

Neuralstem, Inc.  
Form 10-K  
April 02, 2018

**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, 2017.**

**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**

State or other jurisdiction of

incorporation or organization

**52-2007292**

(I.R.S. Employer

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:

| <b>Title of each class</b>     | <b>Name of each exchange on which registered</b> |
|--------------------------------|--|
| 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.

☐

## Edgar Filing: Neuralstem, Inc. - 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 ☒

Emerging Growth Company

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the Company’s common equity was last sold as of the last business day of the registrant’s most recently completed second fiscal quarter based upon the closing price of the common stock as reported by NASDAQ on such date, was \$55,416,345.

The number of shares outstanding of Registrant’s common stock, \$0.01 par value at February 28, 2018 was 15,160,014.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement relating to its 2018 annual meeting of shareholders (the “2018 Proxy Statement”) are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2018 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.



**NEURALSTEM, INC**

**ANNUAL REPORT ON FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2017**

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## **PART I**

*We urge you to read this entire Annual Report on Form 10-K, including the “Risk Factors” section, the financial statements and the related notes included therein. As used in this Annual Report, unless context otherwise requires, the words “we,” “us,” “our,” “the Company,” “Neuralstem” and “Registrant” refer to Neuralstem, Inc. and its subsidiary. Also, any reference to “common share” or “common stock,” refers to our \$.01 par value common stock. Additionally, any reference to our “Series A Preferred Stock” refers to our Series A 4.5% Convertible Preferred Stock. 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, 2017), 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 neural 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 patented technology platform has three core components:

1. Over 300 lines of human, regionally specific neural stem cells, some of which have the potential to be used to treat serious or life-threatening diseases through direct transplantation into the central nervous system;
2. Proprietary screening capability – our ability to generate human neural stem cell lines provides a platform for chemical screening and discovery of novel compounds against nervous system disorders; and
3. Small molecules that resulted from Neuralstem's neurogenesis screening platform that may have the potential to treat wide variety of nervous system conditions

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

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 10 U.S. issued and pending patents and over 70 foreign issued and pending patents related to our stem cell technologies for use in treating disease and injury. We own over 15 U.S. issued and pending patents and over 70 foreign issued and pending patents related to our small molecule compounds.

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



## **Recent Clinical and Business Highlights**

### **Business Highlights**

On November 6, 2017, we strengthened our clinical research team with the appointment of David Recker, MD, as Chief Medical Officer. Dr. Recker has more than 20 years of experience in drug development in multiple therapeutic areas including CNS and cell therapy and has been involved in numerous aspects of clinical strategy development, including product registration and marketing support, clinical trial development and execution, data interpretation, key opinion leader development and support.

On September 18, 2017, we strengthened our board of directors with the appointment of Cristina Csimma, Pharm.D, MHP. Dr. Csimma has considerable experience in the biopharmaceutical industry and in drug development. In addition, on December 18, 2017, Tianjin Pharmaceuticals Group International Holdings Co., LTD (the sole holder of the Series A Preferred Stock) appointed Xi Chen, PhD as their designated director per the terms of the Series A Preferred Stock. Dr. Chen has extensive healthcare management and research experience in both China and North America.

On September 5, 2017 we were awarded two additional patents by the United States Patent and Trademark Office (USPTO). These patents broadly protect methods for using neural stem cells to treat neurodegenerative disorders, a key component of the Company's platform. The first new patent, U.S. Patent No. 9,744,194, covers methods of treating neurodegenerative disorders through transplantation of neural stem cells. The second new patent, U.S. Patent No. 9,750,769, covers neural stem cells engineered to express IGF-1, a neurotrophic molecule with broad therapeutic potential in the treatment of neurodegenerative disorders.

On August 2, 2017, Neuralstem was awarded a Small Business Innovation Research (SBIR) grant by the National Institutes of Health (NIH) to evaluate in preclinical studies the potential of NSI-189, a novel small molecule compound, for the prevention and treatment of diabetic neuropathy. The award of approximately \$1 million will be paid over a two-year period, if certain conditions are met.

On August 1, 2017, we closed a public offering of 3,000,000 shares of common stock and 2,250,000 common stock purchase warrants at a public purchase price of \$2.00 per share and accompanying warrant. We received gross proceeds of \$6.0 million and approximately \$5.4 million of net proceeds from this offering.

In June 2017, Neuralstem (NASDAQ: CUR) was added to the Russell Microcap® Index as part of the FTSE's annual reconstitution of its family of U.S. indexes. The Russell Microcap® Index measures the performance of the microcap segment of the U.S. equity market.

