UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 December 31, 2018

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: 001-38546

NEURONETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-1051425**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3222 Phoenixville Pike, Malvern, Pennsylvania 19355
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (610) 640-4202

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2018) was approximately $352.4 million after giving effect to the closing of the registrant's initial public offering on July 2, 2018.

The number of shares of Registrant's Common Stock outstanding as of February 28, 2019 was 18,054,628.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2019 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2018, are incorporated by reference into Part III of this Report.

NEURONETICS, INC.

Annual Report on Form 10-K for the year ended December 31, 2018

Table of Contents

[THIS PAGE INTENTIONALLY LEFT BLANK]

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, business strategy, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations, future results of current and anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere herein. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained in this Annual Report on Form 10-K, whether as a result of any new information, future events, changed circumstances or otherwise.

Disclosure Channels to Disseminate Information

The Company announces material information to the public about the Company, its products and services and other matters through a variety of means, including filings with the Securities and Exchange Commission, press releases, public conference calls, the Company’s website (https://neurostar.com/neuronetics/), including the Investors section thereof, and/or social media, including its Facebook page (https://www.facebook.com/NeuroStarAdvancedTMS/), Twitter account (@TMSTherapy), Instagram account (@NeurostarAdvancedTMS), YouTube account (https://www.youtube.com/channel/UCmCPFlXKw1dXP--_fygpmJw) and/or LinkedIn account (https://www.linkedin.com/company/neuronetics-inc./), in order to achieve broad, non-exclusionary distribution of information to the public. The Company encourages investors and others to review the information it makes public in these locations, as such information could be deemed to be material information. Please note that this list may be updated from time to time.

PART I

Item 1. Business.

Overview

We are a commercial stage medical technology company focused on designing, developing and marketing products that improve the quality of life for patients who suffer from psychiatric disorders. Our first commercial product, the NeuroStar Advanced Therapy System, is a non-invasive and non-systemic office-based treatment that uses transcranial magnetic stimulation, or TMS, to create a pulsed, MRI-strength magnetic field that induces electrical currents designed to stimulate specific areas of the brain associated with mood. The system is cleared by the United States Food and Drug Administration, or FDA, to treat adult patients with major depressive disorder, or MDD, that have failed to achieve satisfactory improvement from prior antidepressant medication in the current MDD episode. NeuroStar Advanced Therapy is safe, clinically effective, reproducible and precise and we believe is supported by the largest clinical data set of any competing TMS system. We believe we are the market leader in TMS therapy based on our U.S. installed base of 907 active NeuroStar Advanced Therapy Systems in approximately 707 psychiatrist offices as of December 31, 2018 and the estimated 62,900 patients treated with approximately 2.3 million treatment sessions through such date. We generated revenues of $52.8 million for the year ended December 31, 2018.

MDD is a mood disorder characterized by the presence of one or both of two major diagnostic criteria: a depressed mood or loss of interest in pleasure that continues for at least two weeks. The presence of at least one of these diagnostic symptoms must be accompanied by several of the following additional symptoms: sleep disturbance, changes in appetite, sexual dysfunction, anxiety, fatigue, difficulty concentrating and suicidal thinking. MDD is a recurrent disease and follows a fluctuating course over an individual's lifetime, with periods of remission and relapse.

The World Health Organization, or WHO, ranks MDD as the single largest contributor to global disability and a major contributor to suicide worldwide. According to a study published in the *Journal of Clinical Psychiatry*, the economic burden of the disease was estimated to be $210 billion in 2010 in the United States, including outpatient and inpatient medical costs, pharmacy costs, suicide related costs and workplace costs. A study published in *Psychological Medicine* reported a global incidence rate of MDD is 3.0% and the WHO estimates that there are over 300 million people in the world living with depression. Based on U.S. Census Bureau data and a study published in the *Journal of the American Medical Association,* we estimate that approximately 21 million people in the United States suffer from MDD annually. Of these people, we estimate approximately 13.3 million are adults aged 22 to 70 years, of whom an estimated 7.6 million, based on data from the *Journal of the American Medical Association*, are being treated by a psychiatrist. We estimate, based on data from the Sequenced Treatment Alternatives to Relieve Depression, or the STAR*D study, that approximately 5.5 million of these patients have failed to achieve remission of their MDD from their prior antidepressant medication therapy and that approximately 3.8 million of those patients have commercial insurance or Medicare coverage for NeuroStar Advanced Therapy. As a result, based on our expected revenues for a standard course of treatment, we believe our total annual addressable market opportunity for treatment sessions in the United States is approximately $9.6 billion.

Initial treatment options for MDD often consist of antidepressant medication prescribed by a primary care physician. Although a variety of antidepressant medications are available, drug therapy has two primary limitations: limited effectiveness and treatment-emergent side effects. These limitations were demonstrated in the STAR*D study, a large clinical trial funded by the U.S. National Institute of Mental Health, or NIMH, that enrolled more than 4,000 adult MDD patients at 41 clinical sites to examine the outcomes to a sequenced series of antidepressant medication attempts that mimicked best practices. In the study, approximately 28% and 21% of patients achieved remission in their first and second medication attempts, respectively. Many patients taking antidepressant medications experience intolerable or troubling side effects that contribute to a delay or failure in attaining an effective or optimal antidepressant dose, poor patient treatment adherence or discontinuation of treatment therapy. The likelihood of achieving remission is limited and declines with each successive medication attempt.

TMS is considered to be an appropriate therapy for the treatment of MDD patients who have failed to achieve satisfactory improvement from prior antidepressant medication. TMS is typically performed as an office-based procedure using a capital equipment system designed to deliver the magnetic pulses necessary to stimulate the specific areas of the brain associated with mood. A course of treatment typically requires treatment sessions five times a week for up to six weeks that can last from as low as three to as long as 45 minutes per session. The effectiveness of TMS depends on the psychiatrist's ability to deliver a precise amount of magnetic pulses to a specific area of the brain in a manner that can be consistently repeated during each treatment session. While TMS has been demonstrated to be a safe and effective treatment alternative for patients suffering from MDD, we believe that competing TMS systems have experienced limited adoption because of their lack of the following: the ability to reproduce consistent treatments, significant clinical data from randomized outcome trials, practice development resources and a cloud-based practice management system.

We designed the NeuroStar Advanced Therapy as a non-invasive therapeutic alternative to treat patients who suffer from MDD and to address many of the key limitations of existing treatment options. We believe our NeuroStar Advanced Therapy provides our psychiatrist customers and their patients with several benefits, including clinically demonstrated response and remission with durable results, a demonstrated safety profile with limited treatment-emergent side effects and high patient adherence. Additionally, NeuroStar Advanced Therapy was designed to provide a precise and reproducible office-based therapy that is also efficient and convenient. Our therapy is delivered without general anesthesia or sedation, enabling the patient to drive and resume normal activities immediately following each treatment session. We couple our product's clinical benefits with significant practice development resources, on-site clinical training and reimbursement and service support to help our psychiatrist customers develop a successful NeuroStar Advanced Therapy practice. We also provide cloud-based practice management solutions that enhance convenience for both psychiatrists and patients. Based on our commercial data, we believe psychiatrists can recoup their initial capital investment in our system by providing a standard course of treatment to approximately 12 patients, assuming these patients receive reimbursement from Medicare or commercial insurance at rates that are similar to what our customers have observed for existing and prior patients. We believe psychiatrists can generate approximately $7,500 to $10,000 of revenue per patient for a standard course of treatment, which may provide meaningful incremental income to their practices.

The safety, effectiveness and durability of NeuroStar Advanced Therapy is supported by a large clinical data set published in 23 articles in peer-reviewed medical journals, including from 11 clinical studies that have collectively enrolled more than 900 adult patients suffering from MDD. In a 307 patient, naturalistic, prospective, observational trial conducted at 42 U.S. clinical sites in patients who had tried and failed to receive relief from one or more medication trials in their current MDD episode, following an acute course of NeuroStar Advanced Therapy, 58% of patients responded, which means they achieved a clinically meaningful reduction in symptoms, and 37% achieved remission. Response and remission were maintained over a 12-month period for a majority of these patients. In the STAR*D study approximately 28% and 21% of patients achieved remission in their first and second medication trials, respectively.

Our growth strategy includes expanding our commercialization efforts in the United States, expanding international opportunities and pursuing pipeline development of our therapy for additional indications. Outside the United States, our products have received marketing authorizations in the European Union and Japan. Our initial international commercial focus is Japan, which has the third largest healthcare spend globally. We have entered into an exclusive distribution agreement with Teijin Pharma Limited, or Teijin, a leading Japanese healthcare company, to further expand our commercialization efforts in this market. We are also evaluating the use of enhancements to our NeuroStar Advanced Therapy System to treat additional indications, which may include bipolar depression and post-traumatic stress disorder.

As of December 31, 2018, we had an installed base of 907 active NeuroStar Advanced Therapy Systems in the United States. We currently sell our NeuroStar Advanced Therapy System and recurring treatment sessions in the United States through our sales and customer support team, which was comprised of 133 people as of December 31, 2018. Our sales force primarily targets 15,100 psychiatrists at 3,600 high-decile psychiatric practices that we estimate, based on data from Symphony Health and our own internal estimates, treat approximately 33% of the total MDD patients in the United States who meet our labeled indication and are insured. Patients are reimbursed by Medicare and the vast majority of commercial payors in the United States for treatment sessions utilizing our NeuroStar Advanced Therapy System.

We generate revenues from initial capital sales of our systems, sales of our recurring treatment sessions and from service and repair and extended warranty contracts. We derive the majority of our revenues from recurring treatment sessions. For the year ended December 31, 2018, we generated revenues of $52.8 million and had a net loss of $24.1 million. Our revenues increased 31% during the year ended December 31, 2018 compared to the year ended December 31, 2017. For the year ended December 31, 2018, our U.S. revenues were $51.5 million, compared to $39.9 million for the year ended December 31, 2017, which represented an increase of 29% compared to the prior period. Revenues from treatment sessions represented 69% of our U.S. revenues for the year ended December 31, 2018 compared to 71% of our U.S. revenues for the prior year.

Market Opportunity and Major Depressive Disorder

Market Opportunity

The WHO estimates that there are over 300 million people in the world living with depression and ranks MDD as the single largest contributor to global disability and a major contributor to suicide worldwide. In the United States, the economic burden of the disease was estimated by the *Journal of Clinical Psychiatry* to be $210 billion in 2010, including outpatient and inpatient medical costs, pharmacy costs, suicide related costs and workplace costs. There were approximately 333 million antidepressant medication prescriptions written in the United States in 2017, representing pharmaceutical sales totaling $5.0 billion, according to IMS Health. Based on U.S. Census Bureau data and a study published in the *Journal of the American Medical Association,* we estimate that approximately 21 million people in the United States suffer from MDD annually. Of these people, we estimate approximately 13.3 million are adults aged 22 to 70 years, of whom an estimated 7.6 million, based on data from the *Journal of the American Medical Association*, are being treated by a psychiatrist. We estimate, based on data from the STAR*D study, that approximately 5.5 million of these patients have failed to achieve remission of their MDD from their prior antidepressant medication therapy and that approximately 3.8 million of those patients have commercial insurance or Medicare coverage for the NeuroStar Advanced Therapy. As a result, based on our expected revenues for a standard course of treatment, we believe our total annual addressable market opportunity for treatment sessions in the United States is approximately $9.6 billion.

In Japan, the country with the third highest aggregate healthcare expenditures worldwide according to Deloitte, we estimate, based on data from the National Center for Biotechnology and Information, that approximately 2.4 million adults suffer from MDD and approximately 655,000 of these adults are being treated for their MDD by a psychiatrist. We estimate, based on data from the STAR*D study, that approximately 475,000 of these patients, all of whom are covered by Japan's single payor healthcare system, have failed to achieve remission of their MDD from prior antidepressant medication therapy and are candidates for treatment with NeuroStar Advanced Therapy. As a result, we believe our total addressable market opportunity for treatment sessions in Japan is over $1.0 billion, assuming psychiatrist reimbursement levels per treatment course per patient are similar to those in the United States.

Major Depressive Disorder

Disease Overview

MDD is a mood disorder characterized by the presence of one or both of two major diagnostic criteria that continues for at least two weeks: a depressed mood or loss of interest in pleasure. The presence of at least one of these diagnostic symptoms must be accompanied by several of the following additional symptoms, for a total of five or more symptoms: sleep disturbance, changes in appetite, sexual dysfunction, anxiety, fatigue, difficulty concentrating and suicidal thinking. In order to be diagnosed with MDD, a patient must display symptoms that are present most of the day, nearly every day, for at least two weeks. A diagnosis of MDD is established by clinical interview and an assessment of whether a patient reports a collection of symptoms defined in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, fifth edition*, or DSM-5. The severity of a patient's symptoms is typically measured by a standardized rating scale from a self-reported questionnaire, such as the Patient Health Questionnaire-9, or PHQ-9, or from an observer-dependent interview, such as the Hamilton Depression Rating Scale, or HAMD. Based in part on these rating scale measures, MDD can be graded on a continuum from mild to severe. The symptoms of the disease may result in role impairment, which refers to a loss of functioning or enjoyment in work, or impairment of household relationships and/or social roles. MDD is often accompanied by, or comorbid with, other mental disorders, with an estimated three-fourths of patients with recurrent MDD suffering from another psychiatric illness or substance abuse disorder. MDD patients also have an increased risk of death from suicide and other more typical causes, such as heart disease.

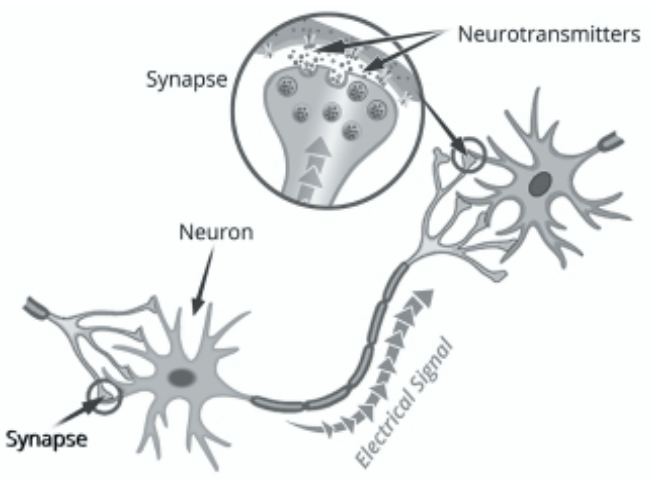
MDD is a recurrent disease and follows a fluctuating course over an individual's lifetime, with periods of remission and relapse. If an initial episode of MDD is resolved, the return of depressive symptoms during the first nine months thereafter is referred to as a relapse of the illness and is generally considered to be part of the same depressive episode. When depressive symptoms return more than 12 months after the initial episode of MDD is resolved, it is considered to be a recurrence of the illness and is deemed a new and distinct episode. A response to treatment is commonly measured as a clinically significant decrease in symptoms on a standardized rating scale from baseline scores. When a patient shows no or nearly no symptoms, the patient is referred to as being in remission. An average episode of MDD lasts approximately four to eight months and approximately three-fourths of all patients who experience an episode of MDD will experience recovery within a year. However, experiencing one episode of MDD places an individual at an estimated 50% risk of experiencing an additional episode of MDD. Approximately 80% of those individuals who have experienced two episodes of MDD will experience an additional episode.

Neuroscience of MDD

The exact causes of MDD are not known but, as with many psychiatric disorders, a variety of factors may be involved, including the physical and chemical characteristics of the brain, hormonal changes, genetics, acute life events, chronic stress, childhood exposure to adversity and other environmental factors. Researchers have identified a network in the brain that affects a person's mood, which can play a significant role in MDD and includes the prefrontal cortex, the anterior cingulate cortex and the limbic brain structures. The basic unit of organization in this network of the brain is the neuron, a specialized cell that responds to both chemical and electrical signals. The release of chemical messengers, or neurotransmitters, in the brain occurs across synapses, or the space between neurons. This release of neurotransmitters results in changes in the electrical properties of the receiving neuron, which in turn triggers a cascade of neuron-to-neuron electro-chemical reactions along a pathway of the brain referred to as a neuronal circuit.

The following diagram depicts the chemical reactions across the neuronal network:

Neurotransmission Mechanism



This communication process across different regions of the brain is ordinarily self-regulated by feedback mechanisms that instruct the originating neuron to stop releasing the neurotransmitter and start reabsorbing it into the cell, a process called reabsorption or reuptake.

In people with MDD, however, this complex system of neuronal communication does not function properly. Receptors may be either oversensitive or insensitive to a specific neurotransmitter, causing their response to its release to be excessive or inadequate. The signal might also be weakened if the originating cell produces too little of a neurotransmitter or if an overly efficient reuptake process reabsorbs too much of the neurotransmitter before the molecules have the chance to bind to the receptors on other neurons.

One of the most important discoveries in neuroscience has been the recognition that improper regulation of one or more of the three major neurotransmitters, serotonin, norepinephrine and dopamine, plays a key role in a patient's depression. This understanding has guided psychiatric drug development and the treatment of depression for more than three decades by placing a major focus on targeting chemically-based mechanisms. The relatively recent introduction of TMS as a targeted, circuit-based treatment option has reintroduced the importance of electrical mechanisms in restoring proper function to neuronal pathways to treat depression.

Current Treatment Landscape

First Line Therapy

In the United States, an initial diagnosis of adult MDD is typically made by the patient's primary care physician. Upon diagnosis, the most common form of treatment is antidepressant medication, which may or may not be accompanied by psychotherapy. The physician typically discusses a number of different treatment options and then designs a treatment plan tailored to the patient's specific symptoms, personal preferences and the psychiatric services that are available near the patient's home.

The most commonly prescribed antidepressant medications are selective serotonin reuptake inhibitors, or SSRIs. SSRIs primarily affect the levels and activity of serotonin in the brain and attempt to address depression by blocking the reuptake of this neurotransmitter, thereby making more serotonin available. During the initial treatment course, a patient may experience uncomfortable side effects and it is common for a patient and the primary care physician to spend time testing different medications within the same and different chemical classes before arriving at a medication regimen that provides symptom relief and is tolerable. Different classes of antidepressant medications may also work on different combinations of underlying neurotransmitters. For example, serotonin norepinephrine reuptake inhibitors, or SNRIs, work by blocking the reuptake of both serotonin and norepinephrine. Other medications may have more diverse effects on all three major neurotransmitters.

Depression-focused psychotherapies are a commonly recommended treatment option for MDD and are generally used in conjunction with an antidepressant medication. The two most well studied and commonly available psychotherapy techniques include cognitive behavioral therapy and interpersonal psychotherapy. These are interactive therapies between a trained professional and a patient.

Second Line Therapy

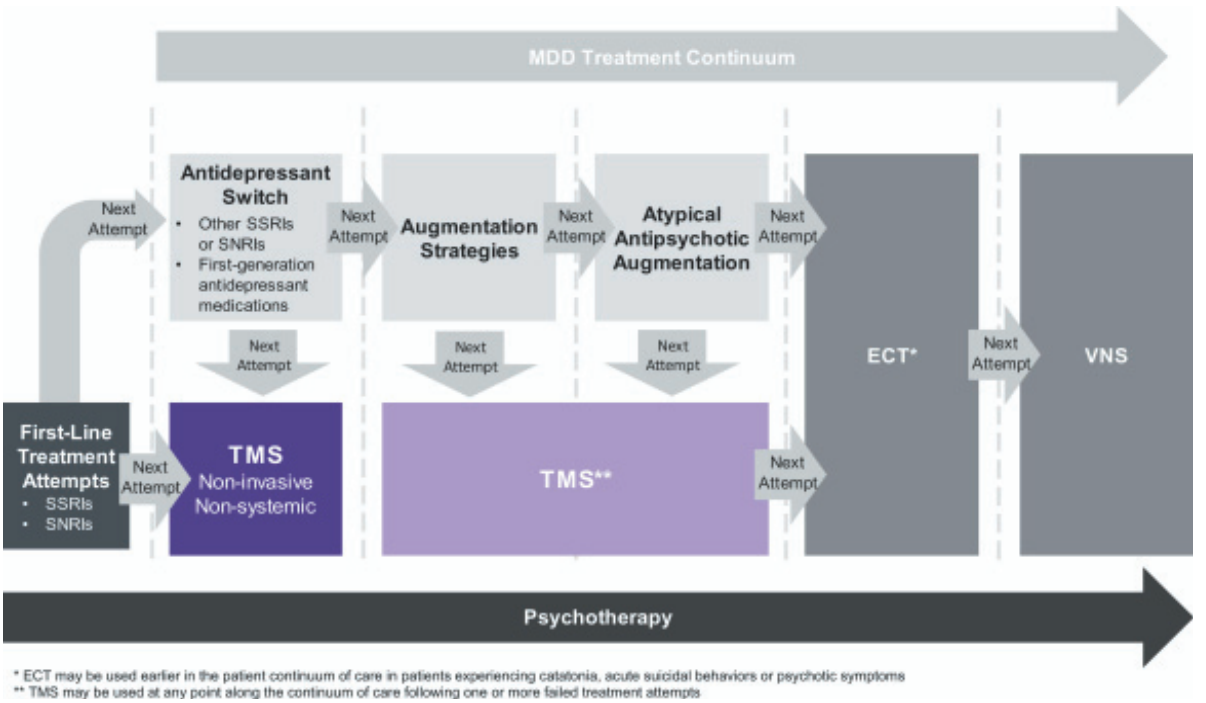
If initial treatment approaches do not adequately relieve a patient's symptoms, a primary care physician will often make a referral for consultation with a psychiatrist trained in psychopharmacology. There are a wide array of options that a psychiatrist may consider as second line therapies after an initial treatment has failed. For example, a psychiatrist may recommend either combining two or more antidepressant medications, which is referred to as combination therapy, or using a second medication such as an atypical antipsychotic that is not an antidepressant along with the initial antidepressant medication to augment the efficacy of such antidepressant, which is referred to as augmentation.

Another second line therapy is TMS, which is considered to be an appropriate alternative for the treatment of a patient with MDD who has failed to achieve satisfactory improvement from prior antidepressant medication in the current MDD episode. TMS differs from drug therapy approaches by using a pulsed, MRI-strength magnetic field to induce electrical currents designed to stimulate specific areas of the brain associated with mood. The target for brain stimulation is the prefrontal cortex, which serves as a starting point to regulate the neuronal circuitry connected to this region of the brain. This stimulation triggers a cascading electro-chemical effect that can pass along the neuronal circuit and reach into the deeper structures of the brain that also regulate mood. This action changes the connections among these structures in a manner that improves the activity of the neuronal circuit and results in an improvement in mood. TMS is typically performed as an office-based procedure using a piece of capital equipment designed to deliver the magnetic pulses necessary to stimulate the neurons. A course of treatment typically requires treatment sessions five times a week for up to six weeks that can last from 19 to as long as 45 minutes per session. The effectiveness of TMS therapy depends on the psychiatrist's ability to deliver a precise amount of magnetic pulses to a specific area of the brain in a manner that can be consistently repeated during each treatment session.

Later Stage Treatment Options

More aggressive options, which are associated with greater medical risk, are sometimes considered for patients that require later stages of treatment and include electroconvulsive therapy, or ECT, and vagus nerve stimulation, or VNS. ECT is a hospital-based treatment approach that is usually reserved for the most critical MDD patients and is considered most frequently in instances where the patient is experiencing catatonia, acute suicidal behaviors requiring inpatient hospitalization or psychotic symptoms. ECT involves the direct application of high voltage electrical current to the surface of the head and must be administered under anesthesia in a controlled hospital setting. VNS is considered the most invasive treatment option currently approved by the FDA for MDD patients who have proven to be severely treatment resistant. VNS involves the surgical implantation of an electrode wrapped around the vagus nerve, which travels through the neck near the carotid artery, and utilizes a pulse generator that is separately implanted under the skin near the patient's collarbone. The pulse generator sends electrical impulses to the electrode throughout the day with the goal of modifying the regions of the brain known to be involved in the regulation of mood.

A general overview of the treatment sequence for a patient with MDD is shown in the diagram below.

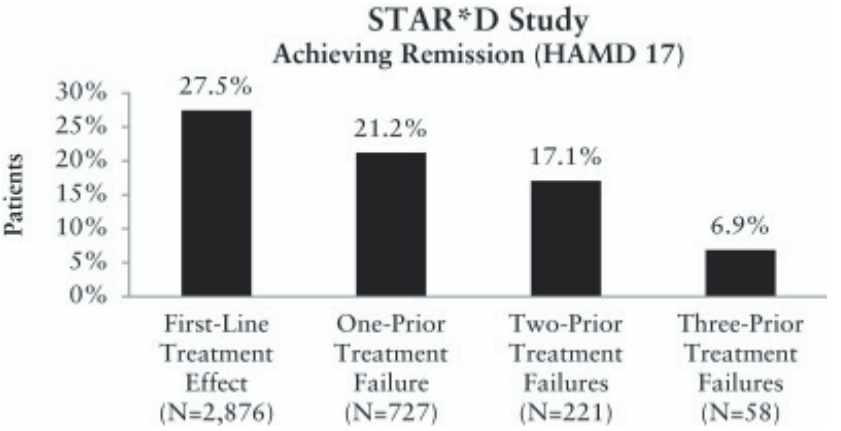


Limitations of Current Therapies

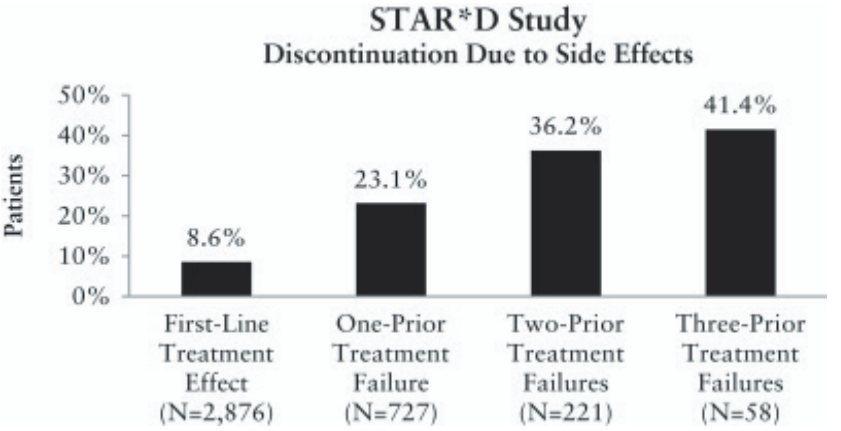
Antidepressant medication therapy

Although a variety of antidepressant medications are available for the treatment of MDD, antidepressant therapy has two primary limitations: limited efficacy and treatment-emergent side effects that interfere with patient adherence to the prescribed treatment regimen. These limitations were demonstrated in the STAR*D study. This study was sponsored by the NIMH and enrolled more than 4,000 adult patients at 41 clinical sites, including outpatients with nonpsychotic MDD. The trial examined the outcomes to a sequenced series of antidepressant medication treatment options that mimicked best practices. Patients whose depression did not remit after the initial treatment trial of using a single-medication SSRI treatment were able to participate in a sequence of up to three treatment trials. The progression that followed included switching to a different class and more complex combination and augmentation treatments for patients who were unable to achieve remission with each of the trials. Brain stimulation techniques, including ECT and VNS, were not examined in this study.

- ***Limited Efficacy***. In the STAR*D study, approximately 28% and 21% of patients achieved remission in their first and second medication attempts, respectively. The likelihood of achieving remission from a medication regimen was limited and declined with each successive augmentation attempt. For patients that had three prior treatment attempts, only approximately 7% achieved remission in response to the fourth monotherapy treatment option used in that study. The following figure depicts the percentage of patients who achieved remission at each stage of monotherapy treatment in the STAR*D study based on analysis of HAMD scores:



- ***Treatment-Emergent Side Effects***. The STAR*D study showed that the likelihood of discontinuing treatment due to treatment-emergent side effects increased with each incremental course of medication. According to the study and as shown in the figure below, approximately 41% of patients who progressed to the fourth monotherapy treatment attempt subsequently discontinued drug treatment. Many patients taking antidepressant medications experience intolerable or troubling side effects that contribute to a delay or failure in attaining an effective or optimal antidepressant dose and often result in poor patient treatment adherence or discontinuation of therapy. These side effects include sexual dysfunction, drowsiness, fatigue, weight gain and nausea. The severity of side effects generally increase as a patient proceeds from initial drug treatment to combination or augmented drug treatments. Later stage treatment options, such as first-generation antidepressants and antipsychotics, have potentially more serious side effects and intolerability, with the risk of potential fatal overdose. The discontinuation of treatment can also result in severe side effects, including dizziness, nausea, lethargy, headache, anxiety and agitation that can last for extended periods.



Since the publication of the STAR*D study results, additional drug therapies have been introduced, including most prominently atypical antipsychotics, which are used as augmentation agents for patients with partial or non-response to initial antidepressant medications given alone. Unfortunately, these augmentation treatments have not significantly improved overall MDD patient response rates and have also introduced additional side effects.

Depression-Focused Psychotherapies

Antidepressant medication therapy for MDD is often administered along with a recommendation for a depression-focused psychotherapy. While these treatment options have demonstrated efficacy in some clinical studies, they also are associated with limitations in practice. For instance, the experience level of the therapist may significantly affect the treatment outcome. Additionally, in order to access these treatments, patients usually require a referral to a psychotherapist who may be located at a different clinical site than their treating psychiatrist. Psychotherapy requires a commitment by a patient to numerous treatment sessions in order to potentially achieve significant improvement, with a typical treatment regimen consisting of 16 sessions.

Later Stage Treatment Options

Both ECT and VNS have significant drawbacks. ECT requires general anesthesia and is administered in a controlled hospital setting with access to emergency resuscitation equipment. ECT is typically administered three times per week for up to 12 treatments, with some patients requiring as many as 20 treatments. ECT patients may experience confusion and memory loss, the two most common side effects of ECT treatments, immediately following a treatment session. Other side effects may include nausea, headache, jaw pain, muscle ache, hypertension and hypotension and life threatening complications including adverse reactions to anesthesia, arrhythmias, ischemia or prolonged seizures. Because of the potentially disabling side effects of ECT, the patient is typically unable to work for the duration of the course of treatment. VNS is considered the most invasive treatment option currently approved by the FDA for MDD patients who have proven to be severely treatment resistant. VNS includes surgical related risks, such as infection or local damage to the recurrent laryngeal nerve, which may lead to permanent voice alteration. Other drawbacks of VNS include the development of cardiac arrhythmias and the periodic repeat surgeries required to replace the pulse generator battery. Finally, reimbursement for the implantation and ongoing monitoring of the VNS device remains problematic, limiting access to the procedure for most patients.

Transcranial Magnetic Stimulation

While TMS has been demonstrated to be a safe and effective treatment alternative for patients suffering from MDD, we believe that most TMS systems have experienced limited adoption for several reasons, including:

- ***Challenges in delivering precise and reproducible treatments***. We believe the design and technology of most TMS systems makes it difficult for psychiatrists to reliably administer precise and reproducible treatments during each treatment session. Notably, most TMS systems do not provide the psychiatrist with the ability to stabilize the patient's head during treatment. If a slight separation of the TMS treatment coil from the patient's head occurs, it may reduce the magnetic field in the patient's brain, resulting in the delivery of a lower dose than what was prescribed. Most TMS systems are unable to track the number of pulses not delivered as a result of this separation and therefore may not administer the prescribed dose.
- ***Lack of clinical data from randomized outcome and other trials.*** Most TMS providers have not conducted, and their systems have not been the subject of, significant clinical trials or naturalistic studies to demonstrate their effectiveness. As a result, when selling their products most TMS providers must rely on smaller or more general studies or clinical trials that were conducted using other TMS systems or the NeuroStar Advanced Therapy System, which may present a barrier to adoption by psychiatrists and patients.
- ***Lack of cloud-based practice management system***. Many psychiatrists and psychiatrist practice groups operate in multiple locations and may use multiple TMS devices. Most TMS systems, however, only allow for the storage of patient data and treatment information on a local computer. Unless connected through an inter or intra-office network, psychiatrists may not be able to access patient treatment data and information regarding the use of the TMS system. Moreover, this can create logistical challenges when psychiatrists seek to treat the patient at multiple locations or on multiple systems at the same location.

- ***Lack of comfort and convenience***. Most TMS systems are adaptations of research devices that have been repurposed. As a result, they frequently lack the ergonomic and other human factors that provide comfort and convenience and that are important for improving the patient experience and acceptance of the treatment. Other TMS systems may also require treatment to be administered for up to 45 minutes per treatment session. Some TMS systems require patients to wear a cap that fits firmly around the head and/or utilizes a chin strap that is attached from one ear to the other, which patients may consider uncomfortable.
- ***Lack of customer support and practice development resources.*** Many psychiatrists are not accustomed to implementing a piece of capital equipment into their practice. As a result, we believe they need multi-day, on-site training for themselves and their staff, marketing and reimbursement support, and help determining the allocation of office space and proper roles of staff for the use of TMS systems. We believe that most TMS providers do not provide comprehensive clinical support and practice development resources that are necessary to operationalize a TMS service line into their practice.

