Neuralstem, Inc.
Form 10-K
March 22, 2019

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 001-33672

NEURALSTEM, INC.

(Exact name of registrant as specified in its charter)

Delaware	**52-2007292**
State or other jurisdiction of	(I.R.S. Employer
incorporation or organization	Identification No.)
20271 Goldenrod Lane	
Germantown, Maryland	**20876**

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code **(301)-366-4841**

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

Title of each class	**Name of each exchange on which registered**
Common stock, $0.01 par value	NASDAQ Stock Market

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

None

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting 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 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 Company’s common equity was last sold as of the last business day of the registrant’s most recently completed second fiscal quarter based upon the closing price of the common stock as reported by NASDAQ on such date, was $14,056,602.

The number of shares outstanding of Registrant’s common stock, $0.01 par value at February 28, 2019 was 18,205,060.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement relating to its 2019 annual meeting of shareholders (the “2019 Proxy Statement”) are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2019 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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NEURALSTEM, INC

ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2018

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PART I

We urge you to read this entire Annual Report on Form 10-K, including the "Risk Factors" section, the financial statements and the related notes included therein. As used in this Annual Report, unless context otherwise requires, the words "we," "us," "our," "the Company," "Neuralstem" and "Registrant" refer to Neuralstem, Inc. and its subsidiary. Also, any reference to "common share" or "common stock," refers to our $.01 par value common stock. Additionally, any reference to our "Series A Preferred Stock" refers to our Series A 4.5% Convertible Preferred Stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this annual report that are not strictly historical are forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and include statements about products in development, results and analyses of pre-clinical studies, clinical trials and studies, future research and development expenses, anticipated cash expenditures, regulatory applications and approvals, and third-party relationships, among other matters. You can identify these forward-looking statements because they involve our expectations, intentions, beliefs, plans, projections, anticipations, or other characterizations of future events or circumstances and may often be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "seek" or "will." These forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that may cause actual results to differ materially from those described in the forward-looking statements These Forward-looking statements by their nature address matters that are uncertain. Specific risks and uncertainties that could cause our actual results to differ materially from those expressed in our forward-looking statements include risks inherent in our ability to conduct and obtain successful results from our clinical trials, our ability to retain management and operate our business, our ability to commercialize our technology, our ability to obtain regulatory approval for our product candidates, our ability to contract with third parties to adequately test and manufacture our proposed products, our ability to protect our intellectual property rights and our ability to obtain additional financing to continue development efforts. These forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties, which could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to those discussed in this Annual Report, and in particular, the risks discussed under the caption "Risk Factors" in Item 1A and those discussed in other documents we file with the Securities and Exchange Commission (SEC). We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

The information contained herein is current as of the date of this Annual Report (December 31, 2018), unless another date is specified.

ITEM 1. BUSINESS

Overview

We are primarily focused on the research and development of nervous system therapies based on our proprietary human neural stem cells and our small molecule compounds with the ultimate goal of gaining approval from the United States Food and Drug Administration ("FDA"), and its international counterparts, to market and commercialize such therapies. Recently, we have also began an in-licensing and acquisition initiative in which we are evaluating novel therapeutics with the potential to be complimentary to our current technologies or that could benefit from our development experience with the ultimate goal of developing such technologies for commercialization.

Our patented technology platform has three core components:

1. Over 300 lines of human, regionally specific neural stem cells, some of which have the potential to be used to treat serious or life-threatening diseases through direct transplantation into the central nervous system;

2. Proprietary screening capability – our ability to generate human neural stem cell lines provides a platform for chemical screening and discovery of novel compounds against nervous system disorders; and

3. Small molecules that resulted from Neuralstem's neurogenesis screening platform that may have the potential to treat wide variety of nervous system conditions

To date, our technology platform has produced two lead assets in clinical development: our NSI-566 stem cell therapy program and our NSI-189 small molecule program.

We believe that we have developed and maintain a strong portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license approximately 10 U.S. issued and pending patents and approximately 55 foreign issued and pending patents related to our stem cell technologies for use in treating disease and injury. We own approximately 15 U.S. issued and pending patents and approximately 75 foreign issued and pending patents related to our small molecule compounds.

We believe our technology, in combination with our expertise, and established collaborations with major research institutions, could facilitate the development and commercialization of products for use in the treatment of a wide array of nervous system disorders including neurodegenerative conditions and regenerative repair of acute and chronic disease.

Recent Highlights

- On January 1, 2019, we appointed Dr. Kenneth Carter as our Executive Chairman. Dr. Carter assumed the role of Principal Executive and Accounting Officer as well as a member and Chairman of our board of directors.

- On October 25, 2018, the company announced publication of a manuscript in Scientific Reports showing that transplantation of NSI-532.IGF1 mitigates disease pathology and improves cognition in a mouse model of Alzheimer's Disease.

- On August 9, 2018, NSI-189 received from FDA the orphan designation for treatment of Angelman Syndrome.

Clinical Programs

We have devoted substantially all of our efforts and financial resources to the pre-clinical and clinical development of our small molecule compounds and our stem cell therapeutics. Below is a description of our most advanced clinical programs, their intended indication and current stage of development:

NSI - 566 (Stem Cells)

The human central nervous system (CNS) has limited capacity for regeneration following injury or the onset of disease. Traditional therapies have mainly focused on minimizing the progression or symptoms of CNS disease or injury, but have not been effective at repairing the underlying cause of such disease. The goal of our cell therapy initiatives is the regeneration of neural function which has been lost to disease or injury. We believe that neuroprotection, neuroregeneration, and/or bridging of damaged neural circuitry may be accomplished by implantation of NSI-566 at the injury site.

Our proprietary technology enables the isolation and large-scale expansion of regionally specific neural stem cells from all areas of the developing human brain and spinal cord and enables the generation of commercially useful quantities of highly characterized allogeneic human neural stem cells that can be transplanted into patients to mitigate the consequences of CNS diseases or injury. We have developed and optimized processes that allow us to manufacture these cells under Good Manufacturing Practices or cGMP compliant conditions as required by the FDA for use in clinical trials and have generated cell banks which we believe are sufficient to provide material to meet all our requirements through to completion of Phase 3 studies. We have exclusive licenses for the manufacturing and use of the surgical platform and cannula that enable administration of the cells to the spinal cord for treatment. Based on our preclinical data we believe that our human neural stem cells will differentiate into neurons and glia after grafting into the patient and will provide neuroprotection and stimulate neuroregeneration.

Our lead stem cell program is the spinal cord-derived neural stem cell line, NSI-566, which is being tested for treatment of paralysis due to Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig’s disease), stroke, and spinal cord injury (“SCI”). To date we have completed Phase 1 and Phase 2 safety and dose escalation studies in subjects with ALS and a Phase1 safety and dose escalation study in subjects with motor deficits due to ischemic stroke. Each of these studies are currently in their long-term follow-up stage. In August 2018, we initiated a non-GCP compliant randomized, double-blind, sham-surgery controlled Phase 2 trial for the treatment of ischemic stroke. We are also conducting a Phase 1 open label study to evaluate the safety of implanting NSI-566 in subjects with chronic SCI.

Amyotrophic Lateral Sclerosis

Amyotrophic lateral sclerosis is a disease of the nerve cells in the brain and spinal cord that control voluntary muscle movement. In 2016 the Centers for Disease Control and Prevention estimated that between 14,000 and 15,000 Americans have ALS. In ALS, nerve cells (motor neurons) waste away or die, and can no longer send messages to muscles. This eventually leads to muscle weakening, twitching, and an inability to move the arms, legs, and body. As

the condition progresses, muscles in the chest area stop working, making it difficult or impossible to breathe. NSI-566 is under development as a potential treatment for ALS by providing cells designed to nurture and protect the patient's remaining motor neurons; and possibly repair some motor neurons which have not yet died but which are diseased. We received orphan designation by the FDA for NSI-566 in ALS.

Motor Deficits Due to Ischemic Stroke

Ischemic stroke, the most common type of stroke, occurs as a result of an obstruction within a vessel supplying blood to the brain. In the US, approximately 1.8 million people live with paralysis due to stroke. Post-stroke motor deficits include paralysis in arms and legs and speech impairment and can be permanent. We believe that NSI-566 may provide an effective treatment for restoring motor deficits resulting from ischemic stroke by both creating new circuitry in the area of injury and through repairing and or nurturing diseased cells to improve function in patients.

Chronic Spinal Cord Injury

Spinal cord injury, or SCI, generally refers to any injury to the spinal cord that is caused by trauma instead of disease, although in some cases it can be the result of diseases. It is estimated that there are 17,000 new cases of SCI per year and that at any given time, there are estimated to be 288,000 people in the United States that are living with SCI. Chronic spinal cord injury (cSCI) refers to the time after the initial hospitalization. SCIs may be caused by trauma to the spinal cord resulting from motor vehicle accidents, falls, and penetrating injuries such as stab or gunshot wounds. We believe that NSI-566 may provide an effective treatment for cSCI by "bridging the gap" in the spinal cord circuitry created following traumatic spinal cord injury and providing new cells to help transmit the signal from the brain to points at or below the point of injury.

Clinical Experience with NSI-566

Amyotrophic Lateral Sclerosis

In January 2010, we commenced a Phase 1 trial of NSI-566 in ALS at Emory University in Atlanta, Georgia. The purpose of the trial was to evaluate the safety of our proposed treatment and procedure in a total of 15 subjects. The dosing of subjects in the Phase 1 trial, as designed, was completed in August of 2012. We commenced a Phase 2 clinical trial in subjects suffering from ALS in September of 2013 to further test the feasibility and safety of the treatment and procedure, and maximum tolerated dose of cells. The Phase 2 dose escalation trial enrolled 15 ambulatory subjects in five different dosing cohorts. Each patient in the final cohort had two separate surgeries.

We have completed all of the transplantations and the observation period of 24 months after the last surgery. The Phase 2 ALS clinical trial met the primary safety endpoints and established what we believe to be the maximum safe tolerated dose. In June 2017, 24-month Phase 2 and combined Phase 1 and Phase 2 data from our ALS trials were presented at the International Society for Stem Cell Research (ISSCR) Annual Meeting, Approaches to Treating ALS, Boston, Massachusetts, by principal investigator Eva Feldman, MD, PhD, Russell N. DeJong Professor of Neurology and Director of Research of the ALS Clinic at the University of Michigan Health. The data showed that the intraspinal transplantation of the cells was safe and well tolerated. Subjects from both the Phase 1 and Phase 2 continue to be monitored for long-term follow-up evaluations.

To date, substantially all of the clinical costs of our ALS studies have been funded by grants.

Ischemic Stroke

In 2013 we commenced an open label, non-GCP compliant, Phase I safety and dose escalation study to test transplantation of NSI-566 in human subjects for the treatment of motor deficits due to ischemic stroke. The trial was conducted at BaYi Brain Hospital in Beijing, China and sponsored by Suzhou Neuralstem, a wholly owned subsidiary of Neuralstem in China. This study was intended to evaluate the safety of direct injections of NSI-566 into the brain and to determine the maximum safe tolerated dose. We completed dosing the final cohort in March 2016, for a total of nine subjects. Subjects were monitored through a 24-month observational follow-up period. Delivery of NSI-566 cells in this population appeared to be safe and well tolerated at all doses.

In June 2018, we presented an abstract at the annual International Society of Stem Cell Research (ISSCR). In the study, 3 cohorts (n=3/cohort) were transplanted with ascending doses of NSI-566, which involved a one-time stereotactic, intracerebral injection of 1.2×10^7, 2.4×10^7, or 7.2×10^7 cells. Immunosuppression therapy with tacrolimus was maintained for 28 days At the 12-Month Visit, compared to Baseline, the mean Fugl-Meyer Motor Score (FMMS, total score of 100) showed 15.6 points of improvement (p=0.0078), the mean Modified Ranking Score (MRS) 0.8 points of improvement (p=0.031), and the mean NIH Stroke Scale (NIHSS) 3.2 points of improvement (p=0.016). The stem cell treatment appears well tolerated at all doses. There were no deaths or serious adverse events related to the treatment.

In August 2018, we initiated a non-GCP compliant Phase 2 trial which is a randomized, double-blind, sham-surgery controlled study. Up to 24 eligible patients will be assigned either to receive NSI-566 stem cells (72 million cells) or sham-surgery at 1:1 ratio. All operations are being conducted at BaYi Brain Hospital, the site of the Phase 1 study, and all follow-up assessments are conducted by blinded, independent neurologists at Beijing Rehabilitation Hospital.

Chronic Spinal Cord Injury

In 2013, we received authorization from the FDA to commence a Phase 1 clinical trial to treat chronic spinal cord injury. The trial, which is taking place at The University of California, San Diego or UCSD, commenced in 2014 and the first subject was treated in October 2014. The study enrolled four AIS A classification thoracic spinal cord injury subjects (motor and sensory complete), one to two years' post-injury at the time of stem cell treatment. In January of 2016 we reported six-month follow-up data on all four subjects. The stem cell treatment was found to be safe and well-tolerated by the subjects enrolled and there were no serious adverse events.

In June 2018, the study investigators published the results of the first cohort in the journal Cell Stem Cell. The results support the potential of transplanted NSI-566 to benefit patients with cSCI. At 18 months to 27 months after surgery, the analysis of motor and sensory function and electrophysiology showed changes in three of the four patients after NSI-566 transplantation. There was no evidence of serious adverse events, suggesting the procedure is well-tolerated.

Substantially all of the clinical costs of this study have been, and will continue to be, funded by grants arranged through UCSD.

Pre-Clinical Experience with NSI-566 and other candidates for our stem cell pipeline

Our preclinical studies with NSI-566 have served to provide the foundation for our ongoing clinical trials by demonstrating performance and efficacy of this cell line in animal models for ALS (Yan et al., 2006; Hefferan et al., 2011; Xu et al., 2006; Xu et al., 2009; Xu et al., 2011), spinal cord injury (Cizkova et al., 2007; Lu et al., 2012; van Gorp et al., 2013), and ischemic stroke (Tajiri et al., 2014), and demonstrated safety in large animals (Usvald et al., 2010; Raore et al., 2011). Additional studies involving NSI-566 or other proprietary cell lines are directed at identifying new therapeutic candidates.

On June 11, 2018, we received a $150,000 Department of Defense contract to support the development of NSI-566 human neural stem cell line as a candidate therapeutic for severe Traumatic Brain Injury (TBI).

Traumatic Brain Injury (TBI).

TBI occurs when a sudden mechanical force induces damage to the brain. TBIs result in cognitive and motor deficits or death. Damage may come from the forceful collision of the skull with a solid object, such as during a fall or car accident, or may be caused by an object penetrating the skull and disrupting brain tissue. The Company is in the midst of a collaboration with investigators at the Miami Project to Cure Paralysis to determine if transplantation of NSI-566 can lead to an improvement in motor function in an animal model for penetrating TBI (such as may occur from a gunshot).

Alzheimer’s disease (AD).

Neuralstem’s NSI532-IGF-1 is a proprietary line of cortical neural stem cells engineered to over-express insulin-like growth factor-1 (IGF-1), which has been shown to have wide-ranging neuroprotective properties. AD is a progressive neurodegenerative disorder of the brain that leads to cognitive decline and memory loss which is the most common cause of dementia in older adults. Researchers at the University of Michigan evaluated the ability of the human neural stem cell line NSI-532.IGF1 to reverse the cognitive impact of neurodegeneration in a mouse model of AD (McGinley et al., 2016). Mice with NSI-532.IGF1 transplanted in the peri-hippocampus performed better on hippocampal-dependent behavioral tasks than untreated mice, demonstrating both enhanced learning cognitive processes and memory consolidation.

Multiple Sclerosis (MS) and demyelinating diseases.

In the case of MS and other demyelinating diseases, the myelin sheath that wraps and insulates axons in the central nervous system can become damaged, leading to inefficient transmission of signals along the nerves of the brain and spinal cord. This loss of conductivity may lead to profound symptoms, including loss of vision, sensation, and muscle strength, Myelin is generated in the CNS by a neural cell type called oligodendrocytes. The Company has developed a human neural stem cell line, NSI-777, that gives rise to large quantities of these myelin-generating cells after grafting in animals. In collaboration with researchers at Johns Hopkins University, we have shown that NSI-777 has high capacity for myelinating axons after grafting into animal models for demyelination. We will continue to pursue NSI-777 to further develop this candidate for potential use in treatment of human demyelinating diseases.

NSI-189 (Small Molecule Pharmaceutical Compound).

NSI-189, a new chemical entity with what we believe to work through a novel mechanism of action and stimulates neurogenesis of human hippocampus derived neural stem cells in vitro and neurogenesis in mouse hippocampus in vivo. Because studies have linked depression with impaired hippocampal neurogenesis, we believe that NSI-189 may provide an effective treatment for patients suffering from Major Depressive Disorder or MDD by promoting synaptogenesis or neurogenesis in the hippocampus.

Major Depressive Disorder (MDD)

Major depressive disorder (also known as recurrent depressive disorder, clinical depression, major depression, unipolar depression, or unipolar disorder) is a mental disorder characterized by episodes of all-encompassing low mood accompanied by low self-esteem and loss of interest or pleasure in normally enjoyable activities. According to the World Health Organization, MDD is the leading cause of disability in the U.S. for persons age 15 to 44. In 2015, an estimated 16.1 million adults aged 18 or older in the United States had at least one major depressive episode in the prior year. This number represented 6.7% of all U.S. adults[1]. Treatment of MDD is characterized by a high level of patient turnover due to low efficacy and high side effects. It is estimated that 67% of patients will fail their first line therapy, 75% will then fail their second line prescription and 80% will then fail their third line prescription[2]. These factors combine to create a significant opportunity for a differentiated therapeutic agent, particularly one that may act through a novel mechanism of action.

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[1] https://www.nimh.nih.gov/health/statistics/prevalence/major-depression-among-adults.shtml. Accessed February 13, 2017.