### **Clinical Programs**

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

***NSI-189 (Small Molecule Pharmaceutical Compound).***

Our lead asset, NSI-189, is a new chemical entity with what we believe to be a novel mechanism of action.

We believe that NSI-189 may provide an effective treatment for patients suffering from Major Depressive Disorder or MDD by promoting synaptogenesis or neurogenesis in the hippocampus. Results to date indicate that NSI-189 promotes neurogenesis in mice and exerts anti-depression effects in MDD patients<sup>[1]</sup>. Data suggests that chronic exposure to stress hormones (glucocorticoids) inhibits release of neurotrophins, thereby inhibiting neurogenesis in the dentate gyrus, which results in hippocampal atrophy and depressive disease symptoms. 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 have anti-depressant and pro-cognitive properties. NSI-189's neurogenesis effect is believed to have a highly specific effect in the hippocampus and subventricular zone, the two well-known neurogenic regions 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 molecular mechanism of action is not yet fully understood, our data suggest that NSI-189 works by a different mechanism of action than current antidepressants. Accordingly, we believe that NSI-189 may have a positive therapeutic response as well as a favorable side-effect profile when compared to currently marketed products.

**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<sup>[2]</sup>. Treatment of MDD is characterized by a high level of patient turnover due to low efficacy and high side effects. It is estimated that 67% of patients will fail their first line therapy, 75% will then fail their second line prescription and 80% will then fail their third line prescription <sup>[3]</sup>. These factors combine to create a significant opportunity for a differentiated therapeutic agent, particularly one that may act through a novel mechanism of action.

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

<sup>[2]</sup> <https://www.nimh.nih.gov/health/statistics/prevalence/major-depression-among-adults.shtml>. Accessed February 13, 2017.

## Clinical Experience with NSI-189

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

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

The study was 80% powered to show an improvement in the primary endpoint, compared to placebo, with an assumed effect size of Cohen's  $d=0.5$  ( $p \leq 0.05$ ). Subjects eligible for the study had to be diagnosed with major depressive disorder, recurrent, as per Diagnostic and Statistical Manual of Mental Disorders V<sup>[4]</sup>, scoring 20 or greater on the MADRS, at screening and baseline and experiencing at least one eight-week MDD episode. The MADRS score was confirmed to be 20 or greater via remote SAFER interview by an independent rater prior to the baseline visit. After the 12-week trial period, eligible subjects were given the opportunity to enroll in a separate six-month observational study to assess the durability of effect defined as the time until the start of a new antidepressant treatment (ADT). Both the interventional and the observational studies were/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.

On July 25, 2017, we announced top-line results from our exploratory Phase 2 clinical trial examining the efficacy of NSI-189 compared to placebo for the treatment of MDD. The study did not meet its primary efficacy endpoint of a statistically significant reduction in depression symptoms on the Montgomery-Asberg Depression Rating Scale (MADRS), compared to placebo. Both doses were well-tolerated with no serious adverse events reported.

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

In addition, we presented data on NSI-189's effect on cognition as measured by computer-administered objective tests of cognition in the MDD patients. Two different test methods were used: Cogstate® and CogScreen®. Cogstate did not yield statistically significant results. In CogScreen® test, NSI-189 40 mg showed statistically significant improvement ( $p<0.05$ ) on objective measures of executive functioning, attention, working memory, and memory.

In safety, NSI-189 appeared to be safe and well tolerated with no serious adverse events. There were no clinically meaningful changes in body weight or BMI, or in sexual function inventory.

### **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.

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[3] 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

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



In December of 2011, we received authorization from the FDA to commence a Phase 1B randomized, double-blind, placebo-controlled, multiple-dose escalation study to evaluate safety, tolerability, pharmacokinetic (PK), and pharmacodynamic (PD) effects of NSI-189 in subjects<sup>[5]</sup> 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.

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 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 ( $\pm 3$ ) and Day 84 ( $\pm 3$ ) (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<sup>[6]</sup>). 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<sup>[7]</sup>.

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  $d = 1.20$ ).

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

[6] <http://www.nature.com/articles/mp2015178>

[7] 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'.

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 nervous system disorders. Additionally, data to date indicate that NSI-189 may have a significant cognitive benefit in diseases that affect memory and cognition. 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<sup>[8]</sup>.

NSI-189 treatment of brain slices from mice with a genetic defect that models Angelman Syndrome (a severe neurogenetic disorder – inherited, orphan condition – that shares symptoms and characteristics similar to those associated with other disorders including autism, cerebral palsy, Prader-Willi syndrome<sup>[9]</sup>) restored LTP to normal levels.