Our Solution

We designed the NeuroStar Advanced Therapy as a non-invasive and non-systemic therapeutic alternative for patients who suffer from MDD. We believe our solution addresses the key limitations of existing MDD treatment options and that NeuroStar Advanced Therapy provides the following principal benefits to our psychiatrist customers and their patients:

- ***Clinically demonstrated safety, efficacy, response and remission with durable results.*** The safety and efficacy of NeuroStar Advanced Therapy has been demonstrated in two large prospective, multisite, randomized, sham-controlled trials. In addition, the efficacy of NeuroStar Advanced Therapy has been demonstrated in a multisite, real world, open-label, clinical trial in which patients who failed to achieve satisfactory improvement from antidepressant medication treatment in their current episode of MDD received an acute treatment course of TMS therapy. Overall, the results of this trial demonstrated that 58% of patients responded to treatment, and 37% achieved remission. In this trial, similar response and remission rates were observed across patients with a wide range of prior drug treatment attempts. The majority of patients in this trial also participated in a 12-month follow-up phase at the conclusion of which the clinician-assessed response rate in these patients was 68% and remission rate was 45%.
- ***Demonstrated safety profile with limited treatment-emergent side effects and high patient adherence.*** NeuroStar Advanced Therapy has a demonstrated safety profile without the systemic side effects typically experienced with antidepressant medications. The adverse events discontinuation rate in our sham-controlled clinical studies has been approximately 5%. For single medication treatment in the STAR*D Study, the adverse events discontinuation rate was 9% to 41%. The most common side effect associated with NeuroStar Advanced Therapy is transient, localized pain or discomfort at or near the treatment location.
- ***Precise and reproducible office-based therapy.*** Patients receive NeuroStar Advanced Therapy for five days a week for up to six weeks in a psychiatrist's office without the need for general anesthesia or sedation. The NeuroStar Advanced Therapy System's proprietary components and software are designed to deliver the recommended TMS treatment dose to the indicated location on the patient's prefrontal cortex consistently. The treatment location is determined with a three-dimensional, laser-guided, six-point coordinate system. The SenStar Connect is a proprietary component of the device designed to ensure our NeuroStar Treatment Coil is functioning properly and positioned against a patient's head. SenStar Connect provides continuous real-time feedback to the clinician throughout the course of treatment and it tracks lost pulses during each treatment session and provides the clinician with the opportunity to readminister any lost pulses at the end of the treatment, all of which helps to ensure that a patient receives the prescribed dose of NeuroStar Advanced Therapy.

- ***Efficient and convenient treatment for the patient and the psychiatrist.*** We have developed and deployed a treatment for MDD using TMS approved by the FDA, with each treatment cleared to be performed in as little as 19 minutes (but may take up to 39 minutes due to patient sensitivity or at the discretion of the treating psychiatrist). Our therapy is delivered while a patient is awake and alert, enabling the patient to drive a vehicle and resume normal activities immediately following each treatment session. The NeuroStar Advanced Therapy System was designed for patient and psychiatrist convenience by establishing a proprietary software system, which we refer to as MT Assist, that allows the psychiatrist to determine the proper dose and motor threshold unique to each patient. After the initial treatment session, the NeuroStar Advanced Therapy System records the treatment coordinates so they do not need to be re-identified in future treatments. Once a psychiatrist has established the patient's coordinates during the initial treatment session, a trained member of the office staff under the supervision of the psychiatrist may administer subsequent treatment sessions.
- ***Unique cloud-based practice management system.*** Our TrakStar practice management system captures all treatment relevant information, and the encrypted information can be downloaded to any NeuroStar Advanced Therapy System in a psychiatrist's network in order to make it convenient for a patient to receive care and increase scheduling flexibility. Patients do not need to be treated by the same NeuroStar Advanced Therapy System for each treatment session, and therefore psychiatrists who own multiple systems do not need to schedule patients to specific devices. A treating psychiatrist can download a patient's encrypted information from TrakStar and analyze it real-time from their laptop, mobile phone or tablet. TrakStar also manages the inventory of purchased treatment sessions, which can be replenished by an office administrator online at any time. The most recent version of TrakStar software that we released enables remote software updates, diagnostics and troubleshooting and performance monitoring to maintain industry-leading up time. TrakStar also captures and records daily system utilization, office productivity and patient outcomes.
- ***Comprehensive customer support and practice development resources***. We believe that we offer the most comprehensive practice support services among all TMS system providers to help our psychiatrist customers operationalize and grow their TMS service line. We provide our customers with marketing support, such as tools to increase awareness with referring psychiatrists, providing customizable advertising materials designed to educate patients within an existing practice and in the local community, and through our digital marketing campaign, which is comprised of paid search, display advertising, social media and public relations. Our clinical practice consultants focus their efforts on helping psychiatrist customers implement our six step Practice Success Program, which includes practice management planning, patient identification, staff training on practice roles, patient consult training, outcomes data analysis, practice marketing, public relations strategies and other support services. Our reimbursement managers help our psychiatrist customers to understand how they can navigate all issues regarding the insurance reimbursement process, including investigation of benefits, prior authorizations and claims documentation. Our field service engineers are responsible for maintenance, repairs and installation of upgrades of our systems, and typically provide a response within 24 hours of a service call. This responsiveness has allowed us to realize over 99% uptime of our installed base. Finally, we also offer our customers a 24/7 support hotline to respond to medical information inquiries and technical questions that arise.

We believe these characteristics address the limitations of antidepressant medications and competing TMS systems and as a result make our NeuroStar Advanced Therapy the most attractive non-invasive therapeutic alternative for our psychiatrist customers when they treat patients who suffer from MDD.

Our Strengths

We are focused on improving the quality of life for patients who suffer from psychiatric disorders, including MDD. Our executive team on average has 20 years of experience in healthcare, developing and commercializing innovative medical technology products. We believe that our focus and experience in treating patients with MDD, combined with the following strengths, will allow us to build our business and potentially expand our market opportunity:

- ***A market leader in TMS therapy.*** We believe we are the market leader in TMS therapy based on our U.S. installed base of 907 active NeuroStar Advanced Therapy Systems in approximately 707 psychiatrist offices as of December 31, 2018 and the estimated 62,900 patients treated with over 2.3 million treatment sessions through such date. We generated revenues of $52.8 million for the year ended December 31, 2018. We believe this commercial scale, combined with our investments in comprehensive practice support services and an experienced direct sales and customer support team provides us meaningful competitive advantages by creating significant barriers to entry to other TMS providers.
- ***Significant body of clinical data and key opinion leader support.*** The safety, efficacy and durability of NeuroStar Advanced Therapy is supported by what we believe is the largest clinical data set of any TMS system. Our therapy has been the subject of 11 clinical studies that have collectively enrolled more than 900 patients suffering from MDD. The results of these studies have been published in 23 articles in peer reviewed medical journals. We have also established strong relationships with key opinion leaders within the psychiatric community, who help us to educate psychiatrists from around the world on innovative treatment modalities such as TMS therapy. These key opinion leaders also help inform our clinical development programs.
- ***Proprietary technology with a broad IP portfolio.*** Our NeuroStar Advanced Therapy incorporates several key proprietary technologies that are designed to ensure the precise delivery and repeatability of our therapy in the clinical setting. As of December 31, 2018, we owned or licensed 34 issued or allowed U.S. patents, 49 issued or allowed foreign patents, eight pending U.S. patent applications, 11 pending foreign patent applications and one pending Patent Cooperation Treaty application. We believe this patent portfolio is substantially larger than that of any competing TMS companies. This portfolio covers key aspects of our technology, including contact sensing, MT Assist and our iron core magnet that allows high patient throughput.
- ***Extensive reimbursement coverage and experience.*** NeuroStar Advanced Therapy is a well-established treatment option for patients with MDD and is reimbursed by many commercial payors and Medicare contractors in the United States. We estimate that, over 65 major private insurers in the United States, including the top 25 largest private insurers, have adopted coverage policies for reimbursement of NeuroStar Advanced Therapy, representing approximately 205 million covered lives or about 95% of the total private payor covered lives in the United States. TMS treatment sessions using NeuroStar Advanced Therapy are also eligible for reimbursement for all Medicare regions, representing an additional 59 million covered lives in the United States in as of December 2018. In addition, our reimbursement team has significant experience working with our psychiatrist customers to help them navigate the reimbursement process. Our reimbursement team has assisted our customers to conduct more than 31,000 benefits investigations. We are also in the process of obtaining reimbursement coverage for NeuroStar Advanced Therapy in Japan, which we expect to receive in the second half of 2019. In April 2018 we received approval to submit reimbursement dossiers with the Japanese Ministry of Health, Labour and Welfare, or JMHLW.
- ***Potential to enhance psychiatrist practice economics.*** Based on our commercial data, we believe our psychiatrist customers can generate between approximately $7,500 to $10,000 of revenues per patient for a standard course of treatment using the NeuroStar Advanced Therapy System, and can recoup their capital investment in our system by treating approximately 12 patients, assuming these patients receive reimbursement from Medicare or commercial insurance at levels that are similar to what our customers have observed for existing and prior patients. We believe that subsequent treatments using our system may significantly increase practice economics for our psychiatrist customers.

Our Strategy

Our goal is to maintain and extend our leadership position in TMS therapy for patients with psychiatric disorders. The key elements of our strategy include:

- ***Improve customer targeting and expand our direct sales and customer support team to accelerate growth.*** To capture new psychiatrist customers, we plan to expand our specialized, direct sales organization that targets MDD treating psychiatric practices that accept reimbursement from private insurance and Medicare. Symphony Health estimates that there are approximately 26,300 group and solo practice sites in the United States with psychiatrists that prescribe antidepressant medications. Our direct sales force primarily targets 15,100 psychiatrists at 3,600 high-decile psychiatric practices that we estimate, based on data from Symphony Health and our own internal estimates, treat approximately 2.5 million patients, representing 33% of the total MDD patients in the United States who meet our labeled indication and are insured. We estimate that approximately 1.2 million of these patients have failed prior antidepressant medication attempts in the current MDD episode and are covered by insurance that will provide reimbursement based on this medical status, resulting in a targeted total addressable market of approximately $3.0 billion. After nearly doubling the number of our business development managers in the last twelve months, we intend to continue to expand our team of 46 business development managers and 7 inside sales representatives that are responsible for driving new customer acquisitions. To reach our target practices, we also plan to expand our advertising efforts, both online and through more traditional approaches, such as targeting leading psychiatric journals, practice outreach and education through monthly webcasts, attendance at key psychiatric trade shows and sponsoring clinical symposiums and product theaters.
- ***Increase utilization of our new and existing installed base of NeuroStar Advanced Therapy Systems.*** We plan to expand our sales and customer support team to increase the number of patients treated by our existing installed base of 907 active NeuroStar Advanced Therapy Systems in the United States and any additional systems that we sell in the future. We intend to hire additional clinical training consultants to our existing team of eight who will focus on the ongoing training of our psychiatrist customers and their staff in order to allow our existing team of 30 clinical practice consultants to focus exclusively on helping increase patient utilization of NeuroStar Advanced Therapy in a practice. Our clinical practice consultants focus their efforts on helping psychiatrist customers implement our six step Practice Success Program. We intend to make further investments in marketing tools, such as our marketing portal, which consists of customizable practice development and advertisement materials all of which are designed to drive patient awareness within an existing practice and in the local community. We recently concluded a three-week national television advertising campaign designed to increase patient awareness of NeuroStar Advanced Therapy. We also plan to invest further in our direct to consumer marketing programs, primarily through digital marketing, which is comprised of paid search, display advertising, social media and public relations to our psychiatrist customers.
- ***Expand our international market opportunities.*** We primarily sell our products within the United States and also sell our products through distributors in countries where we have received regulatory approval, including Japan, Saudi Arabia, The United Arab Emirates, Singapore, and the Republic of Korea. We plan to primarily focus our commercial efforts outside of the United States on Japan. We plan to work with Teijin to obtain reimbursement approval for the NeuroStar Advanced Therapy System in the second half of 2019 and to provide sales, marketing and clinical support to ensure our commercial success. We will continue to opportunistically evaluate additional markets outside the United States and Japan for commercial expansion.
- ***Pursue enhancements of our NeuroStar Advanced Therapy System and pipeline development for additional indications.*** We plan to continue our research and development efforts to enhance the hardware and software components of our NeuroStar Advanced Therapy System for the treatment of MDD and other psychiatric disorders. We also plan to evaluate the use of enhancements to our NeuroStar Advanced Therapy System to treat other psychiatric disorders, which may include bipolar depression and post-traumatic stress disorder, or PTSD.

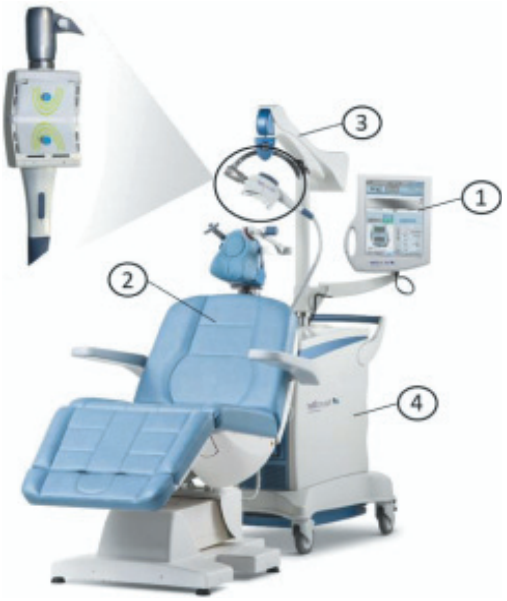
The NeuroStar Advanced Therapy System

Product

Our NeuroStar Advanced Therapy System is comprised of the NeuroStar Mobile Console, Patient Positioning System, NeuroStar Treatment Coil and TrakStar practice management system. NeuroStar Treatment Sessions and SenStar Treatment Links, which we refer to as treatment sessions, represent the consumable portion of the NeuroStar Advanced Therapy Treatment System.

NeuroStar Mobile Console and Patient Positioning System

Our NeuroStar Mobile Console and Patient Positioning System are comprised of the following components:



1. ***LCD touch screen and graphical user interface***. Our LCD touch screen and graphical user interface provide the operator clear visual directions for sequencing the TMS treatment. User confirmation is required on critical steps to ensure accuracy.

2. ***Patient Positioning System***. The patented patient positioning system includes an electromechanically controlled chair to recline the patient during treatment and a three-dimensional positioning device that uses laser alignment and six calibrated coordinates to accurately position the patient's head during treatment.

3. ***Gantry Arm***. The gantry arm mechanically counterbalances the NeuroStar Treatment Coil and allows the operator to consistently move and place it into position. Once in position, electromechanical brakes stabilize the NeuroStar Treatment Coil and gantry arm.

4. ***Mobile Console.*** The mobile console houses the embedded computer and power electronics responsible for generating the prescribed pulse sequence.

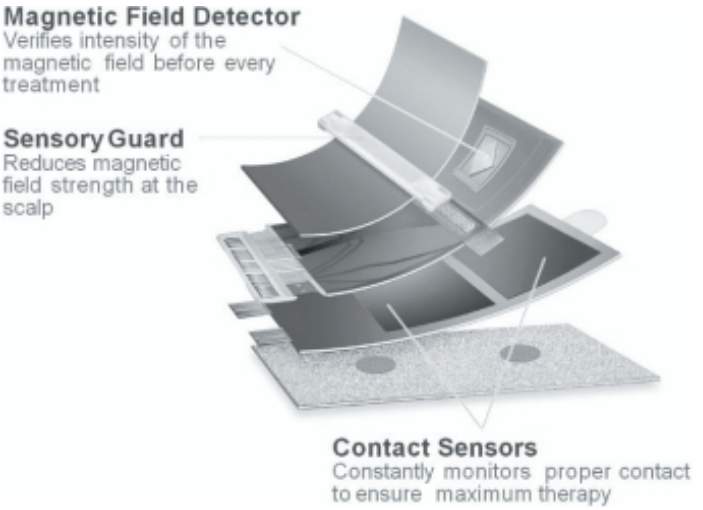
NeuroStar Treatment Coil

Our proprietary NeuroStar Treatment Coil produces the magnetic field that induces the electric current at the prescribed treatment site. The iron core in our NeuroStar Treatment Coil provides efficient energy conversion and management of the magnetic field. This allows our NeuroStar Treatment Coil to function at higher operating power and lower temperatures. Our NeuroStar Treatment Coil assembly includes a small fan and sensor to assist in cooling, and temperature tracking, and ensure patient comfort and safety. This temperature management feature allows for short intervals between treatment sessions. The coil face is set at a 140-degree angle to conform with the patient's head to ensure contact across the magnet face.

SenStar

SenStar is a thin, flexible electronic circuit, as shown in the figure below, that functions in both the treatment delivery and procedure fee management for our NeuroStar Advanced Therapy System. Embedded in each SenStar is a magnetic field detector. At the start of each treatment, the NeuroStar Advanced Therapy System performs a self-test that includes verifying the magnetic field is operating within the specified limits. Each SenStar also includes a sensory guard to reduce topical irritation and improve patient comfort at the skin-coil interface.

SenStars also contain a patented contact sensor that allows the NeuroStar Advanced Therapy System to monitor and provide real-time visual feedback to the operator that the NeuroStar Treatment Coil is in proper contact with the patient's head. The system tracks any pulses lost during treatment and will highlight lost pulses on the graphical user interface. At the end of treatment, the system allows the operator to administer any missed pulses to complete the full prescribed dose.



We sell two versions of the SenStar: the SenStar Treatment Link and the SenStar Connect. *SenStar Connect* is a multi-use device for the U.S. market. To activate a treatment session, a provider needs to purchase an encrypted activation code to enable the SenStar Connect to deliver one treatment session. NeuroStar Treatment Sessions are purchasable online 24 hours a day, any day of the year. The treatment inventory is electronically managed between the NeuroStar Advanced Therapy System and TrakStar systems using digital encryption technology. *SenStar Treatment Link* is a single use consumable. SenStar treatment links are used outside the United States and enable one treatment session. Each is programmed for the country of use.

TrakStar Practice Management System

The TrakStar patient data management system component is a cloud or local application that interfaces with the NeuroStar Advanced Therapy Systems. TrakStar maintains patient information, prescription, treatment and medication history, positioning coordinates, depression scores and psychiatrist notes.

TrakStar automatically synchronizes patient data on all NeuroStar Advanced Therapy Systems on the network. Thus the information to treat a patient is available on every system in every office within a practice. After each treatment is completed, the data is automatically uploaded to TrakStar. This seamless data integration simplifies record management and office workflow. TrakStar supports multiple reports including patient treatment history, patient depression score trending, practice outcomes and system utilization.

TrakStar cloud allows the psychiatrist to see status of other NeuroStar Advanced Therapy Systems in real-time, and access patient data anywhere and anytime using an internet browser. TrakStar cloud is hosted in Microsoft Azure and employs multiple levels of security. Patient data is encrypted both in transit and at rest. Third-party experts successfully completed penetration testing and an overall business security assessment and certified us as compliant with National Institute of Standards and Technology, or NIST, and Health Information Technology for Economic and Clinical Health, or HITECH, standards. We also monitor traffic for cybersecurity threats on an ongoing basis.

The NeuroStar Advanced Therapy Process

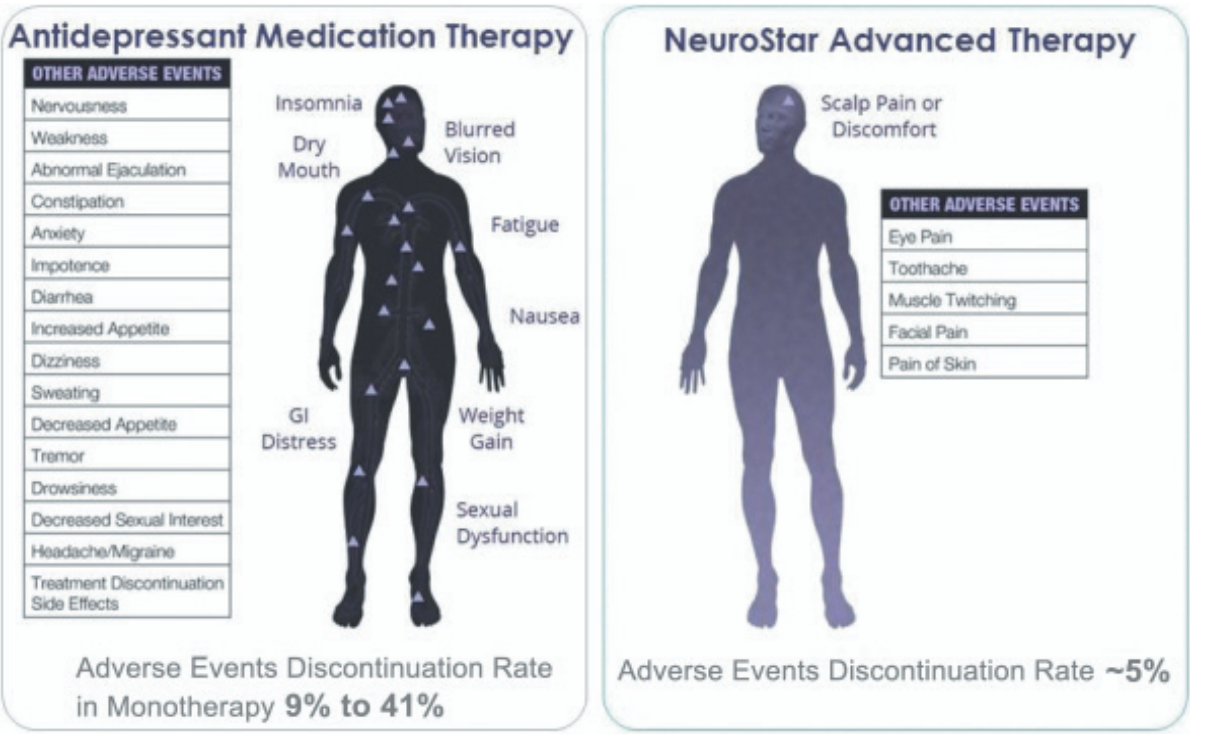
The Treatment Procedure

NeuroStar Advanced Therapy is an in-office treatment that has been cleared to be performed in as little as 19 minutes per session (but may take up to 39 minutes due to patient sensitivity or at the discretion of the treating psychiatrist) and is performed while the patient is awake, alert and seated and reclined comfortably in the treatment chair. A course of treatment consists of sessions administered five days a week for up to six weeks. During the first treatment session, two essential steps are performed. First, the patient's cortex is mapped with the NeuroStar Treatment Coil to identify the area of the brain controlling the thumb. Once the specific location on the motor cortex is found, the second step involves the use of a proprietary software algorithm, which assists the psychiatrist in estimating the physiologically appropriate magnetic field intensity for each treatment session based on the intensity needed to stimulate movement in the thumb. After these two steps are performed, the location of the motor cortex then also serves as a reference point to enable the psychiatrist to properly position the NeuroStar Treatment Coil over the left prefrontal cortical surface, resting the coil lightly in contact with the patient's scalp. Accuracy of positioning of the treatment coil for pulse delivery is assured by use of the NeuroStar Advanced Therapy System's three-dimensional positioning device. Once the coil is properly positioned, the device delivers NeuroStar Advanced Therapy using a highly targeted pulsed magnetic field to stimulate cortical neurons. Our therapy provides targeted stimulation of the prefrontal cortex and engages the neuronal circuitry connected to this region and known to be involved in the regulation of mood.

During treatment, accurate positioning of our NeuroStar Treatment Coil is maintained by use of a proprietary contact sensing and navigation system, which helps to ensure precise targeting of the treatment and assurance of accurate therapeutic dosing for each session. The patient typically hears a clicking sound during coil operation and feels a tapping sensation on the head for the duration of the session. Over the course of each treatment, the patient receives 3,000 pulses. Real-time feedback ensures the patient receives a full dose with safe and effective care. When the session is completed, the psychiatrist removes the coil and the patient is able to immediately resume normal activities.

The Patient Experience

Our clinical studies indicate that most patients find the NeuroStar Advanced Therapy easy to tolerate when contrasted with alternative MDD treatments. After completion of a treatment session, a patient may immediately resume his or her normal activities, including work and exercise. NeuroStar Advanced Therapy patients generally do not experience the systemic side effects associated with drug therapy. The most typical side effect after treatment with NeuroStar Advanced Therapy, as shown in the figure below, is pain or discomfort near the treatment area, which is generally temporary and typically self-resolves within one week. In our sham-controlled clinical trials, approximately 5% of patients discontinued treatment due to adverse events.



Potential Indications for Use and Research and Development

We selectively invest in research and development for the use of the NeuroStar Advanced Therapy System in psychiatric disorders. Throughout our history, we have provided material support to 50 investigator-initiated trials of such prospective additional indications. We are currently considering a number of potential future indications for the use of the NeuroStar Advanced Therapy System, including, but not limited to, those described below.

Bipolar Depression

Bipolar depression is a psychiatric disorder characterized by a recurrent episodes of mania and depression. The depressed phase of bipolar disorder is considered to be a form of treatment resistant depression and is the most difficult to treat phase of bipolar disorder. The depressive episode diagnostic criteria in bipolar depression are identical to our current MDD indication. Although bipolar depression represents a smaller market than MDD, this disease state has few treatment options available and many patients experience suboptimal outcomes. Current treatment options for patients with bipolar depression include the use of mood stabilizers, including lithium carbonate, anticonvulsant, and second-generation antipsychotics. While these treatments are effective in managing the recurrent mania, there are few effective treatments for the depressed phase of the illness. For example, antidepressant medications may lead to instability in resolution of the manic episodes if administered alone, and the use of second-generation antipsychotic medications can be associated with undesirable long-term medical side effects, including weight gain or the development of metabolic syndrome. Based on early research, we are evaluating whether treatment with our NeuroStar Advanced Therapy System could be beneficial to these patients. If we were to pursue an additional indication in bipolar depression, we would need to conduct additional clinical trials, file an investigational device exemption and clinical trial protocols with the FDA, submit a 510(k) pre-market notification and receive clearance prior to commercialization.

Post-Traumatic Stress Disorder

Post-traumatic stress disorder, or PTSD, is a psychiatric disorder that develops in some people who have experienced an overwhelming traumatic event, such as witnessing death in a military or civilian setting, or as a result of severe physical abuse such as assault or rape. This exposure to a traumatic stressor can lead to a later unwanted re-experiencing of symptoms, avoidance behavior, alteration in cognition and mood and states of increased physiological arousal. Treatment options for PTSD include psychotherapy and SSRI antidepressant medications. We believe NeuroStar Advanced Therapy may represent a potential new treatment option for PTSD patients. If we were to pursue an additional indication in PTSD, we would need to conduct additional clinical trials, file an investigational device exemption and clinical trial protocols with the FDA, submit a 510(k) pre-market notification and receive clearance prior to commercialization.

Adolescent MDD

We completed patient enrollment with 112 adolescent MDD patients in a prospective, 13-center, randomized, sham-controlled, double-blind pivotal clinical trial with three phases that mirrors the design of our original adult, randomized, controlled trial. The purpose of this study is to evaluate the acute and long-term safety and efficacy of NeuroStar Advanced Therapy in treating adolescents with MDD. The trial utilizes a double-blind control design to minimize variability and allow for blinded assessment of the safety and efficacy of NeuroStar Advanced Therapy, using an active NeuroStar Treatment Coil compared to a system utilizing a sham NeuroStar Treatment Coil. Patients were randomly allocated in a one-to-one ratio to either active NeuroStar Treatment Coil or sham NeuroStar Treatment Coil. At the time of enrollment, patients were antidepressant-free for at least one week and up to four weeks, depending on medication washout period.

The first phase is designed to evaluate the antidepressant effects of active NeuroStar Advanced Therapy compared with sham treatment when administered five times per week for a six week acute course of therapy. The primary endpoint of this phase is the difference between active and sham arms using the 24-Item Hamilton Depression Rating Scale, or HAMD24, total score change from baseline score over the six week acute phase. Safety will be assessed at every treatment visit by recording adverse events. We are currently completing the analysis of all phases of the study, including the randomized controlled trial, open label extension and six-month follow-up study. Based on a preliminary analysis conducted in the second quarter of 2018, the primary endpoint in the first phase of the trial was not met. Although we cannot directly attribute clinical trial outcomes from other studies to our own clinical trials, we believe several clinical trials for antidepressant medications failed to meet the primary efficacy endpoint in their studies for MDD in adolescents and children. These include duloxetine, venlafaxine and, most recently, desvenlafaxine. To date, the data safety monitoring board has not identified any serious safety issues in the study population, including suicidality and seizure.

Consistent with our clinical trial protocols, patients who have completed the first phase were eligible to participate in the second phase of our clinical trial, which is a separate, open-label extension study. The second phase trial is designed to evaluate the benefit of active treatment administered five times per week for a six-week acute course of NeuroStar Advanced Therapy in patients who received active or sham treatment and did not receive protocol-defined clinical benefit in the first phase. Patients remain antidepressant medication free during the second phase. This trial will provide descriptive data on patients who are switched from sham to active treatments or receive a longer course of active treatment up to 12 weeks.

Patients who met the criteria for at least partial response in either the first or second phases of the trial were eligible to be followed in a third phase that will be a separate six-month follow up phase. Patients entering the third phase first undergo a three-week transition during which they will be gradually tapered off NeuroStar Advanced Therapy. Patients who experience symptom worsening during this phase of the study may receive reintroduction of NeuroStar Advanced Therapy. Patients remain antidepressant medication free during the third phase of the trial. The purpose of this phase is to provide descriptive data on the six-month follow-up period and any retreatments received by patients.

Although we believe we are unlikely to seek a label expansion for the NeuroStar Advanced Therapy System for the treatment of adolescent MDD, we plan to evaluate next steps with respect to our clinical development efforts for this indication following the completion of the data analysis. We do not expect that the results from the clinical trial will be sufficient to obtain approval of our system for this indication. Nevertheless, we do not believe these clinical trial results or the failure to obtain approval of our NeuroStar Advanced Therapy System for the treatment of adolescents with MDD will have a material impact on our current or future business.

Research and Development and Clinical Operations

Continued innovation through research and development is critical to our future success as a leader in improving the quality of life for patients who suffer from psychiatric disorders. Our research and development activity is performed with a mix of internal and third party contract resources. As of December 31, 2018, our research and development and clinical operations team consisted of 33 employees with expertise in electronic, mechanical or electrical design, software, biomedical engineering, neuroscience and clinical trial design and management. Our research and development expenses, including spending on our clinical trials and development efforts, totaled $8.2 million and $7.9 million for the years ended December 31, 2018 and 2017, respectively. Our current research and development efforts are focused primarily on platform extensions for our NeuroStar Advanced Therapy System and a series of enhancements to our TrakStar cloud-based software application. Our clinical development efforts are focused on further expanding the use of our products in additional indications. We coordinate our development efforts with our intellectual property strategies in order to enhance our ability to obtain patent and other intellectual property protection.

Clinical Results and Studies

Overview of Clinical Trial Evidence for the Safety and Efficacy of NeuroStar Advanced Therapy

Clinical evidence supporting the safety and efficacy of NeuroStar Advanced Therapy has been published in 23 peer reviewed medical journals, involving an aggregate of over 900 adult patients and more than 60 investigators. We have sponsored the largest prospective, multisite, randomized, sham-controlled trial ever conducted of a TMS device, enrolling 325 patients with treatment resistant MDD at 23 U.S. and international study sites. Results from this trial served as the basis of our initial FDA 510(k) clearance of the NeuroStar Advanced Therapy System in 2008. The clinical data from this trial were reported in *Biological Psychiatry* in 2007. A second, industry-independent prospective, multisite, randomized, sham-controlled trial, funded by the NIMH using the NeuroStar Advanced Therapy System, enrolled 199 patients with treatment resistant MDD across four major academic medical centers in the United States. The clinical data from this trial were submitted to the FDA in 2014, leading to an expanded labeling for our NeuroStar Advanced Therapy System for an indication of use in adult patients who have failed to benefit from one or more prior antidepressant medications in the current episode of MDD. This data was published in 2010 in *Archives of General Psychiatry*, now published as *JAMA Psychiatry*. We sponsored the largest, post-market naturalistic outcomes study of the use of the NeuroStar Advanced Therapy System in routine clinical practice. This study enrolled 307 patients with treatment resistant MDD seeking care at 42 U.S. study sites. Patients

in this study were assessed at the beginning and end of their prescribed acute treatment course, and 257 of these patients agreed to be followed for a period of 12 months to characterize the durability of the long-term outcome in clinical practice. Results of this study were published in the *Journal of Clinical Psychiatry* in 2012 and in *CNS Spectrums* in 2014.

Efficacy endpoints reported in these clinical trials used validated and well-accepted measures of symptomatic benefit to characterize antidepressant medication treatment in clinical trials and included those measures listed in Figure 1. An accepted goal of treatment with an antidepressant is the definitive resolution of the symptoms, which is defined as remission. Remission is defined using a validated, clinician-administered rating scale such as the 17 or 24-item versions of HAMD or the Montgomery-Asberg Depression Rating Scale, or MADRS. Patients who achieve an endpoint score below 8 points on the 17-item HAMD, below 11 points on the 24-item HAMD or below 10 points on the MADRS, are considered to have reached remission of illness. A clinically global, psychiatrist rated scale, such as the Clinical Global Impressions-Severity of Illness, or CGI-S, scale can also grade remission if a patient reaches an end of treatment score of one or two on that scale.

Depression Assessment Scale	Response Criteria	Remission Criteria
MADRS	50% change from baseline	<10
HAMD17	50% change from baseline	<8
HAMD24	50% change from baseline	<11
CGI-S	≤3 score	≤2 score
PHQ-9	<10	<5

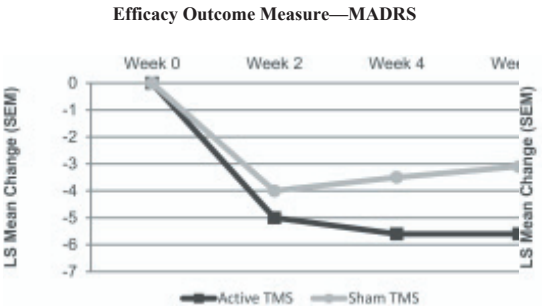
Figure 1. Validated measures of symptomatic benefit to characterize antidepressant treatment effect.

Patient-rated outcomes are also used to verify symptom improvement. In the NeuroStar Advanced Therapy clinical trial data, the PHQ-9 scale was used, with a score below five indicating remission of illness. Significant clinical improvement that does not constitute remission is termed response, and is graded by a 50% or greater reduction of score from baseline on the HAMD and MADRS scales, and a score of one, two or three on the CGI-S or a score below 10 on the PHQ-9. Outcomes are also reported for each of these rating scales as a mean change in total score from baseline, called continuous outcome measures. Standardized effect size measures are used to assess the statistical magnitude of treatment benefit (active versus control) in a clinical trial, and because they are normalized measures, allow the comparison of treatment benefit across different clinical studies. Standardized effect sizes of greater than 0.50 are considered large, between 0.30 and 0.50 are considered medium and below 0.30 are considered small.