[2] Rush AJ, Fava M, et al; STAR#D Investigators Group.Sequenced Treatment Alternatives to Relieve Depression (**STAR*D**); rationale and design Control Clin Trials. 2004 Feb;25(1):119-42

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Clinical Experience with NSI-189

We have completed an exploratory Phase 2 randomized, placebo-controlled, double-blind clinical trial for the treatment of MDD in an outpatient setting.

The study randomized 220 subjects into three cohorts: NSI-189 40 mg twice daily (BID), NSI-189 40 mg once daily (QD), or placebo. After the initial screening period, the dosing portion of the trial was 12 weeks in duration. There was a two week wash out period for those subjects enrolled who were taking an anti-depressant at the time of screening.

The study was 80% powered to show an improvement in the primary endpoint, compared to placebo, with an assumed effect size of Cohen's d=0.5 ($p \leq 0.05$). Subjects eligible for the study had to be diagnosed with major depressive disorder, recurrent, as per Diagnostic and Statistical Manual of Mental Disorders V^3, scoring 20 or greater on the MADRS, at screening and baseline and experiencing at least one eight-week MDD episode. The MADRS score was confirmed to be 20 or greater via remote SAFER interview by an independent rater prior to the baseline visit. After the 12-week trial period, eligible subjects were given the opportunity to enroll in a separate six-month observational study to assess the durability of effect defined as the time until the start of a new antidepressant treatment (ADT). Both the interventional and the observational studies were conducted under the direction of study principal investigator (PI) Maurizio Fava, MD, Executive Vice Chair, Department of Psychiatry and Executive Director, Clinical Trials Network and Institute, Massachusetts General Hospital.

On July 25, 2017, we announced top-line results from the trial. The study did not meet its primary efficacy endpoint of a statistically significant reduction in depression symptoms on the Montgomery-Asberg Depression Rating Scale (MADRS), compared to placebo. Both doses were well-tolerated with no serious adverse events reported.

On December 5, 2017, we presented an updated analysis – including reports on all secondary scales – from the Phase 2 study of NSI-189 in MDD at the 56th American College of Neuropsychopharmacology (ACNP) Annual Meeting. Three additional patient reported outcomes showed statistically significant improvements in depressive and cognitive symptoms: Symptoms of Depression Questionnaire (SDQ): 40mg, p=0.044, Cognitive and Physical Functioning Questionnaire (CPFQ): 40 mg; p = 0.035, and Quick Inventory of Depressive Symptomatology Scale (QIDS-SR): 40 mg; p = 0.040 (Stage 2). Thus, with all three patient reported outcome scales (SDQ, CPFQ, and QIDS-SR) NSI-189 reached statistical significance over placebo.

In addition, we presented data on NSI-189's effect on cognition as measured by computer-administered objective tests of cognition in the MDD patients. Two different test methods were used: Cogstate® and CogScreen®. Cogstate did

not yield statistically significant results. In CogScreen® test, NSI-189 40 mg showed statistically significant improvement ($p<0.05$) on objective measures of executive functioning, attention, working memory, and memory.

NSI-189 appeared to be safe and well tolerated with no serious adverse events. There were no clinically meaningful changes in body weight or BMI, or in sexual function inventory. The study results have been published (Papakostas GI, et al. (2019). Mol Psychiatry. 2019 Jan 9. doi: 10.1038/s41380-018-0334-8. [Epub ahead of print] PubMed PMID: 30626911).

Phase 1 Pharmacokinetics and Safety in Healthy Subjects

In February of 2011 we commenced a two-part Phase 1A clinical trial to evaluate the safety and pharmacokinetics of NSI-189 in healthy volunteers. No dose-limiting toxicity was observed during the study and no serious adverse events (AE) were noted. All AEs were considered mild in intensity and none were considered to have a reasonable causal relationship to study drug. NSI-189 was found to be safe and well tolerated at the tested doses.

In December of 2011, we received authorization from the FDA to commence a Phase 1B randomized, double-blind, placebo-controlled, multiple-dose escalation study to evaluate safety, tolerability, pharmacokinetic (PK), and pharmacodynamic (PD) effects of NSI-189 in subjects[4] with MDD. The primary outcome measure was to assess drug safety by number and severity of adverse events in drug versus the placebo group.

Trial data for the Phase 1A and 1B were presented in June 2014 at the American Society of Clinical Psychopharmacology Annual Meeting (ASCP) and published in the journal Molecular Psychiatry (Fava et al., 2015[5]). NSI-189 was well tolerated and there were no serious (grade 4 or 5) adverse events.

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[3] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Washington, DC: American Psychiatric Association; 2013.

[4] https://www.clinicaltrials.gov/ct2/show/NCT01520649?term=neuralstem&rank=3

[5] http://www.nature.com/articles/mp2015178

In summary, notwithstanding the results of our Phase 2 randomized, placebo-controlled, double-blind clinical trial for the treatment of MDD, we still believe that NSI-189, may have a significant benefit on depressive and cognitive symptoms in patients with MDD and other related disorders.

Orphan Drug Designation for Angelman Syndrome

On August 9, 2018, NSI-189 received orphan designation for the treatment of Angelman syndrome. Angelman syndrome (AS) is a rare congenital genetic disorder caused by a lack of function in the UBE3A gene on the maternal 15th chromosome. It affects approximately one in 15,000 people - about 500,000 individuals globally. Symptoms of AS include developmental delay, lack of speech, seizures, and walking and balance disorders. Individuals with AS may never walk or speak and require life-long care, placing a significant burden on patients and caregivers. There are currently no FDA-approved therapies for the treatment of Angelman syndrome.

Mechanism of Action Studies with NSI-189

Evidence to date suggests that NSI-189 has a novel mechanism of action when compared to currently marketed therapies. Screening assays indicate that NSI-189 does not bind appreciably to known neurotransmitter receptors or transporters. These tests have included 48 neurotransmitter related receptors, ion channels, and enzymes, plus in excess of 450 protein kinases. The resulting data lead us to believe that NSI-189 acts via a mechanism that is distinct from currently marketed SSRI, SNRI, or NDRI compounds

Discovery of NSI-189: Our Proprietary and Novel Screening Platform

NSI-189’s potential was identified using our stem cell-based screening platform. Our human neural stem cell lines form the foundation for functional cell-based assays used to screen for small molecule compounds that can affect biologically relevant outcomes such as neurogenesis, synapse formation, and protection against toxic insults. We have developed over 300 unique stem cell lines representing multiple regions of the developing brain and spinal cord at different time points in development, enabling the generation of almost unlimited numbers of physiologically relevant human neural cells for screening, target validation, and mechanism-of-action studies. This platform provides us with a unique and powerful tool to identify new chemical entities to treat a broad range of nervous system conditions.

The discovery process for NSI-189 started with the initiation of a high content screen of 10,269 small molecules and led to the identification of 16 compounds that were capable of inducing neurogenesis, the birth of new neurons in

hippocampal stem cells in culture. These 16 compounds were then tested for toxicity *in vitro* and in mice and were evaluated for their ability to induce neurogenesis in healthy adult mice after oral administration. Seven of the starting 16 compounds, representing three structural classes, were advanced as orally active neurogenic leads. Compounds were evaluated in three mouse models of depression and NSI-189 was advanced as the lead small molecule candidate due to its anti-depressant behavioral effect, and its ability to both induce hippocampal neurogenesis and increase hippocampal volume.

Our Technologies

Stem Cells.

Our stem cell-based technology has both therapeutic and screening characteristics.

From a therapeutic perspective, our stem cell-based technology enables the isolation and large-scale expansion of regionally specific, human neural stem cells from all areas of the developing human brain and spinal cord thus enabling the generation of physiologically relevant human neurons of all types. We believe that our stem cell technology will assist the body in producing a neurotrophic environment to support weakened/diseased cells and/or replacing malfunctioning or dead cells as a way to treat disease and injury. Many significant and currently untreatable human diseases arise from the loss or malfunction of specific cell types in the body. Our focus is to develop effective methods to protect, repair, and regenerate the damaged neural circuits with implantation of neural stem cells.

Small Molecule Pharmaceutical Compounds.

Utilizing our proprietary stem cell derived screening capability, we have discovered and patented a series of neurogenic small molecule compounds. We believe our low molecular weight organic compounds can efficiently cross the blood/brain barrier. In mice, research indicated that the small molecule compounds can both stimulate neurogenesis of the hippocampus and increase its volume. We believe the small molecule compounds may promote synaptogenesis or neurogenesis in the human hippocampus in indications such as MDD.

Research

Substantial resources have been and will be devoted to our research programs. Our efforts are directed at developing therapies utilizing our stem cells and small molecule regenerative drug candidates. This research is conducted internally, through the use of third party laboratories, consulting companies under our direct supervision, and through collaboration with academic institutes.

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Manufacturing

We currently manufacture our cells both in-house and on an outsourced basis. We outsource the manufacturing of our pharmaceutical compounds and our clinical supply of stem cells to cGMP compliant third-party manufacturers. We manufacture neural stem cells in-house for use in our research and collaborative programs.

Intellectual Property

We have developed and maintain a portfolio of patents and patent applications that form the basis for our research and development efforts. We own or exclusively license approximately 10 issued and pending U.S. patents and approximately 55 issued and pending foreign patents related to our stem cell technologies for use in treating disease and injury. We own approximately 15 issued and pending U.S. patents and approximately 75 issued and pending foreign patents related to our small molecule compounds. Our issued patents have expiration dates ranging from 2019 through 2034.

When appropriate, we seek patent protection for inventions in our core technologies and in ancillary technologies that support our core technologies or which we otherwise believe will provide us with a competitive advantage. We accomplish this by filing patent applications for discoveries we make, either alone or in collaboration with scientific collaborators and strategic partners. Typically, although not always, we file patent applications both in the United States and in select international markets. In addition, we plan to obtain licenses or options to acquire licenses to patent filings from other individuals and organizations that we anticipate could be useful in advancing our research, development and commercialization initiatives and our strategic business interests.

In addition to patenting our technologies, we also rely on confidential and proprietary information and take active measures to control access to that information, including the use of confidentiality agreements with our employees, consultants and certain of our contractors.

Our policy is to require our employees, consultants and significant scientific collaborators and sponsored researchers to execute confidentiality and assignment of invention agreements upon the commencement of an employment or consulting relationship with us. These agreements generally provide that all confidential information developed or made known to the individual by us during the course of the individual's or entity’s relationship with us, is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees and consultants, the agreements generally provide that all inventions conceived by the individual or entity in the course of rendering services to us shall be our exclusive property.

The patent positions of pharmaceutical and biotechnology companies, including ours, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced before or after the patent is issued. Consequently, we do not know whether any of our pending applications will result in the issuance of patents, or if any existing or future patents will provide significant protection or commercial advantage or will be circumvented by others. Since patent applications are secret until the applications are published (usually eighteen months after the earliest effective filing date), and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file patent applications for such inventions. There can be no assurance that patents will issue from our pending or future patent applications or, if issued, that such patents will be of commercial benefit to us, afford us adequate protection from competing products, or not be challenged or declared invalid.

In the event that a third party has also filed a patent application relating to inventions claimed in our patent applications, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office or USPTO, to determine priority of invention, which could result in substantial uncertainties and costs, even if the eventual outcome is favorable to us. There can be no assurance that our patents, if issued, would be held valid by a court of competent jurisdiction.

A number of pharmaceutical, biotechnology and other companies, universities and research institutions have filed patent applications or have been issued patents relating to cell therapy, stem cells and other technologies potentially relevant to or required by our proposed products. We cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed.

If third party patents or patent applications contain claims infringed by our technology and such claims are ultimately determined to be valid, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative non-infringing technology. If we are unable to obtain such licenses or develop or obtain alternative non-infringing technology at a reasonable cost, we may not be able to develop certain products commercially. There can be no assurance that we will not be obliged to defend ourselves in court against allegations of infringement of third party patents. Patent litigation is very expensive and could consume substantial resources and create significant uncertainties. An adverse outcome in such a suit could subject us to significant liabilities to third parties, require us to seek licenses from third parties, or require us to cease using such technology.

In-licensing or Acquisition Strategy.

In addition to the development of our current product candidates, we have initiated an in-licensing or acquisition strategy to further expand our product pipeline. Our in-licensing strategy consists of evaluating early clinical or late preclinical stage opportunities in therapeutic areas that can benefit from our current product candidates or core expertise in drug development. Such in-licensing or acquisition opportunities may be in stem cell related technologies, CNS or in other therapeutic areas. We believe that this element of our corporate strategy could diversify some of the risks inherent in focusing on limited therapeutic areas and could increase our probability of commercial success.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multinational pharmaceutical companies, specialty biotechnology companies and chemical and medical products companies. Many of these companies are well-established and possess greater resources for technical, research, development, financial, sales and marketing initiatives than we do. Other, less well-established companies have formed or may form strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that may provide research and development and commercialization advantages to these competitors. Academic institutions, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those we are developing. Moreover, many of these competitors may be able obtain patent protection, or FDA and other regulatory approvals that may impede our freedom to develop and commercialize our programs.

The diseases and medical conditions we are targeting have a demographic in which there are large numbers of patients who do not respond to current therapies or have limited therapies available. Nevertheless, we expect that our technologies and product candidates, if or when approved, will compete with a variety of therapeutic products and procedures offered by other pharmaceutical and biotechnology companies. Many pharmaceutical and biotechnology companies are investigating new drugs and therapeutic approaches for the same or similar indications. These companies' efforts may achieve new efficacy profiles, extend the therapeutic window for such products, alter the prognosis of these diseases, or prevent their onset. We believe that our products, if or when approved, will attempt to compete with these products principally on the basis of improved and extended efficacy and safety and their overall economic benefit to the health care system. Competition for our products may be in the form of existing and new drugs, other forms of cell transplantation, surgical procedures, gene therapy or other proprietary technology and expertise. We expect that all of these products will compete with our product candidates, if or when approved, based on efficacy, safety, cost and intellectual property positions. We cannot be certain that that other entities have not filed patents that block our freedom to commercialize our programs and we may be required to seek licenses from these entities in order to commercialize certain of our proposed products, and such licenses may not be granted or be extremely expensive to obtain.

If we develop products that receive regulatory approval, they would then have to compete for market acceptance and market share. For our potential products, an important success factor will be the timing of market introduction of competitive products. This timing will be a function of the relative speed with which we and our competitors can develop products, complete the clinical testing and approval processes, and supply commercial quantities of a product to the market. These competitive products may also impact the timing of clinical testing and approval processes by limiting the number of clinical investigators and subjects available to test our potential products.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in our research and development and will be a significant factor in the manufacture and marketing of our proposed products. The nature and extent to which such regulation applies to us will vary depending on the nature of any products we may develop. Governmental authorities, including the FDA and comparable regulatory authorities in other countries, regulate the design, development, testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising, promotion and marketing of pharmaceutical products, including drugs and biologics, under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations, and, for biologics, under the Public Health Service Act, or PHSA, and its implementing regulations. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, import restrictions, injunctive actions and criminal prosecutions of both companies and individuals. In addition, administrative remedies can involve requests to recall violative products; the refusal of the government to enter into supply contracts; or the refusal to approve pending product approval applications until manufacturing or other alleged deficiencies are brought into compliance. The FDA also has the authority to cause the withdrawal of approval of a marketed product or to impose labeling restrictions. The process of obtaining approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and money, and there can be no guarantee that approvals will be granted.

United States Product Development Process

We believe that, in the United States, our human neural stem cell candidates are regulated as biologic pharmaceuticals, or biologics, and our small-molecule compounds are regulated as drugs.

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- Completion of preclinical testing of new pharmaceutical or biological products, generally conducted in the laboratory and in animal studies in accordance with GLP standard, and applicable requirements for the humane use of laboratory animals or other applicable regulations to evaluate the potential efficacy and safety of the product candidate;
- Submission of the results of these studies to the FDA as part of an Investigational New Drug application, which must become effective before clinical testing in humans can begin;
- Manufacturing of investigational medicine under cGMP standard;
- Performance of adequate and well-controlled human clinical trials according to GCPs and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the product candidate for its intended use;
- Submission to the FDA of a biological license application, or BLA, for any biologic or a new drug application, or NDA, for any new chemical entity drug we seek to market that includes substantive evidence of safety, purity, and potency, or safety and effectiveness from results of nonclinical testing and clinical trials;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced, packaged and distributed, to assess compliance with cGMPs, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity, and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- Potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA or NDA; and
- FDA review and approval of the NDA, or licensure, of the BLA.

Typically, human clinical evaluation involves a time-consuming and costly three-phase process.

- Phase 1. The product is initially introduced into healthy human volunteers and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be required and conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated similar trials. Similarly, an institutional review board, or IRB, can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients.

Human cell-based therapies in the field of regenerative medicine are relatively novel. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of such products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

United States Review and Approval Process

After the completion of clinical trials of a product candidate, FDA approval of a BLA or NDA must be obtained before commercial marketing of the product. The BLA or NDA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information as well as a significant user fee. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA or NDA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

The FDA may refuse to file any BLA or NDA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information. Once the submission is accepted for filing, the FDA reviews the BLA or NDA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is safe and effective for its intended use, and in each case, whether the product is being manufactured in accordance with cGMP or GTP, if applicable. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA or NDA must submit a proposed REMS. The FDA will not approve a BLA or NDA without a REMS, if required.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA or NDA does not satisfy its regulatory criteria for approval and deny approval via a letter detailing such deficiencies. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the FDA denies an application, the applicant may either resubmit the BLA or NDA, addressing all of the deficiencies identified by the FDA, or withdraw the application.

United States Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as off-label use, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. We rely, and expect to continue to rely, on third parties for the production of some, or all, clinical and commercial quantities of our products in accordance with cGMP and GTP regulations, as applicable. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, GTP and other laws.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative

enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

European, China and Other Regulatory Review and Approval

Whether or not FDA approval has been obtained, approval of a product by comparable regulatory authorities in Europe, China and other countries will be necessary prior to commencement of marketing the product in such countries. The regulatory authorities in each country may impose their own requirements and may refuse to grant an approval, or may require additional data before granting it, even though the relevant product has been approved by the FDA or another authority. As with the FDA, the regulatory authorities in the European Union, China and other developed countries have lengthy approval processes for biological and pharmaceutical products. The process for gaining approval in particular countries varies, but generally follows a similar sequence to that described for FDA approval.