NSI-189 treatment preserved brain function and hippocampal proliferation at normal levels in a rat model of cognitive impairment induced by irradiation<sup>[10]</sup>.

#### **2. NSI-189 and neuroregeneration<sup>[11]</sup>:**

NSI-189 was demonstrated to be effective in the prevention and reversal of peripheral neuropathies in mouse models of Type 1 and preventative in 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<sup>[12]</sup>.**

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<sup>[8]</sup> 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.

<sup>[9]</sup> <https://www.angelman.org/what-is-as/diagnosis/>

<sup>[10]</sup> 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.

<sup>[11]</sup> Johe K, Marquez A, Anaya C, Kifle B, Muttalib N, Jolivald 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)

<sup>[12]</sup> 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

Oral administration of NSI-189 to mice with ischemic stroke led to a significant increase in neurogenesis in the hippocampus accompanied by a significant recovery from motor deficit. This evidence suggests that NSI-189 can induce recovery from stroke-induced brain damage. 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 mouse hippocampal cells, NSI-189 lead to the upregulation of growth factors such as Stem Cell Factor (SCF) and Brain Derived Neurotrophic Factor (BDNF), as well as increasing neurite outgrowth.

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

The discovery process for NSI-189 started with the initiation of a high content screen of 10,269 small molecules and led to the identification of 16 compounds that were capable of inducing neurogenesis, the birth of new neurons in hippocampal stem cells in culture. These 16 compounds were then tested for toxicity *in vitro* and in mice, and were evaluated for their ability to induce neurogenesis in healthy adult mice after oral administration. Seven of the starting 16 compounds, representing three structural classes, were advanced as orally active neurogenic leads. Compounds were evaluated in three mouse models of depression and NSI-189 was advanced as the lead small molecule candidate due to its anti-depressant behavioral effect, and its ability to both induce hippocampal neurogenesis and increase hippocampal volume.

***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 neuroprotection, neuroregeneration, and/or bridging of damaged neural circuitry may be accomplished by implantation of NSI-566 at the injury site.

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

Our lead stem cell program is the spinal cord-derived neural stem cell line, NSI-566, which is being tested for treatment of paralysis due to Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig's disease), stroke, and spinal cord injury. To date we have completed Phase 1 and Phase 2 safety and dose escalation studies in subjects with ALS and a Phase 1 safety and dose escalation study in subjects with motor deficits due to ischemic stroke. Each of these studies are currently in their long-term follow-up stage. Recently the Phase 1 safety study in subjects with chronic spinal cord injury (cSCI) AISA A<sup>[13]</sup> thoracic spinal cord injury subjects was expanded – under the auspices of UC San Diego – to include cervical spinal-cord injury subjects.

### *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<sup>[14]</sup>. In ALS, nerve cells (motor neurons) waste away or die, and can no longer send messages to muscles. This eventually leads to muscle weakening, twitching, and an inability to move the arms, legs, and body. As the condition progresses, muscles in the chest area stop working, making it difficult or impossible to breathe. NSI-566 is under development as a potential treatment for ALS by providing cells designed to nurture and protect the patient's remaining motor neurons; and possibly repair some motor neurons which have not yet died but which are diseased. We received orphan designation by the FDA for NSI-566 in ALS.

### *Motor Deficits Due to Ischemic Stroke*

Ischemic stroke, the most common type of stroke, occurs as a result of an obstruction within a vessel supplying blood to the brain. In the US, approximately 1.8 million people live with paralysis due to stroke.<sup>[15]</sup> Post-stroke motor deficits include paralysis in arms and legs and speech impairment and can be permanent. We believe that NSI-566 may provide an effective treatment for restoring motor deficits resulting from ischemic stroke by both creating new circuitry in the area of injury and through repairing and or nurturing diseased cells to improve function in patients.

### *Chronic Spinal Cord Injury*

Spinal cord injury, or SCI, generally refers to any injury to the spinal cord that is caused by trauma instead of disease, although in some cases it can be the result of diseases. It is estimated that there are 17,000<sup>14</sup> 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<sup>[16]</sup>. Chronic spinal cord injury (cSCI) 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 cSCI 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 24 months after the last surgery. The Phase 2 ALS clinical trial met the primary safety endpoints and established what we believe to be the maximum safe tolerated dose of 16 million cells delivered in 40 injections over two surgeries. In June 2017, 24-month Phase 2 and combined Phase 1 and Phase 2 data from our ALS trials were presented at the International Society for Stem Cell Research (ISSCR) Annual Meeting, Approaches to Treating ALS, Boston, Massachusetts, by principal investigator Eva Feldman, MD, PhD, Russell N. DeJong Professor of Neurology and Director of Research of the ALS Clinic at the University of Michigan Health. The data showed that the intraspinal transplantation of the cells was safe and well tolerated. Subjects from both the Phase 1 and Phase 2 continue to be monitored for long-term follow-up evaluations.