Randomized Controlled Trial

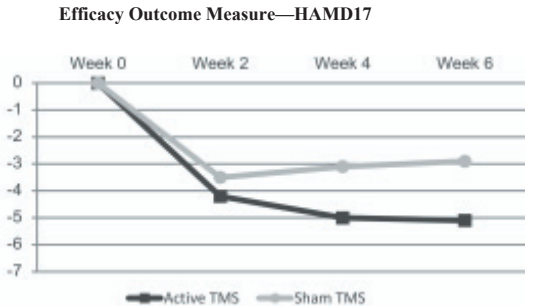
Our U.S. registration trial was a prospective, multisite, randomized, sham-controlled trial at 23 U.S. and international study sites that enrolled 325 patients from January 2004 through August 2005 to evaluate the safety and efficacy of NeuroStar Advanced Therapy in patients who met DSM-IV criteria for MDD, with a moderate level of treatment resistance based on rigorous evidence of failure of benefit from prior treatment with a research-grade exposure to at least one and up to four complete antidepressant medication trials. Patients were randomized to either active NeuroStar Advanced Therapy or sham-controlled TMS. The primary efficacy endpoint of this trial was a statistically significant, or $P<0.05$, average baseline to endpoint change in MADRS score for patients in the active NeuroStar Advanced Therapy treatment group when compared to the change in MADRS score for the sham-controlled TMS patient treatment group using the last visit MADRS score through week four of the acute phase. The trial design consisted of three phases: a one week, no-treatment lead-in phase; a six week acute treatment phase of daily TMS sessions scheduled in a 5-day sequence, for a maximum of 30 sessions during which NeuroStar Advanced Therapy was given in the active treatment arm as a monotherapy in medication-free patients, and a three week taper phase during which time all patients were begun on an open-label, single antidepressant medication and followed for six months to examine the durability of the acute effect of TMS.

Results for the overall trial population demonstrated clinically meaningful improvement on the primary efficacy outcome measure, baseline to endpoint change on the MADRS at four weeks, as shown in Figure 2 (MADRS, P=0.057, standardized effect size = 0.38), although the primary efficacy endpoint of the trial was not achieved. Additionally, several secondary outcome measures demonstrated statistically and clinically significant benefit for active NeuroStar Advanced Therapy compared with sham-controlled TMS. Among these secondary outcome measures were a superior outcome on the HAMD, with both the 17 and 24-item versions showing baseline to endpoint change for active NeuroStar Advanced Therapy at four weeks, as shown in Figure 3 (17-Item change: P=0.006, standardized effect size = 0.55) and as shown in Figure 4 (24-Item change: P=0.012, standardized effect size = 0.48). These outcomes were sustained at the secondary efficacy time point at week six, with a significant advantage in favor of active NeuroStar Advanced Therapy.



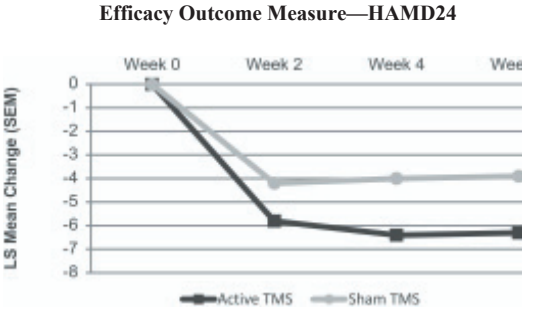
P = 0.057 for week 4 contrast

Figure 2. MADRS total score change from baseline during the acute treatment phase.



P = 0.006 for week 4 contrast

Figure 3. HAMD17 total score change from baseline during the acute treatment phase.



P = 0.012 for week 4 contrast

Figure 4. HAMD24 total score change from baseline during the acute treatment phase.

We also observed a statistically significant benefit in categorical outcomes of response and remission rates on the MADRS, as shown in Figure 5, the HAMD17, as shown in Figure 6, and the HAMD24, as shown in Figure 7. In this trial, NeuroStar Advanced Therapy was well tolerated and safe. The dropout rate for any reason was low and similar in the active therapy (7.7%) and sham-controlled TMS (8.2%) treatment groups at four weeks, and discontinuation specifically because of side effects was similar in the active therapy (4.5%) and sham-controlled TMS (3.4%) treatment groups. The trial demonstrated that NeuroStar Advanced Therapy administered over a period of six weeks was effective in treating MDD and with a favorable tolerability profile.

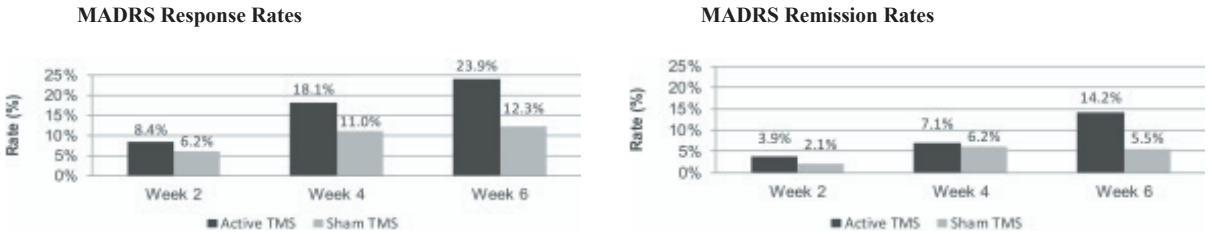


Figure 5. MADRS categorical outcome assessments during the acute treatment phase.

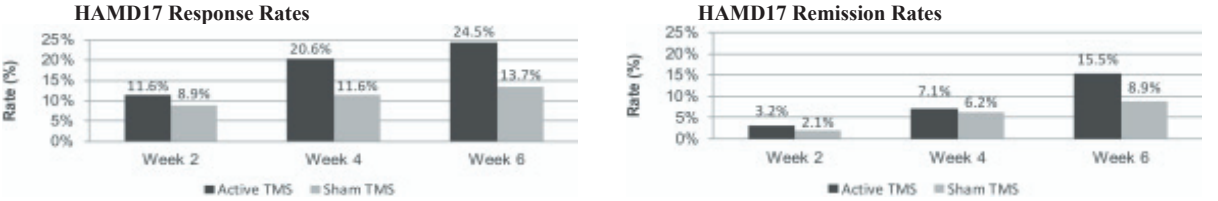


Figure 6. HAMD17 categorical outcome assessments during the acute treatment phase.

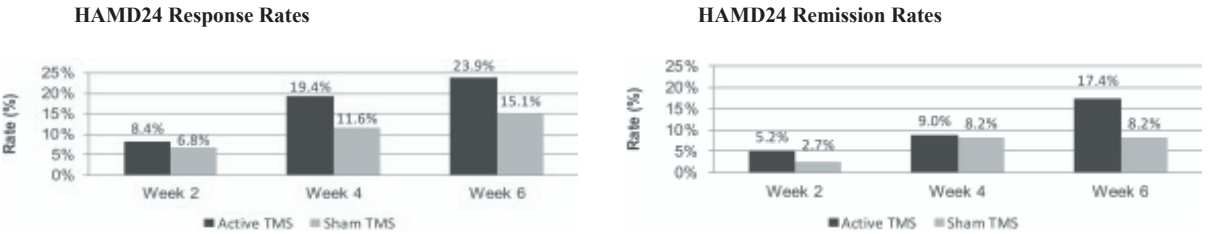


Figure 7. HAMD24 categorical outcome assessments during the acute treatment phase.

Our NeuroStar Advanced Therapy System received marketing authorization from the FDA in 2008 based on the results of this initial registration trial. The FDA review determined that statistical significance for the primary outcome measure was obtained for the patients in that portion of the study population (N=164) who had failed to benefit from one prior research grade antidepressant medication treatment trial (MADRS, P=0.0006). The original FDA-authorized indication for use in MDD based on this trial was for adult patients who failed to benefit from one prior antidepressant medication in the current episode.

NIMH-Sponsored Randomized Controlled Trial—the Optimization of TMS, or OPT-TMS Study

The U.S. NIMH sponsored a prospective, multisite, randomized, sham-controlled trial at four U.S. study sites that enrolled 199 patients from October 2004 through March 2009 to evaluate the safety and efficacy of NeuroStar Advanced Therapy in patients who met DSM-IV criteria for MDD, with at least a moderate level of treatment resistance to at least one and up to four complete antidepressant medication trials. Patients were randomly allocated 1:1 to either active NeuroStar Advanced Therapy or sham-controlled TMS. The primary efficacy endpoint of this trial was remission, measured using the 24-item HAMD scale. The trial design consisted of three phases: a two week no treatment lead-in phase, a three-week fixed-treatment phase of daily TMS sessions scheduled in a 5-day sequence, for a maximum of 15 sessions during which NeuroStar Advanced Therapy was given in the active treatment arm as a monotherapy in antidepressant medication-free patients and a variable, three-week treatment continuation for clinical improvers.

Results from the trial demonstrated that for the entire treatment resistant patient population, for the primary analysis of remission, there was a statistically significant effect of daily NeuroStar Advanced Therapy as monotherapy (odds ratio, 4.2; 95% confidence interval, 1.32–13.24; P=0.02). There were 18 remitters (N=13 or 14.1% in the active therapy and N=5 or 5.1% in the sham-controlled TMS treatment groups). NeuroStar Advanced Therapy was well tolerated, with no difference in adverse events between the active therapy and sham-controlled TMS treatment groups. Discontinuation specifically because of side effects was 5.4% in the active therapy treatment group. These results indicate that the likelihood of achieving remission using the NeuroStar Advanced Therapy System increased by more than four times when compared to sham-control TMS, which is clinically meaningful.

The results of this clinical trial became available after we received our original marketing authorization in 2008. We submitted the clinical data from this trial to the FDA and received a new FDA 510(k) clearance in 2014 that expanded our original indication to adult patients who have failed to benefit from one or more prior antidepressant medications in the current episode of MDD.

Acute Efficacy and Long-Term Durability in Real-World Clinical Settings Study

The acute efficacy of treatment with the NeuroStar Advanced Therapy System was evaluated in a prospective, multisite, naturalistic, observational trial at 42 U.S. study sites that enrolled 307 patients from 2010 through 2012 to evaluate the effectiveness of NeuroStar Advanced Therapy in real-world clinical practice settings in patients who met DSM-IV criteria for MDD. The mean patient age was 48.6 years and the mean number of medication trials in the current episode that were of adequate dose and duration was 2.5, indicating a treatment resistant population of patients with MDD. Outcome assessments were obtained at baseline, week two, at the point of maximal acute treatment benefit and at week six in cases where the acute course of TMS therapy extended beyond six weeks. This naturalistic study design permitted patients to continue concurrent antidepressant medications during treatment with NeuroStar Advanced Therapy if they were directed to do so by the prescribing psychiatrist. The primary efficacy endpoint of this trial was the change from baseline to endpoint on the CGI-S. Secondary outcome measures included baseline to endpoint change on the PHQ-9.

The average number of NeuroStar Advanced Therapy treatment sessions across the acute phase was 28.3 (standard deviation: 10.1). Results from the trial demonstrated that there was a statistically significant mean change in depression severity from baseline to end of treatment on the CGI-S (-1.9 ± 1.4, P<0.0001) and for the PHQ-9 (-8.7 ± 7.2, P<0.0001). Clinician-assessed response rate for CGI-S was 58.0% and the remission rate was 37.1%, as shown in Figure 8. Patient-reported outcomes measured using the PHQ-9 was 56.4% for response, and 28.7% for remission, as shown in Figure 9. Notably, the outcomes were consistent across patients with both low and high grades of treatment resistance. Patients with low treatment resistance had been treated without success with one antidepressant medication in their current illness episode and patients with high grades of treatment resistance had been treated with two or more antidepressants without benefit. These results further support NeuroStar Advanced Therapy as an effective therapy for those who have failed to benefit from antidepressant medication.

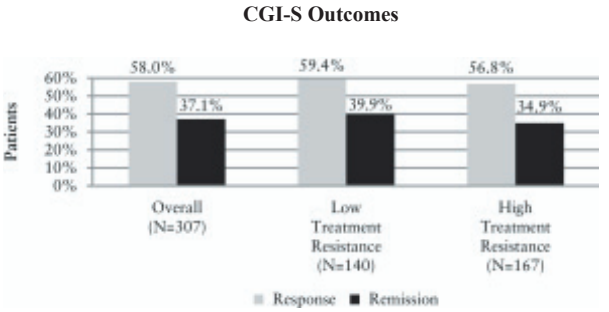


Figure 8. Categorical CGI-S response and remission outcomes—stratified by baseline level of treatment resistance (low versus high).

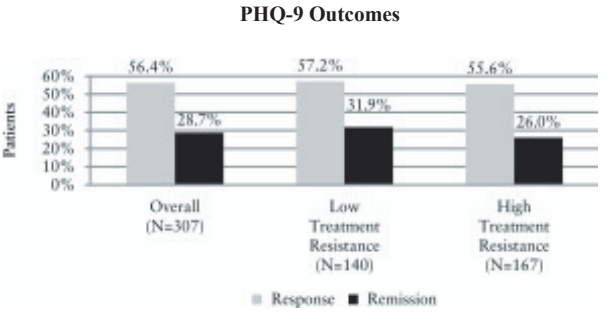


Figure 9. Categorical PHQ-9 response and remission outcomes—stratified by baseline level of treatment resistance (low vs. high).

The long-term durability of the clinical effect resulting from treatment with NeuroStar Advanced Therapy was also studied as part of this report over 12 months of follow-up. In the long-term phase, 257 patients who had participated in the acute treatment outcomes entered into long-term follow-up where their treatment outcomes were monitored over the next twelve months. This trial was conducted between March 2010 and August 2012. Clinical assessments using the CGI-S and the PHQ-9 were obtained at three, six, nine, and 12 months. A total of 205 patients provided data across the entire12-month trial period. Concurrent medication use and NeuroStar Advanced Therapy reintroduction were allowed for recurrent symptoms and were recorded during the long-term follow-up period.

Compared with baseline scores obtained prior to acute TMS treatment, the statistically significant reduction in mean standard deviation CGI-S and PHQ-9 total scores at the end of acute TMS treatment were sustained throughout the 12-month follow-up period (end of 12 months follow-up: CGI-S 2.8 and PHQ-9 8.6, both P<0.0001). The proportion of patients who achieved remission at the conclusion of acute TMS treatment remained similar to that observed following the conclusion of the long-term follow-up phase: CGI-S (total score 1 or 2), 41.2% (end of acute) and 45.1% (end of long-term), as shown in Figure 10; PHQ-9 (total score < 5), 31.1% (end of acute) and 37.0% (end of long-term). These results demonstrate that NeuroStar Advanced Therapy provides a sustained durability of effect over 12 months of follow-up in a patient population receiving minimal to no benefit with antidepressant medications.

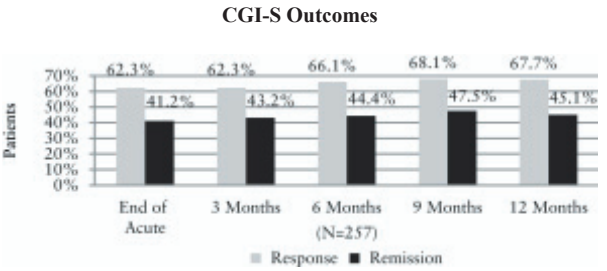


Figure 10. Categorical CGI-S response and remission outcomes during long-term follow-up phase.

Our Outcome Registry

In 2016, we launched our voluntary outcome registry to measure and record the outcomes of MDD patients treated with our NeuroStar Advanced Therapy System. Since inception, we have recorded results for over 1,500 patients at approximately 50 treatment facilities. For the patients treated with our products who completed self-evaluations, such as PHQ-9, and have had their results submitted to the registry, our data indicates remission and response rates of 32% and 62%, respectively. For the more than 600 patients treated with our products who have been evaluated using an observer-dependent interview, such as CGI-S, and have had their results submitted to the registry, our data indicates remission and response rates of 53% and 75%, respectively. Although we believe that these results demonstrate the potential of our products to treat patients with MDD, our registry is voluntary and only a portion of psychiatrists using our products have reported their outcomes. Therefore, these results may not be representative of response and remission rates for all MDD patients treated with our products.

Sales and Customer Support Team and Psychiatrist Training

As of December 31, 2018, our sales and customer support team consisted of 133 employees working collaboratively across the following departments: 96 sales, 6 marketing, 22 field service and customer support, and 9 reimbursement. Additionally, our clinical team consisted of 7 employees.

Sales and Marketing—United States

Our commercialization team selectively markets and sells the NeuroStar Advanced Therapy System and recurring treatment sessions in the United States. Our primary focus is on selling to psychiatrists, with primary care physicians and pain management specialists representing a small percentage of our customer base. We target approximately 3,600 high-decile psychiatric practices, who we estimate, based on data from Symphony Health and our own internal estimates, treat approximately 33% of MDD patients who meet our labeled indication and are insured. We target these practices by the number of psychiatrists within their practices, the number of patients they treat and their acceptance of commercial insurance and Medicare. We believe that our psychiatrist targeting strategy makes for a well-defined customer base that is accessible by our direct sales organization.

We have structured our sales and customer support team with specialized roles to sell our NeuroStar Advanced Therapy Systems and recurring treatment sessions, while delivering customer service at each stage of the implementation process. Our business development managers are responsible for identifying key customer prospects, educating them on the value of NeuroStar Advanced Therapy System, gaining their commitment for capital placement and introducing our clinical practice consultants. Our clinical practice consultants enhance the operational experience for providers and drive implementation of the NeuroStar Advanced Therapy System into our customers' practices. We created the role of clinical training consultant to partner with our psychiatrist providers to conduct initial and ongoing on-site clinical training to ensure clinical and practice success.

Practice Management Support and Psychiatrist Training—United States

Our clinical practice consultants play a pivotal role in ensuring the success of our customers as they implement a new service line into their practice. In the early stages of implementation, they help the practice set goals, educate on the types of patients that can benefit from our therapy and assist in preparing the office work flow and staffing needs. As the office prepares to begin scheduling consults, the clinical practice consultants will train the office staff on how to talk with patients about TMS and how to use patient educational tools such as presentations, videos and starter kits. Once the practice begins treating patients, they will educate the psychiatrist on how to track clinical outcomes, interpret data and how to effectively convey results to existing and potential patients and referring physicians. Our clinical practice consultants also work with our customers to increase awareness with referring physicians and develop external marketing tactics. Our dedicated reimbursement managers help each practice navigate all issues regarding the reimbursement process including investigation of benefits, prior authorizations and claims documentation. This group has assisted our customers to conduct over 31,000 benefit investigations.

Psychiatrists and staff training on the NeuroStar Advanced Therapy System is a key to success within each practice. Our clinical training consultants take the burden of clinical training off our clinical practice consultants and provide a dedicated training resource to each customer. Clinical training consultants conduct at least a three-day, hands on training course that is scheduled after system installation at each practice and also provide ongoing advanced on-site clinical training.

Field Support—United States

Our field service engineers are responsible for maintenance, repairs and installation of upgrades. We provide a 24/7 support hotline to respond to medical information inquiries and technical questions that arise in all time zones. We pledge to have a field service engineer on-site within 24 hours of a service call. Because of the size and geographical coverage of our field service engineers and our standard 24-hour response time, NeuroStar Advanced Therapy Systems experience over 99% uptime, helping to ensure uninterrupted patient treatments.

International

We market our products in a few select markets outside the United States through independent distributors. In Japan, we have an exclusive distribution agreement with Teijin, for the commercialization of our products.

Distribution Agreement with Teijin Pharma Limited

In October 2017, we entered into a seven and a half year distribution agreement with Teijin Pharma Limited, or Teijin, for the exclusive distribution of our NeuroStar Advanced Therapy System to customers who will treat patients with MDD in Japan. Under the distribution agreement, Teijin is generally restricted from selling competing products in Japan. Our distribution agreement provides that we will have primary responsibility for obtaining reimbursement approval for use of NeuroStar Advanced Therapy System for the treatment of MDD in Japan, and Teijin will promote the sales of NeuroStar Advanced Therapy System for treatment of MDD in Japan. We have agreed to provide sales and technical support training to Teijin for our NeuroStar Advanced Therapy Systems.

Teijin is required to purchase minimum dollar values of NeuroStar Advanced Therapy Systems and treatment sessions from us following reimbursement approval by the JMHLW, TMS treatment for MDD (or, if such approval requires certified training on the NeuroStar Advanced Therapy System by a third party, then upon the first psychiatrist being issued his or her training certification). In April 2018, we were approved to submit reimbursement dossiers to the JMHLW.

In 2017, under our distribution agreement with Teijin, we received an upfront payment of $0.75 million and a milestone payment of $2.0 million following JMHLW's approval of marketing the NeuroStar Advanced Therapy System for the treatment of MDD in Japan. These upfront and milestone payments have been deferred and are being recognized as revenue over the seven and one half year term of the agreement. Teijin is required to pay us a milestone payment tied to JMHLW issuing reimbursement for use of our products for the treatment of MDD in Japan.

The distribution agreement is scheduled to expire on March 31, 2025, subject to earlier termination if we or Teijin breach the agreement, Teijin fails to maintain distributor-level permits and approvals, Teijin fails to purchase from us specified dollar values of its sales forecasts, reimbursement for treatment of MDD using the NeuroStar Advanced Therapy System is not obtained from JMHLW by specified dates or such reimbursement is below specified minimums, Teijin reasonably believes that it is not commercially reasonable to continue distributing the NeuroStar Advanced Therapy System in Japan or bankruptcy related events occur. The term of the distribution agreement will be automatically extended for two years unless either party gives the other party at least two years' prior written of notice of non-renewal, except that we cannot decline to renew the agreement if Teijin has purchased 100% of its sales forecasts over the term of the agreement.

Competition

Our currently marketed products are, and any future products we develop and commercialize will be, subject to intense competition. The industry in which we operate is subject to rapid change and is highly sensitive to the introduction of new products or other market activities of current or new industry participants. If we are not successful in convincing others of the merits of our products or educating them on the use of our products, they may not use our products or use them effectively and we may be unable to increase our sales. Key competitive factors affecting the commercial success of the NeuroStar Advanced Therapy System and any other product candidates we may develop are likely to be efficacy, safety and tolerability profile, reliability, convenience of administration, price, treatment times, other indications outside of MDD and reimbursement.

We have competitors that sell other forms of TMS therapy, including Brainsway, Magstim, MagVenture, CloudTMS and Nexstim, that compete directly with the NeuroStar Advanced Therapy System and have TMS therapy treatment times as short as 20, 37, three, 19 and 37 minutes, respectively. Competing TMS therapy companies have developed and may develop additional treatments that can be administered for shorter time periods or for indications outside of MDD, or may develop treatments that have improved efficacy when compared to our products or that require a less significant investment of resources from psychiatrists. We also face competition from pharmaceutical and other companies that develop products, such as antidepressant medications, for the treatment of psychiatric disorders. Our commercial opportunity could be reduced or eliminated if these competitors develop and commercialize antidepressant medications or other treatments that are safer, more convenient or more effective than the NeuroStar Advanced Therapy System. At any time, these and other potential market entrants may develop treatment alternatives that may render our products uncompetitive.

In addition, our competitors may have greater financial resources or more established distribution networks than we do, or may be acquired by enterprises that have more established distribution networks than we do. Our competitors may also develop and patent processes or products earlier than we can or obtain domestic or international regulatory clearances or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar products. We also compete with our competitors in acquiring technologies and technology licenses complementary to our products or advantageous to our business. In addition, we compete with our competitors to engage the services of independent distributors outside the United States, both those presently working with us and those with whom we hope to work as we expand.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our products and services, to operate without infringing the proprietary rights of others, and to prevent others from infringing our proprietary rights. We rely on a combination of patents, trade secrets, copyrights and trademarks, as well as contractual protections, to establish and protect our intellectual property rights. We seek to protect our proprietary position by, among other things, filing patent applications in the United States and internationally. Our patent estate includes patents and applications with claims directed to our NeuroStar Advanced Therapy Systems and broader claims for potential future products and developments. On a worldwide basis, as of December 31, 2018, our patent estate included over 100 issued or allowed patents and pending patent applications for our products and novel design methods, manufacturing process, novel TMS devices and systems and future combination products that are mainly designed to treat psychiatric conditions or perform diagnostic procedures. In the United States, as of December 31, 2018, we owned or licensed 34 issued or allowed patents and eight patent applications filed that are directed to our TMS technology. Outside the United States, as of December 31, 2018, we owned or licensed 49 issued or allowed patents, 11 pending patent applications and one pending Patent Cooperation Treaty application.

These U.S. issued patents are expected to remain in effect until between 2019 and 2035. Our core patents in the United States will not expire before 2024. Our non-U.S. patents are expected to remain in effect until between 2024 and 2035. Our worldwide intellectual property portfolio includes multiple pending patent applications relating to methods and apparatuses for the treatment of psychiatric health conditions in Australia, Canada, the European Union, Japan and the United States. Our patents and patent applications mainly relate to iron core technology, including materials, manufacturing methods, geometries, applications, and open core technologies, TMS design patents, including coil position, motor threshold level determination, contact sensing, and articulation arm designs, patient comfort, TMS support technologies and pulse monitoring, and potential next generation technologies.

In some instances, we submit patent applications directly with the USPTO as provisional patent applications. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in an application. We file U.S. non-provisional applications and Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the 152 PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to ensure that maximum coverage and value are obtained for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. The patent positions of medical device companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. In addition, we have licensed rights under proprietary technologies of third parties to develop, manufacture and commercialize specific aspects of our products and services. It is uncertain whether the issuance of any third party patent would

require us to alter our development or commercial strategies, alter our processes, obtain licenses or cease certain activities. The expiration of patents or patent applications licensed from third parties or our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future technology may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention.

We further own trade secrets relating to our technology, and we maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We seek to protect our trade secrets and know-how by entering into confidentiality agreements with third-parties, consultants and employees who have access to such trade secrets and know-how. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us are to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we enter into employment agreements that require employees to assign to us any inventions, trade secrets or know-how that they develop while employed by us. Although we take steps to protect our proprietary information and trade secrets, including through agreements with our employees and consultants, these agreements may be breached, or third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. To the extent that our employees, consultants, scientific advisors or other contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know how and inventions.

For a more comprehensive discussion of the risks related to our intellectual property, please see "Risk Factors—Risks Related to Intellectual Property."

Manufacturing and Supply

We manage all aspects of product supply through our operations team based in Malvern, Pennsylvania. We outsource the manufacture of components and high level assemblies, which are produced and tested to our specifications. We rely on third party providers to provide components used in existing products and we expect to continue to do so for future products.

We manage our arrangements with our third-party manufacturers and suppliers to adjust delivery schedules and quantities of components to match our changing manufacturing requirements. We forecast our component needs based on historical trends, current utilization patterns and sales forecasts of future demand. We establish our relationships with our third-party manufacturers and suppliers through supplier contracts and purchase orders. In most cases, these supplier relationships may be terminated by either party upon short notice. Currently, we are engaged with Sparton Medical Systems to supply our console; Molex Incorporated to supply our SenStar Treatment Link; Paragon Micro to supply our computer systems as well as other companies to supply components of our chairs and treatment packs.

In order to mitigate against the risks related to a single-source of supply, we qualify alternative suppliers when possible, maximize the use of commercial, off the shelf components and materials, minimize specialized or proprietary manufacturing processes, and develop contingency plans for responding to disruptions, including maintaining adequate inventory of any critical components. To date, we have not experienced material delays in obtaining any of our components, nor has the ready supply of finished products to our customers or clinicians been adversely affected by component supply issues.

Reimbursement, Payor Relations and Customer Support

Coverage and Reimbursement in the United States

Sales of a medical device, which is utilized for in-office medical treatments, depends, in part, on the extent to which such treatments using that medical device will be covered by third-party payors, such as government health care programs, including Medicare and Medicaid private insurance and managed healthcare organizations. Even if a third-party payor covers a particular treatment, the resulting reimbursement payment rates may not be adequate to

cover a provider's cost to purchase such medical device or ensure that purchase will be profitable for the provider. Additionally, patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the treatment and may be unwilling to undergo such treatment in the absence of coverage and adequate reimbursement.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a treatment is neither experimental nor investigational; safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; supported by peer reviewed medical journals; and included in clinical practice guidelines.

In the United States, there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, coverage and reimbursement for treatments can differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for an in-office treatment are made on a plan-by-plan basis. One payor's determination to provide coverage for a specific treatment does not assure that other payors will also provide coverage, and adequate reimbursement.

In addition, the federal government and state legislatures have continued to implement cost containment programs, including price controls and restrictions on coverage and reimbursement. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical services. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net sales and results of operations.

Based on our estimates, over 65 major private insurers in the United States, including the top 25 largest private insurers, have coverage policies for reimbursement of NeuroStar Advanced Therapy, representing approximately 205 million covered lives or about 95% of the total payor covered lives in the United States. Treatments using NeuroStar Advanced Therapy are also eligible for reimbursement from Medicare, representing an additional 59 million covered lives in the United States as of January 2018.

Government Regulation

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our products are subject to regulation as medical devices under the FDCA, as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in other jurisdictions governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA clearance or approval for a product, we must obtain authorization before commencing clinical trials or obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States. The marketing authorization process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification or PMA approval. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and efficacy. Class I includes devices with the lowest risk to the patient and are those for which safety and efficacy can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable

portions of the quality systems regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and efficacy of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA.

Our NeuroStar Advanced Therapy System is classified as a Class II medical device. We initially received marketing authorization of this device through the *de novo* classification process. Subsequently, we have cleared any changes made to our system through the 510(k) clearance process.

510(k) Marketing Clearance Pathway

To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, 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 found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from nine to twelve months, but may take significantly longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

Pre-Market Approval Process

A PMA application must be submitted if the medical device is in Class III (although the FDA has the discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) process. A PMA application must be supported by, among other things, extensive technical, preclinical, clinical trials, manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA will usually be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

De novo Classification Process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified as Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified as Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. We originally obtained marketing authorization for our system using the *de novo* classification process after receiving a not substantially equivalent determination following the submission of a 510(k) premarket notification. We have subsequently used the 510(k) clearance process to obtain authorization from the FDA for changes to our marketed system.

Clinical Trials

A clinical trial is typically required to support a PMA application or *de novo* classification, and is sometimes required for a 510(k) pre-market notification. Clinical trials generally require submission of an application for an Investigational Device Exemption, or 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 investigational 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 more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA as well as the appropriate institutional review boards, or IRBs, at the clinical trial sites, and the informed consent of the patients participating in the clinical trial is obtained. After a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk. Any trials we conduct must be conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy. Moreover, the results of a clinical trial may not be sufficient to obtain clearance or approval of the product.

Changes to Marketed Devices

After a device receives 510(k) marketing clearance, or *de novo* classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, a de novo classification or PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications today are accomplished by a manufacturer documenting the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for every change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

Post-Market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury or serious adverse events, if the malfunction were to recur;
- correction, removal and recall 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;
- complying with regulations requiring Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database (GUDID);
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and efficacy data for the device.

We may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance and risk-benefit analysis. Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export or import approvals for our products; or
- criminal prosecution.

U.S. and Foreign Healthcare Laws and Compliance Requirements

Healthcare providers, physicians and third-party payors play a primary role in the recommendation, prescription and payment for medical treatments. A medical device manufacturer's arrangements with third-party payors, providers and patients may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect its business or the financial arrangements and relationships through which it markets, sells and distributes its products. Even if a medical device manufacturer does not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations are applicable to its business. In addition, a portion of our business is subject to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as a business associate of our covered entity customers. To provide our covered entity customers with services that involve the use or disclosure of PHI, we are required to enter into business associate agreements. As a business associate, we are also directly liable for compliance with HIPAA. The laws that may affect a medical device manufacturer's ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, or the PPACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the False Claims Act, or FCA, which can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, companies have been prosecuted under the FCA in connection with alleged off-label promotion of devices and allegedly providing free products to customers with the expectation that the customers would bill federal health care programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;
- HIPAA, among other things, imposes criminal liability for 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 creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes privacy, security, transmission and breach reporting obligations with respect to individually identifiable health information upon "covered entities" subject to the law, including health plans, healthcare clearinghouses and certain healthcare providers and their respective business associates that perform services on their behalf that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the PPACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare and Medicare Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- foreign and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; state laws that require device manufacturers to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; 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 pricing information; and other federal and state laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts and data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018).

Because of the breadth of these laws and the narrowness of their statutory exceptions and regulatory safe harbors, it is possible that some of a medical device manufacturer's business activities could be subject to challenge under one or more of these laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their 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.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If a medical device manufacturer's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if it becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of operations, any of which could adversely affect the ability of a medical device manufacturer to operate its business and the results of its operations.

United States Healthcare Reform

In the United States, a number of legislative and regulatory proposals have been considered or enacted to change the healthcare system in ways that could affect a medical device manufacturer's business. Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. For example, in 2010, the PPACA was enacted, which includes measures to significantly change the way health care is financed by both governmental and private insurers, and significantly impacts the medical device industry. Among other ways in which it may impact a medical device manufacturer's business, the PPACA:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, although the effective rate paid may be lower. Under the Consolidated Appropriations Act of 2016, the excise tax was suspended through December 31, 2017, and under the continuing resolution on appropriations for fiscal year 2018, or 2018 Appropriations Resolution, signed by President Trump on January 22, 2018, was further suspended through December 31, 2019;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical efficacy research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- expands the eligibility criteria for Medicaid programs.