Other Health Care Laws

In the event any of proposed products are ever approved for marketing, we may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our product candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician sunshine and privacy and security laws and regulations.

Other Regulations

We are also subject to various U.S. federal, state, local and international laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our business. We cannot accurately predict the extent of government regulation which might result from future legislation or administrative action.

For additional information about governmental regulations as well as risk related to our business that could affect our planned and intended business operations, see the *"Risk Factors"* Section of this Annual Report.

Employees

As of February 28, 2019, we had six full-time employees. We also use the services of numerous outside consultants in business and scientific matters.

Our Corporate Information

We were incorporated in Delaware in 2001. Our principal executive offices are located at 20271 Goldenrod Lane, Germantown, Maryland 20876, and our telephone number is (301) 366-4841. Our website is located at www.neuralstem.com.

We have not incorporated by reference into this report the information in, or that can be accessed through, our website and you should not consider it to be a part of this report.

Where to Find More Information

We make our public filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all exhibits and amendments to these reports. Also, our executive officers, directors and holders of more than 10% of our common stock, file reports with the SEC on Forms 3, 4 and 5

regarding their ownership of our securities. These materials are available on the SEC's web site, http://www.sec.gov. You may also read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Alternatively, you may obtain copies of these filings, including exhibits, by writing or telephoning us at:

NEURALSTEM, INC

20271 Goldenrod Lane

Germantown, Maryland 20876

Attn: Chief Financial Officer

Tel: (301) 366-4841

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. We have described below a number of uncertainties and risks which, in addition to uncertainties and risks presented elsewhere in this Annual Report, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Annual Report should be considered carefully in evaluating our company and our business and the value of our securities.

Risks Relating to Our Stage of Development, Capital Structure and Listing of Our Securities

We may not be able to continue as a going concern if we do not obtain additional financing.

We have incurred losses since our inception and have not demonstrated an ability to generate revenues from sales or services. Our ability to continue as a going concern is dependent on generating cash from the sale of our common stock and/or obtaining debt financing. Our cash, cash equivalents and short-term investment balance at December 31, 2018 was approximately $5.8 million. Based on our current expected level of operating expenditures, we expect to be able to fund our operations into the third quarter of 2019. Our ability to remain a going concern is wholly dependent upon our ability to continue to obtain sufficient capital to fund our operations.

Accordingly, despite our ability to secure capital in the past, there is no assurance that additional equity or debt financing will be available to us when needed or that we may be able to secure funding from any other sources. In the event that we are not able to secure funding, we may be forced to curtail operations, delay or stop ongoing clinical trials, cease operations altogether or file for bankruptcy.

Our auditors have expressed substantial doubt about our ability to continue as a going concern.

Our auditors' report on our December 31, 2018 financial statements expressed an opinion that our capital resources as of the date of their audit report were not sufficient to sustain operations or complete our planned activities for the upcoming year unless we raised additional funds. Our current cash level raises substantial doubt about our ability to continue as a going concern past the third quarter of 2019. If we do not obtain additional capital by such time, we may no longer be able to continue as a going concern and may cease operation or seek bankruptcy protection.

If we are unable to successfully retain and integrate a new management team, our business could be harmed.

On June 9, 2018 our former President, Chief Executive Officer and Chief Financial Officer, Richard Daly informed our board of directors that he intended to resign his position as director as well as his positions as President, Chief Executive Officer and Chief Financial Officer after a to be determined transitional period. Mr. Daly's last day was July 31, 2018. Effective August 1, 2018, we appointed Jim Scully as our interim Chief Executive Officer, president and principal accounting officer while we continued our search for a permanent candidate. Effective January 1, 2019, we appointed Dr. Kenneth Carter as our Executive Chairman. In such role, Dr. Carter will be our Principal Executive and Accounting Officer. Our success depends largely on the development and execution of our business strategy by our senior management team. The recent transitions in our executive team may be disruptive to our business, and if we are unable to manage an orderly transition, our business may be adversely affected. Additionally, since our management team consists of a limited number of individuals, the loss of any members or key personnel would likely harm our ability to implement our business strategy and respond to the rapidly changing market conditions in which we operate. There may be a limited number of persons with the requisite skills to serve in these positions, and we cannot assure you that we would be able to identify or employ such qualified personnel on acceptable terms, if at all. We cannot assure you that management will succeed in working together as a team. In the event we are unsuccessful, our business and prospects could be harmed.

Our common stock does not currently meet the continued listing requirements for the Nasdaq Capital Market and accordingly is subject to delisting.

On November 29, 2018, we received a written notice from the Nasdaq Stock Market LLC that we are not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock had been below $1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until May 28, 2019, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for at least ten consecutive business days during this 180 calendar day period. In the event we do not regain compliance by May 28, 2019, we may be eligible for an additional 180 calendar day grace period if we meet the initial listing standards, with the exception of bid price, for the Nasdaq Capital Market, and provide written notice to Nasdaq of our intention to

cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

If we do not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We will then be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing. We cannot be sure that our share price will comply with the requirements for continued listing of our shares on the Nasdaq Capital Market in the future or that we will comply with the other continued listing requirements. If our shares lose their status on the Nasdaq Capital Market, we believe that our shares would likely be eligible to be quoted on the inter-dealer electronic quotation and trading system operated by Pink OTC Markets Inc., commonly referred to as the Pink Sheets and now known as the OTCQB market. These markets are generally considered not to be as efficient as, and not as broad as, the Nasdaq Capital Market. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

The liquidity of our common stock may be affected if we undertake a reverse stock split.

On November 29, 2018, we received a written notice from the Nasdaq Stock Market LLC that we are not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock had been below $1.00 per share for 30 consecutive business days. In the event the price of our common stock does not substantially appreciate to a price above $1.00, and remain at or above $1.00 for 10 consecutive business days, we may be required to undertake a reverse stock split. In the event we are required to undertake a reverse stock split to regain compliance, the liquidity of our common stock may be adversely affected given the reduced number of shares that will be outstanding following the reverse stock split. In addition, the reverse stock split may increase the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

In the event we are required to undertake a reverse stock split, the market price of our common stock may decline.

On November 29, 2018, we received a written notice from the Nasdaq Stock Market LLC that we are not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock was been below $1.00 per share for 30 consecutive business days.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until May 28, 2019, to regain compliance with the minimum bid price requirement. In the event the price of our common stock does not substantially appreciate to a price above $1.00, we may be required to undertake a reverse stock split. Historically, after a reverse stock split, the market price of a company's shares declines.

If our common stock were delisted from NASDAQ, the Company would be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on NASDAQ and the trading price of the common stock were below $5.00 per share on the date the common stock were delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

We could become the subject to securities litigation.

Commencing in 2017, we have seen a dramatic decrease in the price of our common stock. Plaintiffs have often initiated securities class action litigation against a company following periods of significant decreases in the market price of the company's securities. Although management is not aware of any threatened litigation, we may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

We have a history of losses.

Since inception in 1996 through December 31, 2018, we have accumulated losses totaling approximately $214 million. As of December 31, 2018, we had a working capital surplus of approximately $5.5 million and stockholders' equity of approximately $6.0 million. Our net losses for the two most recent fiscal years have been approximately $4.9 million and $15.7 million for 2018 and 2017, respectively. We have generated no significant revenue from the sales of our proposed products.

Our ability to generate revenues and achieve profitability will depend upon our ability to complete the development of our proposed products, obtain the required regulatory approvals, manufacture and market and sell our proposed products. To date, we have not generated any revenue from the commercial sale of our proposed products. No assurances can be given as to exactly when, if at all, we will be able to fully develop, commercialize, market, sell and/or derive any, let alone material, revenues from our proposed products.

We will need to raise additional capital to continue operations.

Since our inception, we have funded our operations through the sale of our securities, credit facilities, the exercise of options and warrants, and to a lesser degree, from grants and research contracts and other revenue generating activities such as licensing. As of December 31, 2018, we had cash, cash equivalents and short-term investments on hand of approximately $5.8 million. We cannot assure you that we will be able to secure additional capital through financing transactions, including issuance of debt, licensing agreements or grants. Our inability to license our intellectual property, obtain grants or secure additional financing will materially impact our ability to fund our current and planned operations.

We have spent and expect to continue spending substantial cash in the research, development, clinical and pre-clinical testing of our proposed products with the goal of ultimately obtaining FDA approval and equivalent international approvals to market such products. We will require additional capital to conduct research and development, establish and conduct clinical and pre-clinical trials, enter into commercial-scale manufacturing arrangements and to provide for marketing and distribution of our products. We cannot assure you that financing will be available if needed. If additional financing is not available, we may not be able to fund our operations, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. If we exhaust our cash reserves and are unable to secure additional financing, we may be unable to meet our obligations which could result in us initiating bankruptcy proceedings or delaying or eliminating some or all of our research and product development programs.

Risks Relating to Our Business

Following our announcements regarding the negative results from our Phase 2 study, we may not generate any future revenues from NSI-189 or its underlying intellectual property and securing additional financing may be more difficult.

On July 25, 2017, we announced that our Phase 2 study of NSI-189 in subjects with MDD failed to achieve statistical significance on its primary endpoint although a subsequent evaluation of the data appeared directionally positive with regard to certain secondary endpoints. Following these clinical results, we may not generate any future revenues from NSI-189 or its underlying intellectual property. Additionally, after similar results, other companies in our industry have found it more difficult to raise capital and when they have been able to raise capital, it has typically been on less favorable terms.

Our business is dependent on the successful development of our product candidates and our ability to raise additional capital.

Our business is significantly dependent on our product candidates which are currently at different phases of pre-clinical and clinical development. The process to approve our product candidates is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the availability of alternative treatments, and the risks and benefits demonstrated in our clinical trials. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. On July 25, 2017, we announced that our Phase 2 clinical trial of NSI-189 in MDD failed to achieve statistical significance on its primary endpoint although a subsequent evaluation of the data appeared directionally positive with regard to certain secondary endpoints. If we are not successful in developing our product candidates, we will have invested substantial amounts of time and money without developing revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data generated in these studies may not be as compelling as the earlier results. This, in turn, could adversely impact our ability to raise additional capital and pursue our business plan and planned research and development efforts.

Our proposed products are not likely to be commercially available for at least several years, if at all. Our development schedules for our proposed products may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our product candidates could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in this section, there can be no assurance that we will be able to successfully complete the development or marketing of any of our proposed product candidates.

Our business relies on technologies that we may not be able to commercially develop and we are unable to predict when or if we will be able to earn revenues.

We have allocated the majority of our resources to the development of our stem cell and small molecule technologies. Our ability to generate revenue and operate profitably will depend on being able to develop these technologies for human applications. These are emerging technologies that may have limited human application. On July 25, 2017, we announced that our Phase 2 clinical trial of NSI-189 in MDD failed to achieve statistical significance on its primary endpoint although a subsequent evaluation of the data appeared directionally positive with regard to certain secondary endpoints. We cannot guarantee that we will be able to develop our technologies or that if developed, our technologies will result in commercially viable products or have any commercial utility or value. We anticipate that the commercial sale of our proposed products and/or royalty/licensing fees related to our technologies, will be our primary sources of revenue. We recognized revenue of approximately $10,000 in each of the years ended December 31, 2018 and 2017, related to the licensing of certain intellectual property to third parties. If we are unable to develop our technologies, we may never realize any significant revenue. Additionally, given the uncertainty of our technologies, product candidates and the need for government regulatory approval, we cannot predict when, or if ever, we will be able to realize revenues related to our products. As a result, we will be primarily dependent on our ability to raise capital through the sale of our securities for the foreseeable future.

Our product development programs are based on novel technologies in an emerging field and are inherently risky.

We are subject to the risks inherent in the development of products based on new technologies. The novel nature of therapies in the field of regenerative medicine creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third party reimbursement, and market acceptance. For example, the pathway to regulatory approval for cell-based therapies, including our stem cell-based product candidates, may be more complex and lengthy than the pathway for conventional drugs. These challenges may prevent us from developing and commercializing products on a timely or profitable basis or at all. Regenerative medicine is still an emerging field. There can be no assurances that we will ultimately produce any viable commercialized products and processes. Even if we are able to produce a commercially viable product, there may be strong competitors in this field and our products may not be able to successfully compete against them.

Our stem cell therapy programs rely on experimental surgical devices and highly invasive experimental surgical procedures.

We are subject to the risks inherent in the use and development of experimental surgical devices and procedures. We have limited experience with medical devices and must rely on outside consultants and manufacturers to develop and seek any required approvals for the device we use in connection with our stem cell therapy program. Additionally, the surgical procedures required to administer our stem cell therapies are experimental, highly invasive and is required to be performed by highly experienced neurosurgeons who have received special training. We cannot guarantee consistent and safe performance of these devices or the surgical procedures. A surgery related adverse event may result in a clinical hold and may have long-term and damaging effects on our ability to complete development of the stem cell therapy programs, including the completion of any ongoing or planned clinical trials. Even if one or more of our programs is successful and receives marketing approval from a regulatory authority, due to the specialized nature of the device and surgical procedure, there may not be sufficient train surgeons to administer our therapy.

We are unable to predict when or if we will be able to earn significant revenues.

Given the uncertainty of our technologies and the need for government regulatory approval, we cannot predict when, or if ever, we will be able to realize revenues related to our products.

Our proposed products are not likely to be commercially available for at least several or more years, if ever. Accordingly, we do not foresee generating any significant revenue during such time. As a result, we will be primarily dependent on our ability to raise capital through the sale of our securities to fund our operations for the foreseeable future.

Our reliance on third parties to manufacture and store our stem cells and small molecule compounds could adversely impact our business.

We currently outsource most of the manufacturing of our stem cells and small molecule pharmaceutical compounds to third party contractors and as such have limited ability to adequately control the manufacturing process and the safe storage thereof. Any manufacturing or storage irregularity, error, or failure to comply with applicable regulatory procedure would require us to find new third parties to outsource our manufacturing and storage responsibilities or our business would be impacted.

The manufacture of our therapeutic products is a complicated and difficult process, dependent upon substantial know-how and subject to the need for continual process improvements. In addition, our suppliers' ability to scale-up manufacturing to satisfy the various requirements of our planned clinical trials is uncertain. Additionally, many of the materials that we use to prepare our cell-based products are highly specialized, complex and available from only a limited number of suppliers. The loss of one or more of these sources would likely delay our ability to conduct planned clinical trials and otherwise adversely affect our business.

If we are unable to complete pre-clinical and clinical testing and trials or if clinical trials of our product candidates are prolonged, delayed, suspended, terminated or fail to reach their endpoints, our business and results of operations could be materially harmed.

Although we have commenced a number of trials, the ultimate outcome of the trials is uncertain. On July 25, 2017, we announced that our Phase 2 clinical trial of NSI-189 in MDD failed to achieve statistical significance on its primary endpoint although a subsequent evaluation of the data appeared directionally positive with regard to certain secondary endpoints. If we are unable to satisfactorily complete our other trials, or if such trials also yield unsatisfactory results, we may be unable to obtain regulatory approval for and commercialize our proposed products. No assurances can be given that our clinical trials will be completed or result in successful outcomes. A number of events, including any of the following, could delay the completion of our planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of our product candidates or other materials necessary to conduct our clinical trials;
- delays in obtaining regulatory agency agreement for the conduct of our clinical trials;
- lower than anticipated enrollment and retention rate of subjects in clinical trials;
- serious and unexpected side effects experienced by patients in our clinical trials which are related to the use of our product candidates; or
- failure of our third-party contractors to meet their contractual obligations to us in a timely manner.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, clinical trial site IRB's, or a data safety monitoring board, or DSMB, overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors. Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the cost, timing or successful completion of a clinical trial. We do not know whether our clinical trials will be conducted as planned, will need to be restructured or will be completed on schedule, if at all. Delays in our clinical trials will result in increased development costs for our drug candidates. In addition, if we experience delays in the completion of, or if we terminate, any of our clinical trials, the commercial prospects for our drug candidates may be harmed and our ability to generate product revenues will be jeopardized. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also

ultimately lead to the denial of regulatory approval of a drug candidate. If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would be unable to commercialize our proposed products, and our business and results of operations could be materially harmed.

The results of pre-clinical studies and clinical trials may not be predictive of the results of our later-stage clinical trials and our proposed products may not have favorable results in later-stage clinical trials or receive regulatory approval.

Seemingly positive results from pre-clinical studies or clinical studies should not be relied upon as evidence that our clinical trials will succeed. Even if our product candidates achieve positive results in pre-clinical studies or during our Phase 1 and Phase 2 studies, we will be required to demonstrate through further clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates as they proceed through clinical trials. If any product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, then we may experience potentially significant delays in, or be required to abandon development of that product candidate. Additionally, failure to demonstrate safety and efficacy results acceptable to the FDA in later stage trials could impair our development prospects and even prevent regulatory approval of our current and future product candidates. Any such delays or abandonment in our development efforts of any of our product candidates would materially impair our ability to generate revenues.

We are subject to numerous risks inherent in conducting clinical trials.

We outsource the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, our proposed products. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay or prevent the completion of our clinical trials.

We or our regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe they present an unacceptable risk to the patients enrolled in our clinical trials or do not demonstrate clinical benefit. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval for our proposed products, which would materially harm our business, results of operations and prospects.

We may be subject to litigation that will be costly to defend or pursue and uncertain in its outcome.

Our business may bring us into conflict with licensees, licensors, or others with whom we have contractual or other business relationships or with our competitors or others whose interests differs from ours. If we are unable to resolve these conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against such parties. Any litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases, could include judgments against us which could have a materially adverse effect on our business.

