Neuralstem, Inc.
Form 10-K
March 23, 2017

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, 2016.
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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	(Do not check if a smaller reporting company)	Smaller reporting company

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 $30,672,818.

The number of shares outstanding of Registrant’s common stock, $0.01 par value at February 28, 2017 was 11,045,480 .

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement relating to its 2017 annual meeting of shareholders (the “2017 Proxy Statement”) are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2017 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, 2016

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PART IV

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. On January 6, 2017, we completed a one-for-thirteen reverse stock split of our common stock. All share and per share information in this report has been adjusted to reflect the reverse stock split.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this annual report that are not strictly historical are forward-looking statements and include statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 such as statements about products in development, results and analyses of pre-clinical studies, clinical trials and studies, research and development expenses, 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 in the forward-looking statements These Forward-looking statements by their nature address matters that are, to different degrees, 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 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, 2016), unless another date is specified.

ITEM 1. BUSINESS

Overview

We are focused on the research and development of nervous system therapies based on our proprietary human neuronal stem cells and our small molecule compounds with the ultimate 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 technology base has produced three primary assets: our NSI-189 small molecule program, our NSI-566 stem cell therapy program and our novel and proprietary new chemical entity screening platform.

Our patented technologies enable the commercial-scale production of multiple types of central nervous system stem cells, which are under development for the potential treatment of central nervous system diseases and conditions. In addition, this ability to generate human neural stem cell lines provides a platform for chemical screening and discovery of novel compounds that we believe may be used to stimulate the brain's capacity to regenerate neurons, thereby potentially treating or reversing pathologies associated with certain nervous system conditions. This proprietary screening platform enabled our discovery of NSI-189.

We have developed and maintain what we believe is a strong portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license over 20 U.S. issued and pending patents and over 120 foreign issued and pending patents in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds.

We believe our technology base, 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.

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, current stage of development and our expected future development plans:

In January 2016 we announced a strategic refocusing to concentrate our resources primarily on our NSI-189 small molecule program. As part of this refocusing, we announced that we will seek external funding to defray all, or substantially all, of the costs associated with our NSI-566 stem cell therapy program. Although we are in active conversations with a number of funding sources to achieve this goal and minimize any delay in progressing our stem cell therapy programs, there can be no assurance that any such funding source will ultimately be secured.

NSI - 189 (Small Molecule Pharmaceutical Compound).

Our lead asset, NSI-189, is a novel new chemical entity. NSI-189 is currently in an ongoing Phase 2 clinical trial for the treatment of major depressive disorder (MDD).

Research indicates that there may be a link between impaired hippocampal neurogenesis and psychiatric disorders such as depression. We believe that NSI-189 may provide an effective treatment for patients suffering from MDD by promoting synaptogenesis or neurogenesis in the hippocampus. Results to date indicate that NSI-189 promotes neurogenesis in rodents and exerts anti-depression effects in MDD patients[1]. NSI-189 stimulates neurogenesis of human hippocampus derived neural stem cells in vitro and stimulates neurogenesis in mouse hippocampus in vivo therefore we believe NSI-189 may be a powerful anti-depressant. NSI-189 is believed to have a highly specific effect in the hippocampus, a well-known neurogenic region in adult CNS.

In a Phase 1B study in subjects with MDD, NSI-189 showed strong potential for efficacy on both depression and cognition scales. Additionally, data from the study indicated that the compound appears to impart a durable effect. While the mechanism of action is not yet fully understood, our data suggest that NSI-189 works by a different mechanism of action than current therapies. Accordingly, we believe that NSI-189 may have a better therapeutic response as well as a favorable side-effect profile when compared to currently marketed products.

We are currently conducting a Phase 2 randomized, placebo-controlled, double-blind clinical trial for the treatment of MDD in an outpatient setting. The study is designed to randomize 220 subjects in three cohorts (two active doses plus placebo), at 12 select trial sites. The trial design incorporates strategies to limit placebo effect. These include using experienced trial sites, a placebo-reducing pre-screen process, and a second confirmatory diagnostic interview performed remotely by the Massachusetts General Hospital (MGH).

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[1] Fava M, et al. Molecular Psychiatry , 8 Dec 2015; doi: 10.1038/mp.2015.178

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Study subjects are randomized to 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 is 12 weeks in duration. There is a two week wash out period for those subject enrolled that were taking an anti-depressant at the time of screening. The primary endpoint is measurement on the Montgomery-Asberg Depression Rating Scale (MADRS). Secondary endpoints include scores on the Hamilton Depression Rating Scale (HAM-D), Symptoms of Depression Questionnaire (SDQ), the MGH Cognitive and Physical Functioning Questionnaire (CPFQ), the Clinical Global Impression-Severity (CGI-S) scale, the Clinical Global Impression of Improvement (CGI-I) scale, and two computerized cognition measurements; Cogstate Brief Battery, and CogScreen. The study is 80% powered to show an improvement in the primary endpoint, compared to placebo, with an effect size of Cohen's d=0.5 ($p \leq 0.05$). Subjects eligible for the study must be diagnosed with major depressive disorder, recurrent, as per Diagnostic and Statistical Manual of Mental Disorders V[2], (DSM-V), scoring 20 or greater on the MADRS, at screening and baseline and experiencing at least one eight-week MDD episode. The MADRS score will be 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 are 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 are being 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.

We enrolled the first subject in May 2016. In September, 2016 we announced that we had achieved 50% enrollment. In February, 2017 we announced that we had completed enrollment in the study. We expect to release the results of this study during the third quarter of 2017.

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. 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[3]. Treatment of MDD is characterized by a high rate 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[4]. These factors combine to create a significant opportunity for a differentiated therapeutic agent, particularly one that may act through a novel mechanism of action.

Early Clinical Experience with NSI-189

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. The first part of the study enrolled thirty-one healthy male and female subjects into a single ascending dose phase. Subjects were administered a single dose (40mg, 60mg, or 80mg) of NSI-189 or placebo. In the second part of the study, 10 subjects received single doses of 40mg oral NSI-189 under fed and fasting conditions in an open label cross-over design. All subjects completed the study. There were no clear gender effects on NSI-189 pharmacokinetics. No dose-limiting toxicity was observed, 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 phosphate in subjects[5] with MDD. The primary outcome measure was to assess drug safety by number and severity of adverse events in drug versus the placebo group. A safety protocol also included a comparison between NSI-189 and placebo of vital signs, standard physical examination, ECG, EEG, standard clinical laboratory tests (hematology and biochemistry), standard neurological exam and the Columbia Suicide Severity Rating Scale. Secondary measurements included pharmacokinetics, and exploratory assessments included clinical scales such as the MADRS, CGI-I, SDQ, and the MGH CPFQ.

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

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

[4] 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

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

Criteria for subjects to be eligible to participate in the study included: a MADRS score of 15 to 30, inclusive, at screening and baseline; and diagnosed with MDD, or recurrent MDD, per DSM-IV-TR criteria and reconfirmed by SCID-CT. Subjects must have had at least two prior depressive episodes and have been currently or had historically been treated with antidepressants. The first cohort received 40 mg QD, the second cohort 40 mg BID, and the third cohort 40 mg three times per day (TID). 24 subjects with MDD were studied, with their diagnosis and illness severity confirmed through an independent, remote SAFER interview from Massachusetts General Hospital Clinical Trial Network, Inc. (MGH CTNI) raters. Each cohort included at least 3 female subjects. Each subject underwent a screening for eligibility (Day -37 to Day -6 or -3) and eligible subjects were admitted into the unit on Day -5 to complete their wash-out before being confirmed for eligibility and for baseline assessments. Eligible subjects received daily dosing of investigational medicinal product (NSI-189 Phosphate or placebo) for 28 days starting on Day 1 and were followed for safety, PK, and PD until discharge. Subjects returned to the unit for extensive follow-up on Day 56 (± 3) and Day 84 (± 3) (End-of-study).

Trial data was 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). NSI-189 was well tolerated and there were no serious (grade 4 or 5) adverse events.

At the end of dosing, efficacy measurements showed statistically significant improvement over placebo on one subject-reported depression scale (SDQ) and one subject-reported cognition scale (CPFQ) and showed a medium to large size effect on all scales studied[6].

Efficacy measurements (MADRS, SDQ, CGI-I and, CPFQ), showed a promising reduction in depressive and cognitive symptoms across all measures with statistically significant improvement in the SDQ and CPFQ scales, and a medium to large effect size for all measures at the cessation of dosing (day 28). These improvements persisted to day 84, 8 weeks after cessation of drug administration. In particular, depression symptoms showed a significant decrease at day 28 as measured by SDQ (P=0.02), with large effect size (Cohen's d = 0.90), which persisted to day 84, 8 weeks after cessation of drug administration (P=0.03), also with large effect size (Cohen's d = 1.10). In addition, CPFQ also showed a significant decrease at day 28 (P= 0.01) with large effect size (Cohen's d = 0.94) and at day 84, (P<0.01, Cohen's d = 1.20).

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[6] Size effect, as measured by Cohen’s d” or “d” is a validated statistical measure of the separation between treatment group(s) and control. Differences of 0.2 are considered ‘small’, 0.5 are considered ‘moderate’ and 0.8 are considered ‘large’.