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". The 2018 Appropriations Resolution delayed the implementation of certain PPACA-mandated fees, including, without limitation, the medical device excise tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. While the Texas District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the PPACA will impact the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015, or MACRA, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of certain products under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. At the state level, individual states in the United States are also increasingly passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

It is likely that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for a medical device manufacturer's products or additional pricing pressure.

Japanese Regulation

In Japan, medical devices must be approved prior to importation and commercial sale by the MHLW. The approval process identifies a Marketing Authorization Holder, or MAH, who is designated as the only authorized seller of products. Manufacturers of medical devices outside of Japan who do not operate through a Japanese entity are able to designate a MAH who will apply for product approval and take responsibility for the medical device as designated. The MHLW evaluates each device for safety and efficacy. As part of its approval process, the MHLW may require that the product be tested in Japanese laboratories. The approval process ranges in length and certain medical devices may require a longer review period for approval. Once a device is approved, the MHLW issues a Shonin to the MAH or designated MAH, thereby permitting such entity to import the device into Japan for sale.

After a device is approved for importation and commercial sale in Japan, the MHLW continues to monitor sales of approved products for compliance with labeling regulations, which prohibit promotion of devices for unapproved uses, and reporting regulations, which require reporting of product malfunctions, including serious injury or death caused by any approved device. Failure to comply with applicable regulatory requirements can result in enforcement action by the MHLW, which may include fines, injunctions, and civil penalties; recall or seizure of our products; operating restrictions; partial suspension or total shutdown of sales in Japan; or criminal prosecution.

Employees

As of December 31, 2018, we had 191 employees, with 133 employees on our sales and customer support team, 33 in research and development, including clinical, regulatory and certain quality functions, 3 employees in operations and 22 employees in general and administrative. We have never had a work stoppage and none of our employees are covered by collective bargaining agreements or represented by a labor union. We believe our employee relations are good.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Corporate Information

We were incorporated in Delaware in April of 2003. Our principal executive offices are located at 3222 Phoenixville Pike, Malvern, Pennsylvania 19355, and our telephone number is (610) 640-4202. Our website address is www.neurostar.com. The information contained on, or accessible through, our website is not incorporated by reference into this Form 10-K, and you should not consider any information contained in, or that can be accessed through, our website as part of this 10-K or in deciding whether to purchase our common stock.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this Annual Report on Form 10-K before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Industry

We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.

We have incurred net losses since inception, including net losses of $24.1 million and $16.1 million for the years ended December 31, 2018 and 2017 respectively. As a result of ongoing losses, as of December 31, 2018, we had an accumulated deficit of $221.0 million. We expect to continue to incur significant sales and marketing, product development, regulatory and other expenses as we continue to expand our marketing efforts to increase adoption of our products and expand existing relationships with our customers, to obtain regulatory clearances or approvals for our products in additional countries and for additional indications, and to develop new products or add new features to our existing products. The net losses we incur may fluctuate significantly from quarter to quarter. We will need to generate significant additional revenues to achieve and sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

We rely on the sale of our NeuroStar Advanced Therapy System and treatment sessions to generate revenues.

At present, we rely on the sale of our NeuroStar Advanced Therapy System and treatment sessions to generate revenues, and we expect to generate substantially all of our revenues in the foreseeable future from sales of these and any related products. Because the market for TMS therapy is still developing and contains a limited number of market participants, sales of our products could be negatively impacted by unfavorable market reactions to our or other TMS devices. If the use of our or other TMS therapies results in serious adverse events, or such products malfunction or are misused, patients and psychiatrists may attribute such negative events to TMS therapy generally, which may adversely affect market adoption of our products. Additionally, if patients undergoing treatment with a NeuroStar Advanced Therapy System perceive the benefits to be inadequate or adverse events too numerous or severe compared to the relevant rates of alternative TMS therapies or pharmaceutical options, it will be difficult to demonstrate the value of our NeuroStar Advanced Therapy System to patients and psychiatrists. As a result, demand for and the use of our NeuroStar Advanced Therapy System may decline or may not increase at the pace or to the levels we expect.

If coverage is unavailable or reimbursement from third-party payors for treatments using our products significantly declines, psychiatrists may be reluctant to use our products.

In the United States, sales of our products will depend, in part, on the extent to which the treatment sessions using our products are covered and reimbursed by third-party payors, including private insurers and government healthcare programs. Even if a third-party payor covers a particular treatment that uses our products, the resulting reimbursement rate may not be adequate to cover a provider's cost to purchase our products or ensure such purchase is profitable for the provider. Further, patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the treatment and may be unwilling to undergo such treatment in the absence of coverage and adequate reimbursement, or due to large annual deductibles associated with certain health insurance plans.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a treatment is neither experimental nor investigational, safe, effective, and medically necessary, appropriate for the specific patient, cost-effective, supported by peer-reviewed medical journals and included in clinical practice guidelines.

In the United States, there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, coverage and reimbursement for treatments can differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for an in-office treatment is made on a plan-by-plan basis. One payor's determination to provide coverage for a specific treatment does not assure that other payors will also provide coverage, and adequate reimbursement.

In addition, the federal government and state legislatures have continued to implement cost containment programs, including price controls and restrictions on coverage and reimbursement. To contain costs, governmental healthcare programs and third-party payors are increasingly challenging the price, scrutinizing the medical necessity and reviewing the cost-effectiveness of medical treatments.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets, including Japan, have government-managed healthcare systems that govern reimbursement for psychiatric treatments and procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of our products may not materialize or grow significantly.

The marketability of our products may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we are unable to adequately train psychiatrists and other treatment providers on the safe and appropriate use of our products, we may be unable to achieve our expected growth.

There is a learning process involved for treatment providers to become proficient in the use of our products, which requires us to spend considerable time and resources for training. It is critical to the success of our commercialization efforts to train a sufficient number of psychiatrists and to provide them with adequate, ongoing instruction and training in the use of our products. This training process generally requires psychiatrists to review and study product materials, engage in multi-day, hands-on training sessions for up to four hours a day and participate in a multi-day observational period prior to treating patients independently. This training process may also take longer than expected or be more complicated than the psychiatrists or their personnel are comfortable with and may therefore affect our ability to increase sales. Convincing psychiatrists to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in these efforts.

Psychiatrists and patients may be slow to adopt and use TMS therapies.

TMS therapy is an emerging treatment option for patients suffering from MDD. As a result, psychiatrist and patient awareness of TMS therapy as a treatment option for MDD, and experience with TMS therapies, is limited. Our success depends in large part on our ability to educate and train psychiatrist and patients, and successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other merits of our NeuroStar Advanced Therapy System. We have been engaging in an active marketing campaign to raise awareness of our NeuroStar Advanced Therapy System and its benefits among psychiatrists, but we cannot assure you that these efforts will be successful or that they will not prove to be cost-prohibitive. Some psychiatrists may also find the initial patient set up and the subsequent procedures for future treatment sessions to be difficult or complicated, or could be wary of the initial investment required for the purchase of the NeuroStar Advanced Therapy System, which may impact their decision to purchase or use the NeuroStar Advanced Therapy System as part of their practice. Similarly, psychiatrists may find it difficult to hire additional staff, allocate sufficient space or operationalize our NeuroStar Advanced Therapy System, which could slow its adoption.

In addition, psychiatrists may not derive sufficient cash flow from using the NeuroStar Advanced Therapy Systems due to their own practice economics or otherwise. Failure to achieve economic benefits from the purchase or use of the NeuroStar Advanced Therapy System would adversely affect our customers' purchase of treatment sessions. These factors could also reduce the number of procedures performed using our NeuroStar Advanced Therapy System, and if we do not facilitate the utilization of our products by our customers, our revenues and results of operations could be harmed.

Our success depends in part upon patient satisfaction with the effectiveness of our NeuroStar Advanced Therapy System.

In order to generate repeat and referral business, patients must be satisfied with the effectiveness of our NeuroStar Advanced Therapy System. Clinical studies demonstrate that, in order to be effective, our products must be used for a period of four to six weeks, and require a patient to return to a psychiatrist's office five days a week during that period in order to receive the recommended course of treatment. Since patients who achieve response or remission using our therapy will obtain these results gradually over this treatment period, their perception of their results may vary depending on their compliance with the prescribed treatment course.

We train our psychiatrist customers to select the appropriate patient candidates for treatment using the NeuroStar Advanced Therapy System, explain to their patients the time-period over which the results from a treatment course can be expected to occur, and measure the success of treatments using medical guidelines. However, our psychiatrist customers may not select appropriate patient candidates for NeuroStar Advanced Therapy treatment, which may produce results that may not meet patients' expectations. In addition, the efficacy of treatment is dependent on proper patient set up at the initial treatment session and duplication of that set up at future treatment sessions. To the extent psychiatrists do not make the proper measurements for a specific patient or use the same procedures at each treatment session, it could result in variability of the treatment efficacy and results for the patient. If patients are not satisfied with the results of our NeuroStar Advanced Therapy System, our reputation and future sales will suffer.

We operate in a very competitive environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected.

Our currently marketed products are, and any future products we develop and commercialize will be, subject to intense competition. The industry in which we operate is subject to rapid change and is highly sensitive to the introduction of new products or other market activities of current or new industry participants. Our ability to compete successfully will depend on our ability to develop products that reach the market in a timely manner, to receive adequate coverage and reimbursement from third-party payors, and to successfully demonstrate to psychiatrists and patients the merits of our products compared to those of our competitors. If we are not successful in convincing others of the merits of our products, including in comparison to those of our competitors, or educating them on the use of our products, they may not use our products or use them effectively and we may be unable to increase our sales.

We have competitors that sell other forms of TMS therapy, including Brainsway, Magstim, MagVenture, CloudTMS and Nexstim, that compete directly with the NeuroStar Advanced Therapy System. Competing TMS therapy companies have developed and may develop additional treatments that can be administered for shorter time periods or for indications outside of MDD, or may develop treatments that have improved efficacy when compared to our products or that require a less significant investment of resources from psychiatrists. We also face competition from pharmaceutical and other companies that develop competitive products, such as antidepressant medications. Our commercial opportunity could be reduced or eliminated if these competitors develop and commercialize antidepressant medications or other treatments that are safer, more convenient or more effective than the NeuroStar Advanced Therapy System. At any time, these and other potential market entrants may develop treatment alternatives that may render our products uncompetitive.

In addition, our competitors may have more established distribution networks than we do, or may be acquired by enterprises that have more established distribution networks than we do. Our competitors may also develop and patent processes or products earlier than we can or obtain domestic or international regulatory clearances or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar products. We also compete with our competitors in acquiring technologies and technology licenses complementary to our products or advantageous to our business. In addition, we compete with our competitors to engage the services of independent distributors outside the United States, both those presently working with us and those with whom we hope to work as we expand.

We may face difficulties encountered by companies in new and evolving markets.

In assessing our prospects, you must consider the risks and difficulties frequently encountered by companies in new and evolving markets. These risks include our ability to:

- manage rapidly changing and expanding operations;
- increase awareness of our brand and strengthen customer loyalty;
- successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments;
- continue to develop and enhance our products and products in development;
- obtain regulatory clearance or approval to commercialize new products and enhance our existing products;
- refrain from infringing on the intellectual property rights of others, and maintaining appropriate legal policies and procedures;
- expand our presence in existing and commence operations in new international markets; and
- attract, retain and motivate qualified personnel.

If we are unable to successfully expand our sales and customer support team and adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenues to achieve or sustain profitability.

Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team in the United States and our independent third-party distributors outside of the United States. If our employees or our independent distributors fail to adequately promote, market and sell our products, our sales could significantly decrease.

In addition, our future sales will largely depend on our ability to increase our marketing efforts and adequately address our customers' needs. We believe it is necessary to expand our sales force, including by hiring additional sales representatives or distributors with specific technical backgrounds that can support our customers' needs.

As we launch new products, expand our product offerings to new indications and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled employees, and distributors with significant technical knowledge in various areas. New hires 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, new hires may not become as productive as may be necessary to maintain or increase our sales. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may be unable to effectively commercialize our products.

The loss of our senior management or our inability to attract and retain highly skilled executives, salespeople and product development personnel could negatively impact our business.

Our success depends on the skills, experience and performance of the members of our executive management team. The individual and collective efforts of these employees will be important as we continue to develop our products and as we expand our commercial activities. We believe that it is challenging to identify individuals with the requisite skills to serve in many of our key positions, and the loss or incapacity of existing members of our executive management team could negatively impact our operations. We do not maintain key man life insurance on any of our employees. The existence of our Chief Executive Officer's employment agreement does not guarantee our retention of our Chief Executive Officer for any period of time.

Our commercial, supply chain and research and development programs and operations depend on our ability to attract and retain highly skilled managers, salespeople and product development and customer training personnel. We may be unable to attract or retain qualified managers, salespeople or product development and customer training personnel in the future due to the competition for qualified personnel in the medical treatment and device fields. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Recruiting and retention difficulties can limit our ability to support our commercial, supply chain and research and development programs. The loss of key employees, the failure of any key employee to perform or our inability to attract and retain skilled employees, as needed, or an inability to effectively plan for and implement a succession plan for key employees could harm our business.

Our long-term growth depends on our ability to commercialize our approved products for current and future indications and to develop and commercialize additional products through our research and development efforts. If we fail to do so we may be unable to compete effectively.

In order to increase our future revenues, we must successfully enhance our existing product offerings and introduce new products in response to changing customer demands and competitive pressures and technologies. Our industry is characterized by intense competition, including from lower-cost competitors, rapid technological changes, new product introductions and enhancements and evolving industry standards. We also face competition from large pharmaceutical companies with greater capital. Our business prospects depend in part on our ability to develop and commercialize new products and applications for our technology, including in new markets that develop as a result of technological, pharmaceutical and scientific advances, while improving the performance and cost-effectiveness of our products. New pharmaceutical products, technologies, techniques or other products could emerge that might offer better combinations of price and performance than our products. It is important that we anticipate changes in technology and market demand, as well as psychiatrist practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis.

We might be unable to successfully further commercialize or develop or obtain regulatory clearances or approvals to market new products or our existing products for additional indications. For example, our NeuroStar Advanced Therapy System did not meet the primary endpoint in the initial phase of the clinical trial of adolescents with MDD. While we intend to complete the remaining phases of this clinical trial, in light of these results we are unlikely to seek clearance for this indication. Additionally, these products and any future products, even if cleared, might not be accepted by psychiatrists or the third-party payors who reimburse for the procedures performed with our products. The success of any new product offering or enhancement to an existing product will depend on numerous additional factors, including our ability to:

- properly identify and anticipate clinician and patient needs;
- demonstrate the benefits associated with the use or our products when compared to the products and devices of our competitors;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

If we do not develop and obtain regulatory clearances or approvals for new products or indications or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

Nevertheless, we must carefully manage our introduction of new products. If potential customers believe such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory as we transition to new products, and we have limited experience in managing product transitions.

We rely on single-source suppliers for some components used in our NeuroStar Advanced Therapy System and on a single manufacturer for the assembly of our NeuroStar Advanced Therapy System, and we may be unable to find replacements or immediately transition to alternative parties for these components.

We rely on single-source suppliers for some components used in our NeuroStar Advanced Therapy System, and we do not have long-term supply contracts with these suppliers. Furthermore, we rely on a single manufacturer for the assembly of the mobile console and patient positioning system used in our NeuroStar Advanced Therapy System. For us to be successful, our suppliers and contract manufacturer must be able to provide us with components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. While these suppliers have generally met our demand requirements on a timely basis in the past, their ability and willingness to continue to do so going forward may be limited for several reasons, including our lack of long-term agreements with those suppliers, our relative importance as a customer of those suppliers, or, as applicable, their ability to produce the components for or provide assembly services to manufacture our NeuroStar Advanced Therapy System. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components or manufactured products, if we cannot obtain an acceptable substitute.

Any transition to a new supplier or contract manufacturer could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our NeuroStar Advanced Therapy System or could require that we modify its design. If we are required to change our contract manufacturer, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. If the change in manufacturer results in a significant change to any product, a new 510(k) clearance from the FDA or similar non-U.S. regulatory authorization may be necessary before we implement the change, which could cause a substantial delay. We cannot assure you that we will be able to identify and engage alternative suppliers or contract manufacturers on similar terms or without delay. Furthermore, our contract manufacturer could require us to move to a different production facility. The occurrence of any of these events could harm our ability to meet the demand for our NeuroStar Advanced Therapy System in a timely and cost-effective manner.

We may be unable to manage our anticipated growth effectively, which could make it difficult to execute our business strategy.

We have been growing rapidly and have a relatively short history of operating as a commercial company. For example, our revenues grew from $40.4 million for the year ended December 31, 2017 to $52.8 million for the year ended December 31, 2018. We intend to continue to grow our business operations and may experience periods of rapid growth and expansion. This anticipated growth could create a strain on our organizational, administrative and operational infrastructure, including our supply chain operations, quality control, technical support and customer service, sales force management and general and financial administration. We may be unable to maintain the quality, or delivery timelines, of our products or customer service or satisfy customer demand if our business grows too rapidly. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, and our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business.

As our commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for our supply chain, customer service, training and education personnel, billing, accounting reporting and general process improvements and expand our internal quality assurance program, among other things. Because our products require us to devote significant resources to training our customers on the use, and educating our customers on the benefits, of our products, we will be required to expand these personnel as we increase our sales efforts. We may not successfully implement these increases in scale or the expansion of our personnel, which could harm our business.

We rely and, in the future, expect to rely on a network of third-party distributors to market and distribute our products internationally, and if we are unable to maintain and expand this network, we may be unable to generate anticipated sales.

We rely, and expect to rely in the future, on a network of third-party distributors to market and distribute our products in international markets. We currently sell our products in five countries outside of the United States and plan to market and sell our products through our exclusive distribution agreement in Japan once we attain reimbursement approval. We are assessing the opportunity to continue expanding into other international markets. We may face significant challenges and risks in managing a geographically dispersed distribution network. We have limited ability to control any third-party distributors. Our distributors may be unable to successfully market and sell our products and may not devote sufficient time and resources to support the marketing, sales, education and training efforts that we believe enable the products to develop, achieve or sustain market acceptance. Additionally, in some international jurisdictions, we rely on our distributors to manage the regulatory process, while complying with all applicable rules and regulations, and we are dependent on their ability to do so effectively. In addition, if a dispute arises with a distributor or if a distributor is terminated by us or goes out of business, it may take time to locate an alternative distributor, to seek appropriate regulatory approvals and to train new personnel to market our products, and our ability to sell those systems in the region formerly serviced by such terminated distributor could be harmed. Any of these factors could reduce our revenues from affected markets, increase our costs in those markets or damage our reputation. In addition, if an independent distributor were to depart and be retained by one of our competitors, we may be unable to prevent that distributor from helping competitors solicit business from our existing customers, which could further adversely affect our sales. As a result of our reliance on third-party distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error and other issues. If the services of any of these third-party distributors become unsatisfactory, we may experience delays in meeting our customers' demands and we may be unable to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver products in a timely manner may damage our reputation and could cause us to lose potential customers.

We face risks associated with our international business.

We currently market and sell our products outside of the United States, including in Japan, and plan to market and sell our products through our exclusive distribution agreement in Japan. Once we attain satisfactory reimbursement approval, we expect that sales of our NeuroStar Advanced Therapy System in Japan will increase.

The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U.S. and other foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. We expect our international activities will be dynamic over the foreseeable future as we continue to pursue opportunities in international markets. Our international business operations are subject to a variety of risks, including:

- difficulties in staffing and managing foreign and geographically dispersed operations, to the extent we establish non-U.S. operations;
- attaining reimbursement under differing and multiple payor reimbursement regimes, government payors or patient self-pay systems;
- difficulties in determining and creating the proper sales pathway in new, international markets;
- compliance with various U.S. and international laws, including export control laws and the U.S. Foreign Corrupt Practices Act of 1977, or the FCPA, and anti-money laundering laws;
- differing regulatory requirements for obtaining clearances or approvals to market our products;
- changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the United States;
- tariffs and trade barriers, export regulations, sanctions and other regulatory and contractual limitations on our ability to sell our products in certain foreign markets;

- potential adverse tax consequences, including imposition of limitations on or increases of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;
- imposition of differing labor laws and standards;
- armed conflicts or economic, political or social instability in foreign countries and regions;
- fluctuations in foreign currency exchange rates;
- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action;
- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us; and
- conducting post-market surveillance on product performance.

We are assessing the opportunity to expand into other international markets. However, our expansion plans may not be realized, or if realized, may not be successful. We expect each market to have particular regulatory hurdles to overcome, and future developments in these markets, including the uncertainty relating to governmental policies and regulations, could harm our business.

Our employees, consultants, distributors and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, distributors and other commercial partners may engage in inappropriate, fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other U.S. healthcare regulators, as well as non-U.S. regulators, including by violating laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees, distributors and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. These risks may be more pronounced, and we may find that the processes and policies we have implemented are not effective at preventing misconduct. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

We rely in part on third parties to conduct our clinical trials. If these third parties fail to perform their duties on time or as expected, we may not be able to obtain regulatory approval for additional indications that we may seek for the NeuroStar Advanced Therapy System.

Our clinical trials are managed by our own staff and personnel, but we rely in part upon certain third-parties, including clinical trial sites, medical institutions, clinical research organizations, or CROs, and private practices, for, among other things, site monitoring, statistical work and electronic data capture in our clinical trials. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocols, and legal, regulatory and scientific standards, including current good clinical practices, or cGCPs, which are

regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for clinical trials. If we or any such third parties fail to comply with applicable cGCPs, the clinical data generated in such trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a marketing application for any particular indication. In addition, if such third parties do not devote sufficient time and resources to our clinical trials or otherwise carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they assist in obtaining is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates in a specified indication.

If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for the treatment of MDD. Our treatments are designed for patients who suffer from significant psychiatric disorders, and these patients are more likely to experience significant adverse health outcomes, which could increase the risk of product liability lawsuits. Furthermore, if psychiatrists are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- material defense costs;
- loss of revenues;
- the inability to commercialize new products or product candidates; and
- diversion of management attention from pursuing our business strategy.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

Our insurance policies protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, cybersecurity liability, employee benefits liability, property, umbrella, workers' compensation, products and clinical trial liability and directors' and officers' insurance. We do not know, however, if these policies will provide us with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We bear the risk of warranty claims on our products.

We bear the risk of warranty claims on the products we supply for two years from the date of delivery. There can be no assurance that we will not face increased claims in the future. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

We could be negatively impacted by violations of applicable anti-corruption laws or violations of our internal policies designed to ensure ethical business practices.

We operate in a number of countries throughout the world, including in countries that do not have as strong a commitment to anti-corruption and ethical behavior that is required by U.S. laws or by our corporate policies. We are subject to the risk that we, our U.S. employees or any future employees or consultants located in other jurisdictions or any third parties such as our distributors that we engage to do work on our behalf in foreign countries may take action determined to be in violation of anti-corruption laws in any jurisdiction in which we conduct business, including the FCPA. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made.

We will face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. We have implemented company policies relating to compliance with the FCPA and similar laws. However, such policies may not be effective at preventing all potential FCPA or other violations. Although our agreements with our international distributors state our expectations for our distributors' compliance with U.S. laws, including the FCPA, and provide us with various remedies upon any non-compliance, including the ability to terminate the agreement, our distributors may not comply with U.S. laws, including the FCPA.

Any violation of the FCPA or any similar anti-corruption law or regulation could result in substantial fines, sanctions, civil and/or criminal penalties and curtailment of operations in certain jurisdictions and might harm our business, financial condition or results of operations.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including for our TrakStar system and accounting, data storage, compliance, purchasing and inventory management. We do not have redundant systems at this time. While we will attempt to mitigate interruptions, we may experience difficulties in implementing upgrades to our information technology systems, which would impact our business operations, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to provide customers with data on patient outcomes, track the usage of our products, timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to access patient data or use our products for treatments. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows. Currently we carry business interruption coverage to mitigate any potential losses, but we cannot be certain that such potential losses will not exceed our policy limits.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis.

Security and privacy breaches may expose us to liability and harm our reputation and business.

As part of our business we receive and process information about our customers, partners and their patients, including protected health information, or PHI, and we may store or contract with third parties to store our customers' data, including PHI. PHI, a subset of individually identifiable information, is regulated at the federal level by the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information and Technology for Economic and Clinical Health Act of 2009, or HITECH, and by various laws at the state level, as more fully described below. We are required to safeguard PHI in accordance with HIPAA and, as a business associate, we are also directly liable for compliance with HIPAA.

While we implemented security measures relating to our NeuroStar Advanced Therapy System and TrakStar database, specifically, and our operations, generally, those measures may not prevent security breaches that could harm our business. Advances in computer capabilities, inadequate technology or facility security measures or other factors may result in a compromise or breach of our systems and the data and PHI we store and process. Our security measures may be breached as a result of actions by third parties or employee error or malfeasance. A party who is able to circumvent our security measures or exploit inadequacies in our security measures, could, among other things, misappropriate proprietary information, including information about our customers and their patients, cause the loss or disclosure of some or all of this information, cause interruptions in our or our customers' operations or expose our customers to computer viruses or other disruptions or vulnerabilities. Any compromise of our systems or the data we store or process could implicate reporting requirements under HIPAA, result in a loss of confidence in the security of our software, damage our reputation, disrupt our business, lead to legal liability and adversely affect our results of operations. Moreover, a compromise of our systems could remain undetected for an extended period of time, exacerbating the impact of that compromise. Actual or perceived vulnerabilities may lead to claims against us by our customers, their patients or other third parties, including the federal and state governments. While our customer agreements typically contain provisions that seek to limit our liability, there is no assurance these provisions will be enforceable and effective under applicable law. In addition, the cost and operational consequences of implementing further data protection measures could be significant.

Employment litigation and unfavorable publicity could negatively affect our future business.

Employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile work place, discrimination, wage and hour, sexual harassment and other employment issues. In recent years there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Companies that have faced employment or harassment related lawsuits have had to terminate management or other key personnel and have suffered reputational harm that has negatively impacted their sales. If we were to face any employment related claims, our business could be negatively affected.

The 2017 comprehensive tax reform law could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation, (Pub. L. 115-97), commonly referred to as the Tax Cuts and Jobs Act of 2017, that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.

A major earthquake, fire or other disaster, such as a major flood, seasonal storms, or terrorist attack affecting our facilities, or those of our third-party manufacturers or suppliers, could significantly disrupt our or their operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our third-party manufacturers or suppliers' damaged manufacturing facilities. These delays could be lengthy and costly. If any of our manufacturers', suppliers' or customers' facilities are negatively impacted by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our or their facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak of epidemic diseases could have a negative effect on our operations.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could harm our business.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, distributors and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of the acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms or at all or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock or other equity-linked securities as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our stock as consideration.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.

Generally accepted accounting principles in the United States, or U.S. GAAP, are subject to interpretation by the Financial Accounting Standards Board, or FASB, the U.S. Securities and Exchange Commission, or SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results and could affect the reporting of transactions completed before the announcement of a change.

Refer to "Note 4. Recent Accounting Pronouncements" in our audited financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K.

Our sales volumes and our results of operations may fluctuate over the course of the year.

We have experienced and may continue to experience meaningful variability in our sales and gross profit among quarters. A number of factors over which we have limited control, such as seasonal variations in revenues, may contribute to fluctuations in our financial results. In the first quarter, our results can be impacted by severe weather and by the resetting of annual U.S. patient healthcare insurance plan deductibles, which may cause delays in patients seeking NeuroStar Advanced Therapy treatments. Historically, we have seen a sequential decline in third quarter revenues, which we believe is attributable to summer vacation plans of psychiatrists and patients. In addition, the fourth quarter has consistently been a strong revenue quarter on a sequential basis primarily due to U.S. psychiatrists' historical timing for capital expenditures and patients' needs to exhaust remaining balances in flexible spending accounts.

Additional factors that we expect may contribute to variability in our sales and gross profit over the course of the year include:

- the growth or decline of our installed system base;
- the unpredictability of future sales by our international distributors, including through our exclusive distributor in Japan;
- the demand for, and pricing of, our products and the products of our competitors;
- the timing of or failure to obtain regulatory clearances or approvals for other products, indications or treatments; or
- the costs, benefits and timing of new product introductions.

Risks Related to Intellectual Property

If we are not able to obtain and enforce patent protection for our technologies, products, or product candidates, development and commercialization of our products and product candidates may be adversely affected.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We have applied, and we intend to continue applying, for patents covering aspects of our technologies that we deem appropriate. However, the patent process is expensive and time consuming, and we may not be able to apply for patents on certain aspects of our current or future products and other technologies in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition.

We cannot offer any assurances about which, if any, of our patent applications will issue or whether any of our issued patents will be found invalid and unenforceable or will be threatened by third parties. Any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. We also cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect and provide exclusivity for our products, any additional features we develop for our products or any new products. Other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. Any successful opposition to these patents or any other patents owned by or, if applicable in the future, licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop. Since patent applications in the US and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our technologies, products, or product candidates. Furthermore, an interference proceeding can be provoked by a third party or instituted by the United States Patent and Trademark Office, or the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013.

The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. Proceedings challenging our patents, which may continue for a protracted period of time, could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for alternative and possibly more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our products;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell, or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe the patents we own or license;
- any of the patents we own or license will be found to ultimately be valid and enforceable;

- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable products or will provide us with any competitive advantages;
- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business.

Our inability to effectively protect our proprietary technologies could harm our competitive position.

Although our competitors have utilized and are expected to continue utilizing technologies similar to ours, our success will depend upon our ability to protect and continue to develop proprietary technologies and products and to defend any advantages afforded to us relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our technologies and thereby erode any competitive advantages we may have. For example, patents for our core technology will begin to expire in the United States in 2024, and our patents outside of the United States are expected to remain in effect until between 2024 and 2035. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We have agreements with our employees and selected consultants that obligate them to assign their inventions to us. If the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, including by refusing or being unavailable to sign assignments, oaths, declarations or other documents, we may not have adequate remedies for any such breach or violation, and we could lose our rights in inventions through such breaches or violations. Furthermore, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the US, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies, products, or product candidates are obtained, once the patent life has expired, we may be open to competition. Patents covering some of our core technology have expired or will expire within the next five years. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our technologies, products, and product candidates, our business and results of operations will be adversely affected.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. Our activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and 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, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies, products, or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates.

Significant litigation regarding patent rights occurs in our industry. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation.

We may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings such as review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office and challenges in U.S. District Court. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, regardless of the merit of the claims, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, including enhanced damages if we are found to have willfully infringed or misappropriated such rights;
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

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. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins, and the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us.

In addition, we generally indemnify our customers and international distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to patent protection, we also rely upon copyright and trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect through non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.

We may be unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. These challenges can be caused by the absence or inconsistency of the application of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop infringement of our foreign patents, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products, and product candidates. While we will endeavor to try to protect our technologies, products, and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property, including studies we commission or reports on the efficacy of our products. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Our patent rights may be affected by developments or uncertainty in the patent statute, patent case law or USPTO rules and regulations. There are a number of recent changes to the patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the United States has recently enacted and is currently implementing the America Invents Act of 2011, a wide-ranging patent reform legislation. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. As an example, the first to file provisions, which became effective March 2013, mean that the party that is first to file in the United States generally is awarded the patent rights, regardless of who invented first. This could have a negative impact on some of our IP and could increase uncertainties surrounding obtaining and enforcement or defense of our issued patents. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the U.S. Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or future patents.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the US in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we in-license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

If we fail to comply with our obligations under license or technology agreements with third parties, we may be required to pay damages and we could lose license rights that are critical to our business.

We license certain intellectual property, and in the future we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. These licenses impose various payment obligations on us. If we fail to comply with any of these obligations, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor could cause us to lose valuable rights, and could prevent us from distributing our products, or inhibit our ability to commercialize future products. Our business could suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Risks Related to Our Capital Structure

We may need to raise additional capital to fund our existing commercial operations, develop and commercialize new products and expand our operations.

Based on our current business plan, we believe that our cash and cash equivalents as of December 31, 2018 and anticipated revenues from sales of our products will be sufficient to meet our anticipated cash requirements for at least the next 24 months. If our available cash balances, potential future borrowing capacity, and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products as a result of the risks described in this Annual Report on Form 10-K, we may seek to sell common or preferred equity or debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing. Our present and future funding requirements will depend on many other factors, including:

- our ability to achieve revenue growth and improve operating margins;
- our ability to improve or maintain coverage and reimbursement arrangements with domestic third-party and government payors;
- our rate of progress in establishing coverage and reimbursement arrangements from international commercial third-party and government payors, particularly in Japan;
- the cost of expanding our operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products and maintaining or improving our sales to our current customers;

- the cost of research and development activities, including research and development relating to additional indications;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products.