We may not be able to obtain government or third-party payor coverage and reimbursement.

Our ability to successfully commercialize our product candidates, if approved, depends to a significant degree on the ability of patients to be reimbursed for the costs of such products and related treatments. We cannot assure you that reimbursement in the U.S. or in foreign countries will be available for any products developed, or, if available, will not decrease in the future, or that reimbursement amounts will not reduce the demand for, or the price of, our products. There is considerable pressure to reduce the cost of therapeutic products. Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA or other relevant authority has not granted marketing approval. Moreover, in some cases, government and other third-party payors have refused to provide reimbursement for uses of approved products for disease indications for which the FDA or other relevant authority has granted marketing approval. Significant uncertainty exists as to the reimbursement status of newly approved health-care products or novel therapies such as ours. We cannot predict what additional regulation or legislation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such regulation or legislation may have on our business. If additional regulations are overly onerous or expensive or if healthcare related legislation makes our business more expensive or burdensome than originally anticipated, we may be forced to significantly downsize our business plans or completely abandon the current business model.

Our products may not be profitable due to manufacturing costs and our inability to receive favorable pricing.

Our products may be significantly more expensive to manufacture than other drugs or therapies currently on the market today due to a fewer number of potential manufacturers, greater level of needed expertise and other general market conditions affecting manufacturers of our proposed products. Even if we are able to receive approval for the reimbursement of our proposed products the amount of reimbursement may be significantly less than the manufacturing costs of our products. Additionally, other market factors may limit the price which we can charge for our proposed products while still being competitive. Accordingly, even if we are successful in developing our proposed products, we may not be able to charge a high enough price for us to earn a profit.

We are dependent on the acceptance of our products by the healthcare community.

Our product candidates, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community, in general, may decide not to accept and utilize these products. The products that we are attempting to develop represent substantial departures from established treatment methods and will compete with a number of more conventional therapies marketed by major pharmaceutical companies. If the healthcare community does not accept our products for any reason, our business will be materially harmed.

We depend on a limited number of employees and consultants for our continued operations and future success.

We are highly dependent on a limited number of employees and outside consultants. Although we have entered into employment and consulting agreements with these parties, these agreements can be terminated at any time. The loss of any of our employees or consultants could adversely affect our opportunities and materially harm our future prospects. In addition, we anticipate growth and expansion into areas and activities requiring additional expertise, such as clinical testing, regulatory compliance, manufacturing and marketing. We anticipate the need for additional management personnel as well as the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our present and planned activities, and there can be no assurance that we will be able to attract and retain the qualified personnel necessary for the development our business.

The employment contracts of certain key employees contain significant anti-termination provisions which could make changes in management difficult or expensive.

We have entered into employment agreements with Dr. Carter and Dr. Johe, our Executive Chairman and Chief Scientific Officer, respectively. The agreements may require the payment of severance in the event such individuals cease to be employed. These provisions make the replacement of these employees very costly and could cause difficulty in effecting any required changes in management or a change in control.

Our competition has significantly greater experience and financial resources.

The biotechnology industry is characterized by rapid technological developments and a high degree of competition. We compete against numerous companies, many of which have substantially greater resources. Several such enterprises have initiated cell therapy research programs and/or efforts to treat the same diseases which we target. Given our current stage of development and resources, it may be extremely difficult for us to compete against more developed companies.

As a result, our proposed products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We believe that our proposed products under development and in pre-clinical testing and clinical trials will address unmet medical needs for those indications for which we are focusing our development efforts. Our competition will be determined in part by the potential indications for which our proposed products are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our proposed products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop our proposed products, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market is expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

Our outsource model depends on third parties to assist in developing and testing our proposed products.

Our strategy for the development, clinical and pre-clinical testing and commercialization of our proposed products is based in large part on an outsource model. This model requires us to engage third parties in order to further develop our technology and products as well as for the day to day operations of our business. In the event we are not able to enter into such relationships in the future, our ability to operate and develop products may be seriously hindered or we may be required to spend considerable time and resources to bring such functions in-house. Either outcome could result in our inability to develop a commercially feasible product or in the need for substantially more working capital to complete the research in-house.

The commercialization of therapeutic products exposes us to product liability claims.

Product liability claims could result in substantial litigation costs and damage awards against us. We attempt to mitigate this risk by obtaining and maintaining appropriate insurance coverage. Historically, we have obtained

liability insurance that covers our clinical trials. If we begin commercializing products, we will need to increase our insurance coverage. We may not be able to obtain insurance on acceptable terms, if at all, and the policy limits on our insurance policies may be insufficient to cover our potential liabilities.

We currently rely heavily upon third party FDA-regulated manufacturers and suppliers for our products

We currently manufacture our cells both in-house and on an outsource basis. We outsource the manufacturing of our pharmaceutical compound to third party manufacturers. We manufacture cells in-house which are not required to meet stringent FDA requirements. We use these cells in our research and collaborative programs. At present, we outsource all the manufacturing and storage of our stem cells and pharmaceuticals compound to be used in clinical testing, and which are subject to higher FDA requirements, to Charles River Laboratories, Inc., of Wilmington, Massachusetts (stem cells) and Albany Molecular Resources, Inc. (small molecule). Failure by our contract manufacturer to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously hurt our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic and unannounced inspections by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs, GTPs and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party manufacturers' compliance with these regulations and standards.

Because manufacturing facilities are subject to regulatory oversight and inspection, failure to comply with regulatory requirements could result in material manufacturing delays and product shortages, which could delay or otherwise negatively impact our clinical trials and product development. Moreover, we do not have quantity or volume commitment orders from these manufacturers and we cannot assure you that the manufacturers will be able to manufacture in the quantity we require on a timely basis or at all. In the event we are required to seek alternative third-party suppliers or manufacturers, they may require us to purchase a minimum amount of materials or could require other unfavorable terms. Any such event would materially impact our business prospects and could delay the development of our products. Moreover, there can be no assurance that any manufacturer or supplier that we select will be able to supply our products in a timely or cost-effective manner or in accordance with applicable regulatory requirements or our specifications. In addition, due to the novelty of our products and product development, there can be no assurances that we would be able to find other suitable third-party FDA-regulated manufacturers on a timely basis and at terms reasonable to us. Even if we were to locate alternative manufacturers there may be delays before they are able to begin manufacturing. Failure to secure such third-party manufacturers or suppliers would materially impact our business.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.

We do not have the in-house capability to conduct clinical trials for our product candidates. We rely, and will rely in the future, on medical institutions, clinical investigators, contract research organizations, contract laboratories, and collaborators to perform data collection and analysis and other aspects of our clinical trials. Our reliance on these third parties for clinical development activities results in reduced control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Our preclinical activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

- the third parties do not successfully carry out their contractual duties;
- the third parties fail to meet FDA and other regulatory obligations or expected deadlines;
- we replace a third party for any reason; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

Risks Relating to Intellectual Property

We may not be able to withstand challenges to our intellectual property rights.

We rely on our intellectual property, including issued and applied-for patents, as the foundation of our business. Our intellectual property rights may come under challenge. No assurances can be given that our current and potential future patents will survive such challenges. For example, in 2005 one of our patents was challenged in the USPTO. Although we prevailed in this particular matter, these cases are complex, lengthy, expensive, and could potentially be adjudicated adversely to our interests, removing the protection afforded by an issued patent. The viability of our business would suffer if such patent protection were limited or eliminated. Moreover, the costs associated with defending or settling intellectual property claims would likely have a material adverse effect on our business and future prospects.

We may not be able to adequately protect against the piracy of the intellectual property in foreign jurisdictions.

We conduct research in countries outside of the U.S., including through our subsidiary in the People's Republic of China. A number of our competitors are located in these countries and may be able to access our technology or test results. The laws protecting intellectual property in some of these countries may not adequately protect our trade secrets and intellectual property. The misappropriation of our intellectual property may materially impact our position in the market and any competitive advantages, if any, that we may have.

We may infringe the intellectual property rights of others and may not be able to obtain necessary licenses to third-party patents and other rights.

A number of companies, universities and research institutions have filed patent applications or have received patents relating to technologies in our field. We cannot predict which, if any, of these applications will issue as patents or how many of these issued patents will be found valid and enforceable. There may also be existing issued patents on which we would infringe by the commercialization of our product candidates. If so, we may be prevented from commercializing these products unless the third party is willing to grant a license to us. We may be unable to obtain licenses to the relevant patents at a reasonable cost, if at all, and may also be unable to develop or obtain alternative non-infringing technology. If we are unable to obtain such licenses or develop non-infringing technology at a reasonable cost, our business could be significantly harmed. Also, any infringement lawsuits commenced against us may result in significant costs, divert our management's attention and result in an award against us for substantial damages, or potentially prevent us from continuing certain operations.

Risks Relating to Our Common Stock

The market price for our common shares is particularly volatile.

The market for our common shares is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than those of a seasoned issuer. The volatility in our share price is attributable to a number of factors. Mainly however, we are a speculative or "risky" investment due to our limited operating history, lack of significant revenues to date and the uncertainty of FDA approval. By way of example, in October of 2018, we completed a registered direct offering of 3,000,000 shares of our common stock and a simultaneous private placement of 3,000,000 common stock purchase warrants. Shortly thereafter, the market price or our common stock decreased substantially. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Additionally, in the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

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The following factors may add to the volatility in the price of our common shares: actual or anticipated variations in our quarterly or annual operating results; the results of clinical trials for our product candidates; FDA's determination with respect to filings for new clinical studies, new drug applications and new indications; government regulations; announcements of significant acquisitions, strategic partnerships or joint ventures; our capital commitments; offerings of our securities and additions or departures of our key personnel. Many of these factors are beyond our control and may decrease the market price of our common shares, regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common shares will be at any time, including as to whether our common shares will sustain their current market prices, or as to what effect the sale of shares or the availability of common shares for sale at any time will have on the prevailing market price.

Future sales of our common stock could cause our stock price to fall.

In October of 2018, we completed a registered direct offering of 3,000,000 shares of our common stock or approximately 20% of our issued and outstanding shares, as well as a private placement of an equal number of common stock purchase warrants. Transactions that result in a large amount of newly issued shares that are readily tradable, or other events that cause current stockholders to sell shares, could place downward pressure on the trading price of our common stock. In addition, the lack of a robust trading market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock. If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

Certain of our outstanding common stock purchase warrants contain price protection provisions (anti-dilution protection) in the event that we sell our securities at prices lower than the current exercise price of such warrants, which may have a negative impact on the trading price of our common stock or impair our ability to raise capital.

As of December 31, 2018, we had 2,982,709 common stock purchase warrants outstanding that were issued in our May 2016 registered offering, May 2016 private placement and August 2017 registered offering that all contain price protection provisions in the event that we sell securities at a price per share below their respective exercise prices (collectively "Price Protection Warrants"). Pursuant to our October 2018 registered offering, the Price Protection Warrants all had their exercise prices adjusted to $0.57 per share. As of February 28, 2019, the most recent closing price of our common stock was $0.47. In the event that we sell securities at a price per share lower than the current exercise price of the Price Protection Warrants, their exercise prices will be further reduced. Any future adjustments to the exercise prices of the Price Protection Warrants may have a negative impact on the trading price of our common stock. Additionally, raising additional capital with new investors may be difficult as a result of the adjustment feature.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As a public company, we incur significant legal, accounting and other expenses that we would not incur as a private company, including costs associated with public company reporting requirements. We also incur costs associated with the Sarbanes-Oxley Act of 2002, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented or to be implemented by the SEC and the Nasdaq. The expenses incurred by public companies generally for reporting, insurance and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers and may divert management's attention. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

We have never paid a cash dividend and do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never paid cash dividends nor do we anticipate paying cash dividends in the foreseeable future. Accordingly, any return on your investment will be as a result of stock appreciation if any.

Our anti-takeover provisions may delay or prevent a change of control, which could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make it difficult to remove our board of directors and management and may discourage or delay "change of control" transactions, which could adversely affect the price of our common stock. These provisions include, among others:

- our board of directors is divided into three classes, with each class serving for a staggered three-year term, which prevents stockholders from electing an entirely new board of directors at an annual meeting;
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors and propose matters to be brought before an annual meeting of our stockholders may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may, without stockholder approval, issue series of preferred stock, or rights to acquire preferred stock, that could dilute the interest of, or impair the voting power of, holders of our common stock or could also be used as a method of discouraging, delaying or preventing a change of control.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us and our business. We currently have limited research coverage by securities and industry analysts. In the event an analyst downgrades our securities the price of our securities would likely decline. If analysts cease to cover us or fails to publish regular reports on us, interest in our securities could decrease, which could cause the price of our common stock and other securities and their trading volume to decline.

Our board of directors has broad discretion to issue additional securities, which might dilute the net tangible book value per share of our common stock for existing stockholders.

We are entitled under our certificate of incorporation to issue up to 300,000,000 shares of common stock and 7,000,000 “blank check” shares of preferred stock. Shares of our blank check preferred stock provide our board of directors with broad authority to determine voting, dividend, conversion, and other rights. As of December 31, 2018, we have issued and outstanding 18,205,060 shares of common stock and we have 14,653,704 shares of common stock reserved for future grants under our equity compensation plans and for issuances upon the exercise or conversion of currently outstanding options, warrants and convertible securities. As of December 31, 2018, we had 1,000,000 shares of preferred stock issued and outstanding which are convertible into 3,887,387 shares of our common stock. Accordingly, we are entitled to issue up to 267,141,236 additional shares of common stock and 6,000,000 additional shares of “blank check” preferred stock. Our board may generally issue those common and preferred shares, or convertible securities to purchase those shares, without further approval by our shareholders. Any preferred shares we may issue will have such rights, preferences, privileges and restrictions as may be designated from time-to-time by our board, including preferential dividend rights, voting rights, conversion rights, redemption rights and liquidation provisions. It is likely that we will be required to issue a large amount of additional securities to raise capital in order to further our development and marketing plans. It is also likely that we will be required to issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our various stock plans. The issuance of additional securities may cause substantial dilution to our shareholders.

Risks Related to Government Regulation and Approval of our Product Candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and our products may not receive regulatory approval.

The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate’s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We are currently undertaking clinical trials for our lead products candidates NSI-189 and NSI-566. We cannot assure you that we will successfully complete any clinical trials in connection with such INDs. Further, we cannot predict when we might first submit any product license application (NDA or BLA) for FDA approval or whether any such product license application will be granted on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals could have a material adverse effect on the marketing of our products and our ability to generate product revenue.

Development of our product candidates is subject to extensive government regulation.

Our research and development efforts, as well as any future clinical trials, and the manufacturing and marketing of any products we may develop, will be subject to, and restricted by, extensive regulation by governmental authorities in the U.S. and other countries. The process of obtaining FDA and other necessary regulatory approvals is lengthy, expensive and uncertain. FDA and other legal and regulatory requirements applicable to our proposed products could substantially delay or prevent us from initiating additional clinical trials. We may fail to obtain the necessary approvals to commence clinical testing or to manufacture or market our potential products in reasonable time frames, if at all. In addition, the U.S. Congress and other legislative bodies may enact regulatory reforms or restrictions on the development of new therapies that could adversely affect the regulatory environment in which we operate or the development of any products we may develop.

A substantial portion of our research and development entails the use of stem cells obtained from human tissue. The U.S. federal and state governments and other jurisdictions impose restrictions on the acquisition and use of human tissue, including those incorporated in federal Good Tissue Practice, or "GTP," regulations. These regulatory and other constraints could prevent us from obtaining cells and other components of our products in the quantity or of the quality needed for their development or commercialization. These restrictions change from time to time and may become more onerous. Additionally, we may not be able to identify or develop reliable sources for the cells necessary for our potential products — that is, sources that follow all state and federal laws and guidelines for cell procurement. Certain components used to manufacture our stem and progenitor cell product candidates will need to be manufactured in compliance with the FDA's GMP. Accordingly, we will need to enter into supply agreements with companies that manufacture these components to GMP standards. There is no assurance that we will be able to enter into any such agreements.

Noncompliance with applicable regulatory requirements can subject us, our third party suppliers and manufacturers and our other collaborators to administrative and judicial sanctions, such as, among other things, warning letters, fines and other monetary payments, recall or seizure of products, criminal proceedings, suspension or withdrawal of regulatory approvals, interruption or cessation of clinical trials, total or partial suspension of production or distribution, injunctions, limitations on or the elimination of claims we can make for our products, refusal of the government to enter into supply contracts or fund research, or government delay in approving or refusal to approve new drug applications.

We cannot predict if or when we will be able to commercialize our products due to regulatory constraints.

Federal, state and local governments and agencies in the U.S. (including the FDA) and governments in other countries have significant regulations in place that govern many of our activities. We are, or may become, subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with its research and development work. The preclinical testing and clinical trials of our proposed products are subject to extensive government regulation that may prevent us from creating commercially viable products. In addition, our sale of any commercially viable product will be subject to government regulation from several standpoints, including manufacturing, advertising, marketing, promoting, selling, labeling and distributing. If, and to the extent that, we are unable to comply with these regulations, our ability to earn revenues, if any, will be materially and negatively impacted.

If our clinical trials fail to demonstrate that any of our product candidates are safe and effective for the treatment of particular diseases, the FDA may require us to conduct additional clinical trials or may not grant us marketing approval for such product candidates for those diseases.

We are not permitted to market our product candidates in the United States until we receive approval of a BLA or NDA from the FDA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with evidence gathered in preclinical and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls used to produce the product are compliant with applicable statutory and regulatory requirements. Our failure to adequately demonstrate the safety and effectiveness of any of our product candidates for the treatment of particular diseases may delay or prevent our receipt of the FDA's approval and, ultimately, may prevent commercialization of our product candidates for those diseases. The FDA has substantial discretion in deciding whether, based on the benefits and risks in a particular disease, any of our product candidates should be granted approval for the treatment of that particular disease. Even if we believe that a clinical trial or trials has demonstrated the safety and statistically significant efficacy of any of our product candidates for the treatment of a disease, the results may not be satisfactory to the FDA. Preclinical and clinical data can be interpreted by the FDA and other regulatory authorities in different ways, which could delay, limit or prevent regulatory approval. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for those of our product candidates involved will be harmed, and our prospects for profitability will be significantly impaired.

Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to unanticipated delays. Despite our efforts, our drug candidates may not:

- offer improvement over existing comparable products;
- be proven safe and effective in clinical trials; or
- meet applicable regulatory standards.

In addition, in the course of its review of a BLA or NDA or other regulatory application, the FDA or other regulatory authorities may conduct audits of the practices and procedures of a company and its suppliers and contractors concerning manufacturing, clinical study conduct, non-clinical studies and several other areas. If the FDA and/or other regulatory authorities conducts an audit relating to a BLA, NDA or other regulatory application and finds a significant deficiency in any of these or other areas, the FDA or other regulatory authorities could delay or not approve such BLA, NDA or other regulatory application. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for those of our products or product candidates involved will be harmed, and our prospects for profitability will be significantly impaired.

Both before and after marketing approval, our product candidates are subject to extensive and rigorous ongoing regulatory requirements and continued regulatory review, and if we fail to comply with these continuing requirements, we could be subject to a variety of sanctions.

Both before and after the approval of our product candidates, we, our product candidates, our operations, our facilities, our suppliers, and our contract manufacturers, contract research organizations, and contract testing laboratories are subject to extensive regulation by governmental authorities in the United States and other countries, with regulations differing from country to country. In the United States, the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, packaging, adverse event reporting, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, requirements and current good clinical practice, or cGCP, requirements for any clinical trials that we conduct post-approval. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: restrictions on the marketing of our products or their manufacturing processes, notices of violation, untitled letters, warning letters, civil penalties, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product candidate, suspension or withdrawal of regulatory approvals, product, seizure or detention, voluntary or mandatory product recalls and related publicity requirements, interruption of manufacturing or clinical trials, operating restrictions, injunctions, import or export bans, and criminal prosecution. We or the FDA, or an institutional review board, may suspend or terminate human clinical trials at any time on various grounds, including a finding that subjects are being exposed to an unacceptable health risk.

The FDA’s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing or new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

If side effects are identified during the time our drug candidates are in development or after they are approved and on the market, we may choose or be required to perform lengthy additional clinical trials, discontinue development of the affected drug candidate, change the labeling of any such products, or withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Even if any of our drug candidates receives marketing approval, as greater numbers of patients use a drug following its approval, an increase in the incidence of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contradictions;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such drug candidates or could harm or prevent sales of any approved products.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for our drug candidates.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

We expect our stem cell product candidates to be regulated by the FDA as biologic products and we intend to seek approval for these products pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biologic products.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our drug candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

We are subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal physician sunshine requirements under the ACA, which require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- HIPAA, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information.

In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that 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 False Claims Act.

These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Failure to comply with domestic and international privacy and security laws can result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws, including protecting electronically stored information from cyberattacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to HIPAA. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

We currently operate one facility located in the United States and one facility located in China. Our corporate offices and primary research facilities are located in Germantown, Maryland, where we lease approximately 1,500 square feet. This lease provides for monthly payments of approximately $5,700 per month. Our prior lease expired on December 31, 2018. We are currently operating on a month-to-month lease as we negotiate an extension.

In 2015, we entered into a lease consisting of approximately 3,100 square feet of research space in San Diego, California. This lease provides for current monthly payments of approximately $12,000 and expires on August 31, 2019. In May 2017, we ceased-use of this property and in April 2018, we entered into an agreement for the sub-lease of the property.

We also lease a research facility in People's Republic of China. This lease expires on March 31, 2019 with lease payments of approximately $3,800 per month. We intend to renew this lease upon its expiration.

ITEM 3. LEGAL PROCEEDINGS

As of the date of this Annual Report, there are no material pending legal or governmental proceedings relating to our company or properties to which we are a party, and to our knowledge there are no material proceedings to which any of our directors, executive officers or affiliates are a party adverse to us or which have a material interest adverse to us.

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable

PART II

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

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "CUR."

Holders

As of February 28, 2019, our common stock was held by approximately 239 record holders. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these holders.

Dividends

We have not paid any cash dividends to date and have no plans to do so in the immediate future. Additionally, we are prohibited from paying any cash dividends under the terms of certain agreements to which we are a party.

Equity Compensation Plan Information

The following table sets forth information with respect to our equity compensation plans as of December 31, 2018.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options and Rights (a)	Weighted-Average **Exercise Price for Outstanding Options and Rights** (b)	Number of Securities Remaining Available for Future Issuance under Equity compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders			
2007 Stock Plan	58,584	$ 11.85	-
2010 Equity Compensation Plan	1,589,338	$ 10.60	-
Equity compensation plans not approved by security holders			
Inducement Plan	800,000	$ 0.43	1,200,000
Total	2,447,922	$ 19.65	1,200,000

Equity Compensation Plans Not Approved by Security Holders

Our Inducement Award Stock Option Plan (“Inducement Plan”) is administered by our board or our compensation committee. The Inducement Plan is intended to be used in connection with the recruiting and inducement of senior management and employees. The issuance of awards under the Inducement Plan is at the discretion of the administrator which has the authority to determine the persons to whom any awards shall be granted and the terms, conditions and restrictions applicable to any award. Pursuant to the Inducement Plan, the Company may grant stock options for up to a total of 2,000,000 shares of common stock to new employees of the Company. As of December 31, 2018, 800,000 grants have been made pursuant to the Inducement Plan. The Inducement Plan is intended to qualify as an inducement plan under NASDAQ Listing Rule 5635(c)(4) and accordingly, the Company did not seek stockholders’

approval.

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Recent Sales or Issuances of Unregistered Securities

The following information is given with regard to unregistered securities sold during the period covered by this report. The following securities were issued in private offerings pursuant to the exemption from registration contained in the Securities Act and the rules promulgated thereunder in reliance on Section 4(2) thereof, relating to offers of securities by an issuer not involving any public offering:

- In August 2018, as partial compensation for services, we issued to one of our consultants, stock purchase options to purchase 250,000 shares of common stock at an exercise price of $1.15 per share. The options are exercisable on the grant date and have a five-year term. 208,979 of the options are issued under our 2010 Equity Compensation Plan. The remaining 41,021 are not issued under the 2010 Equity Compensation Plan and consequently are considered unregistered securities.

- In October 2018, we issued 3,000,000 common stock purchase warrants in conjunction with our registered direct public offering. Pursuant to the public and private offerings, we sold an aggregate of 3,000,000 shares of registered common stock and simultaneously issued the investors 3,000,000 common stock purchase warrants. The common stock was issued at a price of $0.70 per share and we received no additional consideration for the warrants. The unregistered warrants have an exercise price of $0.75 per share of common stock, will be exercisable commencing six months following the issuance date and will expire five and one-half years from issuance. As partial compensation for the offering, we also issued out placement agent warrants to purchase 180,000 shares of common stock. The warrants are identical to the ones issued the investors except that the: (i) term is five (5) years, and (ii) exercise price is $0.875 per share.

- In December 2018, as an inducement to Dr. Carter’s employment, we granted an Inducement Option to purchase 800,000 shares of common stock at an exercise priced of $0.425 per share. The Inducement Option has a term of ten years, and vests as follows: 200,000 on the January 1, 2019 employment start date, 200,000 over the two-year period from the employment start date and 400,000 based on the achievement of certain performance-based milestones. The Inducement Option also provides that if within 12 months following the employment start date, the Company enters into a transaction to sell securities in a capital raising effort Mr. Carter will be awarded additional options based on his percentage ownership prior to such transaction. Note that the Company has determined that there is no accounting grant date for this award until the beginning of employment or January 1, 2019. Consequently, this grant is not accounted for until such time.

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable.

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

Our Management's Discussion and Analysis of Financial Condition and Results of Operations or MD&A, is provided in addition to the accompanying financial statements and notes to assist readers in understanding our results of operations, financial condition and cash flows. Our MD&A is organized as follows:

- *Executive Overview* — Overview discussion of our business in order to provide context for the remainder of MD&A.
- *Trends & Outlook* — Discussion of what we view as the overall trends affecting our business and the strategy for 2019.
- *Critical Accounting Policies*— Accounting policies that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.
- *Results of Operations*— Analysis of our financial results comparing the: (i) year ended December 31, 2018 to the comparable period of 2017.
- *Liquidity and Capital Resources*—Analysis of cash flows and discussion of our financial condition and future liquidity needs.

Executive Overview

We are focused on the research and development of therapies for the treatment of central nervous system diseases, which are based on our proprietary human neural stem cells and our small molecule compounds with the goal of gaining approval from the United States Food and Drug Administration or FDA, and its international counterparts, to market and commercialize such therapies. We are headquartered in Germantown, Maryland.

Our patented technology platform has three core components:

1. Over 300 lines of human, regionally specific neural stem cells, some of which we believe have the potential to be used to treat serious or life-threatening diseases through direct transplantation into the central nervous system;

2. Proprietary screening capability – our ability to generate human neural stem cell lines provides a platform for chemical screening and discovery of novel compounds; and

3. Small molecules that have resulted from Neuralstem's neurogenesis screening platform that we believe may have the potential to treat wide variety of nervous system conditions.

Our technology platform to date has produced four lead assets, two in clinical development and two in preclinical development: our NSI-566 stem cell therapy program (clinical stage), NSI-189 small molecule program (clinical stage) and NSI-532 and NSI-577, both of which are second-generation stem cell therapy programs (preclinical stage).

We have developed a portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license approximately 15 U.S. issued and pending patents and approximately 70 foreign issued and pending patents related to our stem cell technologies for use in treating disease and injury. We own approximately 15 U.S. issued and pending patents and approximately 75 foreign issued and pending patents related to our small molecule compounds.

We believe our technology, in combination with our expertise, and established collaborations with major research institutions, could facilitate the development and commercialization of products for use in the treatment of a several nervous system disorders including neurodegenerative conditions and regenerative repair of acute and chronic disease.

Trends & Outlook

Revenue

We generated no revenues from the sale of our proposed therapies for any of the periods presented.

We have historically generated minimal revenue from the licensing of our intellectual property to third parties as well as payments under a settlement agreement.

On a long-term basis, we anticipate that our revenue will be derived primarily from licensing fees and sales of our small molecule compounds and licensing fees and royalties from our cell-based therapies. Because we are at such an early stage in the clinical trials process, we are not yet able to accurately predict when we will have a product ready for commercialization, if ever.

Research and Development Expenses

Our research and development expenses consist primarily of clinical trial expenses, including; payments to clinical trial sites that perform our clinical trials and clinical research organizations (CROs) that help us manage our clinical trials, manufacturing of small molecule drugs and stem cells for both human clinical trials and for pre-clinical studies and research, personnel costs for research and clinical personnel, and other costs including research supplies and facilities.

We focus on the development of therapies with potential uses in multiple indications and use employee and infrastructure resources across several projects. Accordingly, many of our costs are not attributable to a specifically identified product and we do not account for internal research and development costs on a project-by-project basis.

We expect that research and development expenses, which include expenses related to our ongoing clinical trials, will increase in the future as funding allows and as we proceed later stage clinical trials.

We have a wholly owned subsidiary in the People’s Republic of China. We anticipate that this subsidiary will primarily: (i) conduct pre-clinical research with regard to proposed stem cells therapies, and (ii) oversee our approved future clinical trials in China, including the current trial to treat motor deficits due to ischemic stroke.

In August 2017, we were awarded a Small Business Innovation Research (“SBIR”) grant by the National Institutes of Health (“NIH”) to evaluate in preclinical studies the potential of NSI-189, a novel small molecule compound, for the prevention and treatment of diabetic neuropathy. The award of approximately $1 million will be paid over a two-year period, if certain conditions are met as mid-term. In June 2018, we were awarded a Department of Defense grant related to our efforts involving stem cell therapy for severe traumatic brain injury. The award of approximately $150,000 will be paid over a six-month period. The proceeds from the awards are recorded as a reduction of our gross research and development expenses, based on the terms and conditions of the grants..

General and Administrative Expenses

General and administrative expenses are primarily comprised of salaries, benefits and other costs associated with our operations including, finance, human resources, information technology, public relations and costs associated with maintaining a public company listing, legal, audit and compliance fees, facilities and other external general and administrative services.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Note 2 of the Notes to Consolidated Financial Statements included elsewhere herein describes the significant accounting policies used in the preparation of the financial statements. Certain of these significant accounting policies are considered to be critical accounting policies, as defined below.

A critical accounting policy is defined as one that is both material to the presentation of our financial statements and requires management to make difficult, subjective or complex judgments that could have a material effect on our financial condition and results of operations. Specifically, critical accounting estimates have the following attributes: (1) we are required to make assumptions about matters that are highly uncertain at the time of the estimate; and (2) different estimates we could reasonably have used, or changes in the estimate that are reasonably likely to occur, would have a material effect on our financial condition or results of operations.

Estimates and assumptions about future events and their effects cannot be determined with certainty. We base our estimates on historical experience and on various other assumptions believed to be applicable and reasonable under the circumstances. These estimates may change as new events occur, as additional information is obtained and as our operating environment changes. These changes have historically been minor and have been included in the financial statements as soon as they became known. Based on a critical assessment of our accounting policies and the underlying judgments and uncertainties affecting the application of those policies, management believes that our financial statements are fairly stated in accordance with U.S. GAAP, and present a meaningful presentation of our financial condition and results of operations. We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our consolidated financial statements:

Use of Estimates - Our financial statements prepared in accordance with U.S. GAAP require us to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Specifically, we have estimated the expected

economic life and value of our patent technology, our net operating loss carryforward and related valuation allowance for tax purposes the fair value of our liability classified warrants and our share-based compensation expenses related to employees, directors, consultants and investment banks. Actual results could differ from those estimates.

Long Lived Intangible Assets - Our long-lived intangible assets consist of our intellectual property patents including primarily legal fees associated with the filings and in defense of our patents. The assets are amortized on a straight-line basis over the expected useful life which we define as ending on the expiration of the patent group. These assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We assess this recoverability by comparing the carrying amount of the asset to the estimated undiscounted future cash flows to be generated by the asset. If an asset is deemed to be impaired, we estimate the impairment loss by determining the excess of the asset's carrying amount over the estimated fair value. These determinations use assumptions that are highly subjective and include a high degree of uncertainty. During the years ended December 31, 2018 and 2017, no significant impairment losses were recognized.

Fair Value Measurements - The fair value of our short-term financial instruments, which primarily include cash and cash equivalents, other short-term investments, accounts payable and accrued expenses, approximate their carrying values due to their short maturities. The fair value of our long-term indebtedness was estimated based on the quoted prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities which approximates the carrying value. The fair values of our liability classified warrants are estimated using Level 3 unobservable inputs.

Share-Based Compensation - We account for share-based compensation at fair value; accordingly, we expense the estimated fair value of share-based awards over the requisite service period. Share-based compensation cost for stock options and warrants issued to employees and board members is determined at the grant date while awards granted to non-employee consultants are generally valued at the vesting date using an option pricing model. Option pricing models require us to make assumptions, including expected volatility and expected term of the options. If any of the assumptions we use in the model were to significantly change, share-based compensation expense may be materially different. Share-based compensation cost for restricted stock and restricted stock units issued to employees and board members is determined at the grant date based on the closing price of our common stock on that date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

Comparison of Our Results of Operations for the Years Ended December 31, 2018 and 2017

Revenue

During each of the years ended December 31, 2018 and 2017, we recognized $250,000 of milestone-based royalties related to a settlement of a prior patent infringement case. In addition, during each of the years ended December 31, 2018 and 2017, we recognized revenue of $10,000 related to ongoing fees pursuant to certain licenses of our intellectual property to third parties.

Operating Expenses

Operating expenses for 2018 and 2017 were as follows:

	Year Ended December 31,		Increase (Decrease)	
	2018	2017	$	%
Operating Expenses				
Research & development costs	$3,960,191	$8,096,095	$(4,135,904)	(51)%
General & administrative expenses	4,559,265	5,471,010	(911,745)	(17)%
Total expense	$8,519,456	$13,567,105	$(5,047,649)	(37)%

Research and Development Expenses

The decrease of approximately $4,136,000 or 51% in research and development expenses was primarily attributable to (i) a $1,580,000 decrease in costs related to our completed NS-189 Phase 2 clinical trial, (ii) a $982,000 decrease in our personnel, facility and other expenses due to our ongoing corporate restructuring and cost reduction efforts (iii) a $958,000 decrease in non-cash share-based compensation expense and (iv) a $497,000 increase in reimbursements under our research grants.

General and Administrative Expenses

The decrease of approximately $912,000 or 17% in general and administrative expenses was primarily attributable to (i) a $1,064,000 decrease in personnel, facility and related expenses due to our ongoing corporate restructuring and cost reduction efforts and (ii) a $178,000 decrease in our non-cash share-based compensation expense partially offset by (iii) a $247,000 increase in tax and insurance expenses and (iv) a $84,000 increase in outsourced consulting and professional services expenses.

Other income (expense)

Other income (expense), net totaled approximately $3,335,000 and ($2,359,000) for the years ended December 31, 2018 and 2017, respectively. Other income, net in 2018 consisted of approximately $3,269,000 of non-cash gains related to the change in the fair value of our liability classified stock purchase warrants and $79,000 of interest income.

Other expense, net in 2017 consisted of approximately $1,470,000 of non-cash losses related to the change in the fair value of our liability classified stock purchase warrants, $564,000 of expense related to the issuance of inducement warrants, $243,000 of expense related to the liability classified warrants issued in conjunction with our August 2017 capital raise and $159,000 of interest expense related primarily to our long-term debt, partially offset by $70,000 of interest income.

Liquidity and Capital Resources

Since our inception, we have financed our operations through the sales of our securities, issuance of long-term debt, the exercise of investor warrants, and to a lesser degree from grants and research contracts as well as the licensing of our intellectual property to third parties.

