, hire additional staff, add operational, financial and management systems and continue to operate as a public company.

Our source of cash, outside of collaboration and product revenues, to date has been proceeds from the issuances of notes with warrants, common stock with and without warrants and unsecured loans, the terms of which are further described below. See also "—Funding Requirements and Outlook" below.

October 2021 Underwritten Public Offering

On October 13, 2021, we entered into 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. 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.

2021 Private Placement

On January 12, 2021, we entered into a purchase agreement with certain accredited investors, pursuant to which the Company, in a private placement (the "2021 Private Placement"), agreed to issue and sell an aggregate of 4,166,682 shares (the "Shares") of the common stock of the Company, and warrants to purchase an aggregate of 4,166,682 shares of common stock (the "2021 Warrants") at an aggregate purchase price of $3.00 per share of common stock and corresponding warrant, resulting in total gross proceeds of $12.5 million before deducting placement agent fees and estimated offering expenses. The 2021 Warrants have an initial exercise price of $5.25 per share. The 2021 Warrants became immediately exercisable beginning on the date of issuance and will expire on the fifth anniversary of such date. Prior to expiration, subject to the terms and conditions set forth in the 2021 Warrants, the holders of such 2021 Warrants may exercise the 2021 Warrants for shares of common stock by providing notice to the Company and paying the exercise price per share for each share so exercised or by utilizing the "cashless exercise" feature contained in each 2021 Warrant. The 2021 Private Placement closed on January 14, 2021.

In connection with the 2021 Private Placement, the Company agreed to file a registration statement with the SEC covering the resale of the Shares, the 2021 Warrants and the shares of common stock issuable upon exercise of the 2021 Warrants. The Company agreed to file such registration statement within 30 days of the execution of the 2021 Purchase Agreement on January 12, 2021 and filed such registration statement on February 10, 2021.

Other Common Stock Offerings

On July 24, 2020, we entered into a Securities Purchase Agreement ("2020 Purchase Agreement") with an accredited investor pursuant to which we, in a private placement, issued and sold 25,000 shares of the Company's common stock for gross proceeds in the amount of $135,000. Under the 2020 Purchase Agreement, we agreed to use the net proceeds from the private placement for funding operations or working capital and general corporate purposes. We granted the investor indemnification rights with respect to representations, warranties and agreements under the 2020 Purchase Agreement.

On October 23, 2019, we entered into securities purchase agreements with certain accredited investors, pursuant to which the Company, in a private placement, issued and sold 47,223 shares of the Company's common stock to the accredited investors at a price of $5.40 per share, for gross proceeds amounting to $0.3 million before deducting offering expenses. We filed a registration statement with the SEC covering the resale of the shares of common stock sold in the private placement on August 11, 2020.

2020 Paulson Convertible Notes

On April 30, 2020, the Company entered into a subscription agreement with certain accredited investors, pursuant to which the Company, in a private placement (the "2020 Paulson Private Placement"), agreed to issue and sell to the investors 13% convertible promissory notes (each, a "2020 Paulson Note" and collectively, the "2020 Paulson Notes") and warrants (each, a "2020 Paulson Warrant" and collectively, the "2020 Paulson Warrants") to purchase shares of the Company's common stock.

Between April 30, 2020 and June 30, 2020, the Company issued 2020 Paulson Notes in an aggregate principal amount of $5.1 million to the accredited investors. The final closing under the 2020 Paulson Private Placement occurred on June 30, 2020. In July 2020, all remaining 2020 Paulson Notes outstanding were automatically converted into Common Stock following the announcement of a Strategic Transaction (as defined in the 2020 Paulson Notes) with Zimmer, Inc. The terms of the 2020 Paulson Notes are summarized below:

The 2020 Paulson Notes had interest at a fixed rate of 13% per annum and required the Company to repay the principal and accrued and unpaid interest thereon on the earlier of (i) December 31, 2020 or (ii) a change of control transaction. If the Company had raised more than $5,000,000 in an equity financing before the maturity date (the "2020 Qualified Financing"), without any action on the part of the subscribers, all of the outstanding principal and accrued and unpaid interest of the 2020 Paulson Notes (the "Outstanding Balance") would have been converted into that number of shares of the securities issued by the Company in the closing on the date a 2020 Qualified Financing occurred equal to: (i) the Outstanding Balance divided by (ii) the lower of 0.6 multiplied by (A) the actual per share price of the securities issued by the Company in the closing on the date a 2020 Qualified Financing occurred and (B) the volume weighted average price ("VWAP") of the common stock for ten (10) trading days immediately preceding the 2020 Qualified Financing.

In addition, as was the case in July 2020, if the Company announced a transaction between the Company and any other company (or an affiliate of any such company) that was included in the S&P 500 Health Care Index as published from time to time by S&P Dow Jones Indices LLC that included an investment or upfront payments resulting in gross proceeds to the Company of at least $2,000,000 upon the execution of such transaction or definitive agreement, and provided for terms of collaboration, manufacturing, distribution, licensing or supply of the Company's products (a "Strategic Transaction") before the maturity date, without any action on the part of the subscribers, the Outstanding Balance would convert into that number of shares of common stock equal to: (i) the Outstanding Balance divided by (ii) the lower of 0.6 multiplied by (A) the VWAP of the common stock for the ten (10) trading days immediately preceding the first announcement of the Strategic Transaction or (B) closing price of the common stock on the day preceding the first announcement by the Company of a Strategic Transaction.

At any time, at the sole election of the holder of such 2020 Paulson Note prior to a 2020 Qualified Financing, Strategic Transaction or change of control transaction, all or a portion of the Outstanding Balance could be converted into that number of shares of common stock equal to: (i) the Outstanding Balance elected by the holder to be converted divided by (ii) an amount equal to 0.6 multiplied by the volume weighted average price of the common stock for the ten (10) trading days immediately preceding the date of conversion.

If a change of control transaction had occurred prior to the conversion of the 2020 Paulson Notes or the maturity date, the 2020 Paulson Notes would have become payable on demand as of the closing date of such transaction. Change of control meant a merger or consolidation with another entity in which the Company's stockholders did not own more than 50% of the outstanding voting power of the surviving entity or the disposition of all or substantially all of the Company's assets.

Each 2020 Paulson Warrant grants the holder the option to purchase the number of shares of common stock equal to (i) 0.5 multiplied by (ii) the principal amount of such subscriber's 2020 Paulson Notes divided by 5.61, with an exercise price per share equal to $5.61. As of the final closing on June 30, 2020, the Company issued 2020 Paulson Warrants exercisable for 456,564 shares of Common Stock in connection with all closings of the private placement.

The 2020 Paulson Warrants are immediately exercisable and expire on April 30, 2023. The exercise price is subject to adjustment in the event of any stock dividends or splits, reverse stock split, recapitalization, reorganization, or similar transaction.

In connection with the 2020 Paulson Private Placement, Paulson Investment Company ("Paulson"), received a cash commission equal to 12% of the gross proceeds from the sale of the 2020 Paulson Notes, and at the final closing of the 2020 Paulson Private Placement, Paulson received 7-year warrants to purchase an amount of Common Stock equal to 136,971 ("Broker Warrants"). The Broker Warrants have an exercise price equal to $5.61.

2020 Paulson Note Conversions

Between May 4, 2020 and July 22, 2020, certain subscribers elected to convert $3,590,353 of the outstanding principal and interest of such subscribers' 2020 Paulson Notes into 1,337,459 shares of common stock. On July 23, 2020, the remaining outstanding principal and interest balance of the 2020 Paulson Notes in the amount of $1,613,961 was converted into 535,178 shares of common stock upon the announcement of the Zimmer Development Agreement that qualified as a Strategic Transaction as discussed above.

2019 Paulson Convertible Notes

On November 1, 2019, the Company entered into a subscription agreement with certain accredited investors, pursuant to which the Company, in a private placement (the "2019 Paulson Private Placement"), agreed to issue and sell to the investors 13% convertible promissory notes (each, a "2019 Paulson Note" and collectively, the "2019 Paulson Notes") and warrants (each, a "2019 Paulson Warrant" and collectively, the "2019 Paulson Warrants") to purchase shares of the Company's common stock.

The initial closing of the private placement was consummated on November 1, 2019, and, on that date and through December 3, 2019, the Company issued 2019 Paulson Notes in an aggregate principal amount of $3,234,800 to the Subscribers for gross proceeds equaling the principal amount. The private placement terminated on December 3, 2019.

The Paulson Notes had a fixed interest rate of 13% per annum and required the Company to repay the principal and accrued and unpaid interest thereon on May 1, 2020 (the "Maturity Date"). If the Company had raised more than $3,000,000 in an equity financing before the Maturity Date (the "Qualified Financing"), each subscriber would have had the option to convert the outstanding principal and accrued and unpaid interest of such subscriber's 2019 Paulson Note (the "Outstanding Balance") into the securities issued by the Company in such Qualified Financing in an amount equal to (i) the Outstanding Balance divided by (ii) the lower of 0.6 multiplied by (A) the actual per share price of securities issued by the Company in the Qualified Financing and (B) the ten day volume weighted average closing price of the common stock prior to the first closing of a Qualified Financing. If a change of control transaction had occurred prior to the earlier of a Qualified Financing or the Maturity Date, the 2019 Paulson Notes would have become payable on demand as of the closing date of such transaction. Change of control meant a merger or consolidation with another entity in which the Company's stockholders did not own more than 50% of the outstanding voting power of the surviving entity or the disposition of all or substantially all of the Company's assets.

Each 2019 Paulson Warrant grants the holder the option to purchase the number of shares of common stock equal to (i) 0.5 multiplied by (ii) the principal amount of such subscriber's 2019 Paulson Notes divided by 5.61, with an exercise price per share equal to $5.61. As of the final closing on December 3, 2019, the Company issued 2019 Paulson Warrants exercisable for 288,305 shares of Common Stock in connection with all closings of the private placement. The 2019 Paulson Warrants are immediately exercisable and expire on November 1, 2022. The exercise price is subject to adjustment in the event of any stock dividends or splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein.

In connection with the private placement, Paulson received a cash commission equal to 12% of the gross proceeds from the sale of the 2019 Paulson Notes, and 10-year warrants to purchase an amount of Common Stock equal to 86,498 shares of common stock at an exercise price equal to $5.61 per share.

Second Amendment of 2019 Paulson Notes

On April 24, 2020, the Company and holders of a majority in aggregate principal amount of the 2019 Paulson Notes entered into an amendment to the 2019 Paulson Notes (the "Second Paulson Amendment") to, among other things:

i. ***Extended the Maturity Date*** – The Second Paulson Amendment extended the maturity date of the 2019 Paulson Notes from May 1, 2020 to November 1, 2020 (in either case, unless a change of control transaction happens prior to such date);

ii. ***Revised Optional Conversion Terms*** – The Second Paulson Amendment provided that the amount of shares to be received upon the a subscriber's optional conversion of the 2019 Paulson Notes prior to a Qualified Financing (as defined in the 2019 Paulson Notes) would have been equal to: (1) the outstanding balance of such subscriber's 2019 Paulson Note elected by the subscriber to be converted divided by (2) an amount equal to 0.6 multiplied by the volume weighted average price of the common stock for the ten (10) trading days immediately preceding the date of conversion; and

iii. ***Revised the Registration Date*** **–** The Second Paulson Amendment provided that promptly following the earlier of (1) May 1, 2020, if the applicable subscriber had converted all or a majority of the outstanding balance of such subscriber's 2019 Paulson Note prior to such date; (2) the final closing a Qualified Financing; and (3) the maturity date, the Company would enter into a registration rights agreement with the applicable subscriber containing customary and usual terms pursuant to which the Company shall agree to prepare and file with the SEC a registration statement on or prior to the 90th calendar day following the registration date, covering the resale of any common stock received on conversion of such 2019 Paulson Notes, and shares of common stock underlying the Warrants.

There were no other significant changes to terms under the Second Paulson Amendment.

2019 Paulson Note Conversions

During the years ended September 30, 2021 and 2020, the 2019 Paulson Notes were converted into 292,754 and 725,394 shares of common stock, respectively. All of the 2019 Paulson notes were converted shares of common stock by December 31, 2020.

Paycheck Protection Program Loan

In connection with the 2020 Coronavirus Aid, Relief, and Economic Security ("CARES Act"), the Company received loan funding of approximately $83,000 under the Paycheck Protection Program ("PPP"), which was forgiven by the U.S. Small Business Administration on June 9, 2021.

Funding Requirements and Outlook

At September 30, 2021, we had approximately $6.9 million in cash deposits. Subsequent to September 30, 2021, we received gross proceeds of approximately $13.4 million in the aggregate from the issuance and sale of common stock in the October 2021 underwritten public offering described below. To date, we have generated limited revenues from commercialization and through milestone payments from our current collaboration with Zimmer, and 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.

Management has noted the existence of substantial doubt about our ability to continue as a going concern. Additionally, our independent registered public accounting firm and our former independent registered public accounting firm included explanatory paragraphs in the reports on our financial statements as of and for the years ended September 30, 2021 and 2020, respectively, noting the existence of substantial doubt about our ability to continue as a going concern. Our existing cash 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.

For a discussion of potential fee payments under the Zimmer Development Agreement, see "Management's Discussion and Analysis of Financial Condition and Results of Operations— Financial Overview—Collaborations Revenue," "Note 7 — Zimmer Development Agreement" included in "Item 8 — Financial Statements and Supplementary Data" in this Report and "Risk Factors —Risks Related to Our Business—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."

Our material 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"). 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. In addition, we have agreements with the WARF Mayo that require us to make certain milestone and royalty payments.

On January 22, 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. 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.

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. Nothing further was due until we started selling our products. As of September 30, 2021, $4,000 in royalty payments were earned by Mayo based on the commencement of commercial sales in fiscal year 2021.

Refer to "Item 1—Business—WARF License", "Item 1—Business—Mayo Foundation for Medical Education and Research License and Development Agreement", "Item 1A—Risk Factors—Risks Related to Our Business—We depend on intellectual property licensed from WARF for our technology under development, and the termination of this license would harm our business" and "Item 1A—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" of this Report.

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 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 Year Ended September 30,	
	2021	**2020**
Net cash used in operating activities	$ (8,602,826)	$(3,425,302)
Net cash used in investing activities	(67,079)	(122,427)
Net cash provided by financing activities	11,534,854	7,323,377
Net increase in cash	$ 2,864,949	$ 3,775,648

Net cash used in operating activities

Net cash used in operating activities was $8.6 million for the year ended September 30, 2021, which consisted of a net loss of $9.9 million partially offset primarily by stock-based compensation, depreciation, amortization related to intangible assets, revaluation of convertible notes, non-cash lease expense and Paycheck Protection Program loan forgiveness, totaling approximately $1.9 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 $0.5 million. The year on year change in operating assets and liabilities was primarily attributable to a net decrease in accounts payable and accrued expenses, and by an increase in our prepaid expenses.

Net cash used in operating activities was $3.4 million for the year ended September 30, 2020, which consisted of a net loss of $13.6 million partially offset primarily by non-cash interest, stock-based compensation, depreciation, amortization related to intangible assets, revaluation of convertible notes and loss on notes extinguishment, totaling approximately $10.6 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 $0.4 million. The year on year change in operating assets and liabilities was primarily attributable to a decrease in accounts payable and accrued expenses, largely in connection with the payment of legal expenses, and by an increase in our prepaid expenses.

Net cash used in investing activities

Net cash used by investing activities for the year ended September 30, 2021 was $0.1 million and consisted of outlays for research and development equipment.

Net cash used by investing activities for the year ended September 30, 2020 was $0.1 million and consisted of outlays for furniture and equipment.