We may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- expand our sales and marketing efforts to increase market adoption of our products and address competitive developments;
- fund development and marketing efforts of any future products or additional features to then-current products;
- acquire, license or invest in new technologies;
- provide for supply and inventory costs associated with plans to accommodate potential increases in demand for our products
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Additional capital may not be available to us at such times or in the amounts we need. Even if capital is available, it might be available only on unfavorable terms. Any issuance of additional equity or equity-linked securities could be dilutive to our existing stockholders, and any new equity securities could have rights, preferences and privileges superior to those of holders of our common stock, including the shares of common stock sold in this offering. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt, pay dividends, repurchase our stock, make investments and engage in merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish or license some rights to our technologies or products, on terms that are not favorable to us. If access to sufficient capital is not available as and when needed, our business will be materially impaired and we may be required to cease operations, curtail one or more product development or commercialization programs, significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all our assets.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2018, we had federal and state net operating loss carryforwards of $53.8 million and $47.3 million, respectively. The federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2023 and 2020, respectively. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2019 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

The terms of our credit facility place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In March 2017, we entered into a $35.0 million credit facility with Oxford Finance LLC, or Oxford, that is secured by a lien covering substantially all of our assets, excluding intellectual property. As of December 31, 2018, the outstanding principal balance under the credit facility was $30.0 million. The final $5.0 million tranche under the credit facility became available to us during the second quarter of 2018 upon achievement of a revenue milestone. We had 60 days to notify Oxford if we elected to borrow. As a result of completing our IPO on July 2, 2018 and receiving the net proceeds therefrom, we elected not to borrow the additional $5.0 million, and it is no longer available to us. The credit facility contains customary covenants and events of default applicable to us. The affirmative covenants include, among others, a covenant that requires us to achieve at least 75% of our trailing 12-month forecasted revenues, as measured each month in accordance with a forecast that we provided to Oxford upon signing the agreement and future forecasts that we are required to deliver to the lenders each year for the life of the credit facility. The negative covenants include, among others, restrictions on us transferring collateral, changing businesses, engaging in mergers or acquisitions, incurring additional indebtedness and encumbering collateral. If we default under the credit facility, Oxford may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, Oxford's right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford could declare a default upon the occurrence of any event that it interprets as a material adverse effect as defined under the credit facility, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by Oxford of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks Related to Government Regulation

Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; marketing, sales and distribution; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

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 sales. The FDA enforces these regulatory requirements through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

We may not receive the necessary clearances or approvals for our future products, and failure to timely obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

An element of our strategy is to continue to upgrade our products, add new features and expand clearance or approval of our current products to new indications. In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or approval of a premarket approval application, or PMA, from the FDA, unless an exemption applies. In the 510(k) clearance

process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended 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 are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. Our ability to successfully obtain clearance for any new indications will be dependent on us submitting data as to the successful completion of clinical trials evidencing safety and efficacy. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down classification, the applicant will then receive authorization to market the device. This device type can then be used as a predicate device for future 510(k) submissions. We initially received marketing authorization of our device through the *de novo* classification process, and we have made changes to our system through subsequent 510(k) clearances. The process of obtaining regulatory clearances or approvals, or completing the *de novo* classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) or authorized through the *de novo* classification process may require a new 510(k) clearance. Each of the PMA approval, *de novo* classification and the 510(k) clearance processes can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months but can last longer. The process of obtaining a PMA is much costlier and more uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials.

Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals or clearances could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

Any modifications to our existing products may require new 510(k) clearance; however, future modifications may be subject to the substantially more costly, time-consuming and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: we may be unable to demonstrate to the FDA's satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use; the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and the manufacturing process or facilities we use may not meet applicable requirements.

Even if granted, a 510(k) clearance, *de novo* classification, or PMA approval imposes substantial restrictions on how our devices may be marketed or sold, and the FDA continues to place considerable restrictions on our products and operations. For example, the manufacture of medical devices must comply with the FDA's Quality System Regulation, or QSR. In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical

device reporting, reporting of corrections and removals, and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions: untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; customer notifications or repair, replacement, refunds, detention or seizure of our products; operating restrictions or partial suspension or total shutdown of production; refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products; withdrawing 510(k) marketing clearances or PMA approvals that have already been granted; refusing to provide Certificates for Foreign Government; refusing to grant export approval for our products; or pursuing criminal prosecution. Any of these sanctions could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our sales and our ability to generate profits.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In order to sell our products in member countries of the EEA our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE Mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our surgical systems, which would prevent us from selling them within the EEA.

We or our distributors will also need to obtain regulatory approval in other foreign jurisdictions in which we plan to market and sell our products, and we or they may not obtain such approvals as necessary to commercialize our products in those territories.

Modifications to our products may require new 510(k) clearances or PMA approvals, and may require us to cease marketing or recall the modified products until clearances are obtained.

Any modification to a 510(k)-cleared product that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to our products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances were not required. We may make similar modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any delay or failure in obtaining required clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our installed systems or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

We or our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or clearances; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees.

Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenues and increased costs.

If treatment guidelines for the psychiatric conditions we are targeting change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our products.

If treatment guidelines for the psychiatric conditions we are targeting or the standard of care for such conditions evolves, we may need to redesign the applicable product and seek new clearances or approvals from the FDA. Our 510(k) clearances from the FDA are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and our business could suffer.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Our product has been authorized for marketing by the FDA for a specific indication. We train our commercial organization and distributors outside the United States to not promote our products for uses outside of the FDA-cleared indications for use, known as "off-label uses." We cannot, however, prevent a psychiatrist from using our products off-label, when in the psychiatrist's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if psychiatrists attempt to use our products off-label. Furthermore, the use of our products for indications other than those cleared by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among psychiatrists and patients.

If the FDA or any foreign regulatory body 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 or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority.

Our products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

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

If we or our distributors do not obtain and maintain international regulatory registrations or approvals for our products, we will be unable to market and sell our products outside of the United States.

Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we or our distributors may not receive regulatory approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory clearance or approval by the FDA does not ensure clearance or approval by regulatory authorities in other countries, and clearance or approval by one or more foreign regulatory authorities does not ensure clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers, patients and third-party payors are subject to scrutiny under these laws. We may also be subject to patient information privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the PPACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it, in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment from Medicare, Medicaid or other federal healthcare programs, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Private individuals can bring federal civil False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," and may share in amounts paid by the entity to the government in fines or settlement. Companies have been prosecuted under the federal civil False Claims Act in connection with alleged off-label promotion of devices and allegedly providing free products to customers with the expectation that the customers would bill federal health care programs for the product. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the federal civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;
- HIPAA, which created additional federal criminal statutes that prohibit, among other things, 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 statements or representations, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Payments Sunshine Act under the PPACA which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose privacy, security transmission and breach reporting obligations with respect to individually identifiable health information, including PHI, upon "covered entities" subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, and their respective business associates that perform services on their behalf that involve individually identifiable health information, including PHI. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; 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 pricing information; data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018); state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with psychiatrists or other potential purchasers of our products. We have also entered into consulting agreements with physicians, which are subject to these laws. Further, while we do not submit claims and our customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support regarding our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with healthcare regulatory laws, certain enforcement bodies have recently increased their 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. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, additional reporting obligations and oversight if we becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition and results of operations.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. 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 statutes, regulations, revisions, or reinterpretations of existing regulations may impose additional costs, lengthen review times of any future products, or make it more difficult to manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future.

For example, in March 2010, the PPACA was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may impact our business, the PPACA:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, although the effective rate paid may be lower. Under the Consolidated Appropriations Act of 2016, the excise tax was suspended through December 31, 2017, and under the continuing resolution on appropriations for fiscal year 2018, or 2018 Appropriations Resolution, signed by President Trump on January 22, 2018, was further suspended through December 31, 2019;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, psychiatrists and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- expands the eligibility criteria for Medicaid programs.

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." The 2018 Appropriations Resolution delayed the implementation of certain PPACA-mandated fees, including, without limitation, the medical device excise tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. While the Texas District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the PPACA will impact the PPACA. As a result, there is significant uncertainty regarding future healthcare reform and its impact on our operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. Additionally, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, the Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015, or MACRA, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of certain products under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. At the state level, individual states in the United States are also increasingly passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile.

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- the actual or anticipated fluctuations in our financial condition and operating results;
- the actual or anticipated changes in our growth rate;
- the commercial success and market acceptance of our products;
- the success of our competitors in developing or commercializing products;
- media exposure of our products or of those of others in our industry;
- our ability to commercialize or obtain regulatory approvals for our products, or delays in commercializing or obtaining regulatory approvals;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the addition or departure of key personnel;
- product liability claims;
- general prevailing economic, industry and market conditions, including factors unrelated to our operating performance or the operating performance of our competitors;
- business disruptions caused by earthquakes, fires or other natural disasters;
- disputes or other developments concerning our intellectual property or other proprietary rights, including litigation;
- the FDA or other U.S. or foreign regulatory actions affecting us or the healthcare or medical device industry;
- healthcare reform measures in the United States;
- third-party payor developments in the United States and other countries;
- sales of our common stock by our directors, officers, or stockholders;
- the timing and amount of our investments in the growth of our business;
- inability to obtain additional funding;
- future sales or issuances of equity or debt securities by us;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; and
- the issuance of new or changed securities analysts' reports or recommendations regarding us.

In addition, the stock markets in general, and the markets for companies like ours in particular, have from time to time experienced extreme volatility that has been often unrelated to the operating performance of the company. These broad market and industry fluctuations may negatively impact the price or liquidity of our common stock, regardless of our operating performance.

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenues or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenues or earnings forecasts that we may provide.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We may remain an emerging growth company until as late as December 31, 2023, though we may cease to be an emerging growth company earlier under certain circumstances, including (i) if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30, in which case we would cease to be an emerging growth company as of the following December 31, or (ii) if our gross revenues exceeds $1.07 billion in any fiscal year. "Emerging growth companies" may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors could 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.

In addition, Section 102 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing not to "opt out" of such extended transition period, and as a result, we will not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

Future sales of our common stock or securities convertible or exchangeable for our common stock may cause our stock price to decline.

If our stockholders or option holders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the price of our common stock could decline. The perception in the market that these sales may occur could also cause the price of our common stock to decline.

Shares of common stock that are either subject to outstanding options, or are outstanding but subject to vesting or reserved for future issuance under our 2018 Equity Incentive Plan, or the 2018 Plan, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act. We have also filed a registration statement permitting certain shares of common stock issued under our 2003 Stock Incentive Plan, or the 2003 Plan, and shares of common stock issued pursuant to the 2018 Plan or our 2018 Employee Stock Purchase Plan, or the 2018 ESPP, to be freely resold by plan participants in the public market, subject to applicable vesting schedules and, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 under the Securities Act. Both the 2018 Plan and the 2018 ESPP contain provisions for the annual increase of the number of shares reserved for issuance under such plans, which shares we also intend to register. If the shares we may issue from time to time under the 2003 Plan, the 2018 Plan or the 2018 ESPP are sold, or if it is perceived that they will be sold, by the award recipients in the public market, the price of our common stock could decline.

Approximately 11,099,375 shares of common stock are entitled to rights with respect to registration under the Securities Act. Such registration would result in these shares becoming fully tradable without restriction under the Securities Act when the applicable registration statement is declared effective. Sales of such shares could cause the price of our common stock to decline.

Our principal stockholders and management own a significant percentage of our stock and are able to exert control over matters subject to stockholder approval.

As of February 28, 2019, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially owned approximately 39.0% of our common stock. Accordingly, these stockholders have an influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, mergers, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the company, even if such a change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets and might affect the prevailing price of our common stock. The significant concentration of stock ownership may negatively impact the price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and the value of our common stock.

As a public company, the Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We have developed disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and regulations, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, or the Exchange Act, is communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to maintain effective controls could negatively impact the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will be required to include in periodic reports we file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on the Nasdaq Global Market.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report we are required to file with the SEC following the date we are no longer an "emerging growth company," as defined in the JOBS Act, depending on whether we choose to rely on certain exemptions set forth in the JOBS Act.

Provisions of our amended and restated charter documents or Delaware law could delay or prevent an acquisition of the company, even if the acquisition would be beneficial to our stockholders, which could make it more difficult for you to change management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws 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. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director;

- a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our board of directors to issue blank-check preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our amended and restated certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns, or within the last three years has owned, 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of our company.

Provisions in our charter documents and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, other than an action or suit to enforce a duty or liability created by the Securities Exchange Act of 1934 or any other claim for which the federal courts have exclusive jurisdiction, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future; therefore, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have never declared or paid any cash dividends on our common stock and do not intend to do so in the foreseeable future. We currently intend to retain all available funds and any future earnings to finance the growth and development of our business. In addition, the terms of our credit agreements contain, and the terms of any future credit agreements we may enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The trading market for our common stock depends, to some extent, on the research and reports that securities or industry analysts publish about us and our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline. If one or more of these analysts cease to cover us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We occupy an approximately 32,000 square foot facility in Malvern, Pennsylvania, under a lease that ends in February 2021, for our corporate headquarters, which includes office and warehouse space. We have an option to extend the lease for an additional five-year term followed by a three-year additional term. We believe that our existing facilities are adequate to meet our needs for the foreseeable future.

Item 3. Legal Proceedings.

The Company is subject from time to time to various claims and legal actions arising during the ordinary course of its business. Management believes that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on the Company's results of operations, financial condition, or cash flows.

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.

Stock Price

Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "STIM" since June 28, 2018. Prior to that time, there was no public market for our common stock. The shares of our common stock sold in our initial public offering (IPO) on June 27, 2018 were priced at $17.00 per share. The following table sets forth the high and low sales price of our common stock, as reported by the Nasdaq Global Market for the period indicated:

	High	Low
Second Quarter (June 28, 2018 through June 30, 2018)	$ 29.84	$ 23.96
Third Quarter	$ 39.39	$ 23.95
Fourth Quarter	$ 34.00	$ 15.40

Holders

As of February 28, 2019, there were approximately 95 holders of record of our common stock, solely based upon the count our transfer agent provided to us as of that date.

Dividends

We have never declared or paid, and do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. In addition, under the terms of our loan and security agreement with Oxford Finance LLC, we may not declare or pay any cash dividends or distributions, subject to certain exceptions, without the consent of Oxford Finance LLC. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, the consent of Oxford Finance LLC, other contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Unregistered Sales of Securities

None.

Warrants

In August 2016, March 2017 and December 2017, we issued preferred stock warrants to Oxford Finance LLC, each of which was immediately exercisable for 588,498 shares of our Series F convertible preferred stock at an exercise price of $0.3356 per share. The August 2016, March 2017 and December 2017 warrants expire on August 31, 2023, March 28, 2024 and December 27, 2024, respectively, if not earlier exercised.

Immediately prior to the closing of our IPO on July 2, 2018, all of our outstanding Series E and Series F convertible preferred stock warrants automatically converted into common stock warrants. Each of these August 2016, March 2017 and December 2017 Series F convertible preferred stock warrants converted into warrants to purchase 20,303 shares of our common stock at an exercise price of $9.73 per share.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act (or Regulation D or Regulation S promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions.

Use of Proceeds

Our IPO was effected through a Registration Statement on Form S-1 (File No. 333-225307) that was declared effective by the SEC on June 27, 2018. On June 27, 2018, 6,325,000 shares of our common stock were sold at a public offering price of $17.00 per share, for aggregate gross proceeds of $107.5 million. As of the date of filing this Annual Report on Form 10-K, the offering has terminated, and all of the securities registered pursuant to the offering were sold prior to termination. Piper Jaffray & Co. and William Blair & Company, L.L.C. acted as joint book-running managers, Canaccord Genuity LLC acted as lead manager and BTIG, LLC and JMP Securities LLC acted as co-managers for the IPO.

On July 2, 2018, received net proceeds $96.5 million after deducting underwriting discounts, commissions and other offering expenses paid by us. The funds shall be used in a manner consistent with the use of proceeds from the IPO as described in our IPO prospectus under the caption "Use of Proceeds," which has not materially changed since the filing of our IPO prospectus with the SEC on June 29, 2018.

Equity Compensation Plans

The following table details information regarding our existing equity compensation plans as of December 31, 2018:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (in thousands) (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) (in thousands) (c)
Equity compensation plans approved by security holders	2,711	$ 3.59	1,556
Equity compensation plans not approved by security holders	-	-	-
Total	2,711	$ 3.59	1,556

See "Item 15. Exhibits and Financial Statement Schedules — Notes to Financial Statements — Note 12. Share-Based Compensation and Note 13. Employee Benefit Plans" for additional information.

Item 6. Selected Financial Data.

The following tables set forth, for the periods and as of the dates indicated, our selected historical financial data. The statements of operations data for the years ended December 31, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 are derived from our audited financial statements appearing at the end of this Annual Report on Form 10-K. The balance sheet data as of December 31, 2016 is derived from audited financial statements that do not appear at the end of this Annual Report on Form 10-K.You should read this data together with the more detailed information contained in our audited financial statements and the related notes thereto and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that should be expected in the future.

	Years ended December 31,		
	2018	2017	2016
Statements of Operations Data:			
Revenues	$ 52,776	$ 40,433	$ 34,228
Cost of revenues	12,447	9,632	6,622
Gross Profit	40,329	30,801	27,606
Operating expenses:			
Sales and marketing	38,264	27,900	21,794
General and administrative	13,667	8,572	6,926
Research and development	8,232	7,937	8,223
Total operating expenses	60,163	44,409	36,943
Loss from Operations	(19,834)	(13,608)	(9,337)
Other (income) expense:			
Interest expense	3,688	2,808	1,835
Other (income) expense, net	575	(357)	62
Net Loss	$ (24,097)	$ (16,059)	$ (11,234)
Net loss per share of common stock outstanding, basic and diluted	$ (2.69)	$ (86.34)	$ (76.95)
Weighted-average common shares outstanding, basic and diluted	8,948	186	146

	As of December 31,		
	2018	2017	2016
Balance Sheet Data:			
Cash and cash equivalents	$ 104,583	$ 29,147	$ 17,040
Working capital	100,914	25,011	9,582
Total assets	117,022	38,938	24,798
Current portion of long-term debt	-	-	4,491
Long-term debt, net	30,395	29,556	15,647
Convertible preferred stock warrant liability	-	478	459
Convertible preferred stock	-	187,136	172,311
Accumulated deficit	(221,043)	(196,946)	(180,887)
Total stockholders' equity (deficit)	71,042	(192,652)	(177,124)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited financial statements and related notes thereto and other financial information included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, some of the information contained in the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. You should review the ''Risk Factors'' section of this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial stage medical technology company focused on designing, developing and marketing products that improve the quality of life for patients who suffer from psychiatric disorders. Our first commercial product, the NeuroStar Advanced Therapy System, is a non-invasive and non-systemic office-based treatment that uses transcranial magnetic stimulation, or TMS, to create a pulsed, MRI-strength magnetic field that induces electrical currents designed to stimulate specific areas of the brain associated with mood. The system is cleared by the United States Food and Drug Administration, or FDA, to treat adult patients with major depressive disorder, or MDD, that have failed to achieve satisfactory improvement from prior antidepressant medication in the current MDD episode. NeuroStar Advanced Therapy is safe, clinically effective, reproducible and precise and we believe is supported by the largest clinical data set of any competing TMS system. We believe we are the market leader in TMS therapy based on our U.S. installed base of 907 active NeuroStar Advanced Therapy Systems in approximately 707 psychiatrist offices as of December 31, 2018 and the estimated 62,900 patients treated with approximately 2.3 million of our treatment sessions through such date. We generated revenues of $52.8 million and $40.4 million for the years ended December 31, 2018 and 2017, respectively.

We designed the NeuroStar Advanced Therapy System as a non-invasive therapeutic alternative to treat patients who suffer from MDD and to address many of the key limitations of existing treatment options. We generate revenues from initial capital sales of our systems, sales of our recurring treatment sessions and from service and repair and extended warranty contracts. We derive the majority of our revenues from recurring treatment sessions. For the year ended December 31, 2018, revenues from sales of our treatment sessions and NeuroStar Advanced Therapy Systems represented 69% and 28% of our U.S. revenues, respectively. For the year ended December 31, 2017, revenues from sales of our treatment sessions and NeuroStar Advanced Therapy Systems represented 71% and 25% of our U.S. revenues, respectively.

We currently sell our NeuroStar Advanced Therapy System and recurring treatment sessions in the United States through our sales and customer support team, which was comprised of 133 people as of December 31, 2018. Our sales force primarily targets 15,100 psychiatrists at 3,600 high-decile psychiatric practices that we estimate, based on data from Symphony Health and our own internal estimates, treat approximately 33% of the total MDD patients in the United States who meet our labeled indication and are insured. We expect to continue to expand our direct sales and customer support team to further penetrate the market by demonstrating the benefits of our NeuroStar Advanced Therapy to psychiatrists and their MDD patients. Some of our customers have and may purchase more than one NeuroStar Advanced Therapy System. Based on our commercial data, we believe psychiatrists can recoup their initial capital investment in our system by providing a standard course of treatment to approximately 12 patients. We believe psychiatrists can generate approximately $7,500 to $10,000 of revenue per patient for a standard course of treatment, which may provide meaningful incremental income to their practices. We have a diverse customer base of psychiatrists in group psychiatric practices in the United States. No single customer accounted for more than 10% of our revenues for the years ended December 31, 2018 or 2017. Patients are reimbursed by Medicare and the vast majority of commercial payors in the United States for treatment sessions utilizing our NeuroStar Advanced Therapy System.

We market our products in a few select markets outside the United States through independent distributors. International revenues represented 2% and 1% of our total revenues for the years ended December 31, 2018 and 2017, respectively. In October 2017, we entered into an exclusive distribution agreement with Teijin Pharma Limited, or Teijin, for the distribution of our NeuroStar Advanced Therapy Systems and treatment sessions to customers who will treat patients with MDD in Japan. We received regulatory approval for our system in Japan in September 2017, and we plan to continue to work with Teijin to obtain reimbursement for NeuroStar Advanced Therapy in Japan. We expect our international revenues to increase as a percentage of our total revenues as we grow our presence in Japan.

Our research and development efforts are focused on the following: hardware and software product developments and enhancements of our NeuroStar Advanced Therapy System and clinical development relating to additional indications, which may include bipolar depression and post-traumatic stress disorder. We outsource the manufacture of components of our NeuroStar Advanced Therapy Systems that are produced to our specifications, and individual components are either shipped directly from our third-party contract manufacturers to our customers or consolidated into pallets at our Malvern, Pennsylvania facility prior to shipment. Final installation of these systems occurs at the customer site.

Our total revenues increased by $12.3 million, or 31%, from $40.4 million for the year ended December 31, 2017 to $52.8 million for the year ended December 31, 2018. For the year ended December 31, 2018, our U.S. revenues were $51.5 million, compared to $39.9 million for the year ended December 31, 2017, which represented an increase of 29% period over period. We expect to continue to incur losses for the next several years as we expand our commercial organization to support our planned sales growth and while continuing to invest in our pipeline indications. As of December 31, 2018, we had an accumulated deficit of $221.0 million.

On July 2, 2018, we closed our initial public offering, or IPO, in which we issued and sold 6,325,000 shares of our common stock, which included shares sold pursuant to an option granted to the underwriters to purchase additional shares, at a public offering price of $17.00 per share. We received net proceeds $96.5 million after deducting underwriting discounts, commissions and other offering expenses paid by us. Our common stock is listed on the Nasdaq Global Market under the trading symbol "STIM." Our primary sources of capital to date have been from our IPO, private placements of our convertible preferred securities, borrowings under our credit facilities and revenues from sales of our products.

Components of Our Results of Operations

Revenues

To date, we have generated revenues primarily from the capital portion of our business and related sales and rentals of the NeuroStar Advanced Therapy System and the recurring revenues from our sale of treatment sessions in the United States.

NeuroStar Advanced Therapy System Revenues. NeuroStar Advanced Therapy System revenues consist primarily of sales or rentals of a capital component, including upgrades to the equipment attributable to the initial sale of the system. NeuroStar Advanced Therapy Systems can be purchased outright or on a rent-to-own basis by certain customers. We had an installed base of 907 and 752 active NeuroStar Advanced Therapy Systems as of December 31, 2018 and 2017, respectively.

Treatment Session Revenues. Treatment session revenues primarily include sales of NeuroStar Treatment Sessions and SenStar treatment links. The NeuroStar Treatment Sessions are access codes that are delivered electronically in the United States. The SenStar treatment links are disposable units containing single-use access codes that are sold and used outside the United States. Access codes are purchased separately by our customers, primarily on an as-needed basis, and are required by the NeuroStar Advanced Therapy System in order to deliver treatment sessions.

Other Revenues. Other revenues are derived primarily from service and repair and extended warranty contracts with our existing customers.

We refer you to the section titled "—Critical Accounting Policies and Use of Estimates—Revenue Recognition" appearing elsewhere in this Annual Report on Form 10-K for additional information regarding how we account for revenues.

Sales in the United States represented 98% and 99% of our total revenues in 2018 and 2017, respectively and have been generated by our direct sales force. Outside the United States, our sales are made through local third-party distributors. International revenues were 2% for the year ended December 31, 2018, compared with 1% for the year ended December 31, 2017. In 2017, we terminated our relationship with our Japanese distributor in anticipation of entering into a new distribution agreement with Teijin, which significantly impacted our international sales for the

year ended December 31, 2017. We expect that both our United States and international revenues will increase in the near term as we continue to expand the installed base of NeuroStar Advanced Therapy Systems and increase the related patient utilization in the United States, as well as grow our presence in Japan. We expect our revenues to be positively impacted to the extent our direct sales force is successful in increasing the rate of adoption and utilization of treatment with TMS Therapy as an alternative to other MDD treatments.

Cost of Revenues and Gross Margin

Cost of revenues primarily consists of the costs of components and products purchased from our third-party contract manufacturers of our NeuroStar Advanced Therapy Systems as well as the cost of treatment packs for individual treatment sessions. We use third-party contract manufacturing partners to produce the components for and assemble the completed NeuroStar Advanced Therapy Systems. Cost of revenues also includes costs related to personnel, royalties, warranty, shipping, and our operations and field service departments. We expect our cost of revenues to increase in absolute dollars as and to the extent our revenues grow.

Our gross profit is calculated by subtracting our cost of revenues from our revenues. We calculate our gross margin as our gross profit divided by our revenues. Our gross margin has been and will continue to be affected by a variety of factors, primarily product sales mix, pricing and third-party contract manufacturing costs. Our gross margins on revenues from sales of NeuroStar Advanced Therapy Systems are lower than our gross margins on revenues from sales of treatment sessions and, as a result, the sales mix between NeuroStar Advanced Therapy Systems and treatment sessions can affect the gross margin in any reporting period.

Sales and Marketing Expenses

Sales and marketing expenses consist of market research and commercial activities related to the sale of our NeuroStar Advanced Therapy Systems and treatment sessions and salaries and related benefits, sales commissions and share-based compensation for employees focused on these efforts. Other significant sales and marketing costs include conferences and trade shows, promotional and marketing activities, including direct and online marketing, practice support programs, television and radio media campaigns, travel and training expenses.

We anticipate a significant increase in headcount in our commercial organization and in expenses in executing on our growth initiatives as we continue to expand our business in the United States and internationally. As a result, we expect our sales and marketing expenses to continue to increase in absolute dollars.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel expenses, including salaries and related benefits, share-based compensation and travel expenses, for employees in executive, finance, information technology, legal and human resource functions. General and administrative expenses also include the cost of insurance, outside legal fees, accounting and other consulting services, audit fees from our independent registered public accounting firm, board of directors' fees and other administrative costs, such as corporate facility costs, including rent, utilities, depreciation and maintenance not otherwise included in cost of revenues.

We anticipate that our general and administrative expenses will increase in absolute dollars because of an expanded infrastructure and an increased headcount. We anticipate higher corporate infrastructure costs including, but not limited to, accounting, legal, human resources, consulting and investor relations fees, listing fees on the Nasdaq Global Market, costs associated with Securities and Exchange Commission, or SEC, reporting and compliance, as well as increased director and officer insurance premiums, as a result of becoming a public company.

Research and Development Expenses

Research and development expenses consist primarily of personnel expenses, including salaries and related benefits and share-based compensation for employees in clinical development, product development, regulatory and quality assurance functions, as well as expenses associated with outsourced professional scientific development services and costs of investigative sites and consultants that conduct our preclinical and clinical development programs. We typically use our employee, consultant and infrastructure resources across our research and development programs.

We plan to incur research and development expenses for the near future as we expect to continue our development of TMS Therapy for the treatment of additional patient populations and new indications, which may include bipolar depression, post-traumatic stress disorder and potential other clinical indications yet to be determined, as well as for various hardware and software development projects. As a result, we expect our research and development expenses to continue to increase in absolute dollars.

Interest Expense

Interest expense consists of cash interest payable under our credit facility and non-cash interest attributable to the accrual of final payment fees and the amortization of deferred financing costs related to our indebtedness.

Other (Income) Expense, Net

Other (income) expense, net consists primarily of the revaluation related to our outstanding convertible preferred stock warrants, which were accounted for as a liability as of June 30, 2018 and marked-to-market at each reporting period, as well as gains and losses on the disposal of fixed assets and interest income earned on our money market account balances. Upon the closing of our IPO on July 2, 2018, all of our outstanding convertible preferred stock warrants converted into warrants to acquire an aggregate of 0.1 million shares of our common stock, resulting in the reclassification of the convertible preferred stock warrant liability into additional paid-in capital.

Results of Operations

Comparison of the Years ended December 31, 2018 and 2017

	Years ended December 31,		Increase/(Decrease)	
	2018	2017	Dollars	Percentage
	(in thousands, except percentages)			
Revenues	$ 52,776	$ 40,433	$ 12,343	31%
Cost of revenues	12,447	9,632	2,815	29%
Gross Profit	40,329	30,801	9,528	31%
Gross Margin	76.4%	76.2%		
Operating expenses:				
Sales and marketing	38,264	27,900	10,364	37%
General and administrative	13,667	8,572	5,095	59%
Research and development	8,232	7,937	295	4%
Total operating expenses	60,163	44,409	15,754	35%
Loss from Operations	(19,834)	(13,608)	(6,226)	46%
Other (income) expense:				
Interest expense	3,688	2,808	880	31%
Other (income) expense, net	575	(357)	932	-261%
Net Loss	$ (24,097)	$ (16,059)	$ (8,038)	50%

	Revenues by Geography Years ended December 31,			
	2018		2017	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
United States	$ 51,477	98%	$ 39,853	99%
International	1,299	2%	580	1%
Total revenues	$ 52,776	100%	$ 40,433	100%

	U.S. Revenues by Product Category Years ended December 31,			
	2018		2017	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
NeuroStar Advanced Therapy System	$ 14,603	28%	$ 10,120	25%
Treatment sessions	35,287	69%	28,391	71%
Other	1,587	3%	1,342	4%
Total U.S. revenues	$ 51,477	100%	$ 39,853	100%

Revenues

Total revenues increased by $12.3 million, or 31%, from $40.4 million for the year ended December 31, 2017 to $52.8 million for the year ended December 31, 2018. Revenues in the United States increased by $11.6 million from 2017 to 2018 due to higher unit sales of both NeuroStar Advanced Therapy Systems and treatment sessions. During the fourth quarter of 2017, we entered into an exclusive distribution agreement with Teijin, which we believe will allow us to increase our revenues in Japan once we obtain reimbursement in that country.

Revenues in the United States increased by $11.6 million, or 29%, from $39.9 million for the year ended December 31, 2017 to $51.5 million for the year ended December 31, 2018. NeuroStar Advanced Therapy System revenues in the United States grew by $4.5 million, or 44%, in the year ended December 31, 2018 compared to the year ended December 31, 2017. The increase in U.S. NeuroStar revenue was primarily driven by higher capital revenue growth of 59% due to higher unit sales, partially offset by a 1% decrease in average selling prices, lower upgrade, rent-to-own, and other related revenue. NeuroStar Advanced Therapy System revenues represented 28% and 25% of U.S. revenues for 2018 and 2017, respectively. We believe the growth in NeuroStar Advanced Therapy System revenues between these two periods was the result of the efforts of our expanded commercial organization and increased marketing efforts. As of December 31, 2018, we had an installed base of 907 active systems in the United States, compared to 752 as of December 31, 2017.

Treatment sessions revenues in the United States represented 69% and 71% of total revenues in the United States for the years ended December 31, 2018 and 2017, respectively, and increased by 24% from $28.4 million for the year end December 31, 2017 to $35.3 million for the year ended December 31, 2018. The increase in United States treatment session revenues was primarily the result of an approximate 25% increase in the number of treatment sessions sold, partially offset by a 5% decline in average selling price due to pre-determined volume pricing discounts within our existing customer base which are triggered when those customers surpass certain high volume thresholds, plus an increase in other treatment session revenue.

Cost of Revenues and Gross Margin

Cost of revenues increased by $2.8 million, or 29%, from $9.6 million for the year ended December 31, 2017 to $12.4 million for the year ended December 31, 2018. The increase was primarily due to increased NeuroStar Advanced Therapy System sales. Gross margin was 76.4% for the year ended December 31, 2018 compared to 76.2% for the year ended December 31, 2017. The gross margin was higher due to increased leverage on our service and operation costs, which were partially offset by the higher mix of NeuroStar Advanced Therapy System revenues in 2018 in relation to treatment session revenue and the reduction in average selling prices of our treatment sessions.

Sales and Marketing Expenses

Sales and marketing expenses increased by $10.4 million, or 37%, from $27.9 million for the year ended December 31, 2017 to $38.3 million for the year ended December 31, 2018. The increase was primarily due to increased personnel costs as a result of our sales and marketing expansion activities, as well as higher marketing expenses and sales commission costs, consistent with our growth in revenues. During 2018, we added 15 new sales territories and undertook several marketing projects to support our expansion plans, including increasing our presence at trade shows, expanding our media campaigns and enhancing our practice support program to include patient starter kits.

General and Administrative Expenses

General and administrative expenses increased by $5.1 million, or 59%, from $8.6 million for the year ended December 31, 2017 to $13.7 million for the year ended December 31, 2018. The increase was primarily due to an increase in personnel and legal, accounting and other professional services expenses required to support the growth of our business and ready the infrastructure for public company reporting.

Research and Development Expenses

Research and development expenses increased $0.3 million, or 4%, from $7.9 million for the year ended December 31, 2017 to $8.2 million for the year ended December 31, 2018. The increase was primarily due to expenses relating to the launch of the next generation of our NeuroStar Advanced Therapy System and TrakStar practice management system, which were partially offset by declines in spending relating to our adolescent study.

Interest Expense

Interest expense increased $0.9 million, or 31%, from $2.8 million for the year ended December 31, 2017 to $3.7 million for the year ended December 31, 2018, primarily as a result of higher cash interest expenses related to the increase in principal borrowings under our current credit facility and higher non-cash interest expenses accrued in connection with final payment fees due to the lender under the agreement.