We had cash, cash equivalents and short-term investments balances of approximately $5.8 million as at December 31, 2018. On October 29, 2018, we closed a registered direct offering with institutional investors pursuant to which we received gross proceeds of $2.1 million.

Based on our expected operating cash requirements, we anticipate our average monthly cash burn rate will decrease and our current cash and investments on hand will be sufficient to fund our operations, into the third quarter of 2019. As explained in the notes to our financial statements and in the report of our independent registered public accounting firm for the year ended December 31, 2018 there is substantial doubt about our ability to continue as a going concern.

We will require additional capital to continue to develop our pre-clinical and clinical development operations. To continue to fund our operations and the development of our product candidates we anticipate raising additional cash through the private and public sales of equity or debt securities, collaborative arrangements, licensing agreements or a combination thereof. Although management believes that such funding sources will be available, there can be no assurance that any such collaborative arrangement will be entered into or that financing will be available to us when needed in order to allow us to continue our operations, or if available, on terms acceptable to us. If we do not raise sufficient funds in a timely manner, we may be forced to curtail operations, delay or stop our ongoing clinical trials, cease operations altogether, or file for bankruptcy. We currently do not have commitments for future funding from any source. We cannot assure you that we will be able to secure additional capital or that the expected income will materialize. Several factors will affect our ability to raise additional funding, including, but not limited to market conditions, interest rates and, more specifically, our progress in our exploratory, preclinical and future clinical

development programs.

Cash Flows – 2018 compared to 2017

	Year Ended December 31,		Increase (Decrease)	
	2018	2017	$	%
Cash and cash equivalents	$5,787,110	$6,674,940	$(887,830)	(13)%
Short term investments	-	5,000,000	(5,000,000)	(100)%
Total cash and short term investments	$5,787,110	$11,674,940	$(5,887,830)	(50)%
Net cash used in operating activities	$(7,692,419)	$(13,416,162)	$5,723,743	(43)%
Net cash provided by (used in) investing	$4,998,286	$(94,046)	$5,092,332	(5,415)%
Net cash provided by financing activities	$1,814,233	$4,990,778	$(3,176,545)	(64)%

The decrease in the balance of our cash and short-term investments of approximately $5.9 million was primarily due to our $8.3 million net operating loss partially offset by our $1.8, net received from our equity raise and $0.6 million of non-cash share-based compensation.

Net Cash Used in Operating Activities

The decrease in our cash used in operating activities of approximately $5,724,000 was primarily due to a decrease in our operating loss adjusted for certain noncash items, including share-based compensation and change in the fair value of liability classified warrants along with a decrease in payments of accounts payable and accrued expenses and receipt of payments related to a milestone-based revenue and reimbursement under our grants.

Cash used in operating activities for the year ended December 31, 2018, of approximately $7,692,000 reflects our $4,925,000 loss for the period adjusted for certain non-cash items including: (i) $634,000 of share-based compensation (ii) ($3,269,000) related to the change in fair value of our liability classified warrants, (iii) ($337,000) of net cash outflows related to changes in our operating assets and liabilities and (iv) $186,000 adjustment for amortization and depreciation.

Net Cash Used in Investing Activities

For the year ended December 31, 2018 cash provided by investing activities was comprised primarily of proceeds from the maturity of our short-term investments.

For the year ended December 31, 2017 cash used in investing activities was comprised of costs related to our patent assets and fixed asset purchases.

Net Cash Provided by Financing Activities

For the year ended December 31, 2017, cash provided by financing activities consisted primarily of approximately $1,828,000 of net proceeds from our October financing transaction.

For the year ended December 31, 2017, cash provided by financing activities consisted primarily of approximately $5,414,000 of net proceeds from our August financing transaction, $3,225,000 from the exercise of common stock purchase warrants partially offset by $3,766,000 of payments of our long-term debt.

Future Liquidity and Needs

We have incurred significant operating losses and negative cash flows since inception. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for general and administrative expenses and other working capital requirements. We rely on cash balances and the proceeds from the offering of our securities, exercise of outstanding warrants and grants to fund our operations.

We intend to pursue opportunities to obtain additional financing in the future through the sale of our securities and additional research grants. On June 23, 2017, our shelf registration statement (Registration No. 333-218608), which replaced our prior expiring shelf registration statement, was declared effective by the SEC. Under such replacement shelf registration statement, we can offer and sell up to $100 million of our securities. Through February 28, 2019, we have sold approximately $12.6 million of securities under our shelf registration statement. Accordingly, we can offer and sell an additional $87.4 million of securities under our shelf registration statement, subject to any limitations imposed by Instruction I.B.6 of Form S-3.

As explained in the notes to our financial statements, if we are not able to raise additional funds when needed, there would continue to be substantial doubt as to our ability to continue as a going concern. The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, current and future progress in our exploratory, preclinical and clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and/or our capital expenditures or to license our potential products or technologies to third parties.

Off-balance Sheet Arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not Applicable.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of Neuralstem, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Neuralstem, Inc. and subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated 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 two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 of the consolidated financial statements, the Company has suffered recurring losses from operations and has accumulated deficit that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Dixon Hughes Goodman LLP

We have served as the Company’s auditor since 2016.

Baltimore, Maryland

March 22, 2019

Neuralstem, Inc.

Consolidated Balance Sheets

	December 31, 2018	2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$5,787,110	$6,674,940
Short-term investments	-	5,000,000
Trade and other receivables	294,057	312,802
Current portion of related party receivable, net of discount	63,938	58,784
Prepaid expenses	363,288	402,273
Total current assets	6,508,393	12,448,799
Property and equipment, net	90,311	172,886
Patents, net	763,543	883,462
Related party receivable, net of discount and current portion	298,238	365,456
Other assets	23,965	13,853
Total assets	$7,684,450	$13,884,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$832,564	$875,065
Accrued bonuses	-	418,625
Other current liabilities	218,602	220,879
Total current liabilities	1,051,166	1,514,569
Warrant liabilities, at fair value	583,734	3,852,882
Other long term liabilities	-	1,876
Total liabilities	1,634,900	5,369,327
Commitments and contingencies (Note 8)		
STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, $0.01 par value; 1,000,000 shares issued and outstanding in both 2018 and 2017	10,000	10,000
Common stock, $0.01 par value; 300 million shares authorized, 18,205,060 and 15,160,014 shares issued and outstanding in 2018 and 2017, respectively	182,051	151,600
Additional paid-in capital	219,481,805	217,050,174
Accumulated other comprehensive income (loss)	(413)	2,631
Accumulated deficit	(213,623,893)	(208,699,276)

Total stockholders' equity	6,049,550	8,515,129
Total liabilities and stockholders' equity	$7,684,450	$13,884,456

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2018	2017
Revenues	$260,000	$260,000
Operating expenses:		
Research and development costs	3,960,191	8,096,095
General and administrative expenses	4,559,265	5,471,010
Total operating expenses	8,519,456	13,567,105
Operating loss	(8,259,456)	(13,307,105)
Other income (expense):		
Interest income	78,780	70,269
Interest expense	(7,698)	(159,066)
Gain (loss) from change in fair value of liability classified warrants	3,269,148	(1,470,174)
Fees related to issuance of liability classified warrants and other expenses	(5,391)	(799,907)
Total other income (expense)	3,334,839	(2,358,878)
Net loss	$(4,924,617)	$(15,665,983)
Net loss per common share - basic and diluted	$(0.32)	$(1.20)
Weighted average common shares outstanding - basic and diluted	15,156,925	13,064,422
Comprehensive loss:		
Net loss	$(4,924,617)	$(15,665,983)
Foreign currency translation adjustment	(3,044)	(1,274)
Comprehensive loss	$(4,927,661)	$(15,667,257)

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

Consolidated Statements of Changes In Stockholders' Equity

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at January 1, 2017	1,000,000	$10,000	11,032,858	$110,329	$204,239,837	$3,905	$(193,033,293)	$11,330,778
Share rounding adjustment relating to 1:13 reverse stock split	-	-	6,537	65	(65)	-	-	-
Share based payments	-	-	-	-	1,769,964	-	-	1,769,964
Issuance of common stock and inducement warrants for warrant exercises	-	-	1,013,464	10,134	7,801,843	-	-	7,811,977
Issuance of common stock for RSU exercises	-	-	4,939	49	(49)	-	-	-
Issuance of common stock and warrants from capital raises, net	-	-	3,022,387	30,224	3,239,443	-	-	3,269,667
Issuance of restricted stock awards	-	-	79,829	799	(799)	-	-	-
	-	-	-	-	-	(1,274)	-	(1,274)

Foreign currency translation adjustments								
Net loss	-	-	-	-	-	-	(15,665,983)	(15,665,983)
Balance at December 31, 2017	1,000,000	10,000	15,160,014	151,600	217,050,174	2,631	(208,699,276)	8,515,129
Share based payments	-	-	-	-	634,082	-	-	634,082
Issuance of common stock and warrants from capital raises, net	-	-	3,000,000	30,000	1,798,000	-	-	1,828,000
Issuance of restricted stock awards			45,046	451	(451)	-	-	-
Foreign currency translation adjustments	-	-	-	-	-	(3,044)	-	(3,044)
Net loss	-	-	-	-	-	-	(4,924,617)	(4,924,617)
Balance at December 31, 2018	1,000,000	$10,000	18,205,060	$182,051	$219,481,805	$(413)	$(213,623,893)	$6,049,550

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(4,924,617)	$(15,665,983)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	185,803	289,208
Share based compensation expenses	634,082	1,769,964
Amortization of deferred financing fees and debt discount	-	59,781
Change in fair value of liability classified warrants	(3,269,148)	1,470,174
Warrant inducement expense	-	563,744
Expenses related to issuance of liability classified warrants	-	242,676
Loss on disposal of fixed assets and patent abandonment	18,342	8,128
Changes in operating assets and liabilities:		
Trade and other receivables	18,745	(302,311)
Related party receivable	62,064	53,081
Prepaid expenses	32,303	297,298
Other assets	(3,991)	1,855
Accounts payable and accrued expenses	(36,991)	(1,522,917)
Accrued bonuses	(418,625)	(434,338)
Other current liabilities	11,490	(230,189)
Other long term liabilities	(1,876)	(16,333)
Net cash used in operating activities	(7,692,419)	(13,416,162)
Cash flows from investing activities:		
Purchases of short-term investments	-	(5,000,000)
Maturity of short-term investments	5,000,000	5,000,000
Patent costs	-	(82,645)
Purchase of property and equipment	(1,714)	(11,401)
Net cash provided by (used in) investing activities	4,998,286	(94,046)
Cash flows from financing activities:		
Proceeds from issuance of common stock from warrants exercised, net of issuance costs	-	3,225,176
Proceeds from sale of common stock, preferred stock and warrants, net of issuance costs	1,828,000	5,510,840
Payments of long-term debt	-	(3,765,568)
Proceeds from short term notes payable	349,578	346,863
Payments of short term notes payable	(363,345)	(326,533)
Net cash provided by financing activities	1,814,233	4,990,778

Effects of exchange rates on cash	(7,930)	(579)
Net decrease in cash and cash equivalents	(887,830)	(8,520,009)
Cash and cash equivalents, beginning of year	6,674,940	15,194,949
Cash and cash equivalents, end of year	$5,787,110	$6,674,940

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

Consolidated Statements of Cash Flows (continued)

	Year Ended December 31,	
	2018	2017
Supplemental cash flow information:		
Cash paid for interest	$7,698	$118,257

See accompanying notes to consolidated financial statements.

NEURALSTEM, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and Business and Financial Condition

Nature of business

Neuralstem, Inc. and its subsidiary are referred to as “Neuralstem,” the “Company,” “us,” or “we” throughout this report. The operations of our wholly-owned and controlled subsidiary located in the People’s Republic of China are consolidated in our condensed consolidated financial statements and all intercompany activity has been eliminated. The Company operates in one business segment.

Neuralstem is a clinical stage biopharmaceutical company that is utilizing its proprietary human neural stem cell technology to create a comprehensive platform of therapies for the treatment of central nervous system diseases. The Company has utilized this technology as a tool for small-molecule drug discovery and to create cell therapy biotherapeutics to treat central nervous system diseases. The Company was founded in 1997 and currently has laboratory and office space in Germantown, Maryland and laboratory facilities in the People’s Republic of China. Our operations to date have primarily focused on developing business strategies, raising capital, research and development activities, and conducting pre-clinical testing and human clinical trials of our product candidates.

Liquidity and Going Concern

The Company has incurred losses since its inception and has not demonstrated an ability to generate significant revenues from the sales of its therapies or services and have not yet achieved profitable operations. There can be no assurance that profitable operations will ever be achieved, or if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and pre-clinical testing, and commercialization of our products will require significant additional financing. These factors create substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

In making this assessment the Company performed a comprehensive analysis of its current circumstances including: its financial position at December 31, 2018, its cash flow and cash usage forecasts for the period covering one-year from the issuance date of this Annual Report and its current capital structure including outstanding warrants and other

equity-based instruments and its obligations and debts.

We expect that our existing cash and cash equivalents will be sufficient to enable us to fund our anticipated level of operations based on our current operating plans into the third quarter of 2019. Accordingly, we will require additional capital to further develop our product candidates, conduct our pre-clinical and clinical development programs and to fund our operations. We anticipate raising additional capital through the private and public sales of our equity or debt securities, collaborative arrangements, licensing agreements or a combination thereof. Although management believes that such capital sources will be available, there can be no assurance that any such collaborative or licensing arrangements will be entered into or that financing will be available to us when needed in order to allow us to continue our operations, or if available, on terms acceptable to us. If we do not raise sufficient capital in a timely manner, among other things, we may be forced to delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and/or our capital expenditures or to license our potential products or technologies to third parties on unfavorable terms. We currently do not have any commitments for future funding from any source.

We have spent and will continue to spend substantial funds in the research, development, pre-clinical and clinical testing of our small molecule and stem cell product candidates with the goal of ultimately obtaining approval from the United States Food and Drug Administration (the “FDA”) and its international equivalents regulatory agencies, to market and sell our products. We have also begun spending funds on the evaluation and new assets and technologies with the goal of acquisition and development. No assurance can be given that (i) the FDA or any other regulatory agency will grant approval for us to market and sell our product candidates, (ii) if regulatory approval is granted, that we will ever be able to sell our proposed products or be profitable, or (iii) that we will be able to identify and acquire and/or in-license promising new assets or technologies.

Note 2. Significant Accounting Policies and Basis of Presentation

Basis of Presentation

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The financial statements include the accounts of the Company and our wholly owned subsidiary. All significant intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The consolidated financial statements include significant estimates for the expected economic life and value of our licensed technology and related patents, our net operating loss and related valuation allowance for tax purposes, the fair value of our liability classified warrants and our share-based compensation related to employees and directors, consultants and advisors, among other things. Because of the use of estimates inherent in the financial reporting

process, actual results could differ significantly from those estimates.

Fair Value Measurements

The carrying amounts of our short-term financial instruments, which primarily include cash and cash equivalents, short-term investments, accounts payable and accrued expenses, approximate their fair values due to their short maturities. The fair value of our long-term indebtedness was estimated based on the quoted prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities and approximates the carrying value. The fair values of our liability classified warrants were estimated using Level 3 unobservable inputs. See Note 3 for further details.

Foreign Currency Translation

The functional currency of our wholly owned foreign subsidiary is its local currency. Assets and liabilities of our foreign subsidiary are translated into United States dollars based on exchange rates at the end of the reporting period; income and expense items are translated at the weighted average exchange rates prevailing during the reporting period. Translation adjustments for subsidiary are accumulated in other comprehensive income or loss, a component of stockholders' equity. Transaction gains or losses are included in the determination of net loss.

Cash, Cash Equivalents, Short-Term Investments and Credit Risk

Cash equivalents consist of investments in low risk, highly liquid money market accounts and certificates of deposit with original maturities of 90 days or less. Cash deposited with banks and other financial institutions may exceed the amount of insurance provided on such deposits. If the amount of a deposit at any time exceeds the federally insured amount at a bank, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail.

Short-term investments consist entirely of fixed income certificates of deposit (“CDs”) with original maturities of greater than 90 days but not more than one year.

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents and short-term investments. Our investment policy, approved by our Board of Directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations. In addition, our certificates of deposit are typically invested through the Certificate of Deposit Account Registry Service (“CDARS”) program which reduces or eliminates our risk related to concentrations of investments above FDIC insurance levels. We attempt to limit our credit and liquidity risks through our investment policy and through regular reviews of our portfolio against our policy. To date, we have not experienced any loss or lack of access to cash in our operating accounts or to our cash equivalents and short-term investments.

Revenue

On January 1, 2018, the Company adopted Topic 606, Revenue from Contracts with Customer using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers; (ii) identification of distinct performance obligations in the contract; (iii) determination of contract transaction price; (iv) allocation of contract transaction price to the performance obligations; and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation. The Company recognizes revenues upon the satisfaction of its performance obligation (upon transfer of control of promised goods or services to customers) in an amount that reflects the consideration to which it expects to be entitled to in exchange for those goods or services. Deferred revenue results from cash receipts from or amounts billed to customers in advance of the transfer of control of the promised services to the customer and is recognized as performance obligations are satisfied. When sales commissions or other costs to obtain contracts with customers are considered incremental and recoverable, those costs are deferred and then amortized as selling and marketing expenses on a straight-line basis over an estimated period of benefit.

Research and Development

Research and development costs are expensed as they are incurred. Research and development expenses consist primarily of costs associated with the pre-clinical development and clinical trials of our product candidates. For the years ended December 31, 2018 and 2017, we recorded approximately $538,000 and $41,000, respectively of cost reimbursements from our grants as an offset to research and development expenses. The Company evaluated the grants and concluded that, based on the specific terms, they represent a cost reimbursement activity as opposed to a revenue generating activity, and are best reflected as an offset to the underlying research and development expense.