Net cash provided by financing activities

Net cash provided by financing activities was $11.5 million for the year ended September 30, 2021, which consisted primarily of net proceeds received upon the issuance of the 2021 Private Placement in the amount of $11.3 million in the aggregate. There were also exercises of stock options and warrants during the year ended September 30, 2021 resulting in additional cash proceeds of $0.3 million, offset in part by deferred offering costs of $49,000.

Net cash provided by financing activities was $7.3 million for the year ended September 30, 2020, which consisted primarily of net proceeds received upon the issuance of the 2020 and 2019 Paulson Notes and the common stock offerings totaling $7.2 million in the aggregate, and $0.1 million in proceeds received from the Paycheck Protection Program.

Critical Accounting Policies and Significant Judgments and Estimates

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of revenue and expenses during the reporting periods. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our financial statements prospectively from the date of the change in estimate.

While our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Product Revenue

Revenues from product sales are recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. At the inception of each 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 our third-party contract manufacturer in connection with our strip and grid cortical electrodes (the "Strip/Grid Products") and outside supplier materials costs in connection with the Electrode Cable Assembly Products. In addition, cost of product revenue includes royalty fees incurred in connection with our license agreements.

Collaborations Revenue

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our agreements, we perform 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) we satisfy 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. 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 we expect to complete our performance obligations under the arrangement. If we cannot reasonably estimate when our performance obligations are either completed or become inconsequential, then revenue recognition is deferred until we can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. We use 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. We allocate 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 our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize 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, we utilize 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. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate 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 our control, such as approvals from regulators, are not considered probable of being achieved until those approvals are received. When our 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 license, collaboration, and other 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, we recognize 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

We account 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 adhering 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 measurement date.

As of September 30, 2021 and 2020, the fair values of cash, accounts receivable, inventory, prepaid, other assets, accounts payable and accrued expenses approximated their carrying values because of the short-term nature of these assets or liabilities. We elected to account for the convertible notes while they were outstanding on a fair value basis under ASC 825 to comprehensively value and streamline the accounting for the embedded conversion options. The fair value of these convertible notes were based on both the fair value of our common stock, discount associated with the embedded redemption features, and cash flow models discounted at current implied market rates evidenced in recent arms-length transactions representing expected returns by market participants for similar instruments and are based on Level 3 inputs.

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

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of NeuroOne Medical Technologies Corporation:

Opinion on the Financial Statements

We have audited the accompanying balance sheet of NeuroOne Medical Technologies Corporation (the "Company") as of September 30, 2021, the related statements of operations, changes in stockholders' equity and cash flows for the year then ended, 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, 2021, and the results of its operations and its cash flows for the year then ended, 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 has recurring losses from operations, an accumulated deficit, expects to incur losses for the foreseeable future and needs additional working capital. These are the reasons that raise substantial doubt about their 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 audit. 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 audit in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. 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. Our audit 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 audit 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 audit provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below 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) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Critical Audit Matter Description

Classification of warrants issued as permanent equity

As described in Note 10 to the financial statements, the Company completed an equity offering during the year which included the issuance of warrants. Management determined the proper classification of the warrants by reviewing the terms and conditions of the issued warrants and applying the applicable accounting guidance, including Accounting Standards Codification (ASC) 480 Distinguishing Liabilities from Equity and ASC 815 Derivatives and Hedging. Management concluded the warrants met the criteria for the classification as permanent equity.

The accounting guidance for determining the proper classification of warrants is highly complex and subject to interpretation. A slight variation in the terms and conditions of the warrant could results in the warrant being classified as a liability, which would also impact the statement of operations, as the subsequent accounting for warrants treated as liabilities is significantly different from those classified as permanent equity.

Due to the complexity in the accounting guidance, the need for management judgment in applying the accounting guidance, and the fact that a slight change in terms can result in significant changes in both the initial accounting and subsequent accounting for the warrants, we identified the evaluation of the classification of the warrants issued during the year as a critical audit matter.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- As part of our risk assessment procedures, we evaluated the design and implementation of the Company's controls over the evaluation and application of the relevant accounting guidance to the specific terms and conditions within the warrant agreements.

- We obtained the Company's accounting analysis for the equity offering during the year. We compared the terms described in the Company's analysis to the terms of the respective agreements to determine the completeness and accuracy of the analysis performed.

- With the assistance of firm personnel having expertise in the accounting for complex equity instruments, we performed a detailed examination of the warrant agreement for the equity offering, with a primary focus on the key terms and conditions regarding the treatment of the warrants upon the occurrence of a fundamental transaction. As warrant holders can obtain cash from the Company only when a fundamental transaction is deemed to be within the Company's control, we agreed with the conclusion to classify the warrants within permanent equity. We also focused on the subsequent rights offering provision and its impact within the indexation guidance, noting the provision was appropriately evaluated when applying the indexation guidance. Therefore, it was determined this would not preclude the Company from classifying the warrants within permanent equity.

- We discussed with the Company's legal counsel the impact of these terms and conditions within the warrant agreements to support the Company's conclusion.

/s/ Baker Tilly US, LLP

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

Minneapolis, Minnesota
December 15, 2021

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
NeuroOne Medical Technologies Corporation
Eden Prairie, Minnesota

Opinion on the Financial Statements

We have audited the accompanying balance sheet of NeuroOne Medical Technologies Corporation (the "Company") as of September 30, 2020, the related statements of operations, changes in stockholders' equity (deficit), and cash flows for the year ended September 30, 2020, 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 at September 30, 2020, and the results of its operations and its cash flows for the year ended September 30, 2020**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, negative cash flows from operations and an accumulated deficit that raise substantial doubt about its 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 include 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 audit. 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 audit 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 audit we were 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor from 2016 to 2021.

Minneapolis, Minnesota

December 8, 2020

NeuroOne Medical Technologies Corporation
Balance Sheets

	As of September 30,	
	2021	**2020**
Assets		
Current assets:		
Cash	$ 6,901,346	$ 4,036,397
Accounts receivable	48,336	—
Inventory	98,287	—
Prepaid and other assets	244,043	118,611
Total current assets	7,292,012	4,155,008
Intangible assets, net	134,207	156,523
Right-of-use asset	288,948	282,211
Property and equipment, net	223,329	166,031
Total assets	$ 7,938,496	$ 4,759,773
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 528,829	$ 762,538
Accrued expenses	644,249	512,762
Convertible promissory notes (Note 8)	—	1,007,206
Deferred revenue	8,622	73,434
Total current liabilities	1,181,700	2,355,940
Operating lease liability, long term	202,895	254,328
Other liabilities	—	83,333
Total liabilities	1,384,595	2,693,601
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized as of September 30, 2021 and 2020; no shares issued or outstanding as of September 30, 2021 and 2020.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized as of September 30, 2021 and 2020; 12,010,019 and 7,393,637 shares issued and outstanding as of September 30, 2021 and 2020, respectively.	35,834	22,181
Additional paid–in capital	47,345,266	32,923,022
Accumulated deficit	(40,827,199)	(30,879,031)
Total stockholders' equity	6,553,901	2,066,172
Total liabilities and stockholders' equity	$ 7,938,496	$ 4,759,773

See accompanying notes to financial statements

NeuroOne Medical Technologies Corporation
Statements of Operations

	Year ended September 30,	
	2021	**2020**
Product revenue	$ 178,146	$ —
Cost of product revenue	275,895	—
Product gross loss	(97,749)	—
Collaborations revenue	64,812	1,926,566
Operating expenses:		
Selling, general and administrative	6,260,266	4,753,036
Research and development	3,925,008	2,075,791
Total operating expenses	10,185,274	6,828,827
Loss from operations	(10,218,211)	(4,902,261)
Interest expense	(3,053)	(7,524,581)
Net valuation change of instruments measured at fair value	1,974	804,529
Loss on note extinguishment	—	(2,017,847)
Other income	271,122	—
Net loss	$ (9,948,168)	$(13,640,160)
Net loss per share:		
Basic and diluted	$ (0.93)	$ (2.52)
Number of shares used in per share calculations:		
Basic and diluted	10,696,799	5,415,424

See accompanying notes to financial statements

NeuroOne Medical Technologies Corporation
Statement of Changes in Stockholders' Equity (Deficit)

	Common Stock		Additional Paid–In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
Balance at September 30, 2019	4,497,930	$ 13,494	$ 15,987,799	$ (17,238,871)	$ (1,237,578)
Issuance of common stock under securities purchase agreement	72,223	217	389,783	—	390,000
Issuance of warrants in connection with convertible notes offering	—	—	696,672	—	696,672
Conversion of convertible notes into common stock	2,598,025	7,794	14,172,676	—	14,180,470
Issuance costs in connection with conversion of convertible notes into common stock	—	—	(161,881)	—	(161,881)
Stock-based compensation	—	—	798,242	—	798,242
Issuance of common stock for consulting services	142,200	427	641,289	—	641,716
Issuance of common stock upon vesting of restricted stock units	57,744	173	395,839	—	396,012
Exercise of stock options	25,515	76	2,603	—	2,679
Net loss	—	—	—	(13,640,160)	(13,640,160)
Balance at September 30, 2020	7,393,637	22,181	32,923,022	(30,879,031)	2,066,172
Issuance of common stock and warrants under securities purchase agreement	4,166,682	12,500	12,487,500	—	12,500,000
Conversion of convertible notes into common stock	292,754	878	1,004,354	—	1,005,232
Issuance costs in connection with securities issuances	—	—	(1,198,080)	—	(1,198,080)
Issuance cost adjustment related to private placement	—	—	50,400	—	50,400
Stock-based compensation	—	—	1,793,199	—	1,793,199
Issuance of common stock for consulting services	74,327	74	(74)	—	—
Issuance of common stock upon vesting of restricted stock units	30,021	63	(63)	—	—
Exercise of stock options	1,552	3	10,143	—	10,146
Exercise of warrants	51,046	135	274,865	—	275,000
Net loss	—	—	—	(9,948,168)	(9,948,168)
Balance at September 30, 2021	12,010,019	$ 35,834	$ 47,345,266	$ (40,827,199)	$ 6,553,901

See accompanying notes to financial statements

NeuroOne Medical Technologies Corporation
Statements of Cash Flows

	Year ended September 30,	
	2021	**2020**
Operating activities		
Net loss	$ (9,948,168)	$(13,640,160)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	80,748	47,609
Stock-based compensation	1,793,199	1,835,970
Non-cash interest on convertible promissory notes	—	5,616,858
Payroll protection program loan forgiveness	(83,333)	—
Fair value change of convertible promissory notes	(1,974)	(804,529)
Issuance costs attributed to financing activities	3,053	1,907,723
Non-cash lease expense	66,382	22,943
Loss on notes extinguishment	—	2,017,847
Change in assets and liabilities:		
Accounts receivable	(48,336)	—
Inventory	(98,287)	—
Prepaid and other assets	(8,320)	(77,609)
Accounts payable	(350,313)	(269,601)
Accrued expenses, deferred revenue, operating lease and other liabilities	(7,477)	(82,353)
Net cash used in operating activities	(8,602,826)	(3,425,302)
Investing activities		
Purchase of property and equipment	(67,079)	(122,427)
Net cash used in investing activities	(67,079)	(122,427)
Financing activities		
Proceeds from issuance of convertible promissory notes	—	8,357,500
Proceeds from issuance of common stock in connection with private placements	8,829,236	390,000
Proceeds from issuance of warrants in connection with private placements	3,670,764	—
Issuance costs in connection with convertible promissory notes	(3,053)	(1,125,241)
Issuance costs in connection with private placements	(1,198,080)	(384,894)
Exercise of warrants	275,000	—
Exercise of stock-options	10,146	2,679
Proceeds from paycheck protection program	—	83,333
Deferred offering costs	(49,159)	—
Net cash provided by financing activities	11,534,854	7,323,377
Net increase in cash	2,864,949	3,775,648
Cash at beginning of period	4,036,397	260,749
Cash at end of period	$ 6,901,346	$ 4,036,397
Supplemental non-cash financing and investing transactions:		
Conversion of convertible promissory notes to equity	$ 1,005,232	$ 14,180,470
Unpaid issuance costs and non-cash adjustments attributed to convertible notes and private placement	$ 50,400	$ 95,735
Non-cash issuance of broker warrants in connection with convertible notes and private placements	$ —	$ 696,672
Operating lease right of use asset obtained in exchange for operating lease	$ 73,118	$ 335,119
Payroll protection program loan forgiveness	$ 83,333	$ —
Unpaid deferred offering costs	$ 67,954	$ —
Unpaid purchases of property and equipment	$ 48,651	$ 16,872

See accompanying notes to financial statements

NeuroOne Medical Technologies Corporation
Notes to Financial Statements

NOTE 1 - Organization and Nature of Operations

NeuroOne Medical Technologies Corporation (the "Company" or "NeuroOne"), a Delaware corporation, is an early-stage medical technology company developing comprehensive neuromodulation cEEG and sEEG recording, 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.

The Company received 510(k) clearance from the FDA for its Evo cortical technology in November 2019, and in September 2021 received 510(k) clearance from the FDA for its 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. To date, the Company has had limited commercial sales.

The Company's common stock commenced trading on The Nasdaq Capital Market on May 26, 2021 under the ticker symbol "NMTC." Previously, the Company's common stock was traded on the OTC Markets quotation system on the OTCQB.

The Company is based in Eden Prairie, Minnesota.

COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic. As a result of the COVID-19 pandemic, the Company has experienced, and will likely continue to experience, delays and disruptions in its pre-clinical and clinical trials, as well as interruptions in its manufacturing, supply chain, shipping, and research and development operations. In April 2020, given the impact of COVID-19 on the Company and in connection with the enactment of the CARES Act, the Company applied for and received loan funding of $83,333 under the Paycheck Protection Program, which was forgiven by the U.S. Small Business Administration in June 2021. The development of the Company's technology was delayed in fiscal year 2021 due to interruptions in global manufacturing and shipping as a result of the COVID-19 pandemic. Additionally, the Company's own staff has been impacted by infections and mandatory quarantines. Further testing and clinical trials, manufacturing, component supply, shipping and research and development operations may be further impacted by the continuing effects of COVID-19.

The extent to which the COVID-19 pandemic may further impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the effect of the pandemic on its suppliers and distributors and the global supply chain, the duration of the pandemic, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease. The COVID-19 pandemic may also impact the Company's business because of employee illness, school closures, and other community response measures.

Although the Company cannot estimate the length or gravity of the impact of the COVID-19 outbreak at this time, if the pandemic continues, it may have a material adverse effect on the Company's results of future operations, financial position, and liquidity for fiscal year 2022 and beyond.

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 $40.8 million as of September 30, 2021. 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. The Company does not have adequate liquidity to fund its operations without raising additional funds and such actions are not solely within the control of the Company. These factors raise substantial doubt about its 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 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. There was also substantial doubt about the Company's ability to continue as a going concern for the financial statements as of and for the year ended September 30, 2020.

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.

In December 2019, the Company merged its wholly-owned subsidiary, NeuroOne Inc., into NeuroOne Medical Technologies Corporation. The merger of the Company's wholly-owned subsidiary did not have a financial impact to the periods presented. Upon close of the merger, the Company did not have any remaining entities that required consolidation for financial statement reporting purposes.

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is 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.

Reverse Stock Split

On March 11, 2021, the Company's Board of Directors (the "Board") approved a one-for-three reverse stock split of the Company's issued and outstanding shares of common stock (the "Reverse Stock Split") effective end-of-day March 31, 2021.