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

[14]  
<https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Amyotrophic-Lateral-Sclerosis-ALS-Fact-Sheet>  
Accessed February 17, 2017

[15] Prevalence and Causes of Paralysis – United States. Armour, B.S. et al. (2016) Am J Public Health. 106: 1855-57.

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



To provide guidance for future studies we undertook additional analyses of the Ph1/Ph2 NSI-566 ALS data using a matched controls approach. In order to facilitate this analysis, we utilized Pooled Resource Open-Access ALS Clinical Trials Database (PRO-ACT). The PRO-ACT platform houses the largest ALS clinical trials dataset ever created. PRO-ACT contains over 8,500 ALS de-identified patient records from multiple completed clinical trials. The PRO-ACT initiative merges data from existing publicly- and privately-conducted ALS clinical trials to generate an invaluable resource for accelerating discovery in the field of ALS. Post-hoc analyses of ambulatory limb-onset ALS participants in Phase 1 and 2 (Ph1/2) open-label intraspinal NSI-566 transplantation studies were compared to participants in PRO-ACT dataset who had complete data >1 month follow-up and matched Ph1/2 participants based on gender, age, disease duration, and baseline ALS functional rating scale-revised (ALSFRS-R). ALSFRS-R and a composite statistic (ALS/SURV), which combines survival and ALSFRS-R functional status, were analyzed. Mean ALSFRS-R at 24 months significantly differed between Ph1/2 and PRO-ACT (Ph1/2  $30.1 \pm 8.6$  vs. PRO-ACT  $24.0 \pm 10.2$ ,  $p=0.048$ ). Using ALS/SURV, the median PRO-ACT participants did not live to 24-months, whereas the median Ph1/2 participant's ALSFRS-R was 23 ( $p=0.0038$ ). We are continuing to analyze the data.

#### NSI-566: ALS Phase I and II, 2-Year Follow-Up vs Historical Data

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

#### *Ischemic Stroke*

In 2013 we commenced an open label, non-GCP, Phase I safety and dose escalation study in human subjects for treatment of motor deficits due to ischemic stroke. The trial was conducted at BaYi Brain Hospital in Beijing, China utilizing NSI-566, our spinal cord stem cells. This study was intended to evaluate safety of direct injections of NSI-566 into the brain and to determine 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.

At the twelve-month interim assessment delivery of NSI-566 cells by this mechanism in this population appeared to be safe and well tolerated at all doses. While not powered for efficacy, pre-specified endpoints (Fugl-Meyer, Modified Rankin Score and NIH Stroke Scale) showed statistically significant improvement in all scales compared to baseline as analyzed using the Wilcoxon signed rank test. Longitudinal MRI studies showed evidence of graft survival and cavity-filling in all 9 patients.

Fugl-Meyer Motor Score

12

Post-treatment (months, 0-12)

### *Chronic Spinal Cord Injury*

In 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 in 2014 and the first subject was treated in October 2014. The study enrolled four AIS A<sup>[17]</sup> 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. This study, under the supervision of UCSD is actively seeking subjects.

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.

*Traumatic Brain Injury (TBI).*

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

*Alzheimer's disease (AD).*

Neuralstem's HK532-IGF-1 is a proprietary line of cortical neural stem cells engineered to over-express insulin-like growth factor-1 (IGF-1), which has been shown to have wide-ranging neuroprotective properties. AD is a progressive neurodegenerative disorder of the brain that leads to cognitive decline and memory loss which is the most common cause of dementia in older adults. Researchers at the University of Michigan evaluated the ability of the human neural stem cell line NSI-532.IGF1 to reverse the cognitive impact of neurodegeneration in AD (McGinley et al., 2016). In a mice model, mice 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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<sup>[17]</sup> "ASIA"; American Spinal Injury Association. A = Complete: No sensory or motor function is preserved in sacral segments S4-S5

*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<sup>[18]</sup> 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 a neurotrophic environment to support weakened/diseased cells and/or 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 to develop effective methods to protect, repair, and regenerate the damaged neural circuits with implantation of neural stem cells.