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In summary, NSI-189, a novel neurogenic compound, has shown promise as a potential treatment for MDD in this Phase 1B, double-blind, randomized, placebo-controlled, multiple-dose study. It is our belief that NSI-189 may have a significant benefit on depressive and cognitive symptoms in patients with MDD and other related disorders.

Pre-Clinical Experience with NSI-189

Our preclinical research on NSI-189 is focused on elucidating its mechanism of action and investigating its potential utility as a broad neuroregenerative drug that can prevent or reverse various types of central and peripheral nerve degeneration and may have a significant cognitive benefit in diseases that impact memory and cognition. Recent preclinical data support the potential benefits of NSI-189 in indications beyond MDD.

Supportive data include the following results obtained in collaboration with academic partners:

1. NSI-189 and cognition:

- Treatment of normal mouse brain slices with NSI-189 produced a concentration and time dependent increase in the magnitude of long-term potentiation (LTP) and short-term potentiation (STP), a measure of synaptic plasticity which is an in vitro biomarker of memory[7].
- NSI-189 treatment of brain slices from mice with a genetic defect that models Angelman Syndrome (which in humans leads to inherited mental retardation) restored LTP to normal levels[7].
- NSI-189 treatment preserved brain function and hippocampal proliferation at normal levels in a rat model of cognitive impairment induced by irradiation[8].

2. NSI-189 and neuroregeneration[9]:

- NSI-189 proved to be effective in the prevention and reversal of peripheral neuropathies in a mouse model of Type 1 diabetes and in the prevention of peripheral neuropathies in a mouse of Type 2 diabetes. Data from these studies, which includes reversal of neuropathic pain and decreased nerve conductance associated with the onset of diabetic symptoms, suggest that NSI-189 may have broad applicability in the treatment of central and peripheral neuropathies arising from diverse etiologies.

3. NSI-189 and neurogenesis[10].

- Oral administration of NSI-189 to rats with ischemic stroke led to a significant recovery from motor deficit. The improvements were maintained post cessation of dosing for the additional 12 week observational period. The sustained improvement suggests that NSI-189 initiated a host brain repair mechanism enabling tissue remodeling of the stroke brain. In cultured rat hippocampal cells, NSI-189 led to the upregulation of growth factors such as Stem Cell Factor (SCF) and Brain Derived Neurotrophic Factor (BDNF), as well as increasing neurite outgrowth.

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[7] Liu Y, Hefferan MP, Johe K, Bi X, Baudry M. NSI-189, a Neurogenic Compound, Enhances Short-term and Long-term Potentiation in C57BL/6 Mice and Reverses LTP Impairment in a Mouse Model of Angelman Syndrome. 2016 Annual Meeting of the Society for Neuroscience.

[8] Allen BD, Acharya MM, Lu CL, Giedzinski E, Parihar VK, Hefferan M, Johe KK, Limoli CL. Reversal of Radiation-Induced Cognitive Impairment by Oral Administration of Neurogenic Small Molecule Compound NSI-189. 2016 Annual Meeting of the Radiation Research Society.

[9] Johe K, Marquez A, Anaya C, Kifle B, Muttalib N, Jolivalt CG, Hefferan M, Calcutt NA. Therapeutic Efficacy of NSI-189 in Diabetic Mice. 2016 Annual Meeting of the Diabetic Neuropathy Study Group of the EASD (European Association for the Study of Diabetes)

[10] Tajiri N, et al. NSI-189, a Small Molecule with Neurogenic Properties, Exerts Behavioral and Neurostructural Benefits in Stroke Rats" *Journal of Cellular Physiology* 232 (2017): accessed February 13, 2017, DOI: 10.1002/jcp.25847

We believe that these data support our view that NSI-189 may be effective in the treatment of a broad range of cognitive and neuroregenerative applications.

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 was discovered 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 impact biologically relevant outcomes such as neurogenesis, synapse formation, and protection against toxic insults. We have developed over 300 unique stem cell lines representing multiple different regions of the developing brain and spinal cord at multiple 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.

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 focus of our cell therapy initiatives is the regeneration of neural function which has been lost to disease or injury. We believe that replacing or supplementing damaged or dead neural cells with fully functional ones may be a useful therapeutic strategy in treating many diseases and conditions of the central nervous system.

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 manufacture and use of the surgical platform and cannula that enable administration of the cells to the spinal cord for treatment utilizing our stem cells. 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 replace the function of cells lost to disease or injury.

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. To date we have completed Phase 1 and Phase 2 safety and dose escalation studies in subjects with ALS, a Phase1 safety and dose escalation study in subjects with motor deficits due to ischemic stroke, and a Phase 1 safety study in subjects with chronic spinal cord injury or cSCI. Each of these studies are currently evaluating patients in a long-term follow-up stage.

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[11]. 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 patients' 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. Annually, approximately 15 million people worldwide suffer stroke[12], of which it is estimated that 87% are ischemic strokes[13]. Post-stroke motor deficits include paralysis in arms and legs 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[14] new cases of SCI per year and that at any given time, there are between 243,000 and 347,000 people in the United States that are living with SCI[14]. Chronic spinal cord injury refers to the time after the initial hospitalization. SCIs are most often traumatic, caused by lateral bending, dislocation, rotation, axial loading, and hyperflexion or hyperextension of the cord or cauda equina. Motor vehicle accidents are the most common cause of SCIs, while other causes include falls, work-related accidents, sports injuries, and penetrating injuries such as stab or gunshot wounds. In certain instances, SCIs can also be of a non-traumatic origin, as in the case of cancer, infection, intervertebral disc disease, vertebral injury and spinal cord vascular disease. We believe that NSI-566 may provide an effective treatment for chronic spinal cord injury by "bridging the gap" in the spinal cord circuitry created in 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 six months after the last surgery concluded in January 2015. The Phase 2 ALS clinical trial met the primary safety endpoints and established what we believe to be the maximum safe tolerated dose of 16 million cells delivered in 40 injections over two surgeries. In September 2015, nine-month Phase 2 and combined Phase 1 and Phase 2 data from our ALS trials were presented at the American Neurological Association Meeting by principal investigator Eva Feldman, MD, PhD, Director of the A. Alfred Taubman Medical Research Institute 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

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[11] https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Amyotrophic-Lateral-Sclerosis-ALS-Fact-Shee Accessed February 17, 2017

[12] http://www.world-heart-federation.org/cardiovascular-health/stroke/. Accessed February 13, 2017

[13] https://www.cdc.gov/stroke/facts.htm. Accessed February 13, 2017

[14] Spinal Cord Injury Facts and Figures at a Glance," National Spinal Cord Injury Statistical Center, accessed March 6, 2017. https://www.nscisc.uab.edu

Ischemic Stroke

During the fourth Quarter of 2013 we commenced a human clinical trial for treatment of motor deficits due to ischemic stroke. The trial is being conducted at BaYi Brain Hospital in Beijing, China utilizing our spinal cord stem cells. This Phase 1 multiple dose escalation study is intended to evaluate safety of direct injections of NSI-566 into the brain. The Phase 1 portion of the trial was designed to confirm the maximum safe tolerated dose.

In March, 2016, we completed dosing the final planned cohort, for a total of nine subjects. Subjects are currently being monitored through their 24 month observational follow-up period. The trial is being conducted by Suzhou Neuralstem, a wholly owned subsidiary of Neuralstem in China.

To date, the Ischemic Stroke program has been funded substantially by Neuralstem.

Chronic Spinal Cord Injury

During the first quarter of 2013, we received authorization from the FDA to commence our proposed 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 during the third quarter of 2014 and the first subject was treated in October 2014. The study enrolled four AISA A^{15} 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. A self-reported ability to contract some muscles below the level of injury in one of the four subjects treated was confirmed via clinical and electrophysiological follow-up examinations. All subjects will be followed for five years.

FDA has approved the protocol amendment to treat an additional cohort of four cervical spinal cord injury patients.

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 a solid 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.

In addition to NSI-566 we have developed an inventory of over 300 unique stem cell lines. These stem cell lines include cortex, hippocampus, midbrain, hindbrain, cerebellum, and spinal cord. We believe these lines possess unique properties and represent candidates for both transplantation-based strategies to treat disease and for screening of compound libraries to discover novel drug therapies.

- NSI-566: 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.

- HK532-IGF-1: Alzheimer's disease (AD).

Neuralstem's HK532-IGF-1 is a proprietary line of cortical neural stem cells engineered to 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 HK-532.IGF1 to reverse the cognitive impact of neurodegeneration in a mouse model of AD (McGinley et al., 2016). Animals with HK532-IGF-1 transplanted in the peri-hippocampus, performed better on hippocampal-dependent behavioral tasks than untreated mice, demonstrating both enhanced learning cognitive processes and memory consolidation.

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[15] "ASIA"; American Spinal Injury Association. A = Complete: No sensory or motor function is preserved in sacral segments S4-S5

- NSI-777: 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 recently shown[16] 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.

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 new cells to replace 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 the development of effective methods to generate replacement cells from neural stem cells. We believe that replacing damaged, malfunctioning or dead neural cells with fully functional ones may be a useful therapeutic strategy in treating many diseases and conditions of the central nervous system.

Small Molecule Pharmaceutical Compounds.