All issued and outstanding common stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, restricted stock units and warrants to purchase shares of common stock. A proportionate adjustment was also made to the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans to reflect the Reverse Stock Split. Any fraction of a share of common stock that was created as a result of the Reverse Stock Split was rounded up to the next whole share. The authorized shares and par value of the common stock and preferred stock were not adjusted as a result of the Reverse Stock Split.

Management's Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, primarily in connection with the convertible promissory notes, and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash. The Company's cash is held by one financial institution in the United States. Amounts on deposit may at times exceed federally insured limits. The Company has not experienced any losses on its deposits since inception, and management believes that minimal credit risk exists with respect to these financial institutions. As of September 30, 2021, the Company had $6.7 million of deposits in excess of federally insured amounts.

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."

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. The Company commenced commercial sales of cEEG strip/grid and electrode cable assembly products in the first quarter of fiscal year 2021.

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") 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

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. 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.

As part of the accounting for these 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.

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 license, collaboration, and other 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, 2021 and 2020, the fair values of cash, accounts receivable, inventory, prepaid, other assets, accounts payable and accrued expenses approximated their carrying values because of the short-term nature of these assets or liabilities. The fair value of the convertible notes while outstanding were based on both the fair value of our common stock, discount associated with the embedded redemption features, and cash flow models discounted at current implied market rates evidenced in recent arms-length transactions representing expected returns by market participants for similar instruments and are based on Level 3 inputs.

There were no transfers between fair value hierarchy levels during the years ended September 30, 2021 and 2020.

There were no financial instruments measured on a recurring basis outstanding as of September 30, 2021. The fair value of financial instruments measured on a recurring basis was as follows as of September 30, 2020:

	As of September 30, 2020			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Convertible notes	$ 1,007,206	—	—	$ 1,007,206
Total liabilities at fair value	$ 1,007,206	—	—	$ 1,007,206

The following table provides a roll-forward of the convertible notes, warrant liability and premium debt conversion derivatives measured at fair value on a recurring basis using unobservable level 3 inputs for the years ended September 30 as follows:

	2021
Convertible notes	
Balance as of beginning of period – September 30, 2020	$ 1,007,206
Conversion of convertible promissory notes to common stock	(1,005,232)
Change in fair value including accrued interest	(1,974)
Balance as of end of period – September 30, 2021	$ —

	2020
Convertible notes	
Balance as of beginning of period – September 30, 2019	$ —
Fair value attributed to convertible promissory notes upon issuance	13,974,358
Fair value attributed to note extinguishment	2,017,847
Conversion of convertible promissory notes to common stock	(14,180,470)
Change in fair value including accrued interest	(804,529)
Balance as of end of period – September 30, 2020	$ 1,007,206

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 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. 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.

Inventories

Inventories are 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 cEEG strip/grid and electrode cable assembly finished good product. The Strip/Grid Products are produced by a third-party contract manufacturer and the Electrode Cable Assembly Products are obtained from outside suppliers.

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 fees relating to corporate matters, intellectual property costs, professional fees for consultants assisting with regulatory, clinical, product development, financial matters, and beginning in the first quarter of fiscal year 2021, sales and marketing in connection with the commercial sale of cEEG strip/grid and electrode cable assembly products.

Income Taxes

For the Company, 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

For the Company, 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 convertible notes, warrants, stock options and restricted stock units, while outstanding, are considered common stock equivalents for this purpose. Diluted earnings is computed utilizing the treasury method for the warrants, stock options and restricted stock units. Diluted earnings with respect to the convertible promissory utilize the if-converted method. 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, 2021 and 2020.

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:

	2021	2020
Warrants	7,503,808	3,390,320
Stock options	1,122,560	492,842
Restricted stock units	11,384	26,698
Unissued vested restricted stock units	1,148	2,063
Convertible notes	—	277,618

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. Recently, the FASB issued the final ASU to delay adoption for smaller reporting companies to calendar year 2023. The Company is currently assessing the impact of the adoption of this ASU on its financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13). The new guidance modifies the disclosure requirements in Topic 820 as follows:

- Removals: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels; and the valuation processes for Level 3 fair value measurements.

- Modifications: for investments in certain entities that calculate net asset value, an entity is required to disclose the timing of liquidation of an investee's assets and the date when restrictions from redemption might lapse only if the investee has communicated the timing to the entity or announced the timing publicly; and the amendments clarify that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date.

- Additions: the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period; and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements.

This guidance is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should all be applied prospectively for only the most recent interim or annual period presented in the initial year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU 2018-13 and delay adoption of the additional disclosures until their effective date. The Company adopted the new guidance on October 1, 2020 and it did not have a material impact on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740) which amends the existing guidance relating to the accounting for income taxes. This ASU is intended to simplify the accounting for income taxes by removing certain exceptions to the general principles of accounting for income taxes and to improve the consistent application of GAAP for other areas of accounting for income taxes by clarifying and amending existing guidance. The ASU is effective for fiscal years beginning after December 15, 2020. The Company does not expect that the adoption of this new guidance will have a material impact on the Company's financial statements and plans to adopt this guidance on a prospective basis for the provisions applicable to the Company.

In August 2020, 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 earnings per share 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 is currently evaluating the impact of ASU 2020-06 on 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. 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. 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 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. We expect the latest expiration of a licensed patent to occur in 2030.

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 through the term of the Mayo Agreement, set to expire May 25, 2037. As of September 30, 2021, $3,894 in royalty fees were incurred given the commencement of commercial sales and were reflected as a component of cost of product revenue during the year ended September 30, 2021.

Legal

PMT Litigation

From time to time, the Company is subject to litigation and claims arising in the ordinary course of business.

On March 29, 2018, the Company was served with a complaint filed by PMT Corporation ("PMT"), the former employer of Mark Christianson, a current Company employee, and Wade Fredrickson, a now former Company employee. The complaint added the Company, NeuroOne, Inc. and Mr. Christianson to its existing lawsuit against Mr. Fredrickson in the Fourth Judicial District Court of the State of Minnesota. In the lawsuit, PMT claims that Mr. Fredrickson and Mr. Christianson, by virtue of their work for the Company and their prior work during employment with PMT, breached their non-competition, non-solicitation and non-disclosure obligations, breached their fiduciary duty obligations, were unjustly enriched, engaged in unfair competition, engaged in a civil conspiracy, tortiously interfered with PMT's contracts and prospective economic advantage, and breached a covenant of good faith and fair dealing. The complaint purported to attach Mr. Fredrickson's noncompete agreement as Exhibit A. Against Mr. Fredrickson, PMT also alleged that he intentionally or negligently spoliated evidence, made negligent or fraudulent misrepresentations, misappropriated trade secrets in violation of Minnesota law, and committed the tort of conversion and statutory civil theft. Against the Company and NeuroOne, Inc., PMT alleged that the Company and NeuroOne, Inc. were unjustly enriched and engaged in unfair competition. PMT asked the Court to impose a constructive trust over the shares held by Mr. Fredrickson and Mr. Christianson and to award compensatory damages, equitable relief, punitive damages, attorneys' fees, costs and interest.

On April 18, 2018, Mr. Christianson, the Company and NeuroOne, Inc. filed a motion for dismissal, which was heard by the Court on October 11, 2018. The motion for dismissal stated that: the contract claims against Mr. Christianson fail because his agreement was not supported by consideration; the Minnesota Uniform Trade Secrets Act preempts plaintiff's claims for unfair competition, civil conspiracy and unjust enrichment; plaintiff fails to state a claim regarding alleged breach of the duties of loyalty and good faith/fair dealing; plaintiff cannot legally obtain a constructive trust; plaintiff has insufficiently pled its tortious interference claims; and Plaintiff has not stated a claim for unfair competition. On January 7, 2019, the judge granted the motion for dismissal with respect to PMT's claim for breach of the duty of good faith and fair dealing, and denied the motion for dismissal with respect to the other claims presented.

In April 2019, PMT served the Company, NeuroOne, Inc. and Christianson with a proposed Second Amended Complaint, which included new claims against the Company and NeuroOne, Inc for tortious interference with contract and tortious interference with prospective business advantage and punitive damages against the Company, NeuroOne Inc. and Christianson. On June 28, 2019, the Company presented evidence indicating that PMT had participated in a fraud on the Court and sought an Order that PMT had waived the attorney client privilege.

On July 16, 2019, the defendants served PMT with a joint notice of motion for sanctions seeking a variety of sanctions for litigation misconduct including, but not limited to, dismissal of the case and an award of attorneys' fees. The Company, NeuroOne Inc and Mr. Christianson further moved for summary judgment on all remaining claims asserted against them as well as for leave to assert counterclaims against PMT for abuse of process. Following hearings on the dispositive motions and defendants' sanctions motion, the district court granted the Company's motion for sanctions on April 29, 2020. Additionally, the district court granted the Company's motion for summary judgment in part with respect to the counts for Christianson's breach of non-confidentiality agreement, and denied the Company's motion for summary judgment on all other counts.

On August 24, 2020, defendants moved the Court to amend their counterclaims for abuse of process against PMT to add a claim for punitive damages with respect to its conduct pertaining to the Fredrickson noncompete. On October 12, 2020 the Court awarded NeuroOne, Inc. $185,000 in Rule 11 sanctions and Fredrickson $145,000 in Rule 11 sanctions with respect to PMT's misconduct relating to the Fredrickson noncompete. PMT and its former litigation counsel, Barnes & Thornburg, were jointly and severally liable for these awards, which were paid on December 11, 2020 and have been recognized in other income in the statements of operations. The Court granted NeuroOne, Inc.'s motion to amend to permit its assertion of the right to assert a punitive damages claim against PMT associated with fighting the allegations relating to the Fredrickson noncompete.

On May 27, 2021 PMT moved for summary judgment on defendants' claims for abuse of process and punitive damages, and on August 5, 2021, the district court granted PMT's motion to dismiss the abuse of process and punitive damage claims.

Trial has been postponed from December 2021 to August of 2022. The Company intends to continue to defend itself vigorously and to continue to aggressively prosecute its affirmative counterclaim against PMT. The outcome of any claim against the Company by PMT was not estimable as of the issuance of these financial statements.

Facility Leases

Headquarters Lease

On October 7, 2019, the Company entered into a non-cancellable lease agreement (the "Lease") with Biynah Cleveland, LLC, BIP Cleveland, LLC, and Edenvale Investors (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 "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 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

In July 1, 2021, the Company entered into a non-cancellable facility lease (the "New 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 term of the New Lease is eighteen months. The facility space under the New 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 New Lease is approximately $4,241.

San Jose Lease:

On December 30, 2020, the Company entered into a non-cancellable lease agreement for short term office space in San Jose, California (the "San Jose Lease") for a three month initial term. After March 31, 2021, the San Jose Lease was cancellable upon a 30-day notice to the landlord. The Company took possession of the office space on January 1, 2021 and the San Jose Lease was terminated upon the commencement of the New Lease discussed above. The base rent under the San Jose Lease was $504 per month.

During the years ended September 30, 2021 and 2020, rent expense associated with the facility leases amounted to $136,826 and $103,189, respectively.

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

	For the Year Ended September 30,	
	2021	**2020**
Cash paid for amounts included in the measurement of lease liability:		
Operating cash flows from operating leases	$ 70,897	$ 38,462
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 73,118	$ 335,119

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

	As of September 30,	
	2021	**2020**
Right-of-use assets	$ 288,948	$ 282,211
Lease liability	$ 315,673	$ 312,176
Weighted average remaining lease term (years)	3.1	4.5
Weighted average discount rate	6.7%	7.0%

Maturity of the lease liability was as follows:

Calendar Year	As of September 30, 2021
2021 (period from October 1, 2021 to December 31, 2021)	$ 32,435
2022	131,220
2023	82,333
2024	84,391
2025	21,227
Total lease payments	351,606
Less imputed interest	(35,933)
Total	315,673
Short-term portion	(112,778)
Long-term portion	$ 202,895

NOTE 5 – Supplemental Balance Sheet Information

Prepaid and Other Assets

Prepaid and other assets consisted of the following:

	As of September 30,	
	2021	2020
Prepaid expenses	$ 151,109	$ 118,010
Deferred offering costs	92,934	—
Other	—	601
Total	$ 244,043	$ 118,611

Intangibles

Intangible assets roll forward is as follows:

	Useful Life	
Net Intangibles, September 30, 2019	12-13 years	$ 178,838
Less: amortization		(22,315)
Net Intangibles, September 30, 2020		156,523
Less: amortization		(22,316)
Net Intangibles, September 30, 2021		$ 134,207

The Company anticipates amortization expense of approximately $21,000 per year for fiscal year 2022 through 2026 based upon the two current license agreements.

Property and Equipment

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

	As of September 30,	
	2021	2020
Equipment and furniture	$ 311,486	$ 195,756
Software	1,895	1,895
Total property and equipment	313,381	197,651
Less accumulated depreciation	(90,052)	(31,620)
Property and equipment, net	$ 223,329	$ 166,031

Depreciation expense was $58,432 and $25,294 for the years ended September 30, 2021 and 2020, respectively.

NOTE 6 - Accrued Expenses and Other Liabilities

Accrued expenses consisted of the following at September 30:

	As of September 30,	
	2021	**2020**
Accrued payroll	$ 376,236	$ 238,212
Operating lease liability, short term	112,778	57,848
Accrued issuance costs	—	50,400
Royalty Fees	72,083	—
Other	83,152	166,302
Total	$ 644,249	$ 512,762

The “other” category is primarily comprised of board fees.

Paycheck Protection Program

The CARES Act, signed into law in March 2020, established the Paycheck Protection Program (“PPP”). The PPP authorizes over $600 billion in forgivable loans to small businesses. Loan amounts may be forgiven to the extent proceeds are used to cover documented payroll, mortgage interest, rent, and utility costs over a 24-week measurement period following loan funding. Loans have a maturity of 2 years and an interest rate of 1%. Prepayments may be made without penalty. In April 2020, the Company received loan funding of $83,333 under the PPP and was recorded as a long-term liability. The PPP loan was forgiven on June 9, 2021 by the U.S. Small Business Administration and was reflected as other income in the accompanying statements of operations. Interest was nominal during the years ended September 30, 2021 and 2020.

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 (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, 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.

Except where Zimmer timely delivers a Design Modification Notice pursuant to Section 1.2, if one or more of the events set forth below occurs on or before the deadline indicated for such event and the Product Availability Date (as defined in the Development Agreement) for the SEEG Products occurs on or before June 30, 2021, then the Company shall receive the additional amount indicated for such event as part of the SEEG Exclusivity Maintenance Fee:

- Design freeze for the SEEG Products by December 15, 2020 - $500,000

- Acceptance of all Deliverables for SEEG Products under the Development Plan (as defined in the Development Agreement) by April 30, 2021 - $500,000

If Zimmer timely delivers a Design Modification Notice to the Company under the Development Agreement, and one or more of the events set forth below occurs on or before the deadline indicated for such event and the Product Availability Date for the SEEG Products occurs on or before June 30, 2021, then the Company shall receive the additional amount indicated for such event as part of the SEEG Exclusivity Maintenance Fee:

- Acceptance of all Deliverables for SEEG Products under the Development Plan other than the Modified Connector by April 30, 2021 - $500,000

- Acceptance of all Deliverables for SEEG Products under the Development Plan, including the Modified Connector by September 30, 2021 - $500,000

For purposes of the Development Agreement, each of the foregoing events shall have occurred only if the Company has demonstrated the achievement of the event to Zimmer's reasonable satisfaction. Notwithstanding the foregoing, the events in Sections 6.1(c)(ii), (iii) and (iv) of the Development Agreement shall not be deemed to be met if FDA Approval for the SEEG Products is not received prior to the applicable deadline.