Other (Income) Expense, Net

Other expense (income), net decreased by $0.9 million from ($0.3) million for year December 31, 2017 to $0.6 million for the year ended December 31, 2018. The fair value remeasurement of the liability related to our outstanding convertible preferred stock warrants decreased by $1.7 million during the year ended December 31, 2018, which was based on the closing stock price on June 29, 2018, following the pricing of our IPO on June 27, 2018. Upon closing of our IPO on July 2, 2018, all of our outstanding convertible preferred stock warrants converted into common stock warrants, resulting in the reclassification of our convertible preferred stock warrant liability into additional paid-in-capital. This decrease was partially offset by a $0.8 million of increase in interest income earned on the proceeds received from the IPO. Other expense (income), net for 2018 includes a one-time $0.1 million non-utilization fee related to the Company's election to not draw down the Term C loan, primarily as a result of the funds received from the IPO.

Comparison of the Years ended December 31, 2017 and 2016

	Years ended December 31,		Increase/(Decrease)	
	2017	2016	Dollars	Percentage
	(in thousands, except percentages)			
Revenues	$ 40,433	$ 34,228	$ 6,205	18%
Cost of revenues	9,632	6,622	3,010	45%
Gross Profit	30,801	27,606	3,195	12%
Gross Margin	76.2%	80.7%		
Operating expenses:				
Sales and marketing	27,900	21,794	6,106	28%
General and administrative	8,572	6,926	1,646	24%
Research and development	7,937	8,223	(286)	-3%
Total operating expenses	44,409	36,943	7,466	20%
Loss from Operations	(13,608)	(9,337)	(4,271)	46%
Other (income) expense:				
Interest expense	2,808	1,835	973	53%
Other (income) expense, net	(357)	62	(419)	*
Net Loss	$ (16,059)	$ (11,234)	$ (4,825)	43%

* Calculation is not meaningful.

	Revenues by Geography Years ended December 31,			
	2017		2016	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
United States	$ 39,853	99%	$ 31,577	92%
International	580	1%	2,651	8%
Total revenues	$ 40,433	100%	$ 34,228	100%

	U.S. Revenues by Product Category Years ended December 31,			
	2017		2016	
	Amount	% of Revenues	Amount	% of Revenues
	(in thousands, except percentages)			
NeuroStar Advanced Therapy System	$ 10,120	25%	$ 5,694	18%
Treatment sessions	28,391	71%	24,630	78%
Other	1,342	4%	1,253	4%
Total U.S. revenues	$ 39,853	100%	$ 31,577	100%

Revenues

Total revenues increased by $6.2 million, or 18%, from $34.2 million for the year ended December 31, 2016 to $40.4 million for the year ended December 31, 2017. Revenues in the United States increased by $8.3 million from 2016 to 2017 due to higher unit sales of both NeuroStar Advanced Therapy Systems and treatment sessions. International revenues declined by $2.1 million primarily due to the transition of our Japanese distributor during the fourth quarter of 2016. During the fourth quarter of 2017, we entered into an exclusive distribution agreement with Teijin, which we believe will allow us to increase our revenues in Japan once we obtain reimbursement in that country.

Revenues in the United States increased by $8.3 million, or 26%, from $31.6 million for the year ended December 31, 2016 to $39.9 million for the year ended December 31, 2017. NeuroStar Advanced Therapy System revenues in the United States grew by $4.4 million from 2016 to 2017, or 78%, based on 64% higher unit volume and 14% higher average selling prices. NeuroStar Advanced Therapy System revenues represented 18% and 25% of U.S. revenues for 2016 and 2017, respectively. We believe the growth in NeuroStar Advanced Therapy System revenues between these two periods was the result of the efforts of our expanded sales and customer support team to place additional systems.

Treatment sessions revenues in the United States increased by $3.8 million from 2016 to 2017, primarily due to an increase in the installed base of NeuroStar Advanced Therapy Systems. Treatment session revenues represented 78% and 71% of total revenues in the United States for the year ended December 31, 2016 and 2017, respectively. The increase in treatment session revenues in the United States was primarily the result of a 24% increase in the number of treatment sessions performed. This was offset by a 9% decline in average selling price due to certain volume pricing discounts within our existing customer base.

Cost of Revenues and Gross Margin

Cost of revenues increased by $3.0 million, or 45%, from $6.6 million for the year ended December 31, 2016 to $9.6 million for the year ended December 31, 2017. The increase was primarily due to increased NeuroStar Advanced Therapy System sales becoming a larger portion of the sales mix. Gross margin was 76% for the year ended December 31, 2017 compared to 81% for the year ended December 31, 2016. The decrease in gross margin was primarily due to the higher mix of NeuroStar Advanced Therapy System revenues in 2017 in relation to treatment sessions revenues and the reduction in the average selling price of our treatment sessions.

Sales and Marketing Expenses

Sales and marketing expenses increased by $6.1 million, or 28%, from $21.8 million for the year ended December 31, 2016 to $27.9 million for the year ended December 31, 2017. The increase was primarily due to increased personnel costs as a result of our sales and marketing expansion activities, as well as higher marketing expenses and sales commission costs, consistent with our growth in revenues. During 2017, we added 15 new sales territories and undertook several marketing projects to support our expansion plans, including increasing our presence at trade shows, expanding our media campaigns and enhancing our practice support program to include patient starter kits.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million, or 24%, from $6.9 million for the year ended December 31, 2016 to $8.6 million for the year ended December 31, 2017. The increase was primarily due to an increase in personnel and legal, accounting and other professional services expenses required to support the growth of our business and ready the infrastructure for public company reporting.

Research and Development Expenses

Research and development expenses decreased $0.3 million, or 3%, from $8.2 million for the year ended December 31, 2016 to $7.9 million for the year ended December 31, 2017. The decrease was primarily due to declines in spending relating to our adolescent study, which were partially offset by expenses relating to the launch of the next generation of our NeuroStar Advanced Therapy System and TrakStar practice management system.

Interest Expense

Interest expense increased $1.0 million, or 53%, from $1.8 million for the year ended December 31, 2016 to $2.8 million for the year ended December 31, 2017, primarily as a result of higher cash interest expenses related to the increase in principal borrowings under our current credit facility and higher non-cash interest expenses accrued in connection with final payment fees due to the lender under the agreement.

Other (Income) Expense, Net

The fair value remeasurement of the liability related to our outstanding convertible preferred stock warrants decreased by $0.3 million during the year ended December 31, 2017 as a result of the change in the fair value of our Series E and Series F convertible preferred stock during 2017.

Liquidity and Capital Resources

Overview

On July 2, 2018, we closed our IPO, in which we issued and sold 6,325,000 shares of our common stock, which included shares sold pursuant to an option granted to the underwriters to purchase additional shares, at a public offering price of $17.00 per share. We received net proceeds of $96.5 million after deducting underwriting discounts, commissions and other offering expenses paid by us.

As of December 31, 2018, we had cash and cash equivalents of $104.6 million and an accumulated deficit of $221.0 million, compared to cash and cash equivalents of $29.1 million and an accumulated deficit of $196.9 million as of December 31, 2017. We incurred negative cash flows from operating activities of $20.6 million and $11.1 million for the years ended December 31, 2018 and 2017, respectively. We have incurred operating losses since our inception, and we anticipate that our operating losses will continue in the near term as we seek to expand our sales and marketing initiatives to support our growth in existing and new markets, invest funds in additional research and development activities and utilize cash for other corporate purposes. Our primary sources of capital to date have been from our IPO, private placements of our convertible preferred securities, borrowings under our credit facilities and sales of our products. As of December 31, 2018, we had $30.0 million of borrowings outstanding under our credit facility, which matures in March 2022.

We expect our revenues and expenses to increase in connection with our on-going activities, particularly as we continue to execute on our growth strategy, including expansion of our sales and customer support teams. We also expect to incur additional costs now that we are a public company. Based on our current business plan, we believe that our cash and cash equivalents as of December 31, 2018 and anticipated revenues from sales of our products will be sufficient to meet our anticipated cash requirements for at least the next 24 months after December 31, 2018. However, if these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional common or preferred equity or debt securities, enter into a new credit facility or another form of third-party funding or seek other debt financing. If we raise additional funds by issuing equity or equity-linked securities, our stockholders would experience dilution and any new equity securities could have rights, preferences and privileges superior to those of holders of our common stock, including the shares of common stock sold in this offering. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. We cannot be assured that additional equity, equity-linked or debt financing will be available on terms favorable to us or our stockholders, or at all. It is also possible that we may allocate significant amounts of capital towards products or technologies for which market demand is lower than expected and, as a result, abandon such efforts. If we are unable to obtain adequate financing when we require it, or if we obtain financing on terms which are not favorable to us, or if we expend capital on products or technologies that are unsuccessful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, or we may be required to delay the development, commercialization and marketing of our products.

Our current and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth and improve operating margins;
- the cost of expanding our operations and offerings, including our sales and marketing efforts;
- our ability to improve or maintain coverage and reimbursement arrangements with domestic third-party and government payors;
- our rate of progress in establishing coverage and reimbursement arrangements from international commercial third-party and government payors, particularly in Japan;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products and maintaining or improving our sales to our current customers;
- the cost of research and development activities, including research and development relating to additional indications, which may include bipolar depression and PTSD;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2018, 2017 and 2016:

	Years ended December 31,		
	2018	2017	2016
Net Cash Used in Operating Activities	$ (20,591)	$ (11,144)	$ (8,541)
Net Cash Used in Investing Activities	(1,011)	(594)	(324)
Net Cash Provided by Financing Activities	97,038	23,845	4,896
Net Increase (Decrease) in Cash and Cash Equivalents	$ 75,436	$ 12,107	$ (3,969)

Net Cash Used in Operating Activities

Net cash used in operating activities for 2018 was $20.6 million, consisting primarily of a net loss of $24.1 million and an increase in net operating assets of $1.6 million, partially offset by non-cash charges of $5.1 million. The increase in net operating assets was primarily due to an increase in accounts receivable and inventory as a result of higher sales volumes. Non-cash charges consisted of depreciation and amortization, non-cash interest expense, share-based compensation, the cost of rental units purchased by customers and the change in the fair value of the liability related to our then-outstanding convertible preferred stock warrants.

Net cash used in operating activities for 2017 was $11.1 million, consisting primarily of a net loss of $16.1 million, offset by an increase in net operating liabilities of $3.2 million and non-cash charges of $1.8 million. The increase in net operating liabilities was primarily due to an increase in deferred revenue representing the initial payment and first milestone payment received in accordance with our Japanese distribution agreement as well as expanding commercial and research activities. Non-cash charges consisted of depreciation and amortization, non-cash interest expense, share-based compensation, the cost of rental units purchased by customers and the change in the fair value of the liability related to our then-outstanding convertible preferred stock warrants.

Net cash used in operating activities for 2016 was $8.5 million, consisting primarily of a net loss of $11.2 million, offset by an increase in net operating liabilities of $1.4 million and non-cash charges of $1.3 million. The increase in net operating liabilities was primarily due to increases in accounts payable and accrued expenses, offset by an increase in inventory primarily due rent-to-own units from one large customer. Non-cash charges consisted of depreciation and amortization, non-cash interest expense, share-based compensation and the change in the fair value of the liability related to our outstanding convertible preferred stock warrants.

Net Cash Used in Investing Activities

Net cash used in investing activities for 2018 was $1.0 million, compared to net cash used in investing activities for 2017 of $0.6 million and $0.3 million for 2016, in each case attributable to purchases of property and equipment and capitalized software costs in 2017 and 2018.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for 2018 was $97.0 million, consisting primarily of $100.0 million of proceeds related to the closing of our IPO on July 2, 2018, partially offset by $3.5 million of payments of costs related to the IPO.

Net cash provided by financing activities for 2017 was $23.8 million, consisting of $14.8 million of net proceeds from the issuance of Series G convertible preferred stock and $10.0 million of borrowings under our current credit facility, offset by payment of $1.0 million of deferred debt issuance costs incurred in connection with our March 2017 amended credit facility.

Net cash provided by financing activities for 2016 was $4.9 million, consisting primarily of $5.0 million of borrowings under our previous credit facility, offset by payment of the related deferred debt issuance costs incurred in connection with a March 2016 amendment.

Indebtedness

Current Credit Facility

In March 2017, we entered into a new loan and security agreement with Oxford Finance LLC, or Oxford, for a credit facility that replaced our previous $25.0 million credit facility with Oxford and which allowed us to borrow up to $35.0 million in three tranches of term loans: a Term A Loan in the amount of $25.0 million, which was drawn down immediately upon closing in March 2017, a Term B Loan in the amount of $5.0 million, which was drawn down in December 2017, and a Term C Loan in the amount of $5.0 million, which became available to us upon the achievement of $45.0 million of trailing twelve month revenues during the second quarter of 2018. Upon achieving the required revenue milestone, we had 60 days to notify Oxford if we elected to borrow the Term C Loan. As a result of completing our IPO on July 2, 2018 and receiving the proceeds therefrom, we elected not to borrow the

additional $5.0 million, and it is no longer available to us. Each term loan accrues interest from the date of borrowing through the date of repayment at a floating per annum rate of interest, which resets monthly and is equal to the greater of (a) 8.15% or (b) the 30-day U.S. LIBOR on the last business day of the month plus 7.38%. At the date of each borrowing, we were required to issue to Oxford warrants to purchase our Series F or later series of convertible preferred stock with a seven-year term and in an amount equal to 3.95% of the first $5.0 million of each tranche borrowed. The credit facility matures and all amounts borrowed thereunder are due on March 1, 2022. As of December 31, 2018, we had borrowed and had outstanding an aggregate of $30.0 million of principal under our credit facility.

The Term A Loan featured an interest-only period through March 2019, during which time we were required to make monthly interest payments, after which time we were required to make monthly payments of principal and interest based on a 36-month amortization schedule. However, upon the achievement of $45.0 million of revenues during the fourth quarter of 2018, the interest-only period was extended for an additional 12 months through March 2020, after which time we will be required to make monthly payments of principal and interest based on a 24-month amortization schedule. In connection with the drawdown of the Term A Loan, we issued to Oxford a warrant to purchase shares of its Series F convertible preferred stock. This convertible preferred stock warrant converted into a warrant to purchase 20,303 shares of our common stock at an exercise price of $9.73 per share. The warrant will expire in March 2024.

The Term B Loan featured an interest-only period through March 2019, during which time we were required to make monthly interest payments, after which time we were required to make monthly payments of principal and interest based on a 36-month amortization schedule. However, due to the achievement of $45.0 million of revenues during the fourth quarter of 2018, the interest-only period was extended for an additional 12 months through March 2020, after which time we will be required to make monthly payments of principal and interest based on a 24-month amortization schedule. In connection with the drawdown of the Term B Loan, we issued to Oxford a warrant to purchase shares of its Series F convertible preferred stock. This convertible preferred stock warrant converted into a warrant to purchase 20,303 shares of our common stock at an exercise price of $9.73 per share. The warrant will expire in December 2024.

In addition to principal and interest payments due under the credit facility, we are required to make final payment fees to Oxford due upon the earlier of prepayment or maturity of each tranche, which increased as a result the extension of the interest-only period and are now equal to 8.5% and 7.5% of the principal amounts of the Term A and Term B Loans, respectively. We accrue the estimated final payment fees using the effective interest rate, with a charge to non-cash interest expense, over the term of borrowing for each tranche. As of December 31, 2018, the effective interest rates for the Term A and Term B Loans were 11.87% and 12.14%, respectively. As of December 31, 2017, the effective interest rates for the Term A and Term B Loans were 10.7% and 11.6%, respectively. If the we prepay our term loans prior to their respective scheduled maturities, we will also be required to make prepayment fees to Oxford equal to 3% if prepaid on or before the first anniversary of funding, 2% if prepaid after the first and on or before the second anniversary of funding, or 1% if prepaid after the second anniversary of funding of the principal amounts borrowed.

Our obligations under the credit facility are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. We have agreed not to pledge or otherwise encumber any of our intellectual property. The loan and security agreement related to our credit facility includes a financial maintenance covenant that requires us to achieve at least 75% of our trailing 12-month forecasted revenues, as measured each month in accordance with a forecast that we provided to Oxford upon signing the agreement and future forecasts that we are required to deliver to Oxford each year for the life of the credit facility, as well as customary affirmative and negative covenants. We were in compliance with all of the covenants under our credit facility as of December 31, 2018.

The loan and security agreement related to our credit facility contains events of default, including, without limitation, events of default upon: (i) failure to make payment pursuant to the terms of the agreement; (ii) violation of covenants; (iii) material adverse changes to our business; (iv) attachment or levy on our assets or judicial restraint on our business; (v) insolvency; (vi) significant judgments, orders or decrees for payments by us not covered by insurance; (vii) incorrectness of representations and warranties; (viii) incurrence of subordinated debt; (ix) revocation of governmental approvals necessary for us to conduct our business; and (x) failure by us to maintain a valid and perfected lien on the collateral securing the borrowing.

Based on a 24-month amortization of the outstanding principal amounts of the Term A and Term B Loans beginning on April 1, 2020 as discussed above, the following table sets forth by year our required future principal payments (in thousands):

Year:	Principal Payments
2019	$ -
2020	11,250
2021	15,000
2022	3,750
Total principal payments	$ 30,000

Previous $25.0 Million Credit Facility

Prior to March 2017, we had a $25.0 million credit facility in place with Oxford, which we entered into in February 2014 and which allowed us to borrow up to $25.0 million in three tranches of term loans: a Term A Loan in the amount of $15.0 million, a Term B Loan in the amount of $5.0 million, and a Term C Loan in the amount of $5.0 million, which was never drawn down. Each term loan accrued interest at per annum rates ranging from 8.5% to 8.9%. This facility featured an interest-only period on all tranches through March 2017, and we were also required to issue convertible preferred stock warrants to Oxford at the time of borrowing of each tranche. These convertible preferred stock warrants converted into common stock warrants immediately prior to the closing of our IPO on July 2, 2018,

We accrued final payment fees using the effective interest rate, with a charge to non-cash interest expense, over the term of borrowing and until our entry into our current credit facility in March 2017, at which time we paid the lender $1.0 million in satisfaction of all final payment fee liabilities due under the prior credit facility.

We evaluated whether our current credit facility entered into in March 2017 represented a debt modification or extinguishment in accordance with ASC 470-50, Debt—Modifications and Extinguishments. Upon determining that the change in cash flows between the previous and current credit facilities was not greater than 10%, we accounted for the transaction as a debt modification. As of March 2017, the unamortized balance of deferred financing costs incurred in connection with the $25.0 million credit facility, and certain additional deferred financing costs incurred in connection with entry into our current credit facility, are being amortized to interest expense through March 2022 utilizing the effective interest method.

Cash and Non-Cash Interest Expense

For the year ended December 31, 2018, we recognized interest expense of $3.7 million, of which $2.9 million was cash and $0.8 million was non-cash interest expense related to the amortization of deferred financing costs and accrual of final payment fees. For the year ended December 31, 2017, we recognized interest expense of $2.8 million, of which $2.1 million was cash and $0.7 million was non-cash interest expense related to the amortization of deferred financing costs and accrual of final payment fees.

Off-Balance Sheet Arrangements

We do not maintain any off-balance sheet arrangements, partnerships or other relationships with unconsolidated entities, often referred to as structured finance or special-purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Commitments and Contractual Obligations

The following table sets forth a summary of our contractual obligations as of December 31, 2018:

	Payments Due by Period				
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
			(in thousands)		
Principal payments on long-term debt	$ -	$ 26,250	$ 3,750	$ -	$ 30,000
Interest and lender fees on long-term debt[1]	2,959	3,762	2,550	-	9,271
Operating leases[2]	547	648	-	-	1,195
Total	$ 3,506	$ 30,660	$ 6,300	$ -	$ 40,466

(1) Interest payable reflects the rate in effect as of December 31, 2018. The interest rate on borrowings under the credit facility is variable and resets monthly. Lender fees reflect final payment fees due.

(2) Reflects obligations primarily related to our office and warehouse/storage leases in Malvern, PA.

Distribution Agreement with Teijin Pharma Limited

In October 2017, we entered into a seven-and-a-half-year distribution agreement with Teijin Pharma Limited, or Teijin, for the exclusive distribution of our NeuroStar Advanced Therapy System to customers who will treat patients with MDD in Japan. Under the distribution agreement, Teijin is generally restricted from selling competing products in Japan. Our distribution agreement provides that we will have primary responsibility for obtaining reimbursement approval for use of NeuroStar Advanced Therapy System for the treatment of MDD in Japan, and Teijin will promote the sales of NeuroStar Advanced Therapy System for treatment of MDD in Japan. We have agreed to provide sales and technical support training to Teijin for our NeuroStar Advanced Therapy Systems.

Teijin is required to purchase minimum dollar values of NeuroStar Advanced Therapy Systems and treatment sessions from us following reimbursement approval by the Japanese Ministry of Health, Labour and Welfare, or JMHLW, for TMS treatment for MDD (or, if such approval requires certified training on the NeuroStar Advanced Therapy System by a third party, then upon the first psychiatrist being issued his or her training certification).

In 2017, under our distribution agreement with Teijin, we received an upfront payment of $0.75 million and a milestone payment of $2.0 million following JMHLW's approval of marketing the NeuroStar Advanced Therapy System for the treatment of MDD in Japan. These upfront and milestone payments have been deferred and are being recognized as revenue over the seven- and one-half year term of the agreement. Teijin is required to pay us a milestone payment tied to JMHLW issuing reimbursement for use of our products for the treatment of MDD in Japan.

The distribution agreement is scheduled to expire on March 31, 2025, subject to earlier termination if we or Teijin breach the agreement, Teijin fails to maintain distributor-level permits and approvals, Teijin fails to purchase from us specified dollar values of its sales forecasts, reimbursement for treatment of MDD using the NeuroStar Advanced Therapy System is not obtained from JMHLW by specified dates or such reimbursement is below specified minimums, Teijin reasonably believes that it is not commercially reasonable to continue distributing the NeuroStar Advanced Therapy System in Japan or bankruptcy related events occur. The term of the distribution agreement will be automatically extended for two years unless either party gives the other party at least two years' prior written of notice of non-renewal, except that we cannot decline to renew the agreement if Teijin has purchased 100% of its sales forecasts over the term of the agreement.

Executive Employment Agreements

We are party to an employment agreement and offer letters with certain members of our executive team that provide for severance and other payments following termination of their employment for various reasons. We refer you to "Item 11. Executive Compensation" in this Annual Report on Form 10-K.

Critical Accounting Policies and Use of Estimates

The preparation of our financial statements in accordance with accounting principles generally accepted in the United States, or GAAP, and the rules and regulations of the SEC requires us to make estimates and assumptions, based on judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates and assumptions on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Although we believe our estimates and assumptions are reasonable when made, they are based upon information available to us at the time they are made. We evaluate our estimates and assumptions on an ongoing basis and, if necessary, make adjustments. Due to the risks and uncertainties involved in our business and evolving market conditions and given the subjective element of the estimates and assumptions made, actual results may differ from estimated results.

We define our critical accounting policies as those accounting policies that are most important to the portrayal of our financial condition and results of operations and require our most difficult and subjective judgments. While our significant accounting policies are more fully described in "Note 3. Summary of Significant Accounting Policies" in our audited financial statements and related notes thereto appearing elsewhere in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies.

Revenue Recognition

Revenue is recognized when title and risk of ownership has been transferred, provided that persuasive evidence of an arrangement exists, the price is fixed and determinable and collectability is reasonably assured. Transfer of title and risk of ownership occurs when the product is shipped or transferred to the customer. We sell to end users in the United States and to third-party distributors outside the United States and do not provide return rights. Sales to distributors outside the United States are made in U.S. dollars.

Our NeuroStar Advanced Therapy System sales in the United States typically have a post-sale training obligation. This obligation is fulfilled after product shipment, and we defer recognizing revenue until training occurs. In accordance with the accounting guidance related to multiple element arrangements, we defer the fair value attributable to the post shipment training and recognize such revenue when the obligation is fulfilled. We base the fair value of the training using stand-alone service rates. Our sales to our third-party distributors outside the United States do not have these post-sale obligations. Our consumable single use and accessory products have no post sale obligations and no return rights. Revenue from the sales of these products are recognized upon delivery. Revenue attributable to the NeuroStar Advanced Therapy Systems purchased on a rent-to-own basis are accounted for as operating leases and revenue is recognized on a straight-line basis over the term of the lease.

In addition, we provide a one to two year warranty for systems sold in the United States. Terms of product warranty differ amongst our third-party distributors outside the United States but are generally two years. We provide for the estimated cost to repair or replace products under any warranty at the time of sale. We also offer our customers in the United States annual service contracts. Revenue from the sale of annual service contracts is recognized on a straight-line basis over the period of the applicable contract. We also earn revenue from customers from services outside of their warranty term or annual service contracts. Such service revenue is recognized as the services are provided.

We had deferred revenue of $1.9 million and $1.6 million at December 31, 2018 and 2017, respectively, primarily related to training, warranty and rent to own units. During the fourth quarter of 2017, we entered into an exclusive Distribution Agreement with Teijin Pharma Limited, which we expect will allow us to increase deliveries to Japan. In connection with the Distribution Agreement, we received an upfront payment as well as the first milestone payment, which are being recognized as revenue over the seven and a half-year term of the agreement. The last milestone payment is due upon achieving reimbursement approval in Japan. At December 31, 2018 and 2017, we had $2.3 million and $2.7 million in deferred revenue, respectively, related to this agreement.

Share-based Compensation

We recognize the grant-date fair value of share-based awards issued as compensation as expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Prior to our IPO, the fair value of restricted stock awards is based on a determination by the board of directors of the estimated fair value of the common stock at the date of grant. The fair value of stock options is estimated at the time of grant using the Black-Scholes option pricing model, which requires the use of inputs and assumptions, the most critical of which prior to our IPO is the estimated fair value of our common stock.

We expect the amount of share-based compensation expense recognized for stock options and restricted stock awards and units to increase for future awards in future periods due to the potential increase in both the value of our common stock and the size of our company in terms of headcount.

Valuation of Common Stock

All options to purchase shares of our common stock are granted with an exercise price per share equal to or greater than the estimated fair value per share of our common stock on the date of grant, based on the information known to us on the date of grant. Prior to our IPO, on each grant date, the fair values of the shares of common stock underlying our stock options were estimated on each grant date by our board of directors, based on information known to us at the date of grant. In order to determine the estimated fair value of our common stock, our board of directors considered, among other things, contemporaneous valuations of our preferred and common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our capital stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our preferred and common stock, including:

- contemporaneous third-party valuations of our preferred and common stock;
- the prices, rights, preferences and privileges of our preferred stock relative to the common stock;
- our business, financial condition and results of operations, including related industry trends affecting our operations;
- the likelihood of achieving a liquidity event, such as an initial public offering or the sale of our company, given prevailing market conditions;
- the lack of marketability of our preferred and common stock;
- the market performance of comparable publicly traded companies; and
- United States and global economic and capital market conditions and outlook.

Since the closing of our IPO, our board of directors has determined the per share fair value of our common stock based on the closing price of our common stock as reported by the Nasdaq Global Market on the date of grant.

JOBS Act Accounting Election

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, or Securities Act, for complying with new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Subject to certain conditions, as an emerging growth company, we may rely on certain other exemptions and reduced reporting requirements under the JOBS Act, including without limitation (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier of (a) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (b) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous six years; or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Recent Accounting Pronouncements

We refer you to "Note 4. Recent Accounting Pronouncements" in our audited financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our cash is held on deposit in demand accounts at a large financial institution in amounts in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Financial instruments that potentially subject us to concentrations of credit risk principally consist of cash equivalents and accounts receivable. We limit our credit risk associated with cash equivalents by placing investments in highly-rated money market funds. We limit our credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary, but we do not require collateral to secure amounts owed to us by our customers.

As discussed above in the section of this Annual Report on Form 10-K titled "—Liquidity and Capital Resources—Indebtedness," our credit facility bears interest at a floating per annum rate of interest, which resets monthly and is equal to the greater of (a) 8.15% or (b) the 30-day U.S. LIBOR on the last business day of the month plus 7.38%. As a result, we are exposed to risks from changes in interest rates. We believe that a one-point increase in interest rates would result in an approximate $0.3 million increase to our interest expense for the year ended December 31, 2018.

Inflationary factors, such as increases in our cost of revenues and operating expenses, may adversely affect our operating results. Although we do not believe inflation has had a material impact on our financial condition, results of operations or cash flows to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin or decrease our operating expenses as a percentage of our revenues if our selling prices of our products do not increase as much or more than our costs increase.

We do not currently have any exposure to foreign currency fluctuations and do not engage in any hedging activities as part of our normal course of business.

Item 8. Financial Statements and Supplementary Data.

The financial statements listed in the Index to Financial Statements beginning on page F-1 are filed as part of this Annual Report on Form 10-K and incorporated by reference herein.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2018.

As a result of becoming a public company, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2019. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The SEC defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be detected or prevented on a timely basis.

Inherent Limitations on Effectiveness of Controls and Procedures

Internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon 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; over time, controls may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of internal control, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance of achieving their objectives. We conduct periodic evaluations of our systems of controls to enhance, where necessary, our control policies and procedure

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2018, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) which materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Code of Conduct

The information required by this item is incorporated by reference to the information set forth in the sections titled "Proposal 1 - Election of Directors," "Executive Officers of the Company," and "Information Regarding the Board and Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our 2019 Proxy Statement.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the section titled "Executive Compensation" in our 2019 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to the information set forth in the section titled "Security Ownership of Certain Beneficial Owners and Management and "Executive Compensation" in our 2019 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to the information set forth in the section titled "Transactions with Related Persons" and "Information regarding the Board of Directors and Corporate Governance" in our 2019 Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to the information set forth in the section titled "Principal Accountant Fees and Services" contained in Proposal 2 in our 2019 Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

The financial statements listed in the Index to Financial Statements beginning on page F-1 are filed as part of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes listed in the Index to Financial Statements beginning on page F-1.

(a)(3) Exhibits

See the Exhibit Index immediately following the signature page of this Annual Report. The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report.

Exhibit Index

Exhibit No.	Description of Document

NEURONETICS, INC.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Neuronetics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Neuronetics, Inc. (the Company) as of December 31, 2018 and 2017, the related statements of operations, changes in convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2003.

Philadelphia, Pennsylvania
March 5, 2019

NEURONETICS, INC.

Balance Sheets
(In thousands, except per share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 104,583	$ 29,147
Accounts receivable, net	5,620	4,267
Inventory	2,432	2,468
Prepaid expenses and other current assets	1,838	1,123
Total current assets	114,473	37,005
Property and equipment, net	1,378	1,359
Other assets	1,171	574
Total Assets	$ 117,022	$ 38,938
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,756	$ 2,513
Accrued expenses	7,548	7,511
Deferred revenue	2,255	1,970
Total current liabilities	13,559	11,994
Long-term debt, net	30,395	29,556
Deferred revenue	1,940	2,275
Deferred rent	86	151
Convertible preferred stock warrant liability	-	478
Total Liabilities	45,980	44,454
Commitments and contingencies (Note 15)		
Convertible preferred stock, $0.01 par value: 308,593 shares previously authorized prior to initial public offering, issuable in series; no and 304,958 shares issued and outstanding at December 31, 2018 and 2017, respectively; no liquidation value at December 31, 2018	-	187,136
Stockholders' Equity (Deficit):		
Preferred stock, $0.01 par value: 10,000 shares authorized; no shares issued or outstanding at December 31, 2018 and 2017, respectively	-	-
Common stock, $0.01 par value: 200,000 shares authorized; 17,744 and 231 shares issued and outstanding at December 31, 2018 and 2017, respectively	177	2
Additional paid-in capital	291,908	4,292
Accumulated deficit	(221,043)	(196,946)
Total Stockholders' Equity (Deficit)	71,042	(192,652)
Total Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)	$ 117,022	$ 38,938

The accompanying notes are an integral part of these financial statements.

NEURONETICS, INC.

Statements of Operations
(In thousands, except per share data)

	Years ended December 31,		
	2018	**2017**	**2016**
Revenues	$ 52,776	$ 40,433	$ 34,228
Cost of revenues	12,447	9,632	6,622
Gross Profit	40,329	30,801	27,606
Operating expenses:			
Sales and marketing	38,264	27,900	21,794
General and administrative	13,667	8,572	6,926
Research and development	8,232	7,937	8,223
Total operating expenses	60,163	44,409	36,943
Loss from Operations	(19,834)	(13,608)	(9,337)
Other (income) expense:			
Interest expense	3,688	2,808	1,835
Other (income) expense, net	575	(357)	62
Net Loss	$ (24,097)	$ (16,059)	$ (11,234)
Net loss per share of common stock outstanding, basic and diluted	$ (2.69)	$ (86.34)	$ (76.95)
Weighted-average common shares outstanding, basic and diluted	8,948	186	146

The accompanying notes are an integral part of these financial statements.

NEURONETICS, INC.

Statement of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at December 31, 2015	264,374	$ 172,311	126	$ 1	$ 3,534	$ (169,653)	$ (166,118)
Issuance of restricted stock awards	-	-	42	1	(1)	-	-
Exercises of stock options	-	-	19	-	67	-	67
Share-based compensation expense	-	-	-	-	161	-	161
Net loss	-	-	-	-	-	(11,234)	(11,234)
Balance at December 31, 2016	264,374	172,311	187	2	3,761	(180,887)	(177,124)
Issuance of Series G convertible preferred stock, net of issuance costs of $175	40,584	14,825	-	-	-	-	-
Issuance of restricted stock awards	-	-	11	-	-	-	-
Exercises of stock options	-	-	33	-	35	-	35
Share-based compensation expense	-	-	-	-	496	-	496
Net loss	-	-	-	-	-	(16,059)	(16,059)
Balance at December 31, 2017	304,958	187,136	231	2	4,292	(196,946)	(192,652)
Conversion of convertible preferred stock into common stock	(304,958)	(187,136)	10,994	109	187,027	-	187,136
Conversion of convertible preferred stock warrants into common stock warrants	-	-	-	-	1,874	-	1,874
Issuance of common stock in initial public offering, net of issuance costs of $3,463	-	-	6,325	64	96,471	-	96,535
Exercises of stock options	-	-	194	2	501	-	503
Share-based compensation expense	-	-	-	-	1,743	-	1,743
Net loss	-	-	-	-	-	(24,097)	(24,097)
Balance at December 31, 2018	-	$ -	17,744	$ 177	$ 291,908	$ (221,043)	$ 71,042

The accompanying notes are an integral part of these financial statements.