Income (Loss) per Common Share

Basic income (loss) per common share is computed by dividing total net income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period.

For periods of net income when the effects are dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted average number of shares outstanding and the dilutive impact of all dilutive potential common shares. Dilutive potential common shares consist primarily of convertible preferred stock, stock options, restricted stock units and common stock purchase warrants. The dilutive impact of potential common shares resulting from common stock equivalents is determined by applying the treasury stock method. Our unvested restricted shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; the calculation of basic and diluted income per share excludes net income attributable to the unvested restricted shares from the numerator and excludes the impact of the shares from the denominator.

For all periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses; accordingly, diluted loss per share is the same as basic loss per share for the years ended December 31, 2018 and 2017. A total of approximately 12.6 and 10.2 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the years ended December 31, 2018 and 2017, respectively as their inclusion would be anti-dilutive.

Share-Based Compensation

We account for share-based compensation at fair value. Share-based compensation cost for stock options and stock purchase warrants granted to employees and board members is generally determined at the grant date while awards granted to non-employee consultants are generally valued at the vesting date using an option pricing model that uses Level 3 unobservable inputs; share-based compensation cost for restricted stock and restricted stock units is determined at the grant date based on the closing price of our common stock on that date. The value of the award is recognized as expense on a straight-line basis over the requisite service period.

Intangible and Long-Lived Assets

We assess impairment of our long-lived assets using a "primary asset" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. No significant impairment losses were recognized during the years ended December 31, 2018 or 2017.

Income Taxes

We account for income taxes using the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected

to be realized. We also recognize a tax benefit from uncertain tax positions only if it is "more likely than not" that the position is sustainable based on its technical merits. Our policy is to recognize interest and penalties on uncertain tax positions as a component of income tax expense.

Corporate tax rate changes resulting from the impacts of the Tax Cuts and Jobs Act of 2017 (the "Tax Act") are reflected in deferred tax assets and liabilities at both December 31, 2018 and 2017.

Significant New Accounting Pronouncements

Recently Adopted Guidance

In May 2014, the Financial Accounting Standards Board ("FASB") issued *Accounting Standard Update ("ASU"), No. 2014-09, Revenue from Contracts with Customers*. This ASU consists of a comprehensive revenue recognition standard that superseded nearly all existing revenue recognition guidance under U.S. GAAP. The guidance is effective for interim and annual periods beginning after December 15, 2017. Either full retrospective adoption or modified retrospective adoption is permitted. In addition to expanded disclosures regarding revenue, this pronouncement may impact timing of recognition in some arrangements with variable consideration or contracts for the sale of goods or services. We adopted this guidance effective January 1, 2018 on a modified retrospective basis and it did not have a material impact on the consolidated financial statements.

In May 2017, the FASB issued *ASU No. 2017-09, Compensation – Stock Compensation*. This ASU provides clarification regarding when changes to the terms or conditions of share-based payment awards should be accounted for as modifications. This guidance is effective for fiscal years beginning after December 15, 2017 and early adoption is permitted. This guidance must be applied prospectively to awards modified after the adoption date. We adopted this guidance effective January 1, 2018 and it did not have a material impact on the consolidated financial statements.

In July 2017, the FASB issued *ASU No. 2017-11, I. Accounting for Certain Financial Instrument with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* Part I of this guidance simplifies the accounting for certain equity-linked financial instruments and embedded features with down round features that reduce the exercise price when the pricing of a future round of financing is lower ("down round protection"). Current accounting guidance provides that instruments with down round protection be classified as derivative liabilities with changes in fair value recorded through earnings. The updated guidance provides that instruments with down round protection are no longer precluded from being classified as equity. This guidance is effective for fiscal years beginning after December 15, 2018 and early adoption is permitted. This guidance must be applied retrospectively. We adopted this guidance on January 1, 2018, and it did not have a material impact on the financial statements.

Unadopted Guidance

In February 2016, the FASB issued *ASU, No. 2016-02, Leases.* This ASU consists of a comprehensive lease accounting standard. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets. The Company expects to make a policy election whereby it will not recognize a lease liability or right of use asset for our short-term leases and that it will combine lease and non-lease elements of leases. Based on our current lease portfolio, we expect the adoption of the guidance will result in recording a right of use asset of approximately $50,000 and a lease liability of approximately $75,000 on our consolidated balance sheet.

In June 2016, the FASB issued *ASU No. 2016-13, Financial Instrument's – Credit Losses*. This ASU relates to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of certain amendments of this guidance must be applied on a modified retrospective basis and the adoption of the remaining amendments must be applied on a prospective basis. We currently expect that the adoption of this guidance will likely change the way we assess the collectability of our receivables and recoverability of other financial instruments. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

In June 2018, the FASB issued *ASU 2018-07, Compensation-Stock Compensation, Improvements to Nonemployee Share-Based Payment Accounting*. This ASU expands the scope of *ASC 718, Compensation – Stock Compensation* to include share-based payment transactions for acquiring goods and services from nonemployees. This guidance provides for the following changes: (1) awards to nonemployees will be measured at the grant date fair value of equity instruments that the entity is obligated to issue, (2) performance-based awards to nonemployees will be measured based on the probability of the performance condition being met and (3) eliminating the need to reassess the classification (equity or liability) of awards to nonemployees upon vesting. The guidance is effective for fiscal years beginning after December 15, 2018. We expect the adoption of this guidance will change the way we measure awards to nonemployees. We have not yet determined the specific impacts of this guidance upon adoption.

In August 2018, the FASB issued *ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU addresses the disclosure requirements for fair value measurements. The guidance intends to improve the effectiveness of the disclosures relating to recurring and nonrecurring fair value measurements. The guidance is effective for fiscal years beginning

after December 15, 2019. Portions of the guidance are to be adopted prospectively while other portions are to be adopted retroactively. Early adoption is permitted. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

In August 2018, the FASB issued *ASU 2018-15, Intangibles – Goodwill and Other – Internal-Use Software*. This ASU addresses the accounting for implementation, setup and other upfront costs paid by a customer in a cloud computing or hosting arrangement. The guidance aligns the accounting treatment of these costs incurred in a hosting arrangement treated as a service contract with the requirements for capitalization and amortization costs to develop or obtain internal-use software. The guidance is effective for fiscal years beginning after December 15, 2019. The guidance can be adopted either retrospectively or prospectively. Early adoption is permitted. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

We have reviewed other recent accounting pronouncements and concluded that they are either not applicable to our business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

Note 3. Fair Value Measurements

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These levels are:

- *Level 1* – inputs are based upon unadjusted quoted prices for identical instruments traded in active markets.
- *Level 2* – inputs are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques (e.g. the Black-Scholes model) for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs including interest rate curves, foreign exchange rates, and forward and spot prices for currencies and commodities.
- *Level 3* – inputs are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques, including option pricing models and discounted cash flow models.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

We have segregated our financial assets and liabilities that are measured at fair value on a recurring into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date.

At December 31, 2018 and December 31, 2017, we had certain common stock purchase warrants that were originally issued in connection with our May 2016 and August 2017 capital raises (See Note 4) that are accounted for as liabilities whose fair value was determined using Level 3 inputs. The following table identifies the carrying amounts of such liabilities:

	Level 1	Level 2	Level 3	Total
Liabilities				
Liability classified stock purchase warrants	$ -	$ -	$3,852,882	$3,852,882
Balance at December 31, 2017	$ -	$ -	$3,852,882	$3,852,882
Liability classified stock purchase warrants	$ -	$ -	$583,734	$583,734
Balance at December 31, 2018	$ -	$ -	$583,734	$583,734

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the year ended December 31, 2018:

	Mark-to-market liabilities - stock purchase warrants
Balance at December 31, 2017	$ 3,852,882
Change in fair value - gain	(3,269,148)
Balance at December 31, 2018	$ 583,734

The following table presents the activity for those items measured at fair value on a recurring basis using Level 3 inputs for the year ended December 31, 2017:

	Mark-to-market liabilities - stock purchase warrants
Balance at December 31, 2016	$ 3,921,917
Issuance of warrants	2,483,848
Exercise of warrants	(4,023,057)
Change in fair value - loss	1,470,174
Balance at December 31, 2017	$ 3,852,882

The (gains) losses resulting from the changes in the fair value of the liability classified warrants are classified as other income or expense in the accompanying consolidated statements of operations. The fair value of the common stock purchase warrants is determined based on the Black-Scholes option pricing model or other option pricing models as appropriate and includes the use of unobservable inputs such as the expected term, anticipated volatility and expected dividends. Changes in any of the assumptions related to the unobservable inputs identified above may change the embedded conversion options' fair value; increases in expected term, anticipated volatility and expected dividends generally result in increases in fair value, while decreases in these unobservable inputs generally result in decreases in fair value.

Note 4. Stockholders' Equity

We have granted share-based compensation awards to employees, board members and service providers. In addition, we have issued warrants to purchase common stock in conjunction with debt and equity offerings. Awards may consist of common stock, restricted common stock, restricted common stock units, common stock purchase warrants, or common stock purchase options. Our common stock purchase options and stock purchase warrants have lives of up to ten years from the grant date. Awards vest either upon the grant date or over varying periods of time. The stock options provide for exercise prices equal to or greater than the fair value of the common stock at the date of the grant. Restricted stock units grant the holder the right to receive fully paid common shares with various restrictions on the holder's ability to transfer the shares. As of December 31, 2018, we have approximately 10.8 million shares of common stock reserved for issuance upon the exercise of share-based awards.

We record share-based compensation expense on a straight-line basis over the requisite service period. Share-based compensation expense included in the statements of operations was as follows:

	Year Ended December 31,	
	2018	2017
Research and development costs	$133,334	$1,091,036
General and administrative expenses	500,748	678,928
Total	$634,082	$1,769,964

Stock Options

A summary of stock option activity and related information for the year ended December 31, 2018 follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2018	1,894,077	$ 19.76	4.7	$108,000
Granted	488,640	$ 1.13		$-
Exercised	-	-		
Forfeited/Expired	(750,055)	$ 27.19		
Outstanding at December 31, 2018	1,632,662	$ 10.78	5.1	$-
Exercisable at December 31, 2018	1,166,127	$ 14.59	4.4	$-

Range of Exercise Prices	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
$1.00 - $3.50	588,640	$ 1.15	7.3	$ -
$3.51 - $13.00	532,236	$ 9.76	4.3	-
$13.01 - $26.00	343,782	$ 14.79	3.1	-
$26.01 - $39.00	65,504	$ 30.85	2.5	-
$39.01 - $56.00	102,500	$ 45.03	4.6	-
	1,632,662	$ 10.78	5.1	$ -

The Company uses the Black-Scholes option pricing model for “plain vanilla” options and other pricing models as appropriate to calculate the fair value of options. Significant assumptions used in these models include:

	Year Ended December 31,	
	2018	2017
Annual dividend	-	-
Expected life (in years)	2.5 - 5.3	0.3 - 6.5
Risk free interest rate	2.5% - 2.8%	0.80% - 2.22%

Expected volatility	97% -113%	62.2%-98.0%

Options granted in the years ended December 31, 2018 and 2017 had weighted average grant date fair values of $0.47 and $1.34, respectively. The total fair value of the options vested during the years ended December 31, 2018 and 2017 was approximately $205,000 and $302,000, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at December 31, 2018 was approximately $179,000 to be recognized over approximately 1.9 years.

On December 12, 2018, the Company granted to its incoming Executive Chairman under the Inducement Award Stock Option Plan a stock option award to purchase 800,000 shares of common stock at a price of $0.425 per share. The award has a term of ten years and vests as follows: (i) 200,000 options vest on the employee start date, (ii) 200,000 vest over a two-year period and (iii) 400,000 vest based on the achievement of certain milestones. The Executive Chairman commenced employment on January 1, 2019 and the Company considers this to be the accounting grant date of the award. Consequently, the award is not included in any of the disclosures noted above.

RSUs

We have granted restricted stock units (RSU's) that entitle the holders to receive shares of our common stock upon vesting and subject to certain restrictions regarding the exercise of the RSU's and the holders' ability to transfer the shares received upon exercise. The fair value of RSU's granted is based upon the market price of the underlying common stock as if they were vested and issued on the date of grant.

A summary of our RSU activity for the year ended December 31, 2018 follows:

	Number of RSU's	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2018	11,235	$ 11.77
Granted	45,046	$ 1.11
Exercised and converted to common shares	-	$ -
Forfeited	-	$ -
Outstanding at December 31, 2018	56,281	$ 3.24
Exercisable at December 31, 2018	33,759	$ 4.66

The total intrinsic value of the outstanding RSU’s at December 31, 2018 was approximately $17,000. The total fair value of RSU’s vested during the years ended December 31, 2018 and 2017, was approximately $50,000 and $25,000, respectively. The total value of all RSU’s that were converted in the year ended December 31, 2017 was approximately $23,000. No RSU’s were converted in the year ended December 31, 2018.

Unrecognized compensation cost for unvested RSU’s outstanding at December 31, 2018 was approximately $25,000 to be recognized over approximately 0.5 years.

Restricted Stock

We have granted restricted stock to certain board members.

A summary of our restricted stock activity for the year ended December 31, 2018 is as follows:

Shares of Restricted Stock	Weighted-Average Grant Date Fair Value

Outstanding at January 1, 2018	49,960	$ 3.00
Granted	45,046	$ 1.11
Vested	(72,483)	$ 2.41
Forfeited	-	$ -
Outstanding at December 31, 2018	22,523	$ 1.11

The total intrinsic value of the outstanding restricted stock at December 31, 2018 was approximately $7,000. The total intrinsic value of all restricted stock vested in the year ended December 31, 2018 was approximately $84,000.

Unrecognized compensation cost for unvested restricted stock outstanding at December 31, 2018 was approximately $25,000 to be recognized over approximately 0.5 years.

Stock Purchase Warrants

We have issued warrants to purchase common stock to certain officers, directors, stockholders and service providers as well as in conjunction with debt and equity offerings and at various times replacement warrants were issued as an inducement for warrant exercises.

In May 2016 and August 2017, we issued a total of 1,746,173 and 2,250,000 common stock purchase warrants, respectively in conjunction with the offering of our securities. Such warrants are classified as liabilities due to the existence of certain net cash settlement provisions contained in the warrants. At December 31, 2018, after giving effect to exercises, 2,982,709 of these common stock purchase warrants remain outstanding and are recorded at fair value as mark-to-market liabilities (see Note 3). In conjunction with our October 2018 common stock and common stock purchase warrant offerings, the exercise price on these 2,982,709 outstanding common stock purchase warrants was adjusted pursuant to existing down-round anti-dilution features. The exercise prices decreased from $2.00 per share of common stock to $0.57 per share of common stock.

In October 2018, we issued 3,000,000 common stock purchase warrants to investors in conjunction with the registered direct offering of our common stock. We also issued an additional 180,000 common stock purchase warrants to our placement agent. (see below under “Preferred and Common Stock’). The investor and placement agent common stock purchase warrants have an exercise price of $0.75 and $0.875, respectively.

A summary of outstanding warrants at December 31, 2018 follows:

Range of Exercise Prices	Number of Warrants Outstanding	Range of Expiration Dates
$0.57 - $0.875	6,162,709	May 2021 - August 2024
$1.11 - $5.79	34,617	May 2021 - May 2023
$12.80 - $12.90	39,296	January 2022
$16.20 - $16.30	174,544	March 2020
$22.10 - $27.90	153,755	March 2019 - January 2021
$34.50 - $39.20	236,556	October 2019 - October 2021
$47.30 - $52.20	275,897	January 2019 - July 2019
	7,077,374	

Preferred and Common Stock

We have outstanding 1,000,000 shares of Series A 4.5% Convertible Preferred Stock issued in December 2016. Shares of the Series A 4.5% Convertible Preferred Stock are convertible into 3,887,387 shares of the Company’s common stock subject to certain ownership restrictions.

In October 2018, we closed a registered direct offering and concurrent private placement with institutional investors. In connection with the offering we issued an aggregate of 3,000,000 shares of common stock in the registered direct offering and 3,000,000 common stock purchase warrants in the private placement. We issued the shares in the registered offering at a price of $0.70 per share. We also issued each investor an accompanying warrant for each share purchased. We received gross proceeds of $2.1 million from this offering. The warrants have an exercise price of $0.75 per share of common stock, will be exercisable commencing with the six-month anniversary of the issuance date and will expire five and one-half years from issuance. The common stock issued in this offering was sold pursuant to our shelf registration statement that was declared effective by the SEC on June 23, 2017 (Registration No. 333-218608). In connection with the offering we also issued our placement agent 180,000 common stock purchase warrants. The placement agent warrants are substantially similar to the investor warrants except that they have an exercise price of $0.875 per share and a term of 5 years.

Note 5. Property and Equipment

The major classes of property and equipment consist of the following at December 31:

	2018	2017
Furniture and fixtures	$35,407	$35,407
Computers and office equipment	138,897	138,897
Lab equipment	818,267	820,507
	992,571	994,811
Less accumulated depreciation	(902,260)	(821,925)
Property and equipment, net	$90,311	$172,886

The above includes approximately $71,000 of equipment located at our research facility in China. Property and equipment are recorded at cost and are depreciated using the straight-line method over the estimated useful lives of the respective assets. Depreciation expense for the years ended December 31, 2018 and 2017, was approximately $84,000 and $100,000, respectively

Note 6. Patents

The Company holds patents related to its stem cell and small molecule technologies. Patent costs are capitalized and are being amortized over the life of the patents. The weighted average remaining unamortized life of issued patents was approximately 9.3 years at December 31, 2018. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell. During the years ended December 31, 2018 and 2017, no significant impairment losses were recognized. The Company's intangible assets and accumulated amortization consisted of the following at December 31, 2018 and 2017:

	2018	2017
Patent asset	$2,006,443	$2,028,557
Accumulated amortization	(1,242,900)	(1,145,095)
Net intangibles	$763,543	$883,462

Amortization expense for the years ended December 31, 2018 and 2017 was approximately $102,000 and $189,000, respectively. The expected average future annual amortization expense over the next five years is approximately $80,000 based on current balances of our intangible assets.