In order to maintain the exclusivity of the SEEG Distribution License, Zimmer must pay the SEEG Exclusivity Maintenance Fee to the Company, on or prior to the SEEG Exclusivity Confirmation Date, in immediately available funds as follows:

- if the Product Availability Date for the SEEG Products occurs on or before June 30, 2021, then $3,000,000, plus the amount of any Interim Fee Bonuses earned pursuant to Section 6.1(c), including any such Interim Fee Bonus earned after June 30, 2021 pursuant to Section 6.1(c)(iv) following the delivery of a Design Modification Notice;

- if the Product Availability Date for the SEEG Products occurs after June 30, 2021, but on or before September 30, 2021, then $3,000,000, plus if Zimmer timely issues a Design A-9 Modification Notice, any Interim Fee Bonus earned pursuant to Section 6.1(c)(iv);

- if the Product Availability Date for the SEEG Products occurs after September 30, 2021, but on or before December 31, 2021, then $2,500,000; and

- if the Product Availability Date for the SEEG Products occurs after December 31, 2021, then $1,500,000.

The Product Availability Date for the SEEG Products has not yet occurred. Notwithstanding any other provision of the Development Agreement, if the Product Availability Date for the SEEG Products has not occurred on or before June 30, 2022, Zimmer shall have the right to terminate the SEEG Distribution License by delivering written notice to the Company to that effect and, upon delivery of such notice, Zimmer shall be relieved of all of its obligations hereunder with respect to SEEG Products, including any obligation to pay the SEEG Exclusivity Maintenance Fee or to purchase, market, distribute or sell any SEEG Products. The Initial Exclusivity Fee and the SEEG Exclusivity Maintenance Fee (including any Interim Fee Bonus(es)), once paid, are non-refundable.

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 the Company may terminate the Development Agreement if Zimmer acquires or directly or indirectly owns a controlling interest in certain competitors of the Company.

At inception of the Zimmer Development Agreement through September 30, 2021, the Company had identified the following three performance obligations under the Zimmer Development Agreement: (1) the Company obligation to license Zimmer rights to certain of its intellectual property; (2) complete SEEG Product development; and (3) complete Strip/Grid Product development. Accordingly, the Company recognized revenue in the amount of $64,812 and $1,926,566 during the years ended September 30, 2021 and 2020, respectively, related to the development of the Products completed during the periods in connection with the Initial Exclusivity Fee payment. The Zimmer Development Agreement was accounted for under the provisions of ASC 606, *Revenue from Contracts with Customers.*

A reconciliation of the closing balance of deferred revenue related to the Zimmer Development Agreement is as follows as of September 30, 2021 and 2020:

Deferred Revenue	
Balance as of September 30, 2019	$ —
Upfront initial exclusivity payment	2,000,000
Revenue recognized	(1,926,566)
Balance as of September 30, 2020	73,434
Revenue recognized	(64,812)
Balance as of September 30, 2021	$ 8,622

The remaining performance obligations reflected in deferred revenue as of September 30, 2021 are expected to be completed in first half of fiscal year 2022.

Product Revenue

In December 2020, the Company commenced commercial sales of its Strip/Grid Products and Electrode Cable Assembly Products in connection with the Development Agreement. Product revenue recognized during the year ended September 30, 2021 was $178,146.

Advertising Expense

Advertising expense is charged to selling, general and administrative expenses during the period that it is incurred. Total advertising expense amounted to $338,837 for the year ended September 30, 2021. Advertising expense during the prior year period was negligible.

NOTE 8 - Convertible Promissory Notes and Warrant Agreements

	As of September 30,	
	2021	**2020**
Paulson convertible notes, principal	$ —	$ 546,000
Accrued interest	—	63,458
Fair value adjustments	—	397,748
	$ —	$ 1,007,206

Paulson Convertible Note Offerings

2019 Paulson Convertible Note Offering

On November 1, 2019, the Company entered into a subscription agreement with certain accredited investors, pursuant to which the Company, in a private placement (the "2019 Paulson Private Placement"), agreed to issue and sell to the investors 13% convertible promissory notes (each, a "2019 Paulson Note" and collectively, the "2019 Paulson Notes") and warrants (each, a "2019 Paulson Warrant" and collectively, the "2019 Paulson Warrants") to purchase shares of the Company's common stock.

The initial closing of the 2019 Paulson Private Placement was consummated on November 1, 2019, and, on that date and through December 3, 2019, the Company issued the 2019 Paulson Notes in an aggregate principal amount of $3,234,800 to the subscribers for gross proceeds equaling the principal amount. The 2019 Paulson Private Placement terminated on December 3, 2019.

The 2019 Paulson Notes had a fixed interest rate of 13% per annum and required the Company to repay the principal and accrued and unpaid interest thereon on November 1, 2020 (the "Maturity Date"). Interest on principal amounted to $5,701 and $213,383 during the years ended September 30, 2021 and 2020, respectively, and was recorded under the net valuation change of instruments measured at fair value in the statements of operations. The subscriber, prior to the Second 2019 Paulson Notes Amendment, had the option to convert the outstanding principal and accrued and unpaid interest of such subscriber's 2019 Paulson Note (the "Outstanding Balance") into common stock in an amount equal to the Outstanding Balance divided by the ten day volume weighted average closing price of the common stock prior to conversion. In addition, both before and after the Second 2019 Paulson Note Amendment, if the Company raised more than $3,000,000 in an equity financing (the "Qualified Financing") before the Maturity Date, each subscriber had the option to convert the Outstanding Balance into the securities issued by the Company in such Qualified Financing in an amount equal to (i) the Outstanding Balance divided by (ii) the lower of 0.6 multiplied by (A) the actual per share price of securities issued by the Company in the Qualified Financing or (B) the ten day volume weighted average closing price of the common stock prior to the first closing of a Qualified Financing. If a change of control transaction had occurred prior to a Qualified Financing or the Maturity Date, the 2019 Paulson Notes would have become payable on demand as of the closing date of such transaction. Change of control meant a merger or consolidation with another entity in which the Company's stockholders did not own more than 50% of the outstanding voting power of the surviving entity or the disposition of all or substantially all of the Company's assets.

The Company elected to account for the 2019 Paulson Notes on a fair value basis under ASC 825 to comprehensively value and streamline the accounting for the embedded conversion options. The fair value of the 2019 Paulson Notes was significantly higher than the proceeds received as of each of the respective issuance dates given the significant redemption discount associated with the Qualified Financing provision. The excess of fair value over proceeds at issuance amounted to $1,831,940 and was recorded to interest expense in the statements of operations during the year ended September 30, 2020. Subsequent to issuance, the fair value change of the 2019 Paulson Notes amounted to a benefit of $1,974 and $1,221,480 during the years ended September 30, 2021 and 2020, respectively, and was recorded under the net valuation change of instruments measured at fair value in the statements of operations.

Each 2019 Paulson Warrant granted the holder the option to purchase the number of shares of common stock equal to (i) 0.5 multiplied by (ii) the principal amount of such subscriber's 2019 Paulson Notes divided by 5.61, with an exercise price per share equal to $5.61. As of the final closing on December 3, 2019, the Company issued 2019 Paulson Warrants exercisable for 288,305 shares of common stock in connection with all closings of the 2019 Paulson Private Placement. The 2019 Paulson Warrants are immediately exercisable and expire on November 1, 2022. The exercise price is subject to adjustment in the event of any stock dividends or splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein. The 2019 Paulson warrants were deemed to be a free-standing instrument and were accounted for as equity. Given that the fair value of the 2019 Paulson Notes exceeded the proceeds received at issuance, there was no value attributed to the 2019 Paulson Warrants in the financial statements.

In connection with the 2019 Private Placement, Paulson Investment Company, LLC ("Paulson") received a cash commission equal to 12% of the gross proceeds from the sale of the 2019 Paulson Notes, and 10-year warrants to purchase an amount of common stock equal to 86,498 shares of common stock at an exercise price equal to $5.61 per share (the "Broker Warrants"). The issuance costs incurred during the year ended September 30, 2021 and 2020 in connection with the 2019 Paulson Private Placement were $3,053 and $865,567, respectively. Issuance costs in 2021 related to legal costs. Issuance costs in 2020 included cash commissions equal to $388,176 and legal and third-party fees in the amount of $57,756. In addition, issuance costs included the value of the Broker Warrants in the amount of $419,635. The issuance costs were recorded as a component of interest in the accompanying statements of operations.

On April 24, 2020, the Company and holders of a majority in aggregate principal amount of the 2019 Paulson Notes entered into an amendment to the 2019 Paulson Notes (the "Second 2019 Paulson Notes Amendment") to, among other things:

i. ***Extended the Maturity Date*** – The Second 2019 Paulson Notes Amendment extended the maturity date of the 2019 Paulson Notes from May 1, 2020 to November 1, 2020 (in either case, unless a change of control transaction happens prior to such date);

ii. ***Revised Optional Conversion Terms*** – The Second 2019 Paulson Notes Amendment provided that the amount of shares to be received upon the subscriber's optional conversion of the 2019 Paulson Notes prior to a 2019 Qualified Financing (as defined in the 2019 Paulson Notes) would have equaled: (1) the Outstanding Balance as defined below of such subscriber's 2019 Paulson Note elected by the subscriber to be converted divided by (2) an amount equal to 0.6 multiplied by the volume weighted average price of the common stock for the ten (10) trading days immediately preceding the date of conversion; and

iii. ***Revised the Registration Date –*** The Second 2019 Paulson Notes Amendment provided that promptly following the earlier of (1) May 1, 2020, if the applicable subscriber converted all or a majority of the Outstanding Balance of such subscriber's 2019 Paulson Note prior to such date; (2) the final closing of a 2019 Qualified Financing; and (3) the maturity date, the Company will enter into a registration rights agreement with the applicable subscriber containing customary and usual terms pursuant to which the Company shall agree to prepare and file with the SEC a registration statement on or prior to the 90th calendar day following the registration date, covering the resale of any common stock received on conversion of such 2019 Paulson Notes, and shares of common stock underlying the Warrants.

The Second 2019 Paulson Notes Amendment was accounted for as a note extinguishment for accounting purposes given the substantive change in the optional redemption feature's conversion formula. The fair value change in the 2019 Paulson Notes associated with the extinguishment was recorded as a loss on notes extinguishment in the accompanying statements of operations in the amount of $2,017,847 during the year ended September 30, 2020. Lastly, in connection with the Second 2019 Paulson Notes Amendment, legal costs in the amount of $1,943 were incurred and recorded as a component of interest in the accompanying statements of operations.

During the years ended September 30, 2021 and 2020, the 2019 Paulson Notes were converted into 292,754 and 725,394 shares of common stock, respectively. All of the 2019 Paulson notes were converted into shares of common stock by December 31, 2020.

Paulson 2020 Convertible Note Financing

On April 30, 2020, the Company entered into a subscription agreement with certain accredited investors, pursuant to which the Company, in a private placement (the "2020 Paulson Private Placement"), agreed to issue and sell to the investors 13% convertible promissory notes (each, a "2020 Paulson Note" and collectively, the "2020 Paulson Notes") and warrants (each, a "2020 Paulson Warrant" and collectively, the "2020 Paulson Warrants") to purchase shares of the Company's common stock.

Between May 1, 2020 and June 30, 2020, the Company issued 2020 Paulson Notes in an aggregate principal amount of $5,122,700 to the Subscribers. The 2020 Paulson Private Placement was terminated on June 30, 2020.

The 2020 Paulson Notes had a fixed interest rate of 13% per annum and require the Company to repay the principal and accrued and unpaid interest thereon on the earlier of December 31, 2020 or a change of control transaction. Interest on principal amounted to $81,613 during the year ended September 30, 2020 and was recorded under the net valuation change of instruments measured at fair value in the statements of operations.

If the Company had raised more than $5,000,000 in an equity financing before the maturity date (the "2020 Qualified Financing"), without any action on the part of the Subscribers, all of the outstanding principal and accrued and unpaid interest of the Notes (the "Outstanding Balance") would have been converted into that number of shares of the securities issued by the Company in the closing on the date a 2020 Qualified Financing occurred equal to: (i) the Outstanding Balance divided by (ii) the lower of 0.6 multiplied by (A) the actual per share price of the securities issued by the Company in the closing on the date a 2020 Qualified Financing occurred and (B) the volume weighted average price of the common stock for ten (10) trading days immediately preceding the 2020 Qualified Financing.

If the Company had announced a transaction between the Company and any other company (or an affiliate of any such company) that was included in the S&P 500 Health Care Index as published from time to time by S&P Dow Jones Indices LLC that included an investment or upfront payments resulting in gross proceeds to the Company of at least $2,000,000 upon the execution of such transaction or definitive agreement, and provides for terms of collaboration, manufacturing, distribution, licensing or supply of the Company's products (a "Strategic Transaction") before the maturity date, without any action on the part of the subscribers, the Outstanding Balance would be converted into that number of shares of common stock equal to: (i) the Outstanding Balance divided by (ii) the lower of 0.6 multiplied by (A) the VWAP of the common stock for the ten (10) trading days immediately preceding the first announcement of the Strategic Transaction or (B) closing price of the common stock on the day preceding the first announcement by the Company of a Strategic Transaction.

At any time, at the sole election of the holder of such 2020 Paulson Note, all or a portion of the Outstanding Balance could have been converted into that number of shares of common stock equal to: (i) the Outstanding Balance elected by the holder to be converted divided by (ii) an amount equal to 0.6 multiplied by the volume weighted average price of the common stock for the ten (10) trading days immediately preceding the date of conversion.

If a change of control transaction had occurred prior to the conversion of the 2020 Paulson Notes or the maturity date, the 2020 Paulson Notes would have become payable on demand as of the closing date of such transaction. Change of control meant a merger or consolidation with another entity in which the Company's stockholders did not own more than 50% of the outstanding voting power of the surviving entity or the disposition of all or substantially all of the Company's assets.

The Company elected to account for the 2020 Paulson Notes on a fair value basis under ASC 825 to comprehensively value and streamline the accounting for the embedded conversion options. The fair value of the 2020 Paulson Notes was significantly higher than the proceeds received as of each of the respective issuance dates given the significant redemption discount associated with the redemption provisions. The excess of fair value over proceeds at issuance amounted to $3,784,918 and was recorded to interest expense in the statements of operations during the year ended September 30, 2020. Subsequent to issuance, the fair value change of the 2020 Paulson Notes amounted to an expense of $416,951 during the year ended September 30, 2020 and was recorded under the net valuation change of instruments measured at fair value in the statements of operations.

Each 2020 Paulson Warrant grants the holder the option to purchase the number of shares of common stock equal to (i) 0.5 multiplied by (ii) the principal amount of such subscriber's 2020 Paulson Notes divided by 5.61, with an exercise price per share equal to $5.61. The 2020 Paulson Warrants are immediately exercisable and expire on April 30, 2023. The exercise price is subject to adjustment in the event of any stock dividends or splits, reverse stock split, recapitalization, reorganization or similar transaction. The Company issued 2020 Paulson Warrants exercisable for 456,564 shares of common stock in connection with all closings of the 2020 Paulson Private Placement through June 30, 2020. The 2020 Paulson warrants were deemed to be a free-standing instrument and were accounted for as equity. Given that the fair value of the 2020 Paulson Notes exceeded the proceeds received at issuance, there was no value attributed to the 2020 Paulson Warrants in the financial statements.