NEURONETICS, INC.

Statements of Cash Flows
(In thousands)

	Years ended December 31,		
	2018	**2017**	**2016**
Cash Flows from Operating Activities:			
Net loss	$ (24,097)	$ (16,059)	$ (11,234)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	882	596	673
Share-based compensation	1,743	496	161
Non-cash interest expense	839	722	391
Change in fair value of convertible preferred stock warrant liability	1,396	(271)	108
Cost of rental units purchased by customers	229	216	15
Changes in certain assets and liabilities:			
Accounts receivable, net	(1,353)	(690)	(123)
Inventory	(435)	(1,068)	(646)
Prepaid expenses and other assets	(237)	(175)	(156)
Accounts payable	606	788	734
Accrued expenses	(52)	1,391	1,201
Deferred revenue	(49)	2,915	363
Deferred rent	(63)	(5)	(28)
Net Cash Used in Operating Activities	(20,591)	(11,144)	(8,541)
Cash Flows from Investing Activities:			
Purchases of property and equipment and capitalized software	(1,011)	(594)	(324)
Net Cash Used in Investing Activities	(1,011)	(594)	(324)
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock in initial public offering	99,998	-	-
Payments of public offering costs	(3,463)	-	-
Proceeds from exercises of stock options	503	35	67
Proceeds from issuance of Series G convertible preferred stock, net	-	14,825	-
Borrowings under credit facilities	-	10,000	5,000
Payments of debt issuance costs	-	(1,015)	(171)
Net Cash Provided by Financing Activities	97,038	23,845	4,896
Net Increase (Decrease) in Cash and Cash Equivalents	75,436	12,107	(3,969)
Cash and Cash Equivalents, Beginning of Year	29,147	17,040	21,009
Cash and Cash Equivalents, End of Year	$ 104,583	$ 29,147	$ 17,040
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 2,786	$ 2,043	$ 1,406
Transfer of inventory to property and equipment	$ 365	$ 296	$ 531
Supplemental disclosure of non-cash investing and financing activities:			
Purchases of property and equipment and capitalized software in accounts payable and accrued expenses	$ 263	$ 45	$ 16
Conversion of convertible preferred stock into common stock	$ 187,136	$ -	$ -
Conversion of convertible preferred stock warrants into common stock warrants	$ 1,874	$ -	$ -
Deferred public offering costs included in accounts payable and accrued expenses	$ -	$ 55	$ -
Allocation of proceeds from debt financing to convertible preferred stock warrant liability	$ -	$ 290	$ 135

The accompanying notes are an integral part of these financial statements.

1. DESCRIPTION OF BUSINESS

Neuronetics, Inc., or the Company, is a commercial stage medical technology company focused on designing, developing and marketing products that improve the quality of life for patients who suffer from psychiatric disorders. The Company's first commercial product, the NeuroStar Advanced Therapy System, is a non-invasive and non-systemic office-based treatment that uses transcranial magnetic stimulation, or TMS, to create a pulsed, MRI-strength magnetic field that induces electrical currents designed to stimulate specific areas of the brain associated with mood. The system was cleared in 2008 by the United States Food and Drug Administration, or the FDA, to treat adult patients with major depressive disorder, or MDD, who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. The Company intends to continue to pursue development of its NeuroStar Advanced Therapy System for additional indications.

Initial Public Offering

On July 2, 2018, the Company closed its initial public offering, or IPO, in which the Company issued and sold 6.325 million shares of its common stock, which included shares sold pursuant to an option granted to the underwriters to purchase additional shares, at a public offering price of $17.00 per share. The Company received net proceeds of $96.5 million after deducting underwriting discounts, commissions and other offering expenses paid by the Company. The Company's common stock is listed on the Nasdaq Global Market under the trading symbol "STIM." In addition, immediately prior to the closing of the IPO on July 2, 2018, (i) all of the Company's outstanding shares of convertible preferred stock converted into an aggregate 11.0 million shares of common stock; (ii) all of the Company's outstanding warrants to purchase convertible preferred stock converted into warrants to purchase common stock; and (iii) the Company filed an amended and restated certificate of incorporation to, among other things, decrease the number of shares of common stock, $0.01 par value per share, authorized for issuance to 200.0 million and to authorize the board of directors to issue up to 10.0 million shares of "blank check" preferred stock, $0.01 par value per share.

Liquidity

As of December 31, 2018, the Company had cash and cash equivalents of $104.6 million and an accumulated deficit of $221.0 million. The Company incurred negative cash flows from operating activities of $20.6 million, $11.1 million and $8.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. The Company has incurred operating losses since its inception, and management anticipates that its operating losses will continue in the near term as the Company seeks to expand its sales and marketing initiatives to support its growth into existing and new markets and invest in additional research and development activities. The Company's primary sources of capital to date have been from its IPO, private placements of its convertible preferred securities, borrowings under its credit facilities and revenues from sales of its products. As of December 31, 2018, the Company had $30.0 million of borrowings outstanding under its credit facility, which matures in March 2022. Management believes that the Company's cash and cash equivalents as of December 31, 2018 and anticipated revenues from sales of its products are sufficient to fund the Company's operations for at least the next 24 months after December 31, 2018.

2. BASIS OF PRESENTATION

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles, or GAAP. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Updates, or ASUs, promulgated by the Financial Accounting Standards Board, or FASB.

Use of Estimates

The preparation of financial statements in accordance with GAAP and the rules and regulations of the United States Securities and Exchange Commission, or SEC, requires the use of estimates and assumptions, based on judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates and assumptions on historical experience, known trends and events and various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Although management believes its estimates and assumptions are reasonable when made, they are based upon information available at the time they are made. Management evaluates the estimates and assumptions on an ongoing basis and, if necessary, makes adjustments. Due to the risks and uncertainties involved in the Company's business and evolving market conditions and given the subjective element of the estimates and assumptions made, actual results may differ from estimated results. The most significant estimates and judgments impact share-based compensation and the valuation of common stock prior to the IPO.

Recapitalization

The Company effected a 0.0345-for-1 reverse split of its common stock on June 14, 2018. The reverse split combined each approximately 29 shares of the Company's issued and outstanding common stock into one share of common stock and correspondingly adjusted the conversion price of its outstanding convertible preferred stock. No fractional shares were issued in connection with the reverse split. Any fractional share resulting from the reverse split was rounded down to the nearest whole share, and in lieu of any fractional share, the Company paid in cash to the holders of such fractional shares an amount equal to the fair market value, as determined by the board of directors, of such fractional shares. All share, per share and related information presented in these financial statements and the related notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2018 and 2017, cash equivalents consisted of money market funds.

Concentrations of Credit Risk

The Company's cash is held on deposit in demand accounts at a large financial institution in amounts in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. Management has reviewed the financial statements of this institution and believes it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to the Company.

Financial instruments that potentially subject the Company to concentrations of credit risk principally consist of cash equivalents and accounts receivable. The Company limits its credit risk associated with cash equivalents by placing investments in highly-rated money market funds. The Company limits its credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary, but it does not require collateral to secure amounts owed by its customers.

Allowance for Doubtful Accounts

The Company maintains allowances for doubtful accounts for estimated losses resulting from amounts deemed to be uncollectible from its customers. These allowances are for specific amounts on certain customer accounts based on facts and circumstances determined on a case-by-case basis.

Inventory

Inventory is stated at the lower of cost and net realizable value, with cost being determined on a first in, first out basis. The Company's inventory is primarily comprised of finished goods.

Property and Equipment and Capitalized Software

Property and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred and costs of improvements and renewals are capitalized. Depreciation and amortization are recognized using the straight-line method based on the estimated useful lives of the related assets. The Company uses an estimated useful life of three years for computers and software, five years for laboratory and office equipment, six years for devices in the rental agreement program and the lesser of five years or the remaining life of the underlying facility lease for leasehold improvements.

Software development costs relating to assets to be sold in the normal course of business are included in research and development and are expensed as incurred until technological feasibility is established. After technological feasibility is established, material software development costs are capitalized. The Company uses an estimated useful life of two years for capitalized software and amortizes these costs beginning at the product release.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Impairment testing requires management to estimate the future net undiscounted cash flows of an asset using assumptions believed to be reasonable. Actual cash flows may differ from the estimates used in the impairment testing. If such assets are considered to be impaired, the Company recognizes an impairment loss when and to the extent that the estimated fair value of an asset is less than its carrying value. The Company has not recorded any impairment of its long-lived assets for the years ended December 31, 2018, 2017, and 2016.

Warrant Liability

The Company's current and previous credit facilities required the Company to issue to the lender of warrants to purchase the Company's convertible preferred stock at the date of borrowing. Because the convertible preferred stock warrants were a form of a contingently redeemable instrument, they were classified as liabilities on the Company's balance sheet. At the date of borrowing, the Company bifurcated the estimated fair value of the convertible preferred stock warrants from the proceeds from borrowing, resulting in the recognition of a debt discount, and recorded a warrant liability on its balance sheet. This warrant liability was revalued at each reporting period, with changes in fair value recorded in the Company's statement of operations as a component of other income or expense. The valuation of the warrant liability was based upon estimates of the fair value of the underlying convertible preferred stock and the related volatility and expected term for an illiquid instrument, which could vary significantly from period to period.

Immediately prior to the closing of the IPO on July 2, 2018, all of the Company's outstanding convertible preferred stock warrants converted into common stock warrants. The warrant liability was remeasured at its estimated fair value and reclassified to additional paid-in capital on the Company's balance sheet.

Deferred Debt Issuance Costs

The Company capitalizes direct costs incurred to obtain debt financing and amortizes these costs to interest expense over the term of the debt using the effective interest method. These costs are recorded as a debt discount are netted against the related debt on the Company's balance sheet.

Revenue Recognition

Revenue is recognized when title and risk of ownership has been transferred, provided that persuasive evidence of an arrangement exists, the price is fixed and determinable and collectability is reasonably assured. Transfer of title and risk of ownership occurs when the product is shipped or transferred to the customer. The Company sells to end users in the United States and to third-party distributors outside the United States and does not provide return rights. Sales to distributors outside the United States are in U.S. dollars.

The Company generates revenues from sales of NeuroStar Advanced Therapy Systems and treatment sessions. NeuroStar Advanced Therapy System revenue consists primarily of a capital component, including updates to the equipment, attributable to the initial sale of the NeuroStar system unit. NeuroStar Advanced Therapy Systems can be purchased outright or on a rent-to-own basis by certain customers. Treatment session revenue primarily includes sales of NeuroStar treatment sessions and SenStar treatment links. The NeuroStar treatment sessions are access codes delivered electronically in the United States. The SenStar treatment links are disposable units containing single-use access codes that are sold and used outside the United States. Access codes are purchased separately by customers, primarily on an as-needed basis, and are required by the NeuroStar Advanced Therapy System in order to deliver the treatment sessions.

The Company's NeuroStar Advanced Therapy System sales in the United States typically have a post-sale training obligation. This obligation is fulfilled after product shipment, and the Company defers recognizing revenue until training occurs. In accordance with the accounting guidance related to multiple element arrangements, the Company defers the fair value attributable to the post-shipment training and recognizes such revenue when the obligation is fulfilled. The Company bases the fair value of the training using stand-alone service rates. The Company's sales to its third-party distributors outside the United States do not have these post-sale obligations. The Company's treatment sessions have no post-sale obligations and no return rights. Revenues on the sales of treatment sessions are recognized upon delivery. Revenue related to operating leases for the Company's NeuroStar Advanced Therapy System is recognized over the term of the lease. Revenue attributable to the NeuroStar Advanced Therapy Systems purchased on a rent-to-own basis are accounted for as operating leases and revenue is recognized on a straight-line basis over the term of the lease.

The Company provides a one to two-year warranty for systems sold in the United States. Terms of product warranty differ amongst its third-party distributors outside the United States but are generally three years or less. The Company provides for the estimated cost to repair or replace products under any warranty at the time of sale. The Company also offers its customers in the United States annual service contracts. Revenue from the sale of annual service contracts is recognized on a straight-line basis over the period of the applicable contract. The Company also earns revenue from customers from services outside of their warranty term or annual service contracts. Such service revenue is recognized as the services are provided.

Research and Development Expenses

Research and development activities are expensed as incurred. Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

Share-based Compensation

The Company recognizes the grant-date fair value of share-based awards issued as compensation as expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. To date, the Company has not issued awards where vesting is subject to market conditions. There was one performance grant in 2018 to the board of directors subject to completion of the IPO, which was achieved in July 2018. The fair value of restricted stock awards and restricted stock units is estimated at the time of grant, based on the grant date fair value of the Company's common stock. The fair value of stock options is estimated at the time of grant using the Black-Scholes option pricing model, which requires the use of inputs and assumptions such as the fair value of the underlying common stock, exercise price of the option, expected term, risk-free interest rate, expected volatility and dividend yield, the most critical of which is the fair value of the Company's common stock prior to the IPO.

The fair value of each grant of stock options awarded during the years ended December 31, 2018, 2017 and 2016 was determined using the following methods and assumptions:

- ***Fair Value of Common Stock.*** Prior to the IPO, its board of directors periodically estimated the fair value of the Company's common stock considering, among other things, contemporaneous valuations of its preferred and common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Since the closing of the IPO, its board of directors has determined the per share fair value of the Company's common stock based on the closing price as reported by the Nasdaq Global Market on the date of grant.
- ***Expected Term.*** Due to the historical lack of a public market for the trading of the Company's common stock and the lack of sufficient company-specific historical data, the expected term of employee stock options is determined using the "simplified" method, as prescribed in SEC Staff Accounting Bulletin (SAB) No. 107 (SAB 107), whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term of nonemployee stock options is equal to the contractual term.
- ***Risk-free Interest Rate.*** The risk-free interest rate is based on the interest rate payable on United States Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.
- ***Expected Volatility.*** The expected volatility is based on historical volatilities of peer companies within the Company's industry which were commensurate with the expected term assumption, as described in SAB 107.
- ***Dividend Yield.*** The dividend yield is 0% because the Company has never paid, and for the foreseeable future does not expect to pay, a dividend on its common stock.

The inputs and assumptions used to estimate the fair value of share-based payment awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different inputs and assumptions, the Company's share-based compensation expense could be materially different for future awards.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases 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. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company accrues interest and related penalties are classified as income tax expense in the statements of operations. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

As of December 31, 2018 and 2017, the Company had deferred tax assets of $53.8 million and $47.3 million, respectively; these deferred tax assets are primarily attributable to federal and state net operating loss carryforwards. Although the loss carryforwards are available to offset future taxable income, they will begin to expire in 2020 for state and 2023 for federal. In addition, prior ownership changes may create a limitation in the Company's ability to

use the net operating loss carryforwards for federal and state income tax purposes. These loss carryforwards have been fully offset by a valuation allowance because management does not consider realization of these deferred tax assets to be more likely than not.

Corporate tax reform was enacted on December 22, 2017 and is effective for the Company for year ended December 31, 2017. The provisions of the corporate tax reform did not have any impact to the Company due to the full valuation allowance position. As a result of the reduced corporate rate, the Company's deferred tax assets were revalued from 34% to 21%, which was fully offset by a reduction in the valuation allowance. In connection with the corporate tax reform, the Medical Device Tax was suspended for another two years.

4. RECENT ACCOUNTING PRONOUNCEMENTS

JOBS Act Accounting Election

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

In May 2014, the FASB issued ASU 2014-09, "*Revenue from Contracts with Customers*" *(Topic 606)*, regarding the accounting for and disclosures of revenue recognition, with an effective date for public companies of annual and interim periods beginning after December 15, 2016. In July 2015, the FASB issued ASU 2015-14, "*Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*," which deferred the effective date of the previously issued revenue recognition guidance by one year. This guidance is effective for public companies for annual and interim periods beginning after December 15, 2017. For all other entities, including emerging growth companies, this standard is effective for annual reporting periods beginning after December 15, 2018, and interim periods with annual periods beginning after December 15, 2019. Early adoption is permitted.

In April 2016 and May 2016, the FASB issued ASU 2016-10, "*Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*" and ASU 2016-12, "*Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*," respectively. Both updates provide improvements and clarification to the previously issued revenue recognition guidance.

The new revenue standard provides a single comprehensive model for accounting for revenue from contracts with customers. The model requires that revenue recognized reflects the actual consideration to which the entity expects to be entitled in exchange for the goods or services defined in the contract, including in situations with multiple performance obligations. In addition, the standard requires quantitative and qualitative disclosures of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers, as well as any judgements related to the standard.

The new revenue standard is principles-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice, and guidance may evolve as companies and the accounting profession work to implement this new standard. The Company will continue to monitor industry activities and any additional guidance provided by regulators, standards setters, or the accounting profession. The Company has also implemented internal controls and processes to enable the preparation of financial information and has reached conclusions on key accounting assessments related to the standard.

The new standard can be adopted using one of two methods: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The Company adopted the standard on January 1, 2019, using the modified retrospective approach and applying the completed contracts practical expedient, with the cumulative effect of adoption recorded within retained earnings on January 1, 2019. However, the Company concluded that all sales prior to January 1, 2019 are completed contracts, as all or substantially all the revenue related to these sales has been recognized as of that date. Therefore, there was no cumulative effect of adoption recorded within retained earnings on January 1, 2019.

The Company determined that the new guidance will not have a material impact on its revenue recognition practices for NeuroStar Advance Therapy Systems and Treatment Sessions. However, the standard changes the Company's accounting treatment for incremental costs to obtain a contract, including sales commissions. The incremental costs of obtaining a contract are those that an entity incurs to obtain a contract with a customer that it would not have incurred if the contract had not been obtained.

Historically, the Company expensed incremental costs to obtain a contract as incurred, including the sales commissions paid for NeuroStar Advance Therapy Systems and Treatment Sessions. Under Topic 606, the Company will capitalize a portion of the sales commissions paid on NeuroStar Advanced Therapy Systems sold after January 1, 2019 and amortize the expense on a straight-line basis over a seven-year period, which is consistent with the transfer of specific anticipated Treatment Session contracts to customers.

Additionally, the standard changes the Company's accounting treatment for milestone payments, specifically related to a future contingent milestone payment in the Company's distribution agreement with Teijin Pharma Limited, or Teijin. Teijin is required to pay the Company a milestone payment tied to Japanese Ministry of Health, Labour and Welfare, or JMHLW, issuing reimbursement for use of its products for the treatment of MDD in Japan. The initial reimbursement amount received from JMHLW is subject to a revision period based the completion of post marketing surveillance studies, which in turn would cause a revision in the milestone payment. The Company estimated the revenue likely to be earned, subject to the constraint that the amount recorded is not probable of a significant revenue reversal, by probability weighting likely reimbursement outcomes and the related milestone payment amounts. As a result of this analysis, the Company concluded that the new guidance will not have an impact on the Company's revenue as of the adoption date.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), with guidance regarding the accounting for and disclosure of leases. The update requires lessees to recognize all leases, including operating leases, with a term greater than 12 months on the balance sheet. This update also requires lessees and lessors to disclose key information about their leasing transactions. This guidance will be effective for public companies for annual and interim periods beginning after December 15, 2018. For all other entities, including emerging growth companies, this standard will be effective for annual reporting periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted.

As a lessee, leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. As a lessor, leases will be classified as either direct financing, sales-type, or operating, with classification affecting the pattern of revenue recognition and related expense, in the income statement. Additionally, the new standard requires quantitative and qualitative disclosures of amount, timing, and judgments related to the accounting for leases and the related cash flows.

The leases standard is required to be applied to leases in existence as of the date of initial application using a modified retrospective transition approach; a full retrospective transition approach is not permitted. The Company adopted the standard on January 1, 2019, using the effective date modified retrospective method transition. Under this adoption method, comparative periods are presented in accordance with Topic 840 and do not include any retrospective adjustments to reflect the adoption of Topic 842.

The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows the Company to carryforward the historical lease classification. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off the balance sheet. The Company will recognize those lease payments in the Statements of Operations on a straight-line basis over the lease term. The Company made an accounting policy election to present all funds collected from lessees for sales and other similar taxes net of the related sales tax expense.

As a lessee, the Company will recognize additional right of use assets and lease liabilities of approximately $1.0 million as of January 1, 2019. The right of use asset and lease liabilities primarily relate to the Company's current non-cancelable office lease with an expiration date in 2021.

Certain costumers have purchased NeuroStar Advanced Therapy Systems on a rent-to-own basis. Prior to adoption of Topic 842, revenue attributable to the NeuroStar Advanced Therapy Systems purchased on a rent-to-own basis were accounted for as operating leases and revenue is recognized on a straight-line basis over the term of the lease. Given the package of practical expedients elected, the Company will continue this revenue recognition for NeuroStar Advanced Therapy Systems sold on a rent-to-own basis as of December 31, 2018.

By granting a customer the right to use a NeuroStar Advanced Therapy System, the Company is performing a revenue generating activity and the revenue recognition should be consistent with the framework in Topic 606. Due to developing customer purchase history, the Company has recently determined customers who purchase NeuroStar Advanced Therapy Systems on a rent-to-own basis are now reasonably certain to exercise the purchase option at the end of the lease. Therefore, NeuroStar Advanced Therapy Systems purchased on a rent-to-own basis will be accounted for as sales-type leases.

As a sales-type lease classification under Topic 842, selling profit or loss will be recognized at lease commencement and the underlying NeuroStar Advance Therapy System will be derecognized. The Company will record a corresponding lease receivable equal to the present value of the future lease payments, adjusted prospectively by interest income and payments. As of January 1, 2019, there was no impact on the Company's financial statements related to the NeuroStar Advanced Therapy Systems purchased on a rent-to-own basis.

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): "*Improvements to Nonemployee Share-Based Payment Accounting*," which largely aligns the accounting for share-based payment awards issued to nonemployees with the accounting for share-based payment awards issued to employees. Under previous GAAP, the accounting for nonemployee share-based payments differed from that applied to employee awards, particularly with regard to the measurement date and the impact of performance conditions. Under the new guidance, (i) equity-classified share-based payment awards issued to nonemployees will be measured at the grant date, instead of the previous requirement to remeasure the awards through the performance completion date, (ii) for performance conditions, compensation cost associated with the award will be recognized when the achievement of the performance condition is probable, rather than upon achievement of the performance condition, and (iii) the current requirement to reassess the classification (equity or liability) for nonemployee awards upon vesting will be eliminated, except for awards in the form of convertible instruments. This new guidance will be effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company currently has no outstanding nonemployee share-based payment awards for which there is unrecognized compensation expense and therefore does not currently expect the adoption of the new guidance to have an effect on its financial statements.

5. FAIR VALUE MEASUREMENT AND FINANCIAL INSTRUMENTS

The carrying values of cash equivalents, accounts receivable, prepaids and other current assets, and accounts payable on the Company's balance sheets approximated their fair values as of December 31, 2018 and 2017 due to their short-term nature. The carrying values of the Company's current credit facility approximated its fair value as of December 31, 2018 and 2017 due to its variable interest rate.

Certain of the Company's financial instruments are measured at fair value using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1: Inputs are quoted prices for identical instruments in active markets.

Level 2: Inputs are quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; or model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3: Inputs are unobservable and reflect the Company's own assumptions, based on the best information available, including the Company's own data.

The following tables set forth the carrying amounts and fair values of the Company's financial instruments as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices In Active Markets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets					
Money market funds (cash equivalents)	$ 87,062	$ 87,062	$ 87,062	$ -	$ -

	December 31, 2017				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices In Active Markets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets					
Money market funds (cash equivalents)	$ 11,149	$ 11,149	$ 11,149	$ -	$ -
Liabilities					
Convertible preferred stock warrant liability	$ 478	$ 478	$ -	$ -	$ 478

The fair value of the convertible preferred stock warrant liability was estimated using the Black-Scholes option pricing model and the following inputs and assumptions as of December 31, 2017:

	December 31, 2017	
	Series E	Series F
Estimated fair value of convertible preferred stock	$ 9.57	$ 11.01
Exercise price	$ 19.55	$ 9.73
Remaining term (in years)	5.0	3.1 - 7.0
Risk-free interest rate	2%	2.0% - 2.3%
Expected volatility	43%	43% - 44%
Dividend yield	0%	0%

The following table presents the changes in Level 3 instruments measured on a recurring basis for the years ended December 31, 2018 and 2017 (in thousands):

Balance at December 31, 2016	$ 459
Issuance of warrants	290
Change in fair value	(271)
Balance at December 31, 2017	478
Change in fair value	1,396
Reclassification to additional paid in capital	(1,874)
Balance at December 31, 2018	$ -

6. ACCOUNTS RECEIVABLE

The following table presents the composition of accounts receivable, net as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Gross accounts receivable - trade	$ 6,120	$ 4,684
Less: Allowances for doubtful accounts	(500)	(417)
Accounts receivable, net	$ 5,620	$ 4,267

Bad debt expense was $0.2 million, $0.1 million and $0.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

The following table presents a rollforward of the allowance for doubtful accounts (in thousands):

	Balance at Beginning of Period	Bad Debt Expense Recognized	Write-offs of Uncollectible Balances	Balance at End of Period
Year ended December 31, 2016	$ (274)	(75)	6	$ (343)
Year ended December 31, 2017	$ (343)	(116)	42	$ (417)
Year ended December 31, 2018	$ (417)	(153)	70	$ (500)

7. PROPERTY AND EQUIPMENT AND CAPITALIZED SOFTWARE

The following table presents the composition of property and equipment, net as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Laboratory equipment	$ 150	$ 150
Office equipment	487	487
Computer equipment and software	1,050	680
Manufacturing equipment	273	273
Leasehold improvements	172	153
Rental equipment	1,262	1,447
Property and equipment, gross	3,394	3,190
Less: Accumulated depreciation	(2,016)	(1,831)
Property and equipment, net	$ 1,378	$ 1,359

As of December 31, 2018 and 2017, the Company had capitalized software costs, net of $1.0 million and $0.4 million, respectively, which are included in “Other assets” on the balance sheet.

Depreciation and amortization expense was $0.9 million, $0.6 million and $0.7 million for the years ended December 31, 2018, 2017 and 2016, respectively.

8. ACCRUED EXPENSES

The following table presents the composition of accrued expenses as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Compensation and related benefits	$ 4,909	$ 4,465
Consulting and professional fees	342	461
Research and development expenses	191	497
Sales and marketing expenses	127	620
Warranty	629	570
Sales tax payable	606	322
Interest payable	251	188
Other	493	388
Accrued expenses	$ 7,548	$ 7,511

9. DEBT

The following table presents the composition of debt as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Outstanding principal	$ 30,000	$ 30,000
Accrued final payment fees	1,468	940
Less debt discounts	(1,073)	(1,384)
Total long-term debt, net	30,395	29,556
Less current portion of long-term debt	-	-
Long-term debt, net	$ 30,395	$ 29,556

For the year ended December 31, 2018, the Company recognized interest expense of $3.7 million, of which $2.9 million was cash and $0.8 million was non-cash interest expense related to the amortization of deferred debt issuance costs and accrual of final payment fees. For the year ended December 31, 2017, the Company recognized interest expense of $2.8 million, of which $2.1 million was cash and $0.7 million was non-cash interest expense related to the amortization of deferred debt issuance costs and accrual of final payment fees. For the year ended December 31, 2016, the Company recognized interest expense of $1.8 million, of which $1.4 million was cash and $0.4 million was non-cash interest expense related to the amortization of deferred debt issuance costs and accrual of final payment fees.

Current Credit Facility

In March 2017, the Company entered into a new loan and security agreement with Oxford Finance LLC, or Oxford, for a credit facility that replaced its previous $25.0 million credit facility with Oxford and which allowed it to borrow up to $35.0 million in three tranches of term loans: a Term A Loan in the amount of $25.0 million, which was drawn down immediately upon closing in March 2017, a Term B Loan in the amount of $5.0 million, which was drawn down in December 2017, and a Term C Loan in the amount of $5.0 million, which became available to the Company upon the achievement of $45.0 million of trailing twelve month revenues during the second quarter of 2018. Upon achieving the required revenue milestone, the Company had 60 days to notify Oxford if it elected to borrow the Term C Loan. As a result of completing its IPO on July 2, 2018 and receiving the net proceeds therefrom, the Company elected not to borrow the additional $5.0 million, and it is no longer available to the Company. Each term loan accrues interest from the date of borrowing through the date of repayment at a floating per annum rate of interest, which resets monthly and is equal to the greater of (a) 8.15% or (b) the 30-day U.S. LIBOR on the last business day of the month plus 7.38%. The Company was also required to issue to Oxford at the date of each borrowing warrants to purchase its Series F or later series of convertible preferred stock with a seven-year term and in an amount equal to 3.95% of the first $5.0 million of each tranche borrowed. The credit facility matures and all amounts borrowed thereunder are due on March 1, 2022. As of December 31, 2018, the Company had borrowed and had outstanding an aggregate of $30.0 million of principal under the credit facility.

The Term A Loan featured an interest-only period through March 2019, during which time the Company was required to make monthly interest payments, after which time the Company was required to make monthly payments of principal and interest based on a 36-month amortization schedule. However, due to the achievement of $45.0 million of revenues during the fourth quarter of 2018, the interest-only period was extended for an additional 12 months through March 2020, after which time the Company will be required to make monthly payments of principal and interest based on a 24-month amortization schedule. In connection with the drawdown of the Term A Loan, the Company issued to Oxford a warrant to purchase shares of its Series F convertible preferred stock. On July 2, 2018, this convertible preferred stock warrant converted into a warrant to purchase 20,303 shares of the Company's common stock at an exercise price of $9.73 per share. The warrant will expire in March 2024.

The Term B Loan featured an interest-only period through March 2019, during which time the Company was required to make monthly interest payments, after which time the Company was required to make monthly payments of principal and interest based on a 36-month amortization schedule. However, due to the achievement of $45.0 million of revenues during the fourth quarter of 2018, the interest-only period was extended for an additional 12 months through March 2020, after which time the Company will be required to make monthly payments of

principal and interest based on a 24-month amortization schedule. In connection with the drawdown of the Term B Loan, the Company issued to Oxford a warrant to purchase shares of its Series F convertible preferred stock. On July 2, 2018, this convertible preferred stock warrant converted into a warrant to purchase 20,303 shares of the Company's common stock at an exercise price of $9.73 per share. The warrant will expire in December 2024.

In addition to principal and interest payments due under the credit facility, the Company is required to make final payment fees to Oxford due upon the earlier of prepayment or maturity of each tranche, which increased as a result the extension of the interest-only period and are now equal to 8.5% and 7.5% of the principal amounts of the Term A and Term B Loans, respectively. The Company accrues the estimated final payment fees using the effective interest rate, with a charge to non-cash interest expense, over the term of borrowing for each tranche. As of December 31, 2018, the effective interest rates for the Term A and Term B Loans were 11.87% and 12.14%, respectively. As of December 31, 2017, the effective interest rates for the Term A and Term B Loans were 10.7% and 11.6%, respectively. If the Company prepays its term loans prior to their respective scheduled maturities, it will also be required to make prepayment fees to Oxford equal to 3% if prepaid on or before the first anniversary of funding, 2% if prepaid after the first and on or before the second anniversary of funding, or 1% if prepaid after the second anniversary of funding of the principal amounts borrowed.

The Company's obligations under the credit facility are secured by a first priority security interest in substantially all of its assets, other than its intellectual property. The Company has agreed not to pledge or otherwise encumber any of its intellectual property. The loan and security agreement related to the credit facility includes a financial maintenance covenant that requires the Company to achieve at least 75% of its trailing 12-month forecasted revenues, as measured each month in accordance with a forecast that the Company provided to Oxford upon signing the agreement and future forecasts that the Company is required to deliver to Oxford each year for the life of the credit facility, as well as customary affirmative and negative covenants. The Company was in compliance with all of the covenants under its credit facility as of December 31, 2018.

The loan and security agreement related to the credit facility contains events of default, including, without limitation, events of default upon: (i) failure to make payment pursuant to the terms of the agreement; (ii) violation of covenants; (iii) material adverse changes to the Company's business; (iv) attachment or levy on the Company's assets or judicial restraint on its business; (v) insolvency; (vi) significant judgments, orders or decrees for payments by the Company not covered by insurance; (vii) incorrectness of representations and warranties; (viii) incurrence of subordinated debt; (ix) revocation of governmental approvals necessary for the Company to conduct its business; and (x) failure by the Company to maintain a valid and perfected lien on the collateral securing the borrowing.

Based on a 24-month amortization of the outstanding principal amounts of the Term A and Term B Loans beginning on April 1, 2020 as discussed above, the following table sets forth by year the Company's required future principal payments (in thousands):

Year:	Principal Payments
2019	$ -
2020	11,250
2021	15,000
2022	3,750
Total principal payments	$ 30,000

Previous $25.0 Million Credit Facility

Prior to March 2017, the Company had a $25.0 million credit facility in place with Oxford, which it entered into in February 2014 and which allowed it to borrow up to $25.0 million in three tranches of term loans: a Term A Loan in the amount of $15.0 million, a Term B Loan in the amount of $5.0 million and a Term C Loan in the amount of $5.0 million, which was never drawn down. Each term loan accrued interest at per annum rates ranging from 8.5% to 8.9%. This facility featured an interest-only period on all tranches through March 2017, and the Company was also required to issue convertible preferred stock warrants to Oxford at the time of borrowing of each tranche. These convertible preferred stock warrants converted into common stock warrants immediately prior to the closing of the Company's IPO on July 2, 2018.

In addition to principal and interest payments due under the previous $25.0 million credit facility, the Company was required to make final payment fees to Oxford upon the earlier of prepayment or maturity and equal to 8.5% and 4.7% of the principal amounts of the Term A and Term B Loans, respectively. The Company accrued final payment fees using the effective interest rate, with a charge to non-cash interest expense, over the term of borrowing and until its entry into the current credit facility in March 2017, at which time the Company paid Oxford $1.0 million in satisfaction of all final payment fee liabilities due under the prior credit facility.