Utilizing our proprietary stem cell derived screening capability, we have discovered and patented a series of small molecule compounds. We believe our low molecular weight compounds can efficiently cross the blood/brain barrier. In mice, research indicated that these compounds both stimulate neurogenesis of the hippocampus and increase its volume. We believe these 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 and consulting companies under our direct supervision, and through collaboration with academic institutes.

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 what we believe is a strong portfolio of patents and patent applications that form the basis for our research and development efforts. We own or exclusively license over 10 U.S. issued and pending patents and over 60 foreign issued and pending patents related to our stem cell technologies for use in treating disease and injury. We own over 10 U.S. issued and pending patents and over 60 foreign issued and pending patents related to our small molecule compounds. Our issued patents have expiration dates ranging from 2017 through 2034. Two of our original patents covering methods and composition of matter associated with our stem cell technologies expired in 2016. In our opinion the expiration of these patents is not material to our intellectual property.

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.

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[16] Hefferan M, Schwartz K, Hazel T, Johe K, Levy M. Remyelinating Human Oligodendrocyte Progenitors for Regenerative Treatment of Demyelinating Diseases and Spinal Cord Injury. 2016 Annual Meeting of the Society for Neuroscience.

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In addition to patenting our technologies, we also rely upon trade-secret protection for our 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.

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 neuronal 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 Good Laboratory Practices (GLPs), 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 (IND) application, which must become effective before clinical testing in humans can begin;
- Performance of adequate and well-controlled human clinical trials according to cGMPs 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 IV 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 risks 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 January 31, 2017, we had eleven (11) full-time employees. Of these full-time employees, seven (7) work on research and development and clinical operations and four (4) work in administration. 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 and Capital Structure

We have a history of losses.

Since inception in 1996 and through December 31, 2016, we have accumulated losses totaling approximately $193,033,000. On December 31, 2016, we had a working capital surplus of approximately $13,571,000 and stockholders' equity of approximately $11,331,000. Our net losses for the three most recent fiscal years have been

approximately $21,075,000, $20,904,000 and $22,629,000 for 2016, 2015 and 2014, 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, 2016, we had cash, cash equivalents and short-term investments on hand of approximately $20.2 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 adequate additional financing, we may be unable to meet operating obligations which could result in us initiating bankruptcy proceedings or delaying, or eliminating some or all of our research and product development programs.

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

Our auditors' report issued in connection with our December 31, 2015 financial statements included an explanatory paragraph indicating that conditions existed that raised substantial doubt about our ability to continue as a going concern. During 2016 we raised an aggregate of $29.1 million through the sale of our securities which is sufficient to fund our planned operations for at least one year from the date of this filing. As a result, our auditors' report with respect to our December 31, 2016 financial statements does not contain a paragraph indicating a going concern uncertainty.

Although we believe that we will be able to raise additional capital in the future there can be no assurance we will be successful in these efforts. Moreover, although our auditors' report issued in connection with our December 31, 2016 financial statements does not contain a paragraph indicating a going concern uncertainty, there can be no assurance that any future auditors' report will not contain such language.

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

We have incurred losses since its 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 its common stock and/or obtaining debt financing.

Our cash and cash equivalents balance at December 31, 2016 was approximately $20,195,000. Based on our current expected level of operating expenditures, we expect to be able to fund our operations into the second quarter of 2018. Our ability to remain a going concern is wholly dependent upon our ability to continue to obtain sufficient financing 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. In the event that we are not able to secure financing, we may be forced to curtail operations, delay or stop ongoing clinical trials, cease operations altogether or file for bankruptcy.

Risks Relating to Our Business

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. 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 the shortening of the commercial lives of such products or in their being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace. 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. 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 $16,000, $10,000 and $19,000 for the years ended December 31, 2016, 2015 and 2014, respectively, related to the licensing of certain intellectual property to third parties and certain subcontractor services that we provided. 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 experimental and highly invasive 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 procedure required to administer our stem cell therapy is 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 the device or the surgical procedure. 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 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 or terminated, our business and results of operations could be materially harmed.

We are currently in clinical trials for NSI-566 and NSI-189, two of our product candidates, with regard to multiple indications. Although we have commenced a number of trials, the ultimate outcome of the trials is uncertain. If we are unable to satisfactorily complete such trials, or if such trials 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, the clinical trial site IRBs, 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 our Phase 1 and Phase 2 trials 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.

Our research and development expenses are subject to uncertainty.

Factors affecting our research and development expenses include, but are not limited to:

- competition from companies that have substantially greater assets and financial resources than we have;
- need for acceptance of our proposed products;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
- amount and timing of operating costs and capital expenditures relating to outsourcing of manufacturing and management of pre-clinical and clinical trials;
- need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- dependence upon key personnel including key independent consultants and advisors.

There can be no guarantee that our research and development expenses will be consistent from period to period. We may be required to accelerate or delay incurring certain expenses depending on the results of our studies and the availability of adequate funding.

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.

There are no assurances that we will be able to submit a pre-market application or obtain FDA approval in order to market and sell our products.

There can be no assurance that even if the clinical trial of any potential product candidate is successfully initiated and completed, that we will be able to submit a Biologics License Application (“BLA”) or New Drug Application (“NDA”) to the FDA, or that any BLA or NDA that we submit will be approved in a timely manner, if at all. If we are unable to submit a BLA or NDA with respect to any future product, or if such application is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject BLAs and NDAs and may require additional clinical trials, even when product candidates performed well or achieved favorable results during initial clinical trials. If we fail to commercialize our product candidates and are unable to generate sufficient revenues to attain profitability our business will be adversely effected.

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 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.

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 Messrs. Daly and Lloyd Jones and Dr. Johe. Each of these employment agreements require the payment of severance, in the event certain conditions are met, if these individuals are terminated. These provisions will make the replacement of these employees very costly and could cause difficulty

in effecting 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 manufacture 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 work, 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.

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. 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.

In January, 2017 we undertook a 1-for-13 reverse stock split in order to regain compliance with Nasdaq minimum bid-price listing standards. On October 18, 2016, we received notice from the Listing Qualifications Staff (the “Staff”) of The NASDAQ Stock Market LLC (“Nasdaq”) indicating that the Staff had determined to delist the Company’s securities from The Nasdaq Capital Market due to the Company’s continued non-compliance with the $1.00 bid price requirement. At the time of receipt of notification from Nasdaq, we had been non-compliant with the minimum bid price requirement for in excess of 180 days. While our 1-for-13 reverse stock split has enabled us to regain compliance with Nasdaq minimum bid price requirements, we cannot be sure we will meet 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.

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.

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. Additionally, we are prohibited from paying any cash dividends under the terms of our loan and security agreement.

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 charter documents and Delaware law contain provisions that could make it difficult for us to be acquired in a transaction that might be beneficial to our stockholders.

Our board of directors has the authority to issue shares of preferred stock and to fix the rights, preferences, privileges, and restrictions of these shares without stockholder approval. Additionally, our Bylaws provide for a staggered board. These provisions in our charter documents, along with certain provisions under Delaware law, may make it more difficult for a third party to acquire us or discourage a third party from attempting to acquire us, even if the acquisition might be beneficial to our stockholders.

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, 2016 we have issued and outstanding 11,032,858 shares of common stock and we have 9,026,609 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, 2016, we had 1,000,000 shares of preferred stock issued and outstanding. Accordingly, we are entitled to issue up to 279,940,533 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 Our Reverse Stock Split

Our reverse stock split may adversely affect the liquidity of our common stock.

On January 6, 2017, we completed a 1:13 reverse stock split and as a result, the liquidity of the shares of our common stock may be affected adversely 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.

The market price of our common stock may further decline.

Historically, after a reverse stock split, the market price of a company's shares declines. On January 6, 2017 we completed a 1:13 reverse stock split. Immediately after the reverse stock split, the price of our common shares was $4.00. As of March 17, 2017, the price of our common stock had increased to $5.71. Although our stock price has increased, there can be no assurance that the price of our common stock will not decline in the future.

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.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

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 the 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 to 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 contraindications;
- 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

We currently operate two facilities 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 license approximately 1,500 square feet. This license provides for monthly payments of approximately $5,500 per month with the term expiring on December 31, 2017.

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 $11,000 and expires on August 31, 2019.

In 2016, we entered into a license for an Incubator Laboratory Facility in Urbana, Illinois. The license provides for monthly payments of $1,800, expires on December 31, 2019 and can be terminated by us upon 90 days written notice. In January, 2017 we served notice to terminate this lease and relinquish the property.

We lease a research facility in People's Republic of China. This lease expires on September 30, 2018 with lease payments of approximately $3,200 per month.

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." The following table sets forth, for the periods indicated, the high and low sale prices for our common stock. The prices are adjusted to retroactively, where applicable, to reflect the 1:13 reverse stock split that was effective on January 6, 2017.

	High	Low
2016		
First Quarter	$14.17	$6.77
Second Quarter	$10.40	$3.25
Third Quarter	$4.52	$2.47
Fourth Quarter	$4.52	$2.86

2015		
First Quarter	$50.96	$23.14
Second Quarter	$31.07	$18.98
Third Quarter	$26.26	$13.26
Fourth Quarter	$17.55	$12.74

Holders

As of February 28, 2017 our common stock was held by approximately 315 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, 2016.