In connection with the 2020 Paulson Private Placement, Paulson received a cash commission equal to 12% of the gross proceeds from the sale of the 2020 Paulson Notes and received 7-year warrants to purchase an amount of common stock equal to 136,971 ("Broker Warrants"). The Broker Warrants have an exercise price equal to $5.61 per share. The issuance costs incurred during the year ended September 30, 2020 in connection with the 2020 Paulson Private Placement were $1,040,213. Issuance costs included cash commissions equal to $614,725 and legal and third-party fees in the amount of $148,451. In addition, issuance costs included the value of the Broker Warrants in the amount of $277,037. The issuance costs were recorded as a component of interest in the accompanying statements of operations.

Between May 4, 2020 and July 22, 2020, certain Subscribers elected to convert $3,590,353 of the outstanding principal and interest of such Subscribers' 2020 Paulson Notes into 1,337,459 shares of common stock. On July 23, 2020, the remaining outstanding principal and interest balance of the 2020 Paulson Notes in the amount of $1,613,961 was converted into 535,178 shares of common stock upon the announcement of the Zimmer Development Agreement that qualified as a Strategic Transaction.

NOTE 9 - Stock-Based Compensation

During the years ended September 30, 2021 and 2020, 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:

	2021	2020
Selling, general and administrative	$ 1,550,841	$ 1,623,629
Research and development	242,358	212,341
Total stock-based compensation expense	$ 1,793,199	$ 1,835,970

The Company's 2016 and 2017 Equity Incentive Plans provide for the issuance of restricted shares and stock options to employees, directors, and consultants of the Company. The Company initially reserved 764,089 shares of common stock for issuance under the 2016 and 2017 Equity Incentive Plans on a combined basis.

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 as of December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board 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, 2021 and 2020, 484,622 and 428,930 shares were added to the 2017 Plan, respectively, as a result of the evergreen provision.

Stock Options

During the years ended September 30, 2021 and 2020, 703,117 and 334,731 stock options were granted to employees, directors and consultants, respectively, with a weighted average grant date fair value of $3.01 and $3.03 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, 2021 and 2020 related to the stock options was $983,301 and $798,242, respectively.

The following table summarizes the Company's stock option plan activity for the years ended September 30, 2021 and 2020 as follows:

	Number of Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value(1)
Outstanding at September 30, 2019	281,956	$ 5.46	9.0	$ 343,406
Granted	334,731	$ 6.18	—	—
Exercised	(25,515)	$ 0.12	—	—
Forfeited/Cancelled	(98,330)	$ 5.91	—	—
Outstanding at September 30, 2020	492,842	$ 6.13	8.8	$ 96,088
Granted	703,117	$ 5.83	—	—
Exercised	(1,538)	$ 6.60	—	—
Forfeited/Cancelled	(71,861)	$ 6.85	—	—
Outstanding at September 30, 2021	1,122,560	$ 5.89	8.8	$ 127,339
Vested and exercisable at September 30, 2021	481,047	$ 5.89	8.2	$ 311,388

(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, 2021 and 2020 of $3.95 and $3.86 per share, respectively. As of September 30, 2021 and 2020, 1,055,376 and 467,327 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:

	2021	2020
Expected stock price volatility	55.9%	53.1%
Expected life of options (years)	6.0	5.6
Expected dividend yield	0%	0%
Risk free interest rate	0.6%	1.4%

During the year ended September 30, 2021 and 2020, 280,557 and 198,191 stock options vested, respectively.

Restricted Stock Units

A summary of restricted stock unit ("RSU") activity is as follows for the years ended September 30, 2021 and 2020:

	Number of Shares
Non-vested at September 30, 2019	10,503
Granted	78,323
Forfeited	(2,335)
Vested	(59,793)
Non-vested at September 30, 2020	26,698
Granted	13,776
Vested	(29,090)
Non-vested at September 30, 2021	11,384

During the years ended September 30, 2021 and 2020, 13,776 and 78,323 RSUs were granted to members of the Company's board of directors and consultants that vest over a period ranging from an immediate to a two year period, with a grant date fair value of $7.26 and $6.27 per unit, respectively. During the years ended September 30, 2021 and 2020, 29,090 and 59,793 RSUs vested, respectively. The total expense for the years ended September 30, 2021 and 2020 related to the RSU's was $163,988 and $396,012, respectively. The number of RSUs forfeited during the years ended September 30, 2021 and 2020 was zero and 2,335, respectively.

Other Stock-Based Awards

2021 Activity

In April 2021, two consulting agreements were executed whereby a total of 62,659 shares of common stock were issued and vested as of September 30, 2021.

In July 2021, two consulting agreements were executed whereby a total of 11,668 shares of common stock were issued and vested as of September 30, 2021.

2020 Activity

In October 2019, two consulting agreements were executed whereby up to 38,334 shares of common stock were issued and vested as of September 30, 2020. On April 22, 2020, the Company entered into an amendment (the "Amendment") to one of the consulting agreements. Pursuant to the Amendment, the Company issued an additional 11,667 shares in exchange for consulting services of which 11,667 shares of common stock were vested as of September 30, 2020 under the Amendment. Vesting was based on a time-based vesting condition ranging over a three to nine-month period commencing upon the execution of the consulting agreements.

In February 2020, an additional consulting agreement was executed whereby up to 30,000 shares of common stock were issued and vested as of September 30, 2020 under this agreement. In addition, on May 21, 2020, 22,195 shares of common stock were issued as compensation to a former 2019 Paulson Note holder related to a prior 2019 Paulson Note conversion and release of liability.

In August 2020, an additional consulting agreement was executed whereby 40,000 shares of common stock were issued, subject to Company repurchase. The stock award under the agreement vests over a six-month period. As of September 30, 2021 and 2020, 33,333 and 6,667 shares vested under this agreement, respectively.

Compensation expense related to the stock awards granted under the consulting agreements and to the former 2019 Paulson Note holder referenced above amounted to $645,910 and $641,716 for the years ended September 30, 2021 and 2020, respectively, and was included in stock-based compensation expense. The expense recognition related to the grants was based on the fair value of the underlying common stock at the point of vesting which ranged from $4.53 to $7.95 per share.

General

As of September 30, 2021, 389,709 shares were available for future issuance on a combined basis under the 2016 and 2017 Equity Incentive Plans. Unrecognized stock-based compensation was $1.7 million as of September 30, 2021. The unrecognized share-based expense is expected to be recognized over a weighted average period of 2.9 years.

NOTE 10 - Stockholders' Deficit

2021 Private Placement

On January 12, 2021, the Company entered into a Common Stock and Warrant Purchase Agreement with certain accredited investors, pursuant to which the Company, in the 2021 Private Placement, agreed to issue and sell an aggregate of 4,166,682 shares of the common stock of the Company and warrants to purchase an aggregate of 4,166,682 shares of common stock (the "2021 Warrants") at an aggregate purchase price of $3.00 per share of common stock and corresponding warrant, resulting in total gross proceeds of $12.5 million before deducting placement agent fees and estimated offering expenses. The 2021 Warrants have an initial exercise price of $5.25 per share. The 2021 Warrants are immediately exercisable and will expire on the fifth anniversary of issuance. Prior to expiration, subject to the terms and conditions set forth in the 2021 Warrants, the holders of such 2021 Warrants may exercise the 2021 Warrants for shares of common stock by providing notice to the Company and paying the exercise price per share for each share so exercised or by utilizing the "cashless exercise" feature contained in each 2021 Warrant. The fair value of the 2021 Warrants was $7.3 million and was based on the Black-Scholes pricing model. Input assumptions used were as follows: a risk-free interest rate of 0.5%; expected volatility of 56.0%; expected life of 5 years; expected dividend yield of 0%; and the underlying traded stock price. $3.7 million of the total proceeds was allocated to the 2021 Warrants based on the relative fair value allocation method, which has been reflected in stockholders' equity. The 2021 Warrants were classified in stockholders' equity as the number of shares were fixed and determinable, and no other provisions precluded equity treatment. The private placement closed on January 14, 2021.

2020 Common Stock Offering

On July 28, 2020, the Company entered into securities purchase agreements with an accredited investor in a private placement, pursuant to which the Company has issued and sold 25,000 shares to such investor, at $5.40 per share for gross proceeds amounting to $135,000.

2019 Common Stock Offering

On October 23, 2019, the Company entered into Securities Purchase Agreements with certain accredited investors, pursuant to which the Company, in a private placement, has issued and sold 47,223 shares of the Company's common stock to the accredited investors at a price of $5.40 per share, for gross proceeds amounting to $255,000. The Company filed a registration statement with the SEC covering the resale of the shares of common stock sold in the private placement on August 11, 2020.

Warrant Activity and Summary

The following table summarizes warrant activity during the years ended September 30, 2021 and 2020:

	Warrants	Exercise Price Per Warrant	Weighted Average Exercise Price	Weighted Average Term (years)
Outstanding and exercisable at September 30, 2019	2,421,940	$ 5.40 - 9.00	$ 7.65	3.60
Issued	968,380	$ 5.61	$ 5.61	—
Exercised	—	$ —	$ —	—
Forfeited	—	$ —	$ —	—
Outstanding and exercisable at September 30, 2020	3,390,320	$ 5.40 - 9.00	$ 7.05	2.89
Issued	4,166,682	$ 5.25	$ 4.29	—
Exercised	(53,194)	$ 5.61-8.25	$ 5.61	—
Forfeited	—	$ —	$ —	—
Outstanding and exercisable at September 30, 2021	7,503,808	$ 5.25-9.00	$ 6.06	3.23

The following table summarizes information about warrants outstanding at September 30, 2021:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual life (Years)	Number Exercisable at September 30, 2021
$ 5.25	4,166,682	4.29	4,166,682
$ 5.40	750,364	0.14	750,364
$ 5.61	916,753	2.68	916,753
$ 6.00	45,173	2.75	45,173
$ 7.50	279,733	2.41	279,733
$ 8.25	62,911	2.75	62,911
$ 9.00	1,282,192	2.18	1,282,192
Total	7,503,808		7,503,808

NOTE 11 - Income Taxes

The effective tax rate for the Company for the years ended September 30, 2021 and 2020 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:

	2021	2020
Income tax benefit at federal statutory rate	(21.0)%	(21.0)%
State income tax, net of federal benefit	(7.7)	(7.7)
Disqualified interest and other	—	17.0
Research credits	(3.7)	(1.3)
Stock-based compensation	1.0	0.2
Valuation allowance	31.4	12.8
Effective tax rate	—%	—%

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

	2021	2020
Deferred tax assets:		
Federal and state operating loss carryforwards	$ 7,575,069	$ 4,936,384
Acquired intangibles	24,541	22,635
Accruals and other	8,370	30,406
Research and development credit carryforwards	812,781	450,081
Stock-based compensation	451,757	255,068
Total deferred tax assets	8,872,518	5,694,574
Deferred tax liabilities:		
Fixed assets	(64,189)	—
Total deferred tax liabilities	(64,189)	—
Valuation allowance	(8,808,329)	(5,694,574)
Net deferred tax assets	$ —	$ —

As of September 30, 2021 and 2020, the Company had gross deferred tax assets of approximately $8,873,000 and $5,695,000, 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 and faces significant challenges to becoming profitable. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance of approximately $8,808,000 and $5,695,000 as of September 30, 2021 and 2020, respectively. The U.S. 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.

As of September 30, 2021 and 2020, the Company's federal net operating loss carryforwards were approximately $26,355,000 and $17,175,000, respectively. The Company had federal research credit carryforwards as of September 30, 2021 and 2020 of approximately $506,000 and $272,000, 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, 2021 and 2020, the Company had state net operating loss carryforwards of approximately $26,355,000 and $17,175,000, respectively. The Company had state research credit carryforwards of approximately $307,000 and $178,000 as of September 30, 2021 and 2020, 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. The Company believes its income tax filing positions and deductions will be sustained upon examination, and accordingly, no reserves or related accruals for interest and penalties have been recorded at September 30, 2021 and 2020.

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 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 Minnesota 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, 2021.

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, 2021 and 2020 was $14,803 and zero, respectively.

NOTE 13 - Subsequent Events

Inducement Plan

On October 4, 2021, the Company adopted the NeuroOne Medical Technologies Corporation 2021 Inducement Plan (the "Plan"), 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 Plan was approved by the Company's Board of Directors without stockholder approval in accordance with such rule.

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. Deferred offering costs in connection with the offering amounted to $92,934 and are reflected in the prepaid and other assets line item in the accompanying balance sheets as of September 30, 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.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURE

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 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, 2021, 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, 2021.

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; 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, 2021, 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, 2021.

Changes in Internal Control Over Financial Reporting

No change in our system of internal control over financial reporting occurred during the quarter ended September 30, 2021 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

Directors and Executive Officers

The Board of Directors of the Company (the "Board") is divided into three classes. Members of each class serve staggered three-year terms. The following table provides information as to each person who is, as of the filing hereof, a director and/or executive officer of the Company:

Name	Position(s)	Age
David Rosa	Class II Director, Chief Executive Officer, and President	57
Mark Christianson	Business Development Director, Medical Sales Liaison	54
Steve Mertens	Chief Technology Officer	59
Ronald McClurg	Chief Financial Officer	63
Jeffrey Mathiesen	Class III Director	61
Paul Buckman	Class I Director and Chairman of the Board	66
Edward Andrle	Class III Director	64

No Family Relationships

There is no family relationship between any director and executive officer or among any directors or executive officers.

Business Experience and Background of Directors and Executive Officers

David Rosa has served as the Chief Executive Officer, President and a director of the Company since July 2017 and served as Chief Executive Officer and a director of NeuroOne, Inc., formerly our wholly-owned subsidiary, from October 2016 until December 2019, when NeuroOne, Inc. merged with and into the Company. From November 2009 to November 2015, Mr. Rosa served as the chief executive officer and president of Sunshine Heart, Inc., n/k/a Nuwellis, Inc. (Nasdaq: NUWE), a publicly-held early-stage medical device company. From 2008 to November 2009, Mr. Rosa served as chief executive officer of Milksmart, Inc., a company that specializes in medical devices for animals. From 2004 to 2008, Mr. Rosa served as the vice president of global marketing for cardiac surgery and cardiology at St. Jude Medical, Inc. Currently, he serves as a director on the board of directors of Biotricity Inc. (Nasdaq: BTCY) Biorestorative Therapies (Nasdaq: BRTX) and Healthcare Triangle, Inc. (Nasdaq: HCTI). Mr. Rosa holds an MBA from Duquesne University and a B.S. in Commerce and Engineering from Drexel University.

Mr. Rosa's qualifications to serve on the Board include his senior leadership experience in the medical device industry. In addition, his day-to-day leadership of the Company gives him critical insights into the Company's operations, strategy and competition, and he facilitates the Board's ability to perform its oversight function. Throughout his career at the Company and his former positions, he has demonstrated strong technical, strategic, and operational expertise, and he possesses in-depth knowledge of the medical device industry on a global basis.

Mark Christianson is a co-founder of the Company and has served as Business Development Director and Medical Sales Liaison of the Company since February 2019. Previously, he served as Vice President of Business Development and Marketing of the Company from July 2017 until February 2019 and served as vice president of sales and marketing of our wholly-owned subsidiary, NeuroOne, Inc., since December 2016. From May 2013 to December 2016 Mr. Christianson served as North American sales manager for Cortec Corporation. From February 2012 to May 2013 Mr. Christianson held the position of business development executive for Robert Half International. From May 2009 to February 2012, Mr. Christianson held the position of regional sales manager for PMT Corporation. Mr. Christianson studied accounting at Augsburg College in Minneapolis. Mr. Christianson brings 15 years of high performing sales, sales management, and project management experience to the NeuroOne team. In addition, he has contributed to the development and corporate strategy of the Company given his experience in the neurological field and his close relationships with key epilepsy opinion leaders.