Management evaluated whether the current credit facility entered into in March 2017 represented a debt modification or extinguishment in accordance with ASC 470-50, Debt—Modifications and Extinguishments. Upon determining that the change in cash flows between the previous and current credit facilities was not greater than 10%, management accounted for the transaction as a debt modification. As of March 2017, the unamortized balance of deferred debt issuance costs incurred in connection with the $25.0 million credit facility, and certain additional deferred debt issuance costs incurred in connection with entry into the current credit facility, are being amortized to interest expense through March 2022 utilizing the effective interest method.

10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

Initial Public Offering

On July 2, 2018, the Company closed its IPO, in which the Company issued and sold 6.325 million shares of its common stock, which included shares sold pursuant to an option granted to the underwriters to purchase additional shares, at a public offering price of $17.00 per share. The Company received net proceeds of $96.5 million after deducting underwriting discounts, commissions and other offering expenses paid by the Company. In addition, immediately prior to the closing of the IPO on July 2, 2018, (i) all of the Company's outstanding shares of convertible preferred stock converted into an aggregate of 11.0 million shares of common stock; (ii) all of the Company's outstanding warrants to purchase convertible preferred stock converted into warrants to purchase common stock; and (iii) the Company filed an amended and restated certificate of incorporation to, among other things, decrease the number of shares of common stock, $0.01 par value per share, authorized for issuance to 200.0 million and to authorize the board of directors to issue up to 10.0 million shares of "blank check" preferred stock, $0.01 par value per share.

Common Stock

The Company's amended and restated certificate of incorporation as of December 31, 2018 authorized the issuance of 200.0 million shares of common stock, $0.01 par value per share, of which 17.744 million were issued and outstanding as of December 31, 2018.

Prior to the IPO, the Company was required to reserve and keep available out of its authorized but unissued shares of common stock a number of shares sufficient to effect the conversion into common stock of all outstanding shares of convertible preferred stock and convertible preferred stock warrants, convertible preferred stock or common stock warrants issuable upon borrowing the Term C Loan under the current credit facility, stock options granted and shares available for grant under its stock incentive plan.

The following table summarizes the total number of shares of the Company's common stock issued and reserved for issuance as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Shares of common stock issued	17,744	231
Shares of common stock reserved for issuance for:		
Convertible preferred stock outstanding:		
Series A-1	-	166
Series A-2	-	898
Series B	-	697
Series C	-	1,063
Series D	-	1,705
Series E	-	1,534
Series F	-	3,531
Series G	-	1,400
Convertible preferred stock warrants outstanding:		
Series E	-	14
Series F	-	91
Warrants issuable upon Term C Loan borrowing	-	20
Common stock warrants outstanding	105	-
Stock options outstanding	2,711	2,444
Restricted stock units outstanding	43	-
Shares available for grant under stock incentive plan	1,312	246
Shares available for sale under employee stock purchase plan	244	-
Total shares of common stock issued and reserved for issuance	22,159	14,040

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Holders of common stock are entitled to receive any dividends that the Company's board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. The Company has never paid, and for the foreseeable future does not expect to pay, a dividend on its common stock.

Convertible Preferred Stock

Prior to the filing of the July 2, 2018 amended certificate of incorporation, the Company's amended certificate of incorporation authorized the issuance of 308.6 million shares of convertible preferred stock, $0.01 par value per share, of which the Company had designated and issued Series A-1, Series A-2, Series B, Series C, Series D, Series E, Series F and Series G shares. Series A-1 through Series E shares of convertible preferred stock are referred to collectively as Junior Securities and are subordinate to shares of Series G and Series F convertible preferred stock. All of the Company's convertible preferred stock was classified outside of stockholders' equity (deficit) because the shares contained deemed liquidation rights that were a contingent redemption feature not solely within the control of the Company.

The following table summarizes the Company's outstanding convertible preferred stock as of December 31, 2017:

	Shares Authorized and Designated (in thousands)	Shares Issued and Outstanding (in thousands)	Carrying Value (in thousands)	Liquidation Value per Share	Liquidation Value (in thousands)
Series A-1	4,800	4,800	$ 900	$ 0.0617	$ 296
Series A-2	25,385	25,385	16,428	$ 0.2052	5,209
Series B	17,000	17,000	16,859	$ 0.3168	5,386
Series C	20,958	20,958	34,841	$ 0.5253	11,009
Series D	49,426	49,426	29,970	$ 0.2874	14,205
Series E	44,873	44,471	29,800	$ 0.5144	22,876
Series F	105,567	102,334	43,513	$ 0.3356	34,343
Series G	40,584	40,584	14,825	$ 0.3696	15,000
Balance at December 31, 2017	308,593	304,958	$ 187,136		$ 108,324

Conversion

Each share and series of convertible preferred stock was convertible into common stock at any time at the option of the holder thereof at the conversion price then in effect (each subject to adjustments upon the occurrence of certain dilutive events). As of July 2, 2018, the conversion price for Series A-1, Series D, Series E, Series F and Series G shares was equal to the original issue price, resulting in a common stock conversion ratio of 1:0.0345. As of July 2, 2018, as a result of past anti-dilution adjustments, the conversion price for Series A-2, Series B and Series C shares was below the original issue price, resulting in common stock conversion ratios of 1:0.03539, 1:0.04103 and 1:0.05071, respectively. Immediately prior to the closing of the IPO on July 2, 2018, all of the Company's outstanding shares of convertible preferred stock converted into 11.0 million shares of common stock.

Liquidation Preferences

As of December 31, 2017

In the event of a liquidation, dissolution or winding up of the Company, either voluntary or involuntary, or in the event of a deemed liquidation event, which includes a sale of the Company as defined in the Company's certificate of incorporation, holders of Series G convertible preferred stock were entitled to receive, in preference to all other stockholders, an amount equal to their original investment amount plus any declared and unpaid dividends. If upon the occurrence of such event the assets and funds available for distribution are insufficient to pay such holders the full amount to which they are entitled, then the entire assets and funds legally available for distribution would be distributed ratably among the holders of the Series G convertible preferred stock in proportion to the full amounts to which they would otherwise be entitled.

After payment in full of the liquidation preference of the Series G convertible preferred stock, holders of Series F convertible preferred stock were entitled to receive, in preference to all holders of Junior Securities and common stock, an amount equal to their original investment amount plus any declared and unpaid dividends. If upon the occurrence of such event the assets and funds available for distribution are insufficient to pay such holders the full amount to which they are entitled, then the entire remaining assets and funds legally available for distribution would be distributed ratably among the holders of the Series F convertible preferred stock in proportion to the full amounts to which they would otherwise be entitled.

After payment in full of the liquidation preferences of the Series G and Series F convertible preferred stock, holders of Junior Securities were entitled to receive an amount equal to $59.2 million in the aggregate. If upon the occurrence of such event the assets and funds available for distribution are insufficient to pay such holders the full amount to which they are entitled, then the entire assets and funds legally available for distribution would be distributed ratably among the holders of the Junior Securities in proportion to the full amounts to which they would otherwise be entitled.

After payment in full of the liquidation preferences of the Series G, Series F and Junior Securities convertible preferred stock, holders of Series F convertible preferred stock were entitled to receive an additional liquidation preference at an amount equal to $0.1678 per share. If upon the occurrence of such event the assets and funds available for distribution are insufficient to pay such holders the full amount to which they would be entitled, then the entire assets and funds legally available for distribution would be distributed ratably among the holders of the Series F convertible preferred stock in proportion to the full amounts to which they would otherwise be entitled.

After payment in full of the liquidation preferences of the Series G, Series F and Junior Securities convertible preferred stock and the additional liquidation preference for holders of Series F convertible preferred stock, holders of common stock and holders of Junior Securities, Series F and Series G convertible preferred stock would be entitled to receive a liquidation preference until the amount distributed to holders of the Series F convertible preferred stock equals $1.0068 plus declared but unpaid dividends on each share and then to the holders of common stock and holders of Junior Securities and Series G convertible preferred stock until the aggregate amount distributed to such holders equals the amount distributed to holders of Series F convertible preferred stock divided by the Series F ownership percentage.

After payments of the above liquidation preferences have been made, any remaining assets would be distributed ratably to holders of common stock and holders of Series G, Series F and Junior Securities convertible preferred stock on an “as-converted” basis.

As of July 2, 2018

Immediately prior to the closing of the IPO on July 2, 2018, all of the Company’s outstanding shares of convertible preferred stock converted into 11.0 million shares of common stock, resulting in the elimination of the Company’s outstanding liquidation preferences.

Dividends

Each class of convertible preferred stock was entitled to receive non-cumulative annual dividends at a rate of 9.0%, if and when declared by the Company’s board of directors. The holders of Series G convertible preferred stock were entitled to dividends in preference to holders of any other class or series of the Company’s stock. The holders of Series F convertible preferred stock were entitled to dividends in preference to all holders of Junior Securities and holders of common stock. The holders of Junior Securities were entitled to dividends in preference to holders of common stock.

In the event a dividend was declared to common stockholders, holders of each class of convertible preferred stock would also receive an equivalent dividend on an “as-converted” basis.

Voting

The holders of each class of convertible preferred stock were entitled to one vote for each share of common stock into which their shares of convertible preferred stock may be converted and, subject to certain convertible preferred stock class votes specified in the Company’s certificate of incorporation or as required by law, the holders of convertible preferred stock and common stock vote together on an “as-converted” basis.

Common Stock Warrants

The following table summarizes the Company's outstanding common stock warrants as of December 31, 2018:

Warrants Outstanding (in thousands)	Exercise Price	Expiration Date
14	$ 19.55	Dec-2022
30	$ 9.73	Feb-2021
20	$ 9.73	Aug-2023
20	$ 9.73	Mar-2024
21	$ 9.73	Dec-2024
105		

Convertible Preferred Stock Warrants

The following table summarizes the Company's outstanding convertible preferred stock warrants as of December 31, 2017:

	Warrants Outstanding (in thousands)	Exercise Price	Expiration Date
Series E	402	$ 0.6746	Dec-2022
Series F	878	$ 0.3356	Feb-2021
Series F	589	$ 0.3356	Aug-2023
Series F	589	$ 0.3356	Mar-2024
Series F	588	$ 0.3356	Dec-2024
	3,046		

11. LOSS PER SHARE

The Company's basic loss per common share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period. The Company's restricted stock awards (non-vested shares) are issued and outstanding at the time of grant but are excluded from the Company's computation of weighted-average shares outstanding in the determination of basic loss per share until vesting occurs.

A net loss cannot be diluted, so when the Company is in a net loss position, basic and diluted loss per common share are the same. If in the future the Company achieves profitability, the denominator of a diluted earnings per common share calculation will include both the weighted-average number of shares outstanding and the number of common stock equivalents, if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and non-vested restricted stock awards and units using the treasury stock method, along with the effect, if any, from the potential conversion of outstanding securities, such as convertible preferred stock.

The following potentially dilutive securities outstanding as of December 31, 2018, 2017 and 2016 have been excluded from the denominator of the diluted loss per share of common stock outstanding calculation (in thousands):

	December 31,		
	2018	2017	2016
Stock options	2,711	2,444	1,826
Non-vested restricted stock awards	4	16	22
Non-vested restricted stock units	43	-	-
Convertible preferred stock warrants	-	105	64
Common stock warrants	105	-	-
Shares of convertible preferred stock "as-converted"	-	10,994	9,594

12. SHARE-BASED COMPENSATION

The amount of share-based compensation expense recognized by the Company by location in its statements of operations for the years ended December 31, 2018, 2017 and 2016 is as follows (in thousands):

	Year ended December 31,		
	2018	2017	2016
Cost of revenues	$ 21	$ 18	$ 5
Sales and marketing	926	141	49
General and administrative	646	226	70
Research and development	150	111	37
Total	$ 1,743	$ 496	$ 161

2018 Equity Incentive Plan

In June 2018, the Company adopted the 2018 Equity Incentive Plan, or 2018 Plan, which authorized the issuance of up to 1.4 million shares in the form of restricted stock, stock appreciation rights and stock options to the Company's directors, employees and consultants. The amount and terms of grants are determined by the Company's board of directors. All stock options granted to date have had exercise prices equal to the fair value, as determined by the closing price as reported by the Nasdaq Global Market on the date of grant, of the underlying common stock on the date of grant. The contractual term of stock options is up to 10 years, and stock options are exercisable in cash or as otherwise determined by the board of directors. Generally, stock options vest 25% upon the first anniversary of the date of grant and the remainder ratably monthly thereafter for 36 months. As of December 31, 2018, there were 1.3 million shares available for future issuance under the 2018 Plan.

2003 Stock Incentive Plan

In April 2003 (and as subsequently amended), the Company adopted the 2003 Stock Incentive Plan, or 2003 Plan, which authorized the issuance of up to 3.1 million shares in the form of restricted stock, stock appreciation rights and stock options to the Company's directors, employees and consultants. The amount and terms of grants are determined by the Company's board of directors. All stock options granted to date have had exercise prices equal to the estimated fair value, as determined by the board of directors, of the underlying common stock on the date of the grant. The contractual term of stock options is up to 10 years, and stock options are exercisable in cash or as otherwise determined by the board of directors. Generally, stock options vest 25% upon the first anniversary of the date of grant and the remainder ratably monthly thereafter for 36 months. As of December 31, 2018, there were no shares available for future issuance under the 2003 Plan. As of the closing of the IPO, all shares available for issuance under the 2003 Plan were carried over to the newly adopted 2018 Plan.

Stock Options

The following table summarizes the Company's stock option activity for the years ended December 31, 2018, 2017 and 2016:

	Number of Shares under Option (in thousands)	Weighted-average Exercise Price per Option	Weighted-average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	1,767	$ 2.52		
Granted	255	$ 2.45		
Exercised	(19)	$ 3.58		
Forfeited	(161)	$ 5.68		
Expired	(16)	$ 19.63		
Outstanding at December 31, 2016	1,826	$ 2.07		
Granted	967	$ 3.03		
Exercised	(33)	$ 1.05		
Forfeited	(316)	$ 2.66		
Outstanding at December 31, 2017	2,444	$ 2.39		
Granted	584	$ 8.33		
Exercised	(194)	$ 2.60		
Forfeited	(123)	$ 3.73		
Outstanding at December 31, 2018	2,711	$ 3.59	7.3	$ 42,773
Exercisable at December 31, 2018	1,613	$ 2.22	6.2	$ 27,921
Vested and expected to vest at December 31, 2018	2,711	$ 3.59	7.3	$ 42,773

The Company recognized share-based compensation expense related to stock options of $1.6 million, $0.4 million and $0.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, there was $3.1 million of total unrecognized compensation cost related to non-vested stock options which the Company expects to recognize over a weighted-average period of 3.1 years. The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2018, 2017 and 2016 was estimated at $5.03, $1.45 and $1.16 per option. The total intrinsic value of stock options exercised during the years ended December 31, 2018, 2017 and 2016 was $3.3 million, $0.1 million and de minimis, respectively.

For the years ended December 31, 2018, 2017 and 2016, the grant-date fair value of stock options was estimated at the time of grant using the following weighted-average inputs and assumptions in the Black-Scholes option pricing model:

	2018	2017	2016
Estimated fair value of common stock	$ 8.41	$ 2.90	$ 2.32
Exercise price	$ 8.41	$ 2.90	$ 2.32
Expected term (in years)	6.0	6.0	6.0
Risk-free interest rate	2.7%	2.0%	1.4%
Expected volatility	65.3%	48.0%	44.2%
Dividend yield	0%	0%	0%

In April 2018, the Company's board of directors granted options to purchase 54,794 shares of common stock to the members of the board. These options have an exercise price of $5.22 and vest in 12 equal monthly installments beginning in March 2018; however, the entire grant was subject to forfeiture if an initial public offering of the Company's common stock did not occur by December 31, 2018. The estimated grant-date fair value of the options awards was $0.2 million. Upon the closing of the IPO on July 2, 2018, the Company recognized the fair value of the vested portion of the awards as share-based compensation expense, with the unvested portion to be recognized as share-based compensation expense ratably over the remaining service period.

Restricted Stock Awards and Restricted Stock Units

The following table summarizes the Company's restricted stock award and restricted stock unit activity for the years ended December 31, 2018, 2017 and 2016:

	Non-vested Restricted Stock Awards (in thousands)	Weighted-average Grant-date Fair Value	Non-vested Restricted Stock Units (in thousands)	Weighted-average Grant-date Fair Value
Non-vested at December 31, 2015	-	$ -	-	$ -
Granted	42	$ 2.03	-	$ -
Vested	(20)	$ 2.03	-	$ -
Non-vested at December 31, 2016	22	$ 2.03	-	$ -
Granted	11	$ 4.06	-	$ -
Vested	(17)	$ 2.90	-	$ -
Non-vested at December 31, 2017	16	$ 2.32	-	$ -
Granted	-	$ -	43	$ 25.21
Vested	(12)	$ 2.32	-	$ 25.92
Non-vested at December 31, 2018	4	$ 2.32	43	$ 25.21

The Company recognized share-based compensation expense related to restricted stock awards and restricted stock units of $0.2 million, $0.1 million and de minimis during the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, there was $0.9 million of unrecognized compensation cost related to non-vested restricted stock awards and restricted stock units which the Company expects to recognize over a weighted-average period of 3.4 years. The total fair value at the vesting date of restricted stock awards and restricted stock units vested during the years ended December 31, 2018, 2017 and 2016 was $0.2 million, $0.1 million and de minimis, respectively.

13. EMPLOYEE BENEFIT PLANS

401(k) Defined Contribution Plan

The Company maintains a 401(k) defined contribution retirement plan which covers all of its employees. Employees are eligible to participate on the first of the month following their date of hire. Under the 401(k) plan, participating employees may defer up to 100% of their pre-tax salary but not more than statutory limits. There is currently no employer matching of employee contributions and employee contributions vest immediately.

2018 Employee Stock Purchase Plan

In July 2018, the Company adopted the 2018 Employee Stock Purchase Plan, or 2018 ESPP, with an initial 0.2 million share reserve, subject to automatic annual increases on January 1st of each year for a period of up to ten years, as defined in the plan document. The purpose of the 2018 ESPP is to enhance employee interest in the success and progress of the Company by encouraging employee ownership of common stock of the Company. The 2018 ESPP provides the opportunity to purchase the Company's common stock at a 15% discount to the market price through payroll deductions or lump sum cash investments. As of December 31, 2018, the Company had not yet approved any offering under the plan.

14. INCOME TAXES

The Company's loss before income taxes was $24.1 million, $16.1 million and $11.2 million for the years ended December 31, 2018, 2017 and 2016, respectively, and was generated entirely in the United States. The Company did not record current or deferred income tax expense or benefit during the years ended December 31, 2018, 2017 and 2016.

A reconciliation of the statutory United States federal income tax rate to the Company's effective tax rate is as follows:

	Tax Year ended December 31,		
	2018	2017	2016
U.S. federal statutory income tax rate	21.0%	34.0%	34.0%
State and local taxes, net of federal benefit	3.8%	2.7%	2.6%
Nondeductible expenses	0.7%	-0.3%	-1.2%
Research and development credits	0.6%	1.3%	2.0%
Tax rate change and true-up	0.6%	-138.0%	-1.2%
Change in valuation allowance	-26.7%	100.3%	-36.2%
Effective income tax rate	0.0%	0.0%	0.0%

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 46,352	$ 41,430
Research and development credits	3,208	3,059
Share-based compensation	523	316
Accruals	853	753
Interest expense - 163(j)	592	-
Capitalized start-up costs	1,295	1,530
Other temporary differences	951	253
Gross deferred tax assets	53,774	47,341
Less: Valuation allowance	(53,774)	(47,341)
Net deferred taxes	$ -	$ -

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. The Company believes that it is more likely than not that the Company's deferred income tax asset associated with its net operating losses will not be realized in the immediate future. As such, there is a full valuation allowance against the net deferred tax assets as of December 31, 2018 and 2017. The valuation allowance increased / (decreased) by $6.4 and $(16.1) million during the years ended December 31, 2018 and 2017, respectively, due primarily to the generation of net operating losses and the federal tax rate reduction during the periods.

	December 31,	
	2018	2017
Balance at the beginning of the period	$ 47,341	$ 63,449
Amounts charges to expense	$ 6,433	$ 6,099
Tax rate change (34% to 21%)	-	(22,207)
Balance at the end of the period	$ 53,774	$ 47,341

The following table summarizes carryforwards of federal net operating losses and tax credits as of December 31, 2018 (in thousands):

	Amount	Expiration Beginning in
Federal net operating losses	$ 187	2023
State net operating losses	$ 112	2020
Research and development credits	$ 3	2023

Under the Tax Reform Act of 1986 (the Act), the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not done an analysis to determine whether or not ownership changes, as defined by the Act, have occurred since inception.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations. Due to net operating loss and tax credit carry forwards that remain unutilized, income tax returns for tax years from inception through 2017 remain subject to examination by the taxing jurisdictions.

In December 2017, the Tax Cuts and Jobs Act (the "2017 Tax Act") was enacted. The 2017 Tax Act includes a number of changes to existing U.S. tax laws that impact the company, most notably a reduction of the U.S. corporate income tax rate from 35 percent to 21 percent for tax years beginning after December 31, 2017. The 2017 Tax Act also provides for a one-time transition tax on certain foreign earnings and the acceleration of depreciation for certain assets placed into service after September 27, 2017 as well as prospective changes beginning in 2018, including repeal of the domestic manufacturing deduction, acceleration of tax revenue recognition, capitalization of research and development expenditures, additional limitations on executive compensation and limitations on the deductibility of interest.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118"), which provided guidance on accounting for the federal tax rate change and other tax effects of the Tax Act. SAB 118 provided a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under ASC 740, Income Taxes. In connection with our adoption of the Tax Act and in consideration of SAB 118, there were no changes made to the provisional amounts recognized in 2017 in connection with the enactment of the Tax Reform Act. The accounting for the income tax effects of the Tax Reform Act is complete as of December 31, 2018.

15. COMMITMENTS AND CONTINGENCIES

Executive Employment Agreements

The Company has entered into an employment agreement and offer letters with certain key executives, providing for compensation and severance in certain circumstances, as defined in the agreements.

Leases

In January 2013, the Company entered into a 93-month lease for its headquarters office and warehouse. The Company also rents certain office equipment. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not yet paid. Landlord allowances for tenant improvements are deferred and recognized as a reduction to rent expense on a straight-line basis and over the remaining lease term.

Rent expense under operating leases was $0.5 million, $0.5 million and $0.6 for the years ended December 31, 2018, 2017 and 2016, respectively.

The following is a schedule of future minimum annual payments at December 31, 2018 under non-cancelable operating lease agreements (in thousands):

For the years ending December 31,	
2019	$ 547
2020	560
2021	88
Total future minimum lease payments	$ 1,195

Legal Matters

The Company is subject from time to time to various claims and legal actions arising during the ordinary course of its business. Management believes that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on the Company's results of operations, financial condition or cash flows.

16. DISTRIBUTION AGREEMENT WITH TEIJIN PHARMA LIMITED

In October 2017, the Company entered into a seven-and-a-half-year distribution agreement with Teijin Pharma Limited, or Teijin, for the exclusive distribution of its NeuroStar Advanced Therapy System to customers who will treat patients with MDD in Japan. Under the distribution agreement, Teijin is generally restricted from selling competing products in Japan. The distribution agreement provides that the Company will have primary responsibility for obtaining reimbursement approval for use of NeuroStar Advanced Therapy System for the treatment of MDD in Japan, and Teijin will promote the sales of NeuroStar Advanced Therapy System for treatment of MDD in Japan. The Company has agreed to provide sales and technical support training to Teijin for its NeuroStar Advanced Therapy Systems.

Teijin is required to purchase minimum dollar values of NeuroStar Advanced Therapy Systems and treatment sessions from the Company following reimbursement approval by the Japanese Ministry of Health, Labour and Welfare, or JMHLW, for TMS treatment for MDD (or, if such approval requires certified training on the NeuroStar Advanced Therapy System by a third party, then upon the first psychiatrist being issued his or her training certification).

In 2017, under the distribution agreement with Teijin, the Company received an upfront payment of $0.75 million and a milestone payment of $2.0 million following JMHLW's approval of marketing the NeuroStar Advanced Therapy System for the treatment of MDD in Japan. These upfront and milestone payments have been deferred and are being recognized as revenue over the seven- and one-half year term of the agreement. Teijin is required to pay the Company a milestone payment tied to JMHLW issuing reimbursement for use of its products for the treatment of MDD in Japan.

The distribution agreement is scheduled to expire on March 31, 2025, subject to earlier termination if we or Teijin breach the agreement, Teijin fails to maintain distributor-level permits and approvals, Teijin fails to purchase from us specified dollar values of its sales forecasts, reimbursement for treatment of MDD using the NeuroStar Advanced Therapy System is not obtained from JMHLW by specified dates or such reimbursement is below specified minimums, Teijin reasonably believes that it is not commercially reasonable to continue distributing the NeuroStar Advanced Therapy System in Japan or bankruptcy related events occur. The term of the distribution agreement will be automatically extended for two years unless either party gives the other party at least two years' prior written of notice of non-renewal, except that the Company cannot decline to renew the agreement if Teijin has purchased 100% of its sales forecasts over the term of the agreement.

17. GEOGRAPHICAL SEGMENT INFORMATION

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. The Company currently operates in one business segment as it is managed and operated as one business. A single management team that reports to the chief operating decision maker comprehensively manages the entire business. The Company does not operate any material separate lines of business or separate business entities with respect to its products or product development.

The Company's revenue was generated in the following geographic regions for the years indicated (in thousands):

	Revenue by Geography Year ended December 31,			
	2018		2017	
	Amount	% of Revenues	Amount	% of Revenues
United States	$ 51,477	98%	$ 39,853	99%
International	1,299	2%	580	1%
Total revenues	$ 52,776	100%	$ 40,433	100%

18. SUPPLEMENTARY FINANCIAL INFORMATION (Unaudited)

Selected financial information for the quarterly periods noted is as follows:

	Three Months ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
	(in thousands except per share data)			
Revenues	$ 10,152	$ 13,252	$ 13,737	$ 15,635
Cost of revenues	2,457	3,245	3,034	3,711
Gross Profit	7,695	10,007	10,703	11,924
Operating expenses:				
Sales and marketing	8,109	9,835	9,672	10,648
General and administrative	2,636	3,078	3,238	4,715
Research and development	1,555	2,330	2,125	2,222
Total operating expenses	12,300	15,243	15,035	17,585
Loss from Operations	(4,605)	(5,236)	(4,332)	(5,661)
Other (income) expense:				
Interest expense	921	900	928	939
Other (income) expense, net	(29)	1,360	(299)	(457)
Net Loss	$ (5,497)	$ (7,496)	$ (4,961)	$ (6,143)
Net loss per share of common stock outstanding, basic and diluted	$ (24.43)	$ (30.60)	$ (0.29)	$ (0.35)
Weighted-average common shares outstanding, basic and diluted	226	245	17,382	17,655

	Three Months ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
	(in thousands except per share data)			
Revenues	$ 7,526	$ 10,308	$ 10,491	$ 12,108
Cost of revenues	1,538	2,501	2,636	2,957
Gross Profit	5,988	7,807	7,855	9,151
Operating expenses:				
Sales and marketing	6,306	6,400	6,566	8,628
General and administrative	1,642	1,837	2,256	2,837
Research and development	2,028	2,147	1,843	1,919
Total operating expenses	9,976	10,384	10,665	13,384
Loss from Operations	(3,988)	(2,577)	(2,810)	(4,233)
Other (income) expense:				
Interest expense	550	711	807	740
Other (income) expense, net	(24)	(420)	136	(49)
Net Loss	$ (4,514)	$ (2,868)	$ (3,753)	$ (4,924)
Net loss per share of common stock outstanding, basic and diluted	$ (27.03)	$ (16.58)	$ (19.35)	$ (23.34)
Weighted-average common shares outstanding, basic and diluted	167	173	194	211

Quarterly computations of net loss per share amounts are made independently for each quarterly reporting period, and the sum of the per share amounts for the quarterly reporting periods may not equal the per share amounts for the year-to-date reporting period. Net loss per share for the three months ended September 30, 2018 and December 31, 2018 include, on a weighted-average basis, the 11.0 million shares of common stock issued upon the conversion of all outstanding shares of convertible preferred stock immediately prior to the closing of the IPO and 6.325 million shares of common stock issued upon the closing of the IPO on July 2, 2018.

[THIS PAGE INTENTIONALLY LEFT BLANK]

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	Ninth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Form 8-K filed July 6, 2018)
3.2	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Form 8-K filed July 6, 2018)
4.1	Specimen Stock Certificate evidencing shares of common stock of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
4.2	Form of Warrant to Purchase Stock, by and between the Registrant and Oxford Finance LLC (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 (File No. 333-225307))
4.3	Warrant to Purchase Stock, by and between the Registrant and Comerica Bank, dated December 20, 2012 (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1 (File No. 333-225307))
10.1◊	Distribution Agreement, by and between the Registrant and Teijin Pharma Limited, dated October 12, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.2	Sixth Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated June 1, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.3	Sixth Amended and Restated Stockholders' Agreement by and among the Registrant and certain of its stockholders, dated June 1, 2017 (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.4+	Employment Agreement by and between the Registrant and Christopher Thatcher, dated as of November 1, 2014, as amended on May 25, 2018 (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.5+	Offer Letter, dated August 11, 2016, by and between the Registrant and Greg Harper (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.6+	Offer Letter, dated February 27, 2017, by and between the Registrant and Peter Donato (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.7	Form of Indemnification Agreement between the Registrant and its non-employee directors and officers (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.8	Loan and Security Agreement by and between Oxford Finance LLC and the Registrant, dated March 28, 2017 (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.9+	Amended and Restated 2003 Stock Incentive Plan of the Registrant, as amended (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.10+	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546))
10.11+	2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.11 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38546))

10.12	Lease Agreement by and between Exeter 3222 Phoenixville, L.P. and the Registrant, dated January 3, 2013 (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 (File No. 333-225307))
10.13+	Form of Non-Qualified Stock Option Agreement for the Amended and Restated 2003 Stock Incentive Plan, as amended, of the Registrant (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.14+	Form of Incentive Stock Option Agreement for the Amended and Restated 2003 Stock Incentive Plan, as amended, of the Registrant (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.15+	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.16+	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.17+	Form of Severance Agreement (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.18+	Form of Restrictive Covenant and Invention Assignment Agreement (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.19+	Offer Letter, dated February 27, 2018, by and between the Registrant and Daniel Guthrie (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.20+	Offer Letter, dated November 10, 2017, by and between the Registrant and Yelena Tropsha (incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
10.21	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (File No. 333-225307))
23.1*	Consent of KPMG LLP, independent registered public accounting firm
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1*	Certification of the principal executive and financial officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350.

* Filed herewith

+ Indicates management contract or compensatory plan.

◊Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and have been separately filed with the Securities and Exchange Commission.

SIGNATURES

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

NEURONETICS, INC.

By: /s/ Christopher Thatcher
Christopher Thatcher
President and Chief Executive Officer

Date: March 5, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this 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/ Christopher Thatcher **Christopher Thatcher**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 5, 2019
/s/ Peter Donato **Peter Donato**	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2019
/s/ Cheryl Blanchard **Cheryl Blanchard**	Director	March 5, 2019
/s/ Stephen Campe **Stephen Campe**	Director	March 5, 2019
/s/ Brian Farley **Brian Farley**	Director	March 5, 2019
/s/ Ronald Hunt **Ronald Hunt**	Director	March 5, 2019
/s/ Wilfred Jaeger, M.D. **Wilfred Jaeger, M.D.**	Director	March 5, 2019
/s/ Glenn Muir **Glenn Muir**	Director	March 5, 2019

Exhibit 31.1

CERTIFICATION

I, Christopher Thatcher, certify that:

1. I have reviewed this Annual Report on Form 10-K of Neuronetics, Inc.;

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

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

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

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

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

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

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

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

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

Date: March 5, 2019

By: /s/ Christopher Thatcher
Name: Christopher Thatcher
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Peter Donato, certify that:

1. I have reviewed this Annual Report on Form 10-K of Neuronetics, Inc.;

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

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

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

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

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

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

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

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

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

Date: March 5, 2019

By: /s/ Peter Donato
Name: Peter Donato
Title: VP, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Christopher Thatcher, President and Chief Executive Officer of Neuronetics, Inc. (the "Company"), and Peter Donato, Vice President, Finance and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 5, 2019

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 5th day of March, 2019.

By:	/s/ Christopher Thatcher	By:	/s/ Peter Donato
Name:	Christopher Thatcher	Name:	Peter Donato
Title:	President and Chief Executive Officer (Principal Executive Officer)	Title:	VP, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)

"This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Neuronetics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing."

Leadership Team

Chris Thatcher
President and Chief Executive Officer

Peter Donato
Chief Financial Officer

Dan Guthrie
Chief Commercial Officer

Yelena Tropsha
Vice President of Commercial Access

Anthony Pui
Vice President of International Commercial Development

Greg Harper
Vice President of Product Development & Operations

Current Board of Directors

Chris Thatcher
President and Chief Executive Officer, Neuronetics, Inc.

Cheryl Blanchard
President and Chief Executive Officer, Keratin BioSciences, Inc.

Stephen Campe
Senior Advisor, Patricia Industries, Inc.

Brian Farley
Former Chief Executive Officer, Entellus Medical Inc.

Ron Hunt
Managing Director, New Leaf Venture Partners

Wilfred Jaeger
Partner, Three Arch Partners

Glenn Muir
Former Chief Financial Officer and Executive Vice President, Hologic, Inc.

Headquarters

3222 Phoenixville Pike
Malvern, Pennsylvania 19355

Transfer Agent

American Stock Transfer
6201 15th Avenue
Brooklyn, New York 11219

Independent Registered Public Accounting Firm

KPMG LLP