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			
2005 Stock Plan, as amended and restated	36,926	$ 30.79	-
2007 Stock Plan	461,666	$ 40.24	-
2010 Equity Compensation Plan	988,719	$ 16.84	30,433
Equity compensation plans not approved by security holders			
Inducement Plan	211,539	$ 8.97	250,000
Total	1,698,850	$ 22.52	280,433

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 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. The Company did not seek approval of the Plan by our stockholders. Pursuant to the Inducement Plan, the Company may grant stock options for up to a total of 461,539 shares of common stock to new employees of the Company. As of December 31, 2016, 211,539 grants have been made pursuant to the Plan. The 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.

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 unregistered securities were issued pursuant to section 4(2) of the Securities Act:

- On February 15, 2016, as an inducement to Mr. Daly's employment, we granted an inducement option to purchase 211,539 shares of Common Stock. The option has a term of ten (10) years, and vests as follows: (i) 52,885 options vest on the six (6) month anniversary of the grant date, (ii) 52,885 options vest on the one (1) year anniversary of the grant date and the remaining 105,769 options vesting quarterly over the subsequent three (3) year period such that the option will be fully vested on the four (4) year anniversary of the grant date.

- On May 12, 2016, we entered into private placement securities purchase agreements with certain accredited investors to purchase 207,693 of common stock and 207,693 common stock purchase warrants at a price of $5.20 per each share and common stock purchase warrant. We received aggregate gross proceeds of approximately $1,080,000 and net proceeds of approximately $925,000. The warrants allow the holder to purchase one share of common stock, had an exercise price of $5.20 per share and a term of 5 years. The warrants contain certain non-standard anti-dilution protection and. Consequently, are being accounted for as derivative instruments recorded at fair value each period. Pursuant to this provision, the exercise price of the warrants was reduced to $3.25 per share based on the December 9, 2016 transaction. This private placement transaction was not made pursuant to any registration statement. Upon closing of the private placement with Tianjin Pharmaceutical Holdings Co., Ltd. (see below), the exercise price of these warrants automatically adjusted to $3.25 per share.

- In July 2016, we issued one of our legal advisors a common stock purchase warrant to purchase 11,539 shares of our common stock at an exercise price of $3.90 per share as partial compensation for legal work. The warrant vests monthly over one year from the grant date, has a term of 5 years and will expire on June 30, 2021. Any vested portion of the warrant can be exercised after 6 months from the issuance date on a cashless basis at any time that the shares underlying the warrant are not subject to a registration statement. The warrant provides for an adjustment to the purchase price and number of shares underlying the warrant upon stock dividends and splits. The warrant does not contain any price protection provisions with regard to subsequent financings.

- At various times from September 2016 through February 2017 we sold an aggregate of 18,216 shares of common stock to certain members of our management. The average purchase price for the shares was $3.84 based on the closing price of our common stock on each purchase date generating $70,000 of proceeds. The shares were issued pursuant to a plan to facilitate the ownership of our common shares by management.

- On December 9, 2016, we closed a strategic investment in our securities by Tianjin Pharmaceutical Group International Holdings Co., Ltd. for the purchase of 2,192,308 shares of common stock at $3.29 per share and 1,000,000 shares of Series A 4.5% Convertible Preferred Stock at $12.7895 per share. The Series A 4.5% Convertible Preferred Stock is convertible into 3,888,568 shares of the Company's common stock subject to certain ownership limitations. We received gross proceeds of $20,000,000 and net proceeds of approximately $19,904,000.

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 2017.

· *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, 2016 to the comparable period of 2015.

· *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 nervous system therapies based on our proprietary human neuronal stem cells and our small molecule compounds with the ultimate 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 and have a wholly-owned subsidiary in China, Suzhou Neuralstem Biopharmaceutical Co. Ltd., or Neuralstem China.

Our technology base has produced three primary assets: Our NSI-189 small molecule program, our NSI-566 stem cell therapy program and our novel and proprietary new chemical entity screening platform. We have two product candidates in clinical development in a total of four indications.

In the cell therapy program, our patented technology enables the commercial-scale production of multiple types of central nervous system stem cells, which are under development for the potential treatment of various central nervous system diseases and conditions. Our lead product is the spinal cord-derived neural stem cell line, NSI-566, which is being tested for treatment of paralysis due to ALS, spinal cord injury and stroke. In addition, our ability to generate human neural stem cell lines provides a platform for screening and discovery of novel CNS-targeted compounds. This proprietary screening platform led to the discovery of our lead molecule, NSI-189, which is being tested for treatment of major depressive disorder.

We have developed and maintain what we believe is a strong portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license over 20 U.S. issued and pending patents and over 120 foreign issued and pending patents in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds.

We believe our technology base, in combination with our expertise, and collaborative projects with major research institutions, could facilitate the development and commercialization of products for use in the treatment of a wide array of central nervous system disorders including neurodegenerative and psychiatric conditions.

There can be no assurances that we will ultimately produce any viable products or processes or that our screening platform will lead to the discovery of any additional product candidates. Even if we are able to produce a commercially viable product, there are strong competitors in this field and our products may not be able to successfully compete against them.

All of our research efforts to date are at the pre-clinical or clinical stage of development. We are focused on leveraging our key assets, including our intellectual property, proprietary know-how, scientific team and facilities, to advance our technologies and clinical programs. In addition, we are pursuing strategic collaborations with members of academia and industry to further advance and discover additional product candidates.

Trends & Outlook

We generated no revenues from the sale of our proposed therapies for any of the years presented. We are mainly focused on successfully managing our current clinical trials. We are also pursuing pre-clinical studies on other central and peripheral nervous system indications in preparation for additional clinical trials.

We recognized $16,000 and $10,000 of revenue related to ongoing fees pursuant to certain licenses of our intellectual property to third parties in each of the years ended December 31, 2016 and 2015 respectively.

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; manufacture of our 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 treatment candidates 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 we proceed with clinical and pre-clinical programs.

We have formed 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.

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 and our stock -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, 2016 and 2015, no significant impairment losses were recognized.

Fair Value Measurements - The carrying amounts of our short-term financial instruments, which primarily include cash and cash equivalents, other 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 is 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. The fair values of our derivative instruments were 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 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, stock 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 Year Ended December 31, 2016 and 2015

Revenue

During each of the years ended December 31, 2016 and 2015, we recognized revenue of $10,000 related to ongoing fees pursuant to certain licenses of our intellectual property to third parties. In addition, in 2016 we received approximately $6,000 of royalties related to a settlement of a prior patent infringement case.

Operating Expenses

Operating expenses for 2016 and 2015 were as follows:

	Year Ended December 31,		Increase (Decrease)	
	2016	2015	$	%
Operating Expenses				
Research & development costs	$13,155,887	$12,637,278	$518,609	4 %
General & administrative expenses	7,497,202	6,529,667	967,535	15 %
Total expense	$20,653,089	$19,166,945	$1,486,144	8 %

Research and Development Expenses

The increase of approximately $519,000 or 4% in research and development expenses was primarily attributable to a $257,000 increase in salaries, benefits and related costs, a $374,000 increase in share based compensation partially offset by reductions in travel and entertainment and facilities and related expenses. The increase in salaries and related was due to severance payments made as a result of our reduction in force in May together with an increase in bonus accrual year over year, partially offset by a reduction in ongoing payroll costs.

General and Administrative Expenses

The increase of approximately of approximately $968,000 or 15% in general and administrative expenses was primarily attributable to a $494,000 increase in legal and professional fees associated with company financing product licensing and Nasdaq compliance efforts, a $121,000 increase in share based compensation and a $268,000 increase in salaries and benefits due to severance payments made as a result of the resignation of our former chief executive officer in March and our reduction in force in May together with an increase in bonus accrual year over year.

Other income (expense)

Other expense, net totaled approximately $438,000 and $1,747,000 and in the years ended December 31, 2016 and 2015, respectively. Other expense, net in 2016 consisted of approximately $1,141,000 of interest expense primarily related to our long-term debt and $464,000 of fees related to the issuance of our derivative instruments, partially offset by a gain of approximately $459,000 related to our entering into a reimbursement agreement with a former executive officer of the Company and $661,000 of gain related to the change in the fair value adjustment of our derivative instruments and approximately $59,000 of interest income.

Other expenses, net in 2015 consisted primarily of approximately $1,816,000 of interest expense principally related to our long-term debt partially offset by approximately $70,000 in 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 $20.2 million as at December 31, 2016. Based on our estimated budget, we anticipate our average monthly cash burn rate will be approximately $2.1 million during the first half of the year due to our ongoing clinical trials and debt repayment and approximately $800,000 for the second half of the year due to completion, during the first half, of both our MDD study and our final debt repayments. Based upon our estimated cash burn rate, we expect to be able to fund our operations, into the second quarter of 2018.

In the event we are not able to secure additional capital by such date we may not be able 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 or 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 – 2016 compared to 2015

	Year Ended December 31,		Increase (Decrease)	
	2016	2015	$	%
Cash and cash equivalents	$15,194,949	$4,716,533	$10,478,416	222%
Short term investments	5,000,000	7,517,453	(2,517,453)	-33 %
Total cash and short term investments	$20,194,949	$12,233,986	$7,960,963	65 %
Net cash used in operating activities	$(15,616,108)	$(18,931,666)	$3,315,558	-18 %
Net cash provided by (used in) investing	$2,356,339	$7,246,441	$(4,890,102)	-67 %
Net cash provided by financing activities	$23,738,728	$3,887,187	$19,851,541	511%

The increase in our cash, cash equivalents and short term investments was primarily due to our raising approximately $28.1 million from the sale of our securities in 2016 and maturities of certain short-term investments partially offset by cash used in our operations, purchase of short-term investments and to repay principal on our long-term debt.