Steve Mertens has served as Chief Technology Officer of the Company since April 2019. From September 2018 through April 2019, Mr. Mertens was a consultant at Steve Mertens Consulting, L.L.C., of which he was the principal and owner. From November 2012 through September 2018, Mr. Mertens served as the senior vice president of research and development and operations at Nuvaira Inc., a privately held lung denervation company developing minimally invasive product for obstructive lung diseases. Prior to Nuvaira**,** Mr. Mertens served as a senior vice president of research and development for Boston Scientific Corporation (NYSE: BSX), guiding a wide range of technologies through product development for the cardiology, electrophysiology and peripheral vascular markets. He holds a bachelor's degree in chemical engineering from the University of Minnesota and a Master's degree in business administration from the University of St. Thomas. Currently, he serves on the board of directors of the University Enterprise Laboratories.

Ronald McClurg has served as Chief Financial Officer of the Company since January 2021. Prior to joining the Company, from October 2003 to June 2019, Mr. McClurg served as vice president - finance & administration and chief financial officer of Incisive Surgical, Inc., a privately-held medical device manufacturer. From 1997 to 2002, Mr. McClurg served as chief financial officer and treasurer of Wavecrest Corporation, a privately-held manufacturer of electronic test instruments for the semiconductor industry. Prior to 1997, Mr. McClurg served as chief financial officer for several publicly-held companies, including Video Sentry Corporation, Insignia Systems, Inc. (Nasdaq: ISIG), and Orthomet, Inc. Currently, he serves on the board of governors of Biomagnetic Sciences, LLC. Mr. McClurg holds a Bachelor of Business Administration degree in accounting from the University of Wisconsin – Eau Claire.

Paul Buckman has served as Chairman of the Board of the Company since August 2017, and served as Chairman of the board of NeuroOne, Inc., from October 2016 until December 2019. Mr. Buckman has served as the president of North America for LivaNova PLC (Nasdaq: LIVN) since April 2019 and previously served as the general manager of Structural Heart for LivaNova PLC from April 2017 to December 2019. Prior to joining LivaNova PLC, Mr. Buckman served as chief executive officer of Conventus Orthopaedics, a Minnesota-based company specializing in peri-articular bone fracture fixation, from September 2013 until March of 2017. Mr. Buckman was chief executive officer of Sentreheart, Inc., a medical technology company focused on closure of various anatomic structures, from February 2012 to September 2013. Previously, Mr. Buckman served as chief executive officer and chairman of Pathway Medical Technologies, Inc., a medical device company focused on treatment of peripheral arterial disease, from September 2008 to February 2012; as chief executive officer of Devax, Inc., a developer and manufacturer of drug eluting stents, from December 2006 to September 2008; as president of the cardiology division of St. Jude Medical, Inc., a publicly traded diversified medical products company, from August 2004 to December 2006; and as chairman of the board of directors and chief executive officer of ev3, LLC, a Minnesota-based medical device company focused on endovascular therapies that Mr. Buckman co-founded from January 2001 to January 2004. Mr. Buckman has worked in the medical device industry for over 40 years, including 10 years at Scimed Life Systems, Inc. and Boston Scientific Corporation (NYSE: BSX), a publicly traded medical device manufacturer, where he held several executive positions before becoming president of the cardiology division in January 2000. Mr. Buckman also currently serves as a director for Helius Medical Technologies Corporation (Nasdaq: HSDT), Ablative Solutions, Inc., ActivOrtho, Inc., a privately held company, Shoulder Innovations, Inc., a privately held company, MDMA, and as chairman of Miromatrix, Inc. He previously served as a director of Aortica, Inc., DyaMX, Inc., Conventus Orthopaedics, Caisson Interventional LLC, Velocimed, Inc., where he was a co-founder, EndiCor, Inc., Microvena, Inc., Sunshine Heart, Inc., n/k/a Nuwellis, Inc. (Nasdaq: NUWE), a publicly-held early-stage medical device company, NexGen Medical, and Micro Therapeutics, Inc. Mr. Buckman received a Master's degree in Business Administration and Finance and a B.A. degree in Business Administration from Western Michigan University. We believe that Mr. Buckman's strong executive experience in medical device companies provides the Company with valuable guidance on product development and operational matters.

Jeffrey Mathiesen has served as a member of the Board of the Company since August 2017, and served as a director of NeuroOne, Inc., from April 2017 until December 2019. He has served as chief financial officer of Helius Medical Technologies, Inc. (Nasdaq: HSDT), a publicly traded medical device company, developing noninvasive platform technologies focused on neurological wellness since June 2021, where he previously served as a director and audit committee chair from June 2020 until June 2021. Additionally, Mr. Mathiesen has served as vice chair and lead independent director since March 2020 and as director and audit committee chair, since 2015, of Panbela Therapeutics, Inc. (Nasdaq: PBLA), a publicly traded biopharmaceutical company developing therapies for pancreatic diseases, and from 2018 to 2020 he served as a member of the board of directors of eNeura, Inc., a privately-held medical technology company providing therapy for both acute treatment and prevention of migraine. Mr. Mathiesen served as advisor to the CEO of Teewinot Life Sciences Corporation, a privately held global leader in the biosynthetic development and production of cannabinoids and their derivatives for consumer and pharmaceutical products from October 2019 to December 2019, and served as chief financial officer from March 2019 to October 2019. In August 2020, Teewinot Life Insurance Sciences filed a voluntary petition under Chapter 11 of the United States Bankruptcy Code. Mr. Mathiesen previously served as chief financial officer of Gemphire Therapeutics Inc., which was acquired by NeuroBo Pharmaceuticals, Inc. (Nasdaq: NRBO) in January 2020, a publicly-held clinical-stage biopharmaceutical company developing therapies for patients with cardiometabolic disorders, from 2015 to 2018, and as chief financial officer of Sunshine Heart, Inc., n/k/a Nuwellis, Inc. (Nasdaq: NUWE), a publicly-held early-stage medical device company, from 2011 to 2015. Mr. Mathiesen received a B.S. in Accounting from the University of South Dakota and is a Certified Public Accountant. We believe that Mr. Mathiesen brings financial insight and leadership and a wealth of experience in capital markets to the Board, as well as knowledge of public company accounting and financial reporting requirements and familiarity with the life sciences industry.

Edward Andrle has served as a member of the Board of the Company since February 2020. He is also a member of the Board of Rainbow Medical, a medical device incubator in Israel, since August 2020. Mr. Andrle most recently served as the general manager of Neuromodulation of LivaNova PLC (Nasdaq: LIVN), a publicly-traded medical device company, from January 2018 to January 2020, and as senior vice president of strategy and business development of LivaNova PLC from September 2015 to January 2018. Prior to these roles, Mr. Andrle served as vice president of business development and strategy of Sorin S.p.A from 2010 to September 2015, when Sorin S.p.A. was merged with Cyberonics, Inc. to become LivaNova PLC. Prior to joining Sorin, he co-founded three medical device companies, Myocor Inc., TERAMED Inc. and StarFire Medical Inc. All three companies were eventually acquired. He also held executive positions with Boston Scientific, Inc. (NYSE: BSX) and Baxter International, Inc. (NYSE: BAX), leading large product portfolios in cardiovascular and dialysis. Mr. Andrle received his MBA from Stanford Graduate School of Business and his B.S. in Chemical Engineering from the University of Notre Dame. We believe that Mr. Andrle's substantial experience in medical device companies and business development experience provides the Company with valuable insight on product development and strategy.

Board and Committee Information

During the Company's fiscal year ended September 30, 2021, the Board held a total of eleven meetings, and each director attended at least 75% of such meetings. Under the policies of the Board, Directors are expected to attend regular Board meetings, Board committee meetings, as applicable, and the Annual Meeting of Stockholders.

Board Leadership Structure

Our Board is currently chaired by Paul Buckman, who has authority, among other things, to call and preside over meetings of our Board, to set meeting agendas and to determine materials to be distributed to the Board and, accordingly, has substantial ability to shape the work of the Board. The positions of our chairman of the Board and Chief Executive Officer are presently separated. Separating these positions allows our Chief Executive Officer, Mr. Rosa, to focus on our day-to-day business, while allowing Mr. Buckman to lead the Board.

Role of the Board in Risk Oversight

Our Board does not have a standing risk management committee, but rather administers its risk oversight function directly through the Board as a whole. The Board's risk oversight is administered primarily through the following:

- review and approval of an annual business plan;
- review of a summary of risks and opportunities at meetings of the Board;
- review of business developments, business plan implementation and financial results;
- oversight of internal controls over financial reporting; and
- review of employee compensation and its relationship to our business plans.

Structure and Operation of the Board

Because our Common Stock is listed on Nasdaq, the Company is subject to the Nasdaq listing requirements regarding committee matters. The Company currently has the following committees: an audit committee, a compensation committee and a nominating and corporate governance committee.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee reviews, evaluates and seeks out candidates qualified to become Board members. The Board includes individuals with a diversity of experience, including scientific, business, financial and academic backgrounds. Nominations may be submitted by directors, officers, employees, stockholders and others for recommendation to the Board. In fulfilling this responsibility, the Company's nominating and corporate governance committee also consults with the Board and the Chief Executive Officer concerning director candidates. The nominating and corporate governance committee's charter is available on our website, *www.n1mtc.com*, under *Investors —Governance*.

The responsibilities of the Company's nominating and corporate governance committee include the following:

- reviewing, evaluating and seeking out candidates qualified to become members of the Board;
- reviewing committee structure and recommending directors for appointment to committees;
- developing, reevaluating (not less frequently than every three years) and recommending the selection criteria for board and committee membership;
- establishing procedures to oversee evaluation of the board, its committees, individual directors and management; and
- developing and recommending guidelines on corporate governance.

The current members of our nominating and corporate governance committee are Mr. Buckman, Mr. Andrle, and Mr. Mathiesen, each of whom has been determined by the Board to be independent under the rules and regulations of the Nasdaq Stock Market LLC. Mr. Andrle is the chair of the nominating and corporate governance committee.

Compensation Committee

The compensation committee's charter is available on our website, *www.n1mtc.com*, under *Investors —Governance*. The responsibilities of the compensation committee include the following:

- fixing salaries of executive officers and reviewing salary plans for other executives in senior management positions;
- reviewing and making recommendations with respect to the compensation and benefits for the Company's non-employee directors, including through equity-based plans;
- evaluating the performance of the Company's chief executive officer and other senior executives and assisting the Board in developing and evaluating potential candidates for executive positions; and
- administering the Company's incentive compensation, deferred compensation and equity-based plans pursuant to the terms of the respective plans.

The current members of the compensation committee include Mr. Buckman, Mr. Andrle, and Mr. Mathiesen. Mr. Buckman is the chair of the compensation committee. The compensation committee may form and delegate authorities to subcommittees as appropriate, including, but not limited to, a subcommittee composed of one or more members of the Board or officers of the Company to grant stock awards under the Company's equity incentive plans.

To qualify as independent to serve on the Company's compensation committee, the listing standards of Nasdaq require a director not to accept any consulting, advisory, or other compensatory fee from the Company, other than for service on the Board, and that the Board consider whether a director is affiliated with the Company and, if so, whether such affiliation would impair the director's judgment as a member of the Company's compensation committee. The Board has concluded that the members of the compensation committee meet the requirements for independence under the rules and regulations of Nasdaq and the SEC.

Audit Committee Matters

The audit committee reviews with management and the Company's independent public accountants the Company's financial statements, the accounting principles applied in their preparation, the scope of the audit, any comments made by the independent accountants upon the financial condition of the Company and its accounting controls and procedures and such other matters as the audit committee deems appropriate. The audit committee's charter is available on our website, *www.n1mtc.com*, under *Investors — Governance*.

The audit committee currently consists of three directors: Mr. Buckman, Mr. Mathiesen and Mr. Andrle. The Board has determined that each of Mr. Buckman, Mr. Mathiesen and Mr. Andrle is "independent" under Nasdaq independence standards. Additionally, the Board has determined that each of Mr. Mathiesen and Mr. Buckman qualifies as an "audit committee financial expert" as that term is defined in rules promulgated by the SEC. The designation of an "audit committee financial expert" does not impose upon such persons any duties, obligations or liabilities that are greater than those generally imposed on each of them as a member of the audit committee and the Board, and such designation does not affect the duties, obligations or liabilities of any other member of the audit committee or the Board. Mr. Mathiesen is the chair of the audit committee.

The functions of the audit committee include:

- Selecting our independent auditors;
- Reviewing the results and scope of the audit and other services provided by our independent auditors; and
- Reviewing and evaluating our audit and control functions.

Code of Business Conduct and Ethics

Our Board has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive officers. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of these provisions, in public filings. A copy of the code of business conduct and ethics is available on our website, *www.n1mtc.com*, under *Investors — Governance*.

Hedging Policy

As part of its insider trading policy, the Board has implemented an anti-hedging policy that applies to the Board, executive officers and employees. Under this policy, these persons are prohibited from engaging in various trading practices which would suggest speculation in Company securities, including financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds or other hedging transactions.

Corporate Governance Guidelines

Our Board has adopted Corporate Governance Guidelines that set forth expectations for directors, director independence standards, Board structure and functions and other policies for the governance of the Company.

ITEM 11. EXECUTIVE COMPENSATION.

Summary Compensation Table for Fiscal Year 2021

The following table shows the compensation earned or received during the fiscal year ended September 30, 2021 and the fiscal year ended September 30, 2020 by each of our named executive officers (as determined pursuant to the SEC's disclosure requirements for executive compensation in Item 402 of Regulation S-K).

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Dave Rosa,	2021	410,844	1,285,899	192,608	—	1,889,351
Chief Executive Officer and President	2020	403,914	547,091	171,886	—	1,122,891
Ron McClurg,	2021	187,500	290,498	44,531	—	522,529
Chief Financial Officer	2020	—	—	—	—	—
Steve Mertens,	2021	242,631	72,169	56,338	—	371,138
Chief Technology Officer	2020	238,966	—	49,281	—	288,247

(1) Amounts reported reflect the aggregate grant date fair value of option awards, calculated in accordance with FASB Topic 718, excluding the impact of potential forfeitures. The weighted-average assumptions used in the valuation of option awards under the Black-Scholes option-pricing model are set forth under "Stock Options" in Note 9 to the Company's financial statements in this Report on Form 10-K.

Narrative to Summary Compensation Table

The compensation program for the Company's named executive officers for fiscal 2021 had three components: base salary, annual cash bonus and stock option grants.

Base Salary. There was a 1.3% increase for cost of living adjustments for the Company's named executive officers for calendar year 2021, as compared to calendar year 2020, except for Mr. McClurg, who joined the Company in January 2021.

Non-Equity Incentive Plan. In fiscal 2021, each of the Company's named executive officers had a target bonus, set forth as a percentage of annual base salary. In fiscal 2021, target bonuses for the Company's named executive officers other than Mr. Rosa's were 25% of base salary. Mr. Rosa's target bonus was set at 50% of base salary pursuant to his employment agreement, as described below.

In February 2021, the Board established weighted performance targets for fiscal 2021 that it would consider in approving bonus payments for fiscal 2021. These targets included various corporate objectives related to uplisting the Company's Common Stock, regulatory submissions, certain research and development, and commercialization milestones, and cash burn targets. In October 2021, the Compensation Committee determined that 95% of the performance targets had been met, and approved the bonus payments to Messrs. Rosa, McClurg and Mertens at 95% each of their respective targets, which targets were 50%, 25% and 25% of each of their base salaries, respectively, as discussed above.