Note 7. Income Taxes

Our provision for income taxes for the years ended December 31, 2018 and 2017 consists of the following:

	2018	2017
Current provision:		
Federal	$-	$-
State	-	-
Foreign	-	-
Total current provision	-	-
Deferred provision (benefit):		
Federal	7,726	17,837,120
State	(2,749,386)	1,417,482
Foreign	-	-
Total deferred provision (benefit)	(2,741,660)	19,254,602
Valuation allowance	2,741,660	(19,254,602)
Consolidated income tax provision	$-	$-

We provide a full valuation allowance on our net deferred tax assets because management has determined that it is more likely than not that we will not earn income sufficient to realize the deferred tax assets during the asset reversal periods.

The difference between income taxes computed by applying the statutory federal income tax rate to consolidated losses before income taxes and the consolidated provision for income taxes is attributable to the following:

	2018	2017
Federal statutory rate	(21.0%)	(34.0 %)
State income taxes, net of Federal benefits	(5.0 %)	(4.1 %)
Rate changes	(66.3%)	155.0 %
Change in fair value of liability classified warrants	(17.3%)	(3.6 %)
Other, including non-deductible expenses	53.9 %	9.6 %
Valuation allowance	55.7 %	(122.9%)
Total	0.0 %	0.0 %

The tax effects of significant temporary differences representing deferred tax assets as of December 31, 2018 and 2017 are:

	2018	2017
Net operating loss carryforwards	$42,580,533	$35,610,806
Stock based compensation expense	2,643,471	6,764,508
Tax credit carryforwards and other	1,005,255	1,112,286
Gross deferred tax assets	46,229,259	43,487,600
Valuation allowance	(46,229,259)	(43,487,600)
Net deferred tax assets	$-	$-

The Company had Federal net operating loss ("NOL") carryforwards of approximately $156.0 million and $146.4 million at December 31, 2018 and 2017, respectively, which began expiring in 2018. The Company also has certain Federal tax credit carryforwards that will expire through 2036. The timing and manner in which these net operating loss carryforwards and credits may be used in any year will be limited to the Company's ability to generate future earnings and also may be limited by certain provisions in the U.S. tax code. The Company has not identified any uncertain tax positions and did not recognize any adjustments for unrecognized tax benefits. The Company remains subject to examination for income tax returns dating back to 2015.

Impact of the Tax Cuts and Jobs Act of 2017

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act of 2017 (the "Tax Act") which included significant changes to the existing income tax laws for domestic corporations. Key features of the Tax Act effective in 2018 include:

- Reduction of the corporate tax rate from 35% to 21%
- Elimination of the alternative minimum tax
- Changes in the deductibility of certain aspects of executive compensation
- Changes in the deductibility of certain entertainment and recreation expenses
- Changes in incentive tax breaks for U.S production activities.

Because of the Company's existing Federal net operating loss carryforwards and current expectations as to the recovery of its net deferred tax assets, the Company believes that the Tax Act will not have a significant impact on its financial results and financial position, including on its liquidity, for the foreseeable future.

Note 8. Commitments and Contingencies

We currently operate one facility located in the United States and one facility located in China. Our corporate offices and primary research facilities are located in Germantown, Maryland, where we lease approximately 1,500 square feet. This lease provides for monthly payments of approximately $5,700 per month. Our prior lease expired on December 31, 2018. We are currently operating on a month-to-month lease as we negotiate an extension.

In 2015, we entered into a lease consisting of approximately 3,100 square feet of research space in San Diego, California. This lease provides for current monthly payments of approximately $12,000 and expires on August 31, 2019. In May 2017, we ceased-use of this property and recognized a loss of approximately $92,000 representing the present value of the expected remaining net payments due under such lease and the costs to vacate the property. In April 2018, we entered into an agreement for the sub-lease of the property and recognized an additional loss of approximately $50,000 reflecting the present value of the revised expected remaining net payments due. Total minimum rentals to be received under the sub-lease are $87,000 at December 31, 2018.

We also lease a research facility in People’s Republic of China. This lease expires on March 31, 2019 with lease payments of approximately $3,800 per month.

Future minimum payments under all leases at December 31, 2018 are as follows:

Year	Amount
2019	115,000
2020	-
2021	-
2022	-
2023 and thereafter	-
Total minimum payments	$115,000

The Company recognized approximately $164,000 and $161,000, in rent expense for the years ended December 31, 2018 and 2017, respectively.

From time to time, we are parties to legal proceedings that we believe to be ordinary, routine litigation incidental to the business. We are currently not a party to any litigation or legal proceeding.

The Company is currently obligated under a written employment agreement with our Chief Scientific Officer (“CSO”). Pursuant to the terms of the agreement, our CSO receives annual salary of $500,000. The agreement also provides for the payment of severance in the event the CSO is terminated in certain circumstances and also provide for the acceleration of vesting with regard to outstanding equity awards.

Note 9. Related Party Receivable

On August 10, 2016, we entered into a reimbursement agreement with a former executive officer. Pursuant to the reimbursement agreement, the former officer agreed to repay the Company, over a six-year period, approximately $658,000 in expenses that the Company determined to have been improperly paid under the Company's prior expense reimbursement policies. In addition to this reimbursement agreement, the Company has implemented and is continuing to implement enhanced policies and procedures for travel expense reimbursements and disbursements.

The $658,000 non-interest-bearing receivable was recorded net of a $199,000 discount to reflect the net present value of the future cash payments. The discount is being amortized through interest income using the effective interest method. The principal amount of $458,000 remains outstanding at December 31, 2018 and is payable in $100,000 annual installments with a final payment due July 2022.

In March 2019, in conjunction with the employee’s termination, we entered into a consulting agreement and release of claims agreement with the employee. As partial consideration for the release, we modified the reimbursement agreement to change the payment terms, extend the maturity and forgive a portion of the receivable.

Note 10. Subsequent Events

None

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

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on an evaluation under the supervision and with the participation of the Company’s management, the Company’s principal executive officer, who is also the principal financial officer, concluded that the Company’s disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) were effective as of December 31, 2018 to provide reasonable assurance that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and (ii) 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.

Inherent Limitations Over Internal Controls

The Company’s internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). The Company’s internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company’s assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Management, including the Company's principal executive officer, who is also the principal financial officer, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the criteria set forth in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the Company's assessment, management has concluded that its internal control over financial reporting was effective as of December 31, 2018 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the fourth quarter of 2018, which were identified in connection with management's evaluation required by paragraph (d) of rules 13a-15 and 15d-15 under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Effective January 1, 2019, we appointed Dr. Kenneth Carter as our Executive Chairman. In such role, Dr. Carter will be our Principal Executive and Financial Officer.

ITEM 9B. OTHER INFORMATION

None

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is set forth under the heading "Directors, Executive Officers and Corporate Governance" in our 2019 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for our 2019 Annual Meeting of Shareholders ("2019 Proxy Statement") and is incorporated herein by reference. Such Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates. The information required by this item regarding delinquent filers pursuant to Item 405 of Regulation S-K will be included under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in the 2019 Proxy Statement and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is set forth under the headings "Director Compensation" and "Executive Compensation" of our 2019 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item is set forth under the headings "Beneficial Owners of Shares of Common Stock" and "Equity Compensation Plan Information" of our 2019 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item is set forth under the heading "Certain Relationships and Related Transactions" of our 2019 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is set forth under the heading “Independent Registered Public Accounting Firm” of our 2019 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements:

2. Exhibits:

			Incorporated by Reference			
Exhibit No.	**Description**	**Filed/ Furnished Herewith**	**Form**	**Exhibit No.**	**File No.**	**Filing Date**
3.01(i)	Amended and Restated Certificate of Incorporation of Neuralstem, Inc. filed on 1/5/2017		8-K	3.01(i)	001-33672	1/6/17
3.02(i)	Certificate of Designation of Series A 4.5% Convertible Preferred Stock		8-K	3.01	001-33672	12/12/16
3.03(ii)	Amended and Restated Bylaws of Neuralstem, Inc. adopted on 11/10/2015		8-K	3.01	001-33672	11/16/15
4.01**	Amended and Restated 2005 Stock Plan adopted on 6/28/07		10-QSB	4.2(i)	333-132923	8/14/07
4.02**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Richard Garr dated 7/28/05		SB-2/A	4.4	333-132923	6/21/06
4.03**	Non-qualified Stock Option Agreement between Neuralstem, Inc. and Karl Johe dated 7/28/05		SB-2/A	4.5	333-132923	6/21/06
4.04**	Neuralstem, Inc. 2007 Stock Plan		10-QSB	4.21	333-132923	8/14/07

4.05	Form of Common Stock Purchase Warrant Issued to Karl Johe on 6/5/07	10-KSB	4.22	333-132923	3/27/08
4.06	Form of Placement Agent Warrant Issued to Midtown Partners & Company on 12/18/08	8-K	4.1	001-33672	12/18/08

4.07	Form of Consultant Common Stock Purchase Warrant issued on 1/5/09	S-3/A	10.1	333-157079	02/3/09
4.08	Form of Series D, E and F Warrants	8-K	4.01	001-33672	7/1/09
4.09	Form of Placement Agent Warrant	8-K	4.02	001-33672	7/1/09
4.10	Form of Consultant Warrant Issued 1/8/10	10-K	4.20	001-33672	3/31/10
4.11	Form of Replacement Warrant Issued 1/29/10	10-K	4.21	001-33672	3/31/10
4.12	Form of Series C Replacement Warrant Issued March of 2010 and May, June and July of 2013 (Original Ex. Price $2.13 and $1.25)	10-K	4.22	001-33672	3/31/10
4.13	Form of employee and consultant option grant pursuant to our 2007 Stock Plan and 2010 Equity Compensation Plan	10-K	4.23	001-33672	3/31/10
4.14	Form of Warrants dated 6/29/10	8-K	4.01	001-33672	6/29/10
4.15**	Amended Neuralstem 2010 Equity Compensation Plan adopted on June 22, 2017	DEF 14A	Appendix I	001-33672	5/1/17
4.16	Form of Consultant Warrant issued 10/1/09 and 10/1/10	S-3	4.07	333-169847	10/8/10
4.17**	Form of Restricted Stock Award Agreement pursuant to our 2007 Stock Plan and 2010 Equity Compensation Plan	S-8	4.06	333-172563	3/1/11
4.18**	Form of Restricted Stock Unit Agreement	S-8	4.08	333-172563	3/1/11
4.19	Form of Common Stock Purchase Warrant issued pursuant to February 2012 registered offering	8-K	4.01	001-33672	2/8/12

4.20	Form of Common Stock Purchase Warrant issued to Consultants in June of 2012 and March 19, 2013		10-Q	4.20	001-33672	8/9/12
4.21	Form of Underwriter Warrant issued to Aegis Capital Corp. on 8/20/12		8-K	4.1	001-33672	8/17/12
4.22	Form of Placement Agent Warrant issued to Aegis Capital Corp. on 9/13/12		8-K	4.1	001-33672	9/19/12
4.23	Form of Consulting Warrant issued January 2011 and March 2012		S-3	4.01	333-188859	5/24/13
	Form of Replacement Warrant issued January, February and May of 2013 (Original Ex. Prices $3.17 and $2.14)					
4.24	Form of Lender Warrant issued March 22, 2013		8-K	4.01	001-33672	3/27/13
4.25	Form of Advisor Warrant issued March 22, 2013		8-K	4.02	001-33672	3/27/13
4.26	Form of Warrant issued June of 2013 and July of 2014 to Legal Counsel		10-Q	4.26	001-33672	8/8/13
4.27	Form of Warrant issued in September 2013 in connection with Issuer's registered direct offering		8-K	4.01	011-33672	9/10/13
4.28	Form of Warrant issued to strategic advisor in August 2013		10-Q	4.28	001-33672	11/12/13
4.29	Form of Investor Warrant issued January 2014		8-K	4.01	001-33672	1/6/14
4.30	Form of Lender Warrant Issued October 28, 2014		8-K	4.01	001-33672	10/29/14
4.31**	Inducement Stock Option Plan adopted 2/15/2016 and as amended on 12/12/2018	*	8-K	4.01	001-33672	2/19/16
4.32**	Form of Inducement Award Non-Qualified Stock Option Grant pursuant to Inducement Stock Option Plan		8-K	4.02	001-33672	2/19/16
4.33	Form of Common Stock Purchase Warrant From May 2016 Public Offering dated May 6, 2016		8-K	4.01	001-33672	5/4/16

4.34	Form of Common Stock Purchase Warrant from May 2016 Private Offering Dated May 12, 2016	8-K	4.01	001-33672	5/13/16
4.35	Form of Series A Preferred Stock Certificate	8-K	4.01	001-33672	9/12/16
4.36	Form of Inducement Warrant issued March 20, 2017 and March 31, 2017	8-K	4.01	001-33672	3/20/17
4.37	Form of Common Stock Purchase Warrant from August 2017 Public Offering Dated August 1, 2017	8-K	4.01	001-33672	7/28/17
4.38	Form of Common Stock Purchase Warrant from October 2018 Offering	8-K	4.01	001-33672	10/29/18
4.39	Form of Placement Agent Common Stock Purchase Warrant from October 2018 Offering	8-K	4.02	001-33672	10/29/18
10.01**	Employment Agreement with Thomas Hazel, Ph.D dated August 11, 2008	10-K/A	10.05	001-33672	10/5/10
10.02**	Employment Agreement with Richard Daly dated February 15, 2016	8-K	10.01	001-33672	2/19/16
10.03**	Employment Agreement with Kenneth Carter dated December 12, 2018	8-K	10.01	001-33672	12/18/18
10.04	Consulting Agreement dated January 2010 between Market Development Consulting Group and the Company and amendments No. 1 and 2.	10-K	10.07	001-33672	3/16/11
10.05**	Renewal of Dr. Tom Hazel Employment Agreement dated 7/25/12	8-K	10.03	001-33672	7/27/12
10.06	Loan and Security Agreement dated March 2013	8-K	10.01	001-33672	3/27/13
10.07	Intellectual Property and Security Agreement dated March 2013	8-K	10.02	001-33672	3/27/13
10.08	At the Market Offering Agreement entered into on October 25, 2013	8-K	10.01	001-33672	10/25/13
10.09	Form of Second Amendment to Loan and Security Agreement dated March of 2013 that was entered into on October 28, 2014	8-K	10.01	001-33672	10/29/14

10.10**	Offer Letter Between Neuralstem, Inc. and Jonathan Lloyd Jones	8-K	10.01	001-33672	5/11/15
10.11**	General Release and Waiver of Claims with I. Richard Garr dated 3/2/2016	8-K	10.01	001-33672	3/4/16
10.12	Form of Securities Purchase Agreement from May 2016 Private Offering	8-K	10.01	001-33672	5/13/16
10.13**	Amendment to General Release and Waiver of claims with I. Richard Garr dated 6/6/16	8-K	10.01	001-33672	6/16/16
10.14	Form of Securities Purchase Agreement between Issuer and Tianjin Pharmaceuticals Holdings, Ltd.	8-K	10.01	001-33672	9/12/16
10.15**	Form of Securities Purchase Agreement between Issuer and Jonathan Lloyd Jones	10-Q	10.22	001-33672	11/8/16
10.16	Form of Securities Purchase Agreement between Issuer and Richard Daly	10-Q	10.23	001-33672	11/8/16
10.17	Form of Letter Agreement for Warrant Exercises on March 20, 2017 and March 30, 2017	8-K	10.01	001-33672	3/20/17
10.18**	Form of Separation Agreement and Release with Jonathan Lloyd Jones dated April 30, 2017	8-K	10.01	001-33672	5/4/17
10.19	Form of Securities Purchase Agreement with Investors from October 2018 Offering	8-K	10.01	001-33672	10/29/18
10.20	Form of Engagement Agreement with H.C. Wainwright & Co. Dated October 25, 2018	8-K	10.02	001-33672	10/29/18
10.21**	Sample Confidential Information and Invention Assignment Agreement	8-K	10.02	001-33672	12/12/18
10.22**	Form of Indemnification Agreement for Directors and Officers	8-K	10.03	001-33672	12/12/18
14.01	Neuralstem Code of Ethics and Conduct	10-K	14.01	001-33672	4/2/2018
14.02	Neuralstem Financial Code of Professional Conduct adopted May 16, 2007	8-K	14.2	333-132923	6/6/07

21.02	Subsidiaries of Registrant		10-K	21.01	001-33672 3/10/14
23.01	Consent of Dixon, Hughes, Goodman LLP	*			
31.1	Certification of the Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	*			
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. § 1350	*			
101.INS	XBRL Instance Document	*			
101.SCH	XBRL Taxonomy Extension Schema	*			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	*			
101.DEF	XBRL Taxonomy Extension Definition Linkbase	*			
101.LAB	XBRL Taxonomy Extension Label Linkbase	*			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	*			

** Filed herein*

*** Management contracts or compensation plans or arrangements in which directors or executive officers are eligible to participate.*

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NEURALSTEM, INC

Dated: March 22, 2019 By: /S/Kenneth Carter
Kenneth Carter, PhD

Executive Chairman

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 following capacities and on the dates indicated.

Name	Title	Date
/s/ Kenneth Carter Kenneth Carter	Executive Chairman (Principal Executive Officer and Financial Officer)	March 22, 2019
/s/ William Oldaker William Oldaker	Director	March 22, 2019
/s/ Binxian Wei Binxian Wei	Director	March 22, 2019
/s/ Cristina Csimma Cristina Csimma	Director	March 22, 2019

/s/ Scott V. Ogilvie Scott V. Ogilvie	Director	March 22, 2019
/s/ Sandford D. Smith Sandford D. Smith	Director	March 22, 2019
/s/ Stanley Westreich Stanley Westreich	Director	March 22, 2019