Net Cash Used in Operating Activities

The decrease in cash used in operating activities during 2016 as compared to 2015 was primarily the result of a reduction of $3.7 million in cash invested in working capital partially offset by an increase of $390,000 in cash used in our daily operations.

Net Cash Used in Investing Activities

We received approximately $2.5 million and $7.5 million, net from the sales and purchases of short-term investments in the years ended December 31, 2016 and 2015, respectively.

Net Cash Provided by Financing Activities

In the year ended December 31, 2016, we received approximately $28.1 million, net primarily from our financings in May and December 2016. In the year ended December 31, 2015 we received approximately $2.9 million from the sale of our equity securities along with $3.1 million from the exercise of warrants. We made principal payments on our long term debt of approximately $4.6 million and $1.2 in the 2016 and 2015, respectively.

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. During 2016 we had two shelf registration statements that were effective. On September 13, 2013, our shelf registration statement (Registration No. 333-190936) registering the sale of up to $50 million of our securities was declared effective by the SEC. Through expiration on September 13, 2016 we had sold or reserved for sale upon the exercise of outstanding warrants approximately $48.2 million of securities under this shelf registration statement. On June 19, 2014, our shelf registration statement (Registration No. 333-196567) registering the sale of up to $100 million of our securities was declared effective by the SEC. To date, through December 31, 2016 we have sold or reserved for sale upon exercise of outstanding warrants approximately $16.0 million of securities under this shelf registration statement.

The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, our progress in our exploratory, preclinical and future 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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

of Neuralstem, Inc.

We have audited the accompanying consolidated balance sheet of Neuralstem, Inc. (the "Company") as of December 31, 2016, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of their internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Neuralstem, Inc. as of December 31, 2016, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Dixon Hughes Goodman LLP

Baltimore, Maryland

March 23, 2017

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Neuralstem, Inc.

Germantown, Maryland

We have audited the accompanying consolidated balance sheet of Neuralstem, Inc. (the "Company") as of December 31, 2015, and the consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Neuralstem, Inc. as of December 31, 2015, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the 2015 consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raises substantial doubt about its ability to continue as a going concern at that date. Management's plans in regard to these matters were also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Stegman & Company

Baltimore, Maryland

March 14, 2016

Neuralstem, Inc.

Consolidated Balance Sheets

	December 31, 2016	2015
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$15,194,949	$4,716,533
Short-term investments	5,000,000	7,517,453
Trade and other receivables	10,491	37,316
Current portion of related party receivable, net of discount	53,081	-
Prepaid expenses	646,195	1,159,782
Total current assets	20,904,716	13,431,084
Property and equipment, net	269,557	343,200
Patents, net	990,153	1,103,467
Related party receivable, net of discount and current portion	424,240	-
Other assets	15,662	71,797
Total assets	$22,604,328	$14,949,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$2,343,936	$1,455,826
Accrued bonuses	852,963	161,362
Current portion of long-term debt, net of fees and discount	3,705,787	4,545,180
Other current liabilities	430,738	263,104
Total current liabilities	7,333,424	6,425,472
Long-term debt, net of fees, discount and current portion	-	3,382,654
Derivative instruments	3,921,917	-
Other long term liabilities	18,209	174,144
Total liabilities	11,273,550	9,982,270
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, $0.01 par value; 1,000,000 and 0 shares issued and outstanding at December 31, 2016 and 2015, respectively	10,000	-
Common stock, $0.01 par value; 300 million shares authorized, 11,032,858 and 7,077,362 shares issued and outstanding in 2016 and 2015, respectively	110,329	70,774
Additional paid-in capital	204,239,837	176,852,115
Accumulated other comprehensive income	3,905	3,071
Accumulated deficit	(193,033,293)	(171,958,682)
Total stockholders' equity	11,330,778	4,967,278

Total liabilities and stockholders' equity	$22,604,328	$14,949,548

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2016	2015
Revenues	$16,246	$10,417
Operating expenses:		
Research and development costs	13,155,887	12,637,278
General and administrative expenses	7,497,202	6,529,667
Total operating expenses	20,653,089	19,166,945
Operating loss	(20,636,843)	(19,156,528)
Other income (expense):		
Interest income	58,835	69,549
Interest expense	(1,141,297)	(1,816,206)
Gain on related party settlement	458,608	-
Gain from change in fair value of derivative instruments	660,253	-
Fees related to issuance of derivative instruments and other expenses	(474,167)	(716)
Total other income (expense)	(437,768)	(1,747,373)
Net loss	$(21,074,611)	$(20,903,901)
Net loss per common share - basic and diluted	$(2.53)	$(2.99)
Weighted average common shares outstanding - basic and diluted	8,345,992	6,989,764
Comprehensive loss:		
Net loss	$(21,074,611)	$(20,903,901)
Foreign currency translation adjustment	834	(2,929)
Comprehensive loss	$(21,073,777)	$(20,906,830)

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 (see Note 2)	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance at January 1, 2015	-	$-	6,753,050	$67,531	$168,700,586	$6,000	$(151,054,781)	$17,719,336
Share based payments	-	-	-	-	2,951,367	-	-	2,951,367
Issuance of common stock for warrant exercises net	-	-	132,662	1,327	3,072,208	-	-	3,073,535
Issuance of common stock for RSU and option exercises net of forfeited shares for exercise price and payment of taxes	-	-	96,246	962	(803,016)	-	-	(802,054)
Issuance of common stock and warrants from capital raises, net	-	-	62,495	625	2,931,299	-	-	2,931,924
Issuance of common stock for restricted stock awards	-	-	32,909	329	(329)	-	-	-
	-	-	-	-	-	(2,929)	-	(2,929)

Foreign currency translation adjustments								
Net loss	-	-	-	-	-	-	(20,903,901)	(20,903,901)
Balance at December 31, 2015	-	-	7,077,362	70,774	176,852,115	3,071	(171,958,682)	4,967,278
Share based payments	-	-	-	-	3,445,539	-	-	3,445,539
Issuance of common stock for RSU and option exercises net of forfeited shares for exercise price and payment of taxes	-	-	4,250	43	(43)	-	-	-
Issuance of preferred stock, common stock and warrants from capital raises, net	1,000,000	10,000	3,951,246	39,512	23,942,226	-	-	23,991,738
Foreign currency translation adjustments	-	-	-	-	-	834	-	834
Net loss							(21,074,611)	(21,074,611)
Balance at December 31, 2016	1,000,000	$10,000	11,032,858	$110,329	$204,239,837	$3,905	$(193,033,293)	$11,330,778

See accompanying notes to consolidated financial statements

Neuralstem, Inc.

Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (21,074,611)	$ (20,903,901)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	337,508	345,460
Share based compensation expenses	3,445,539	2,951,367
Amortization of deferred financing fees and debt discount	347,491	870,530
Gain from change in fair value of warrant obligations	(660,253)	-
Expenses related to issuance of derivative instrument	466,541	-
Loss on disposal of fixed assets	10,284	-
Changes in operating assets and liabilities:		
Trade and other receivables	26,825	188,208
Related party receivable	(477,321)	-
Prepaid expenses	513,156	(840,772)
Other assets	55,663	(13,998)
Accounts payable and accrued expenses	879,076	(1,045,765)
Accrued bonuses	691,601	(485,598)
Other current liabilities	(21,672)	253,427
Other long term liabilities	(155,935)	(250,624)
Net cash used in operating activities	(15,616,108)	(18,931,666)
Cash flows from investing activities:		
Purchases of short-term investments	(5,000,000)	(7,517,453)
Maturity of short-term investments	7,517,453	15,007,478
Patent costs	(63,026)	(67,312)
Purchase of property and equipment	(98,088)	(176,272)
Net cash provided by investing activities	2,356,339	7,246,441
Cash flows from financing activities:		
Proceeds from issuance of common stock from warrants exercised, net	-	3,073,535
Proceeds from sale of common stock, preferred stock and warrants, net of issuance costs	28,118,962	2,931,924
Payments of taxes on stock option exercises	-	(802,054)
Payments of long-term debt	(4,569,540)	(1,154,150)
Payment on fees for future financing	-	(45,000)
Proceeds from short term notes payable	313,483	-
Payments of short term notes payable	(124,177)	(117,068)
Net cash provided by financing activities	23,738,728	3,887,187

Effects of exchange rates on cash	(543)	(4,409)
Net increase (decrease) in cash and cash equivalents	10,478,416	(7,802,447)
Cash and cash equivalents, beginning of year	4,716,533	12,518,980
Cash and cash equivalents, end of year	$ 15,194,949	$ 4,716,533

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2016	2015
Supplemental cash flow information:		
Cash paid for interest	$ 990,857	$ 954,746
Cash paid for income taxes	$ -	$ -
Supplemental schedule of non cash investing and financing activities:		
Issuance of common stock for cashless exercise of options, warrants and RSUs	$ 8,936	$ 1,981,945

See accompanying notes to consolidated financial statements.