Equity Grants. In connection with Mr. McClurg's appointment as Chief Financial Officer, the Board granted Mr. McClurg an option exercisable for 60,000 shares of the Company's Common Stock, with an exercise price of $4.71. Twenty-five percent of the shares underlying the option vest on January 1, 2022 and the remaining 75% vest in 36 equal monthly installments thereafter.

In January 2021, the Board granted Mr. Rosa, Mr. McClurg and Mr. Mertens options exercisable for 416,667, 46,667, and 23,334 shares, respectively, each with an exercise price of $5.97. Twenty-five percent of the shares underlying the option vest on January 27, 2022 and the remaining 75% vest in 36 equal monthly installments thereafter, except that Mr. Rosa's options are subject to acceleration upon achieving certain performance milestones. On May 6, 2021, the Compensation Committee determined that the performance criteria on 83,333 of Mr. Rosa's options were met resulting in the accelerated vesting of those options on such date. As of September 30, 2021, 20% of the shares underlying Mr. Rosa's options had vested upon the achievement of performance milestones.

Employment Agreement and Arrangements

We have an employment agreement with our Chief Executive Officer, Mr. Rosa, and an offer letter for each of Mr. McClurg and Mr. Mertens. Each of our named executive officers has also executed our standard form of proprietary information, inventions assignment and non-competition agreement.

Mr. Rosa

Mr. Rosa's employment agreement ("Amended Employment Agreement") was effective on August 4, 2017, continues through the third anniversary and automatically renews for an additional one-year period at the end of the initial term and each anniversary thereafter, provided that Mr. Rosa notifies the Board of such renewal at least 30 days prior to the expiration of the initial term or any renewal terms and the Board does not notify Mr. Rosa of its intention not to renew the Amended Employment Agreement.

The Amended Employment Agreement also entitles Mr. Rosa to, among other benefits, the following compensation: (i) an opportunity to participate in any stock option, performance share, performance unit or other equity based long-term incentive compensation plan commensurate with the terms and conditions applicable to other senior executive officers; and (ii) participation in welfare benefit plans, practices, policies and programs provided by the Company and its affiliated companies (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) to the extent available generally or to our other senior executive officers. Mr. Rosa is entitled to receive a target award value, determined in accordance with the policies and practices generally available to other senior executive officers, for an annual cash bonus and if determined by the Board or a committee of the Board, a long-term incentive bonus. Mr. Rosa is entitled to retain all shares of Common Stock he held as of the commencement date. Mr. Rosa is also entitled to certain severance benefits.

Pursuant to the Amended Employment Agreement, regardless of the manner in which Mr. Rosa's service terminates, Mr. Rosa is entitled to receive amounts earned during his term of service, including salary and other benefits. The Company is permitted to terminate Mr. Rosa's employment for the following reasons: (i) death or disability, (ii) Termination for Cause (as defined below) or (iii) for any other reason or no reason. Mr. Rosa is permitted Termination for Good Reason (as defined below) of his employment. In addition, he may terminate his employment upon written notice to the Company 30 days prior to the effective date of such termination.

In the event of Mr. Rosa's death during the employment period or a termination due to his disability, his beneficiaries or legal representatives shall be provided the sum of (i) any annual base salary earned, but unpaid, for services rendered to the Company on or prior to the date on which the employment period ends and (ii) certain other benefits provided for in the employment agreement (the "Unconditional Entitlements"). In the event of Mr. Rosa's Termination for Cause by the Company or the termination of Mr. Rosa's employment as a result of his resignation other than a Termination for Good Reason, Mr. Rosa shall be provided the Unconditional Entitlements.

In the event of a Termination for Good Reason by Mr. Rosa or the exercise by the Company of its termination rights to terminate Mr. Rosa other than by Termination for Cause, death or disability, Mr. Rosa shall be provided the Unconditional Entitlements and, subject to his signing and delivering to the Company and not revoking a general release of claims in favor of the Company and certain related parties, the Company shall provide Mr. Rosa: (a) a severance amount equal to the aggregate annual base salary he would have earned from the day after his termination date through the end of the employment period and a prorated portion of his cash bonus for the year in which the termination date occurs, provided, however, in no event would the severance amount be less than 12 months or more than 18 months of his annual base salary; (b) continued health insurance coverage for 12 months following his termination date, provided that such coverage shall cease if Mr. Rosa becomes eligible to receive health insurance coverage from another employer group health plan; (c) vesting of all stock options in accordance with the stock option award documents, subject to the same conditions that would be applicable to Mr. Rosa if he remained employed through the end of the employment period; and (d) continued vesting of equity awards in accordance with the terms of the award agreements, provided, however, Mr. Rosa would have 90 days from the termination date to exercise any vested options (the "Conditional Benefits").

In the event of a change in control during the employment period or within two years after a change in control, if the Company terminates Mr. Rosa other than due to Mr. Rosa's death or disability or a Termination for Cause, or Mr. Rosa effects a Termination for Good Reason, the Company will pay to Mr. Rosa, in a lump sum in cash within 30 days after the termination date, the aggregate of: (i) the Unconditional Entitlements; and (ii) the amount equal to the product of 1.5 times the sum of (y) Mr. Rosa's annual base salary, and (z) the greater of the target bonus for the then current fiscal year under the 2016 Equity Incentive Plan and 2017 Equity Incentive Plan or any successor annual bonus plan and the average annual bonus paid to or for the benefit of Mr. Rosa for the prior three full years (or any shorter period during which Mr. Rosa had been employed by the Company). In addition, the Company shall provide Mr. Rosa the Conditional Benefits minus Mr. Rosa's severance amount.

Under the Amended Employment Agreement, "Termination for Cause" means a termination of Mr. Rosa's employment by the Company due to (A) an act or acts of dishonesty undertaken by Mr. Rosa and intended to result in substantial gain or personal enrichment to Mr. Rosa at the expense of the Company, (B) unlawful conduct or gross misconduct that is willful and deliberate on Mr. Rosa's part and that, in either event, is materially injurious to the Company, (C) the conviction of Mr. Rosa of, or Mr. Rosa's entry of a no contest or nolo contendere plea to, a felony, (D) breach by Mr. Rosa of his fiduciary obligations as an officer or director of the Company, (E) a persistent failure by Mr. Rosa to perform his duties and responsibilities of his employment under the Amended Employment Agreement, which failure is not remedied by Mr. Rosa within 30 days after his receipt of written notice from the Company of such failure, provided, however, the Company is not obligated to provide written notice and opportunity to cure if the action or conduct is not reasonably susceptible to cure, or (F) material breach of any terms and conditions of the Amended Employment Agreement, any contract or agreement between Mr. Rosa and the Company, or of any Company policy, or of any statutory duty he owes to the Company, which breach has not been cured by Mr. Rosa within ten days after written notice thereof to Mr. Rosa from the Company.

Under the Amended Employment Agreement, "Termination for Good Reason" means a termination of Mr. Rosa's employment by Mr. Rosa within 30 days of the Company's failure to cure, in accordance with the procedures set forth below, any of the following events: (A) a reduction in his annual base salary as in effect immediately prior to such reduction by more than 10% without his written consent, unless such reduction is made pursuant to an across the board reduction applicable to all senior executives of the Company; (B) a material reduction in his duties, position and responsibilities as in effect immediately prior to such reduction without his written consent; provided, however, that a mere change in title or reporting relationship following a Change in Control by itself will not constitute "Good Reason" for Mr. Rosa's resignation, and further provided that the acquisition of the Company and subsequent conversion of the Company to a division or unit of the acquiring entity will not by itself result in a "reduction" of duties, position or responsibility; or (C) a material breach of any material provision of the Amended Employment Agreement by the Company. A termination by Mr. Rosa shall not be treated as a Termination for Good Reason if Mr. Rosa consented in writing to the occurrence of the event giving rise to the claim of Termination for Good Reason or unless Mr. Rosa shall have delivered a written notice to the Board within 45 days of Mr. Rosa's having actual knowledge of the occurrence of one of such events stating that Mr. Rosa intends to terminate his employment by Termination for Good Reason and specifying the factual basis for such termination, and such event, if capable of being cured, shall not have been cured within 21 days of the receipt of such notice.

Mr. McClurg

On January 1, 2021, the Company and Mr. McClurg executed an employment offer letter (the "McClurg Offer Letter") under which, effective January 1, 2021, Mr. McClurg was appointed Chief Financial Officer of the Company. The McClurg Offer Letter provides that Mr. McClurg is an at-will employee of the Company meaning that either Mr. McClurg or the Company may end the employment relationship at any time, for any reason, and with or without notice or cause. Under the McClurg Offer Letter, the Company agreed to provide Mr. McClurg: (a) an annual base salary in the amount of $250,000, subject to review and adjustment based upon the Company's normal performance review practices; (b) an annual performance bonus of up to 25% of Mr. McClurg's then effective base salary for the applicable bonus year based upon his performance and the Company's performance, all as determined in the sole discretion of the Board or committee thereof; (c) the right to participate in the benefit programs and arrangements that the Company makes available to its employees, including paid vacation and sick leave, contributory and non-contributory welfare and benefit plans, disability plans, and medical, death benefit and life insurance plans for which Mr. McClurg is eligible under the terms of those plans; and (d) subject to the terms of Company's 2017 Equity Incentive Plan, a stock option award to purchase 60,000 shares of the Company's Common Stock with an exercise price of $4.71 per share, 25% of which will vest on January 1, 2022, with the balance vesting in equal monthly installments on the last day of each month over the next thirty-six (36) months following January 1, 2022.

Mr. Mertens

On March 6, 2019, the Company and Mr. Mertens executed an employment offer letter (the "Mertens Offer Letter") under which, effective April 1, 2019, Mr. Mertens was appointed Chief Technology Officer of the Company. The Mertens Offer letter provides that Mr. Mertens is an at-will employee of the Company meaning that either Mr. Mertens or the Company may end the employment relationship at any time, for any reason, and with or without notice or cause. Under the Mertens Offer Letter, the Company agreed to provide Mr. Mertens: (a) an annual base salary in the amount of $235,000, subject to applicable deductions and adjustment; (b) an annual discretionary bonus of up to 25% percent of Mr. Merten's base salary based on his performance and the Company's performance, all as determined in the sole discretion of the Board or committee thereof; (c) subject to the terms of Company's 2017 Equity Incentive Plan, a stock option award to purchase 43,149 shares of the Company's common stock with an exercise price of $7.14 per share, 25% of which vested on May 13, 2019, and 75% of which vest in 36 equal monthly installments beginning on April 1, 2020; and (d) the right to participate in the benefit programs and arrangements that the Company makes available to its employees, including paid vacation and sick leave, contributory and non¬contributory welfare and benefit plans, disability plans, and medical, death benefit and life insurance plans for which Mr. Mertens is eligible under the terms of those plans.

Potential Payments Upon Termination or Change in Control

David Rosa

For a discussion of payments to Mr. Rosa upon termination or change in control under his Amended Employment Agreement, see "*Employment Agreement and Arrangements— Mr. Rosa*" above.

2017 Equity Incentive Plan

In April 2017, the Board adopted and the stockholders approved the 2017 Equity Incentive Plan. The 2017 Equity Incentive Plan is designed to provide a vehicle under which a variety of stock-based and other awards can be granted to the Company's employees, consultants and directors, which align the interests of award recipients with those of our stockholders, reinforce key goals and objectives that help drive stockholder value, and attract, motivate and retain experienced and highly qualified individuals who contribute to the Company's financial success. The Board believes that the 2017 Equity Incentive Plan serves a critical role in attracting and retaining high caliber employees, consultants and directors essential to our success and in motivating these individuals to strive to meet our goals.

Corporate Transactions. The 2017 Equity Incentive Plan provides that in the event of certain specified significant corporate transactions, including: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 90% of our outstanding securities, (3) the consummation of a merger or consolidation where we do not survive the transaction, and (4) the consummation of a merger or consolidation where we do survive the transaction but the shares of our Common Stock outstanding before such transaction are converted or exchanged into other property by virtue of the transaction, unless otherwise provided in an award agreement or other written agreement between us and the award holder, the plan administrator may take one or more of the following actions with respect to such stock awards:

- arrange for the assumption, continuation, or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;

- accelerate the vesting, in whole or in part, of the stock award and provide for its termination before the transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us;
- cancel or arrange for the cancellation of the stock award before the transaction in exchange for a cash payment, or no payment, as determined by the Board; or
- make a payment, in the form determined by our Board, equal to the excess, if any, of the value of the property the participant would have received on exercise of the awards before the transaction over any exercise price payable by the participant in connection with the exercise.

The plan administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner and is not obligated to treat all participants in the same manner. In the event of a change in control, awards granted under the 2017 Equity Incentive Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement. Under the 2017 Equity Incentive Plan, a change in control is defined to include (1) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock, (2) a merger, consolidation, or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity), (3) a sale, lease, exclusive license, or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders, and (4) an unapproved change in the majority of the Board.

Outstanding Equity Awards at Fiscal Year-End 2021

As of September 30, 2021, our named executive officers had no outstanding stock awards. The following table sets forth information regarding outstanding option awards held by our named executive officers as of September 30, 2021:

NAME	GRANT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS EXERCISABLE (#)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS UNEXERCISABLE (#)	OPTION EXERCISE PRICE ($)	OPTION EXPIRATION DATE
Steven Mertens	May 13, 2019	26,968(1)	16,181	7.14	May 13, 2029
Steven Mertens	January 27, 2021	0(2)	23,334	5.97	January 27, 2031
David Rosa	November 5, 2019	143,797(3)	2,870	6.42	November 5, 2029
David Rosa	January 27, 2021	83,333(4)	333,334	5.97	January 27, 2031
Ronald McClurg	January 1, 2021	0(5)	60,000	4.71	January 1, 2031
Ronald McClurg	January 27, 2021	0(6)	46,667	5.97	January 27, 2031

(1) 25% of the shares underlying the option vested immediately upon grant; the remaining vest monthly in equal increments over a 36 month period beginning April 1, 2020.

(2) 25% of the shares underlying the option vest on January 27, 2022; the remaining vest monthly in equal increments over a 36 month period thereafter.

(3) 25% of the shares underlying the option vested on November 5, 2020 and the remaining 75% vest in 36 equal monthly installments beginning on December 1, 2020, subject to acceleration upon achieving certain performance milestones. As of September 30, 2021, 20% of the shares underlying the options had vested upon the achievement of performance milestones.

(4) 25% of the shares underlying the option vest on January 27, 2022; the remaining vest monthly in equal increments over a 36 month period thereafter, subject to acceleration upon achieving certain performance milestones. As of September 30, 2021, 20% of the shares underlying the options had vested upon the achievement of performance milestones.

(5) 25% of the shares underlying the option vest on January 1, 2022; the remaining vest monthly in equal increments over a 36 month period thereafter.

(6) 25% of the shares underlying the option vest on January 27, 2022; the remaining vest monthly in equal increments over a 36 month period thereafter.

Chief Executive Officer Pay Ratio

As a "smaller reporting company", we are not required to provide information relating to the ratio of total compensation of our Chief Executive Officer to the median of the annual total compensation of all of our employees, as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Non-Employee Director Compensation

On March 29, 2018, our Board approved a Non-Employee Director Compensation Policy effective as of January 1, 2018 whereby our non-employee directors receive a mix of cash and share-based compensation intended to encourage non-employee directors to continue to serve on our Board, further align the interests of the directors and stockholders, and attract new non-employee directors with outstanding qualifications. Directors who are employees or officers of the Company do not receive any additional compensation for Board service.

Pursuant to this policy, each of our non-employee directors receive an annual retainer of $50,000, except that our non-executive chairman receives an annual retainer of $100,000. Additionally, the chairman and members of our Audit Committee receive an additional annual payment of $12,500 and $5,000, respectively, and the chairmen and members of each of our Compensation and Nominating and Corporate Governance Committees receive an additional annual payment of $10,000 and $4,000, respectively.

Additionally, on the date of each annual stockholder meeting of the Company, each director automatically receives an equity award with an aggregate value on the date of grant equal to $50,000. Two-thirds of the equity award is issued in the form of restricted stock units, and one-third is issued in the form of stock options, each of which vest in twelve monthly installments, subject to such director's continued service.

The following table provides compensation information for the fiscal year ended September 30, 2021 for each non-employee member of the Board.

Name	Fees Earned or Paid in Cash ($)[1]	Stock Awards ($)[2]	Option Awards ($)[2]	Total ($)
Paul Buckman	112,000	33,338(3)	16,666(4)	162,004
Edward Andrle	62,000	33,338(5)	16,666(6)	112,004
Jeffrey Mathiesen	66,500	33,338(7)	16,666(8)	116,504

(1) These represent amounts earned in fiscal year 2021.

(2) Stock option and RSU awards were granted under the 2017 Equity Incentive Plan. The amounts reported reflect the aggregate grant date fair value of each equity award granted to the Company's non-employee directors during the fiscal year ended September 30, 2021, as computed in accordance with ASC 718. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions.

(3) At the end of fiscal year 2021, Mr. Buckman had 3,446 outstanding stock awards.

(4) At the end of fiscal year 2021, Mr. Buckman had 77,466 outstanding stock options.

(5) At the end of fiscal year 2021, Mr. Andrle had 3,446 outstanding stock awards.

(6) At the end of fiscal year 2021, Mr. Andrle had 12,591 outstanding stock options.

(7) At the end of fiscal year 2021, Mr. Mathiesen had 3,446 outstanding stock awards.

(8) At the end of fiscal year 2021, Mr. Mathiesen had 66,126 outstanding stock options.

As a named executive officer of the Company, compensation paid to Mr. Rosa for fiscal 2021 is fully reflected under "*Executive Compensation — Summary Compensation Table.*"

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

The following table sets forth the beneficial ownership of our Common Stock as of December 6, 2021 for:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our Common Stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

The table lists applicable percentage ownership based on 16,187,722 shares of Common Stock outstanding as of December 6, 2021.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws. In addition, the rules include shares of our Common Stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of December 6, 2021. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Except as otherwise noted below, the address for persons listed in the table is c/o NeuroOne Medical Technologies Corporation, 7599 Anagram Dr., Eden Prairie, MN 55344.

Name and address of beneficial owner	Number of shares of Common Stock beneficially owned	Percentage of Common Stock beneficially owned[1]
Greater than 5% Stockholders:		
James E. Besser[2] 2 Calle Candina, #1701 San Juan, Puerto Rico, 00907 United States of America	1,747,651	10.8%
Directors and Named Executive Officers:		
David Rosa	606,669[3]	3.7%
Paul Buckman	105,804[4]	*
Jeffrey Mathiesen	99,852[5]	*
Edward Andrle	23,906[6]	*
Steve Mertens	37,296[7]	*
Ronald McClurg	27,917[8]	*
All Current Directors and Officers as a Group (7 persons)	1,252,614[9]	7.5%

(1) Based on 16,187,722 shares of Common Stock outstanding as of December 6, 2021.

(2) Based on Form 3 filed by James E. Besser, Morgan C. Frank, Manchester Management Co LLC, Manchester Management PR, LLC, and Manchester Explorer, L.P.on January 21, 2021 (the "Form 3") and Form 13G filed by Manchester Explorer, L.P., Manchester Management Company, LLC, Manchester Management PR, LLC, JEB Partners, L.P., Messrs. Frank and Besser on January 21, 2021. The Form 3 also reported ownership of 1,666,669 shares of Common Stock issuable upon the exercise of outstanding warrants. The reported securities and warrants are directly owned by Manchester Explorer, L.P., JEB Partners, L.P. and by Mr. Frank in his personal capacity. The reported securities and warrants are indirectly beneficially owned by Manchester Management PR, LLC and Manchester Management Company, LLC as a result of having investment discretion over Manchester Explorer, L.P. and JEB Partners, L.P. The reported securities and warrants may also be deemed to be indirectly beneficially owned by Mr. Besser, as the Managing Member of Manchester Management PR, LLC and Manchester Management Company, LLC and by Mr. Frank, who serves as a portfolio manager and as a consultant for Manchester Management Company, LLC. Manchester Explorer, L.P. reports shared voting power over 1,181,930 shares and shared investment power over 1,333,334 shares; Manchester Management Company, LLC and Manchester Management PR, LLC report shared voting power over 1,181,930 shares and shared investment power over 1,500,000 shares; JEB Partners, L.P.

reports shared voting and investment powers over 166,667 shares; Mr. Besser reports sole voting power over 164,317 shares, shared voting power over 1,181,930 shares, sole investment power over 164,317, and shared investment power over 1,664,317 shares; and Mr. Frank reports sole voting and investment powers over 83,334 shares, shared voting power over 1,181,930 shares, and shared investment power over 1,583,334 shares. The reporting persons disclaim beneficial ownership of the reported securities and warrants except to the extent of their pecuniary interest therein. The percentage in this table reflects that the reporting persons may not exercise the warrants to the extent such exercise would cause the reporting persons to beneficially own a number of shares of common stock that would exceed 9.99% of our then outstanding common stock following such exercise.

(3) Includes 342,061 shares of Common Stock issuable upon exercise of outstanding options that have vested or vest within 60 days of December 6, 2021.

(4) Includes 765 restricted stock units that vest within 60 days of December 6, 2021, and 75,905 shares of Common Stock issuable upon exercise of outstanding options.

(5) Includes 765 restricted stock units that vest within 60 days of December 6, 2021, and 64,565 shares of Common Stock issuable upon exercise of outstanding options.

(6) Includes 765 restricted stock units that vest within 60 days of December 6, 2021, and 11,030 shares of Common Stock issuable upon exercise of outstanding options.

(7) Includes 37,296 shares of Common Stock issuable upon exercise of outstanding options that have vested or vest within 60 days of December 6, 2021.

(8) Includes 27,917 shares of Common Stock issuable upon exercise of outstanding options that have vested or vest within 60 days of December 6, 2021.

(9) Includes 2,296 restricted stock units that vest within 60 days of December 6, 2021, and 558,774 shares of Common Stock issuable upon exercise of outstanding options.

* Less than 1%

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our officers and directors, and greater than 10% stockholders, to file reports of ownership and changes in ownership of our securities with the SEC. Based on our review of these reports and written representations from reporting persons, we believe that all reporting persons complied with all filing requirements during the fiscal year ended September 30, 2021, except for David A. Rosa who had one late Form 4 filing related to the vesting of a portion of a stock option grant from the Company.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of September 30, 2021 with respect to compensation plans under which shares of our Common Stock may be issued.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))(1)(2) (c)
Equity compensation plans not approved by security holders(3)	0	$ 0	0
Equity compensation plan approved by security holders	1,122,560	$ 5.89	389,709
Total	1,122,560	$ 5.89	389,709

(1) The number of shares of common stock reserved for issuance under our 2017 Equity Incentive Plan automatically increases on January 1st of each calendar year, starting on January 1, 2018 through January 1, 2027, to an amount equal to 13% of the total number of fully-diluted shares of our common stock as of December 31 of the preceding calendar year, or a lesser number of shares determined by our Board.

(2) Consists of 241,338 shares remaining available for issuance under the 2017 Equity Incentive Plan and 148,371 shares remaining available for issuance under the 2016 Equity Incentive Plan.

(3) There are no other securities available for future issuance under Company Plans as of September 30, 2021. The Company adopted an Inducement Plan subsequent to September 30, 2021.

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

Certain Relationships and Related Transactions

The following includes a summary of transactions since October 1, 2019 to which NeuroOne, Inc. or the Company has been a participant in which the amount involved exceeded or will exceed the lesser of $120,000 or 1% of the average of the Company's total assets at year end for the last two completed fiscal years, and in which any of our directors, executive officers or holders of more than five percent of our capital stock, or any members of their immediate family, had or will have a direct or indirect material interest.. Other than described below, there have not been, nor are there currently any proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which include equity and other compensation, termination, change in control and other arrangements, which are described under "Item 11 - Executive Compensation."

Lock-Up Agreements

On October 21, 2019, Wade Fredrickson, a holder of over 5% of our Common Stock, entered into a lock-up agreement with the Company in which he agreed, subject to certain exceptions, not to offer, sell, transfer or otherwise dispose of the Company's securities for a period of 18 months following the effective date of the agreement. On January 12, 2021, all of our directors, officers, and certain stockholders (including Wade Fredrickson) entered into lock-up agreements in which they agreed, subject to certain exceptions, not to offer, sell, transfer or otherwise dispose of the Company's securities for a period of 90 days following the effectiveness of a resale registration statement to be filed in connection with the Company's January 2021 private placement.

Indemnification Agreements

Our Certificate of Incorporation contains provisions limiting the liability of directors, and our bylaws provides that we indemnify each of our directors to the fullest extent permitted under Delaware law. Our Certificate of Incorporation and bylaws also provide our Board with discretion to indemnify our officers and employees when determined appropriate by the Board. In addition, we have entered into an indemnification agreement with our directors and our executive officers.

Policies and Procedures for Transactions with Related Parties

To assist the Company in complying with its disclosure obligations and to enhance the Company's disclosure controls, the Board approved a formal policy in January 2018 regarding related person transactions. A "related person" is a director, officer, nominee for director or a more than 5% stockholder (of any class of the Company's voting stock) since the beginning of the Company's last completed fiscal year, and their immediate family members. A related person transaction is any transaction or any series of transactions in which the Company was or is to be a participant, the amount involved exceeds $120,000, and in which any related person had or will have a direct or indirect material interest.

Specifically, the policy establishes a process for identifying related persons and procedures for reviewing and approving such related person transactions. In addition, directors and executive officers are required to complete an annual questionnaire in connection with the Company's proxy statement for its annual meeting of stockholders, which includes questions regarding related person transactions, and such persons also are required to provide written notice to the Company or outside legal counsel of any updates to such information prior to the annual meeting.

The Audit Committee and/or the independent directors of the Board review such proposed business transactions to ensure that the Company's involvement in such transactions is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and is in the best interests of the Company and its stockholders.

Director Independence

Nasdaq listing standards require that the Company's Board consist of a majority of independent directors, as determined under the applicable rules and regulations of Nasdaq. Based upon information requested from and provided by each proposed director concerning his or her background, employment and affiliations, including family relationships, the Company believes that each current member of the Board qualifies as an "independent director" as defined under the applicable rules and regulations of the SEC and the listing requirements and rules of Nasdaq, except Mr. Rosa, the Company's President and Chief Executive Officer. In making such independence determinations, the Board considers the current and prior relationships that each non-employee director has with the Company and all other facts and circumstances that the Board deems relevant in determining each non-employee director's independence, including the participation by the Company's non-employee directors, or their affiliates, in certain financing transactions and the beneficial ownership of the Company's Common Stock by each non-employee director.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table shows the fees for professional services rendered to us by Baker Tilly US, LLP ("Baker Tilly") or BDO USA, LLP ("BDO") for services in respect of the fiscal years ended September 30, 2021 and 2020, which were approved by the Audit Committee in accordance with its established policies and procedures.

	FISCAL YEAR 2021		FISCAL YEAR 2020	
FEE CATEGORY	**Baker Tilly**	**BDO**	**Baker Tilly**	**BDO**
Audit fees	$ 126,745	$ 159,633	$ —	$ 251,799
Audit-related fees	—	—	—	—
Tax fees	—	—	—	—
All other fees	—	—	—	—
Total fees	$ 126,745	$ 159,633	$ —	$ 251,799

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our Audit Committee generally pre-approves all audit and permitted non-audit and tax services provided by the independent registered public accounting firm. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The independent registered public accounting firm and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date. Our Audit Committee may also pre-approve particular services on a case-by-case basis. All of the services relating to the fees described in the table above were approved by our Audit Committee.

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)
10.4 +	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)

10.5 +	Restricted Stock Purchase Agreement by and between NeuroOne, Inc. and Thomas Bachinski, dated as of April 10, 2017 (incorporated by reference to Exhibit 10.13 on the Registrant's Current Report on Form 8-K filed on July 20, 2017)
10.6 +	2017 Equity Incentive Plan of the Company (incorporated by reference to Appendix G to Schedule 14C filed on April 20, 2017)
10.7 +	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)
10.8 +	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)
10.9 +	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)
10.10 +	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)
10.11 +	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)
10.12 +	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)
10.13 +	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)
10.14	Form of Capital Stock Purchase Warrant pursuant to August 2017 Subscription Agreement (incorporated by reference to Exhibit 4.2 on the Registrant's Current Report on Form 8-K filed on August 23, 2017)
10.15	Form of Capital Stock Purchase Warrant issued pursuant to October 2017 Subscription Agreement (incorporated by reference to Exhibit 4.2 on the Registrant's Current Report on Form 8-K filed on October 6, 2017)
10.16	Form of Amended and Restated Capital Stock Purchase Warrant issued pursuant to Amended and Restated Promissory Note and Warrant Subscription Agreement (incorporated by reference to Exhibit 4.2 on the Registrant's Current Report on Form 8-K filed on December 20, 2017)
10.17	Form of Replacement Warrant issued pursuant to August 2017 Subscription Agreement, as amended (incorporated by reference to Exhibit 4.2 on the Registrant's Current Report on Form 8-K filed on March 16, 2018)
10.18	Form of Additional Warrant issued pursuant to August 2017 Subscription Agreement, as amended (incorporated by reference to Exhibit 4.3 on the Registrant's Current Report on Form 8-K filed on March 16, 2018)
10.19 +	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.40 to 10-K filed April 16, 2018)

10.20	Form of Warrant (incorporated by reference to Exhibit 4.1 to 8-K filed July 13, 2018)
10.21	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to 8-K filed July 13, 2018)
10.22 +	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)
10.23	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)
10.24	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)
10.25 +	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)
10.26	Form of Conversion Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on March 6, 2019)
10.27	Form of Paulson Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on July 5, 2019)
10.28	Form of HRA Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed on July 5, 2019)
10.29	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)
10.30	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)
10.31	Form of Common Stock Purchase Warrant issued pursuant to November 2019 Promissory Note and Warrant Subscription Agreement (incorporated by reference to Exhibit 4.2 on the Registrant's Current Report on Form 8-K filed on November 7, 2019)
10.32	Form of Broker Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on January 24, 2020)
10.33	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)
10.34	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).
10.35 +	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).
10.36	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).
10.37	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).
10.38	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).
10.39	Amendment to Exclusive Development and Distribution Agreement by and between the Company and Zimmer, Inc. dated January 6, 2021

16.1	Letter from BDO USA, LLP (incorporated by reference to Exhibit 16 on the Registrant's Current Report on Form 8-K filed on June 24, 2021).
21.1	Subsidiaries of the Registrant
23.1	Consent of Baker Tilly US, LLP
23.2	Consent of BDO USA, 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
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	104 Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* 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 and would be competitively harmful if publicly disclosed 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, 2021

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, 2021
/s/ RONALD MCCLURG Ronald McClurg	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 15, 2021
/s/ PAUL BUCKMAN Paul Buckman	Chairman of the Board of Directors	December 15, 2021
/s/ EDWARD ANDRLE Edward Andrle	Member of the Board of Directors	December 15, 2021
/s/ JEFFREY MATHIESEN Jeffrey Mathiesen	Member of the Board of Directors	December 15, 2021