NEURALSTEM, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and Business

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 China are consolidated in our consolidated financial statements.

Neuralstem is a clinical stage biopharmaceutical company that is utilizing its proprietary human neural stem cell technology to create a comprehensive platform 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 San Diego, California, and in the People’s Republic of China. Our operations to date have been directed primarily toward developing business strategies, raising capital, research and development activities, and conducting pre-clinical testing and human clinical trials of our product candidates.

Liquidity

The Company has incurred losses since its inception and has not demonstrated an ability to generate revenues from sales 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.

Our cash, cash equivalents and short term investments balance at December 31, 2016 was approximately $20.2 million. 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 second quarter of 2018. In the event we are not able to secure additional capital by such date we may not be able to continue as a going concern. Accordingly, 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 or 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, 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. We currently do not have 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, to market and sell our products. No assurance can be given that (i) FDA or other regulatory agency approval will ever be granted for us to market and sell our product candidates, or (ii) if regulatory approval is granted, that we will ever be able to sell our proposed products or be profitable.

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.

The Board of Directors approved a 1-for-13 reverse stock split of the Company’s common stock effective January 6, 2017. Stockholders' equity and all references to share and per share amounts in the accompanying consolidated financial statements have been retroactively adjusted to reflect the 1-for-13 reverse stock split for all periods presented.

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, our net operating loss carry forward and related valuation allowance for tax purposes and our stock-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 is 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. The fair values of our derivative instruments 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 subsidiaries that have not been sold, substantially liquidated or otherwise disposed of 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 and Credit Risk

Cash equivalents consist of investments in low risk, highly liquid money market funds 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 and 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 CDs are 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 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.

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.

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 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, 2016 and 2015. A total of approximately 8.7 and 2.8 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the years ended December 31, 2016 and 2015, 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 warrants granted to employees and board members is determined at the grant date using an option pricing model that uses level 3 unobservable inputs; share-based compensation cost for restricted stock and restricted stock units granted 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.

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, 2016 or 2015.

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.

Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified for consistency with the current period presentation. These reclassifications had no material effect on the reported results of operations.

Significant New Accounting Pronouncements

In April 2015, the FASB issued *ASU 2015-03 – Interest-Imputation of Interest, Simplifying the Presentation of Debt Issuance Costs*. This ASU requires that deferred debt issuance costs related to a recognized debt liability be presented in the balance sheet as a deduction of the carrying amount of the debt liability (similar to debt discounts). This change is effective for fiscal years beginning after December 15, 2015 and early adoption is permitted. This change has been applied retrospectively. This new pronouncement results in our reclassifying amounts previously reflected as current and long-term assets to a contra-liability, which reduces the carrying value of the associated debt instruments. To conform to this standard, approximately $90,000 was reclassified on our December 31, 2015 balance sheet from current assets to current portion of long term debt and approximately $9,000 was reclassified from non-current assets to long term debt.

In August 2014, the FASB issued *ASU No. 2014-15, Presentation of Financial Statements – Going Concern*. This ASU requires entities to evaluate for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). Additionally, management is required to provide certain

footnote disclosures if it concludes that substantial doubt exists or when it concludes its plans alleviate substantial doubt about the company's ability to continue as a going concern. ASU 2014-15 became effective for us on December 15, 2016. The standard impacted our disclosures but had no effect on our financial position, results of operations or cash flows.

In February 2016, the FASB issued *ASU 2016-02, Leases*. This ASU requires the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements. This ASU will become effective for annual periods beginning after December 15, 2018. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In March 2016, the FASB issued *ASU 2016-09, Improvements to Employee Share Based Payment Accounting*. This ASU address areas for simplification in several aspects of accounting for share-based payment including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The ASU will become effective for annual reporting periods after December 15, 2016. The impact of the adoption of this ASU is not expected to be material to the Company’s consolidated financial statements.

The Company has reviewed other recent accounting pronouncements released during the year and concluded that they are either not applicable to the 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 into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date.

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair value of all other financial instruments (prepaid expenses, accounts payable, accrued expenses and long-term debt) approximate their carrying values because of their short-term nature.

At December 31, 2016, we had certain common stock purchase warrants issued in connection with our May 2016 capital raises (See Note 5) that are accounted for as derivative instruments whose fair value was determined using Level 3 inputs. The following table identifies the carrying amounts of such assets and liabilities at December 31, 2016:

	Level 1	Level 2	Level 3	Total
Liabilities				
Derivative instruments - stock purchase warrants	$ -	$ -	$3,921,917	$3,921,917
Balance at December 31, 2016	$ -	$ -	$3,921,917	$3,921,917

We had no financial assets or liabilities measured at fair value using Level 3 inputs on a recurring basis at December 31, 2015.

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, 2016:

	Derivative instruments - stock purchase warrants
Balance at December 31, 2015	$ -
Issuance of warrants	4,582,170
Change in fair value	(660,253)
Balance at December 31, 2016	$ 3,921,917

The (gains) losses resulting from the changes in the fair value of the derivative instruments are classified as the “change in fair value of derivative instruments” 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 for “plain vanilla” stock options and 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. Debt

In October 2014, we entered into an agreement to refinance and amend the terms of our March 2013 loan and security agreement. The amended loan provided for refinancing of approximately $5.6 million of outstanding balance of the initial loan along with approximately $4.4 million of new principal for a total of $10 million in principal. The amended loan provides for a variable interest rate based on prime with a floor of 10% and matures in April 2017. The loan provides for interest only payments through September 2015; payments of principal and interest of approximately $461,000 from October 2015 through December 2015, of approximately $435,000 from January 2016 through December 2016, of approximately $437,000 from January 2017 through March 2017 and a final balloon payment of approximately $2.8 million in April 2017. The loan amendment generated approximately $4.3 million in net proceeds after fees and expenses. The loan amendment is accounted for as a debt extinguishment in accordance with guidance provided for in ASC 470, Debt resulting in a loss on extinguishment of approximately $446,000. In conjunction with the loan amendment we recorded a debt discount relating to the beneficial conversion feature. Such discount is being amortized as interest expense over the term of the debt using the effective interest method.

In conjunction with the loan amendment, we issued the lender a five-year common stock purchase warrant to purchase 5,784 shares of common stock at an exercise price of $34.58 per share. The warrant contains standard anti-dilution protection but does not contain any anti-dilution price protection for subsequent offerings. The value of the warrant was accounted for in calculating the loss on extinguishment.

We also incurred expenses with various third parties in connection with the loan amendment, consisting of approximately $86,000 in cash, 2,163 shares of common stock valued at approximately $80,000, and a three-year common stock purchase warrant to purchase 4,474 shares at an exercise price of $34.58 per share. The warrant is classified as equity and has terms substantially similar to the lender warrant. These fees related to the loan amendment are recorded as a deferred financing fees netted against the carrying amount of the loan and are being amortized as interest expense over the term of the debt using the effective interest method.

At December 31, 2016, remaining principal payments due under this loan are approximately $3,766,000 payable in 2017.

Note 5. Stockholders' Equity

We have granted share-based compensation awards to employees, board members and service providers. Awards may consist of common stock, restricted common stock, restricted common stock units, warrants, or stock options. Our stock options and warrants have lives of up to ten years from the grant date. The stock options and warrants vest either upon the grant date or over varying periods of time. The stock options we grant provide for option exercise prices equal to or greater than the fair market 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. Vesting of the restricted stock units is similar to that of stock options. As of December 31, 2016, we have approximately 5.1 million shares of common stock reserved for issuance of such 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,	
	2016	2015
Research and development costs	$1,767,732	$1,394,194
General and administrative expenses	1,677,807	1,557,173
Total	$3,445,539	$2,951,367

Included in the general and administrative expense for the year ended December 31, 2016 is approximately $407,000 related to the acceleration of the vesting of options for the previous CEO who left during the first quarter. In addition,

approximately $42,000 and $15,000 is included in research and development and general and administrative expenses, respectively for the year ended December 31, 2016 related to the modification of certain awards in conjunction with our corporate reorganization. See Note 10.

No income tax benefit was recognized in the consolidated statements of operations for stock-based compensation for the years presented due to the Company’s net loss position.

Stock Options

A summary of stock option activity and related information for the year ended December 31, 2016 follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2016	1,315,666	$ 27.09	5.0	$ 550,000
Granted	436,347	$ 7.91		
Exercised	-	-		
Forfeited/Expired	(60,026)	$ 14.05		
Outstanding at December 31, 2016	1,691,987	$ 22.60	5.1	$ -
Exercisable at December 31, 2016	1,303,198	$ 26.42	4.1	$ -
Vested and expected to vest at December 31, 2016	1,685,187	$ 22.67	5.1	$ -

Range of Exercise Prices	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
$3.50 - $13.00	718,072	$ 9.72	7.3	$ -
$13.01 - $26.00	379,774	$ 15.30	5.1	-
$26.01 - $39.00	163,032	$ 32.35	2.5	-
$39.01 - $65.00	431,109	$ 46.77	2.4	-
	1,691,987	$ 22.60	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,	
	2016	**2015**
Annual dividend	-	-
Expected life (in years)	5.8 - 7.3	4.0 - 6.0
Risk free interest rate	1.34% - 1.75%	1.39% - 1.78%
Expected volatility	69.0% - 80.2%	68.6% - 71.8%

The Company estimates the expected term using the "simplified-method" as it does not have sufficient historical exercise data to provide a reasonable estimate.

The options granted in the years ended December 31, 2016 and 2015 had weighted average grant date fair values of $5.18 and $24.57, respectively. The total fair value of the options vested during the years ended December 31, 2016 and 2015 was approximately $2,643,000 and $2,215,000, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at December 31, 2016 was approximately $2,247,000 to be recognized over approximately 1.5 years.

RSUs

We have granted restricted stock units (RSUs) that entitle the holders to receive shares of our common stock upon vesting and subject to certain restrictions regarding the exercise of the RSUs and the holders' ability to transfer the shares received upon exercise. The fair value of RSUs 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, 2016 follows:

	Number of RSU's	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2016	11,615	$ 27.69
Granted	-	
Exercised and converted to common shares	(4,250)	$ 22.96
Forfeited	(502)	$ 26.26
Outstanding at December 31, 2016	6,863	$ 30.70
Exercisable at December 31, 2016	6,863	$ 30.70

There were no RSUs granted in the years ended 2016 or 2015. The total fair value of the shares vested during the year ended December 2015, was approximately $33,000. No shares vested during 2016. The total intrinsic value of the outstanding restricted stock units at December 31, 2016 was approximately $24,000. The total value of all restricted stock units that were converted in the year ended December 30, 2016 was approximately $35,000.

Restricted Stock

We have granted restricted stock to certain board members.

A summary of our restricted stock activity for the year ended December 31, 2016 is as follows:

	Shares of Restricted Stock	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2016	16,455	$ 24.31
Granted	-	
Vested	(16,455)	$ 24.31
Forfeited	-	
Outstanding at December 31, 2016	-	

All restricted stock was vested as of December 31, 2016. The total intrinsic value of all restricted stock vested in the year ended December 31, 2016 was approximately $111,000.

Stock Purchase Warrants

In the past, 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, we issued 1,746,172 stock purchase warrants in conjunction with our equity raise transactions. Such warrants are classified as derivative liabilities and are recorded at fair value each period due to the existence of non-standard anti-dilution conditions contained in the warrants. In accordance with these non-standard anti-dilution conditions the exercise price of these warrants was reduced from $5.20 to $3.25 as a result of our December 2016 equity transaction.

A summary of warrant activity for the year ended December 31, 2016 follows:

	Number of Warrants	Weighted-Average Exercised Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2016	1,511,763	$ 30.36	3.1	$ 309,724
Granted	1,757,712	$ 3.25	4.4	
Exercised	-	$ -		
Forfeited	(110,771)	$ 50.10		
Outstanding at December 31, 2016	3,158,704	$ 14.58	3.4	$ 454,000
Exercisable at December 31, 2016	3,152,920	$ 14.60	3.5	$ 454,000

The stock purchase warrants granted in the years ended December 31, 2016 and 2015 had a weighted average grant date fair value of $4.26 and $14.04, respectively.

Stock purchase warrants exercised in 2015 had an intrinsic value of approximately $5,126,000.

Preferred and Common Stock

During the year ended December 31, 2015, we issued 62,494 shares of common stock as a result of sales under our At the Market Offering Agreement. The shares were sold at an average price of $49.01 per share and we received approximately $2,932,000 in net proceeds.

During the year ended December 31, 2015, we issued a total of 131,185 shares of our common stock upon the exercise of outstanding common stock purchase warrants. The warrants were exercised at an average exercise price of $25.22. We received approximately $3,074,000 of net proceeds from the exercises.

During the year ended December 31, 2015, we issued a total of 97,723 shares of our common stock upon the cashless exercise of 169,923 outstanding common stock purchase warrants, stock options and conversion of 22,798 RSU’s. The warrants and options were exercised at an average price of $8.00. The exercises and conversion resulted in 94,998 warrants, options and RSU’s being forfeited and we received no proceeds from the exercises or conversions.

During the year ended December 31, 2015, we issued 32,908 shares of common stock as restricted stock awards to our independent directors in accordance with our Director Compensation Plan. These shares are reserved under our 2010 employee option plan and they vest quarterly over the director compensation year in September 2015, December 2015, March 2016, and June 2016.

During the year ended December 31, 2016, we issued 4,250 shares of our common stock upon the conversion of 4,752 outstanding restricted stock units.

On May 3, 2016, we completed a public offering of 1,538,462 shares of common stock and 1,538,462 common stock purchase warrants at a public offering price of $5.20 per each share and common stock purchase warrant. We received aggregate gross proceeds of $8.0 million and net proceeds of approximately $7,229,000 from the offering. The warrants allow the holder to purchase one share of common stock, have an exercise price of $5.20 per share and a term of 5 years. The warrants contain certain non-standard anti-dilution protection and consequently, are being accounted for as derivative instruments recorded at fair value each period (See Note 3). The costs directly related to this offering were allocated between the common stock and the derivative instruments with those being allocated to the derivative instruments being expensed as incurred and those allocated to the common stock being charged directly to additional paid-in capital. This offering was made pursuant to our shelf registration statement declared effective by the SEC on June 19, 2014 (Registration No. 333-196567). Upon closing of the December 9, 2016 private placement (see below), the exercise price of these warrants automatically adjusted to $3.25 per share.

On May 12, 2016, we entered into private placement securities purchase agreements with certain accredited investors to purchase 207,692 of common stock and 207,692 common stock purchase warrants at a price of $5.20 per each share and common stock purchase warrant. We received aggregate gross proceeds of approximately $1,080,000 and net proceeds of approximately $925,000. The warrants allow the holder to purchase one share of common stock, have an exercise price of $5.20 per share and a term of 5 years. The warrants contain certain non-standard anti-dilution protection and consequently, are being accounted for as derivative instruments recorded at fair value each period (See Note 3). The costs directly related to this offering were allocated between the common stock and the derivative instruments with those being allocated to the derivative instruments being expensed as incurred and those allocated to the common stock being charged directly to additional paid-in capital. This private placement transaction was not made pursuant to any registration statement. Upon closing of the December 9, 2016 private placement (see below), the exercise price of these warrants automatically adjusted to $3.25 per share.

During the year ended December 31, 2016 we issued 12,784 shares of common stock as a result of stock sales to certain employees at an average price of $3.90. We received $50,000 of proceeds from these sales.

On December 9, 2016, we closed a strategic investment in our securities by Tianjin Pharmaceutical Group International Holdings Co., Ltd. Pursuant to the terms of the transaction we sold 2,192,308 shares of common stock at $3.29 per share and 1,000,000 shares of Series A 4.5% Convertible Preferred Stock at $12.7895 per share. The Series A 4.5% Convertible Preferred Stock are convertible into 3,888,568 shares of the Company's common stock subject to certain ownership restrictions. We received gross proceeds of $20,000,000 and net proceeds of approximately $19,904,000. This private placement transaction was not made pursuant to any registration statement.

Note 6. Property and Equipment

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

	2016	2015
Furniture and fixtures	$35,407	$31,610
Computers and office equipment	127,497	136,558
Leasehold improvements	15,005	40,290
Lab equipment	816,419	763,293
	994,328	971,751
Less accumulated depreciation	(724,771)	(628,551)
Property and equipment, net	$269,557	$343,200

The above includes approximately $69,000 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, 2016 and 2015, was approximately $161,000 and $148,000, respectively

Note 7. 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 8.5 years at December 31, 2016. 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, 2016 and 2015, no significant impairment losses were recognized. The Company's intangible assets and accumulated amortization consisted of the following at December 31, 2016 and 2015:

	2016	2015
Patent asset	$1,950,823	$1,887,798
Accumulated amortization	(960,670)	(784,331)
Net intangibles	$990,153	$1,103,467

Amortization expense for the years ended December 31, 2016 and 2015 was approximately $176,000 and $197,000, respectively. The expected average future annual amortization expense over the next five years is approximately $96,000 based on current balances of our intangible assets.

Note 8. Income Taxes

Our provision for income taxes for the years ended December 31, 2016 and 2015 consists of the following:

	2016	2015
Current provision:		
Federal	$-	$-
State	-	-
Foreign	-	-
Total current provision	-	-
Deferred provision (benefit):		
Federal	(5,626,995)	(6,645,222)
State	(1,183,093)	(955,515)
Foreign	-	-
Total deferred provision (benefit)	(6,810,088)	(7,600,737)
Valuation allowance	6,810,088	7,600,737
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:

	2016	2015
Federal statutory rate	(34.0%)	(34.0%)
State income taxes, net of Federal benefits	(4.2 %)	(4.3 %)
Stock based compensation	7.6 %	0.5 %
Other	(2.6 %)	0.9 %
Valuation allowance	33.2 %	36.9 %
Total	0.0 %	0.0 %

The tax effects of significant temporary differences representing deferred tax assets as of December 31, 2016 and 2015:

	2016	2015
Net operating loss carryforwards	$51,249,822	$39,555,984
Stock based compensation expense	10,118,401	10,659,107
Tax credit carryforwards and other	1,373,979	5,717,023
	62,742,202	55,932,114
Valuation allowance	(62,742,202)	(55,932,114)
Net deferred tax assets	$-	$-

The Company had Federal net operating loss (“NOL”) carryforwards of approximately $133.6 and $116.3 million at December 31, 2016 and 2015, respectively, which begin expiring in 2016. 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 2013.

Note 9. Commitments and Contingencies

We currently operate two facilities 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 license approximately 1,500 square feet. This license provides for monthly payments of approximately $5,500 per month with the term expiring on December 31, 2017.

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 $11,600 and expires on August 31, 2019.

We also lease a research facility in People’s Republic of China. This lease expires on September 30, 2018 with lease payments of approximately $3,200 per month.

Future minimum payments under all leases at December 31, 2016 are as follows:

Year	Amount
2017	244,227
2018	172,254
2019	97,132
2020	-
2021 and thereafter	-
Total minimum payments	$513,613

The Company recognized approximately $243,000 and $318,000, in rent expense for the years ended December 31, 2016 and 2015, respectively.

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

The Company is currently obligated under three written employment agreements and a general release agreement. The employment agreements are with our: (i) Chief Executive Officer, (ii) Chief Scientific Officer (“CSO”) and (iii) Chief Financial Officer (“CFO”): Pursuant to the terms of the agreements, our CEO, CSO and CFO receive annual salaries of $410,000, $490,000 and $315,000, respectively. The agreements also provide for the payment of severance in the event one of the executives is terminated and in certain circumstances, the agreements also provide for the acceleration of vesting with regard to options.

On March 1, 2016, Neuralstem, Inc. (the “Company”) entered into a General Release and Waiver of Claims (“General Release”) with I. Richard Garr in connection with his resignation as the Company’s chief executive officer, which agreement was subsequently amended on June 16, 2016. Pursuant to the amended General Release, Mr. Garr will: (i) continue to receive his monthly salary of $36,667 until March 1, 2017, (ii) receive a lump sum payments of $177,000 to be paid on June 1, 2016, (iii) receive healthcare benefits until January 1, 2017, and (iv) be entitled to the immediate vesting of any previously outstanding but unvested equity awards (collectively, the “Severance”).

Note 10. Cost-Reduction Plan

On May 20, 2016 we announced that we had committed to a cost-reduction plan in order to better utilize our resources on the implementation of our refocused clinical and corporate strategy. This cost-reduction plan includes a reduction in force across all of the Company’s departments. With the exception of an on-going lease obligation on our facility in San Diego, California, we completed this cost-reduction plan in the quarter ended June 30, 2016. As a result of this cost-reduction plan we incurred total costs of approximately $470,000 comprised of $413,000 for severance and other

employee payments, and $57,000 of non-cash costs for the modification of employee stock options. Of the total expense, $312,000 is included in research and development expense and $158,000 is included in general and administrative expense in our statement of operations for the year ended December 31, 2016. At December 31, 2016, all amounts have been paid.

Note 11. 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 is recorded net of a $199,000 discount to reflect the net present value of the future cash payments. The Company recorded a non-operating gain of $459,000 for the year ended December 31, 2016. The discount will be amortized through interest income using the effective interest method. The entire amount of $658,000 remains outstanding at December 31, 2016 and is payable in $100,000 annual installments with a final balloon payment due six years from issuance.

Note 12. Subsequent Events

The Board of Directors approved a 1-for-13 reverse stock split of the Company’s common stock effective January 6, 2017. Stockholders' equity and all references to share and per share amounts in the accompanying consolidated financial statements have been retroactively adjusted to reflect the 1-for-13 reverse stock split for all periods presented.

On March 20, 2017 we entered into a letter agreement with certain shareholders with respect to the issuance of one (1) inducement warrant for every three (3) shares purchased upon exercise of outstanding common stock purchase warrants issued in our May 6, 2016 registered offering. Under the agreement, and subject to certain conditions, the shareholders agreed to exercise their outstanding warrants to purchase 692,309 shares of common stock at an exercise price of $3.25 per share. The exercise generated approximately $2,250,000 proceeds to Neuralstem. We agreed to issue the shareholders additional warrants to purchase 230,770 shares of common stock at an exercise price of $5.80 per share, such warrants expire on March 20, 2018.

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

Previously disclosed in our Current Report on Form 8-K filed with the SEC on June 6, 2016.

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ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of the Company's management, the Company's principal executive officer and principal financial officer have 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, 2016 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 ("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 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 and 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, 2016 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with 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 2016, 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.

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 2017 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for our 2017 Annual Meeting of Shareholders ("2017 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 2017 Proxy Statement and is incorporated herein by reference.

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ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is set forth under the headings “Director Compensation” and “Executive Compensation” of our 2017 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 2017 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 2016 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 2017 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements: See “Index to Financial Statements” in Part II, Item 8 of this Form 10-K.

2. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Form 10-K.

Certain of the agreements filed as exhibits to this Form 10-K contain representations and warranties by the parties to the agreements that have been made solely for the benefit of the parties to the agreement. These representations and warranties:

- may have been qualified by disclosures that were made to the other parties in connection with the negotiation of the agreements, which disclosures are not necessarily reflected in the agreements;
- may apply standards of materiality that differ from those of a reasonable investor; and
- were made only as of specified dates contained in the agreements and are subject to later developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time, and investors should not rely on them as statements of fact.

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 23, 2017

By: /S/Richard J Daly

Richard J Daly

President and Chief Executive Officer

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/Richard J. Daly Richard Daly	President, Chief Executive Officer, and Director (Principal executive officer)	March 23, 2017
/s/ William Oldaker William Oldaker	Director	March 23, 2017
/s/ Scott V. Ogilvie Scott V. Ogilvie	Director	March 23, 2017
/s/ Sandford D. Smith Sandford D. Smith	Director	March 23, 2017
/s/ Catherine A. Sohn Catherine A. Sohn	Director	March 23, 2017
/s/ Stanley Westreich Stanley Westreich	Director	March 23, 2017

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INDEX TO EXHIBITS

Exhibit No.	Description	Filed/ Furnished Herewith	Incorporated by Reference			
			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		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	11/16/16
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	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	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 21, 2013	DEF 14A	Appendix I	001-33672	4/30/13
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	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	5/3/16
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

10.01**	Employment Agreement with I. Richard Garr dated January 1, 2007 and amended as of November 1, 2005	SB-2	10.1	333-132923	6/21/06
10.02**	Amended terms to the Employment Agreement of I Richard Garr dated January 1, 2008	10-K	10.02	001-33672	3/31/09
10.03**	Amended terms to the employment Agreement of I. Richard Garr dated March 1, 2015	8-K	10.01	001-33672	3/2/15
10.04**	Employment Agreement with Karl Johe dated January 1, 2007 and amended as of November 1, 2005	SB-2	10.2	333-132923	6/21/06
10.05**	Amended terms to the Employment Agreement of Karl Johe dated January 1, 2009	10-K	10.04	001-33672	3/31/09
10.06**	Employment Agreement with Thomas Hazel, Ph.D dated August 11, 2008	10-K/A	10.05	001-33672	10/5/10
10.07**	Employment Agreement with Richard Daly dated February 15, 2016	8-K	10.01	001-33672	2/19/16
10.08	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
10.09**	Renewal of I. Richard Garr Employment Agreement dated 7/25/12	8-K	10.01	001-33672	7/27/12
10.10**	Renewal of Dr. Karl Johe Employment Agreement dated 7/25/12	8-K	10.02	001-33672	7/27/12
10.11**	Renewal of Dr. Tom Hazel Employment Agreement dated 7/25/12	8-K	10.03	001-33672	7/27/12
10.12**	Amendment of terms of Karl Johe Employment Agreement dated 9/17/14	8-K	10.01	001-33672	9/18/14
10.13	Loan and Security Agreement dated March 2013	8-K	10.01	001-33672	3/27/13
10.14	Intellectual Property and Security Agreement dated March 2013	8-K	10.02	001-33672	3/27/13

10.15	At the Market Offering Agreement entered into on October 25, 2013	8-K	10.01	001-33672	10/25/13
10.16**	Form of Amendment to Karl Johe Employment Agreement	8-K	10.01	001-33672	9/18/14
10.17	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
10.18**	Offer Letter Between Neuralstem, Inc. and Jonathan Lloyd Jones	8-K	10.01	001-33672	5/11/15
10.19**	General Release and Waiver of Claims with I. Richard Garr dated 3/2/2016	8-K	10.01	001-33672	3/4/16
10.20	Form of Securities Purchase Agreement from May 2016 Private Offering	8-K	10.01	001-33672	5/13/16
10.21	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
10.22	Form of Securities Purchase Agreement between Issuer and Tianjin Pharmaceuticals Holdings, Ltd.	8-K	10.01	001-33672	9/12/16
10.23**	Form of Securities Purchase Agreement between Issuer and Jonathan Lloyd Jones	10-Q	10.22	001-33672	11/7/14
10.24	Form of Securities Purchase Agreement between Issuer and Richard Daly	10-Q	10.23	001-33672	11/7/14
14.01	Neuralstem Code of Ethics	SB-2	14.1	333-132923	6/21/06
14.02	Neuralstem Financial Code of Profession Conduct adopted on May 16, 2007	8-K	14.2	333-132923	6/6/07
21.01	Subsidiaries of the Registrant	10-K	21.01	001-33672	3/10/14
23.01	Consent of Dixon Hughes Goodman LLP	*			
23.02	Consent of Stegman & Company	*			
31.1 / 31.2	Certification of the Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	*			
32.1 /32.2	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.*