*Small Molecule Pharmaceutical Compounds.*

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

## Research

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

## 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 70 foreign issued and pending patents related to our stem cell technologies for use in treating disease and injury. We own over 15 U.S. issued and pending patents and over 70 foreign issued and pending patents related to our small molecule compounds. Our issued patents have expiration dates ranging from 2018 through 2034.

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

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<sup>[18]</sup> 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.

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 FDCA, and its implementing regulations, and, for biologics, under the Public Health Service Act, or PHSA, and its implementing regulations. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, import restrictions, injunctive actions and criminal prosecutions of both companies and individuals. In addition, administrative remedies can involve requests to recall violative products; the refusal of the government to enter into supply contracts; or the refusal to approve pending product approval applications until manufacturing or other alleged deficiencies are brought into compliance. The FDA also has the authority to cause the withdrawal of approval of a marketed product or to impose labeling restrictions. The process of obtaining approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and money, and there can be no guarantee that approvals will be granted.

### *United States Product Development Process*

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

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

Completion of preclinical testing of new pharmaceutical or biological products, generally conducted in the laboratory and in animal studies in accordance with 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 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 4 clinical trials, may be required and conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

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

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

#### *United States Review and Approval Process*

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

The FDA may refuse to file any BLA or NDA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information. Once the submission is accepted for filing, the FDA reviews the

BLA or NDA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is safe and effective for its intended use, and in each case, whether the product is being manufactured in accordance with cGMP or GTP, if applicable. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA or NDA must submit a proposed REMS. The FDA will not approve a BLA or NDA without a REMS, if required.

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

#### *United States Post-Approval Requirements*

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

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

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

#### *European, China and Other Regulatory Review and Approval*

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

#### *Other Health Care Laws*

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

#### **Other Regulations**

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

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

## **Employees**

As of January 31, 2018, we had six (6) full-time employees. Of these full-time employees, four (4) work on research and development and clinical operations and two (2) 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](http://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 through December 31, 2017, we have accumulated losses totaling approximately \$209 million. On December 31, 2017, we had a working capital surplus of approximately \$10.9 million and stockholders' equity of approximately \$8.5 million. Our net losses for the two most recent fiscal years have been approximately \$15.7 million and \$21.1 million for 2017 and 2016, 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, 2017, we had cash, cash equivalents and short-term investments on hand of approximately \$11.7 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.

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

We have incurred losses since our inception and have not demonstrated an ability to generate revenues from sales or services. Our ability to continue as a going concern is dependent on generating cash from the sale of our common stock and/or obtaining debt financing. Our cash, cash equivalents and short-term investment balance at December 31, 2017 was approximately \$11.7 million. Based on our current expected level of operating expenditures, we expect to be able to fund our operations into the first quarter of 2019. Our ability to remain a going concern is wholly dependent upon our ability to continue to obtain sufficient capital to fund our operations.

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



## **Risks Relating to Our Business**

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

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

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

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

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

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

We have allocated the majority of our resources to the development of our stem cell and small molecule technologies. Our ability to generate revenue and operate profitably will depend on being able to develop these technologies for human applications. These are emerging technologies that may have limited human application. On July 25, 2017, we announced that our Phase 2 clinical trial of NSI-189 in MDD failed to achieve statistical significance on its primary endpoint although a subsequent evaluation of the data appeared directionally positive with regard to certain secondary endpoints. We cannot guarantee that we will be able to develop our technologies or that if developed, our technologies will result in commercially viable products or have any commercial utility or value. We anticipate that the commercial sale of our proposed products and/or royalty/licensing fees related to our technologies, will be our primary sources of revenue. We recognized revenue of approximately \$10,000 and \$16,000 for the years ended December 31, 2017 and 2016, 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 procedures required to administer our stem cell therapies are experimental, highly invasive and is required to be performed by highly experienced neurosurgeons who have received special training. We cannot guarantee consistent and safe performance of these devices or the surgical procedures. A surgery related adverse event may result in a clinical hold and may have long-term and damaging effects on our ability to complete development of the stem cell therapy programs, including the completion of any ongoing or planned clinical trials. Even if one or more of our programs is successful and receives marketing approval from a regulatory authority, due to the specialized nature of the device and surgical procedure, there may not be sufficient train surgeons to administer our therapy.

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

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

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

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

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

The manufacture of our therapeutic products is a complicated and difficult process, dependent upon substantial know-how and subject to the need for continual process improvements. In addition, our suppliers' ability to scale-up

manufacturing to satisfy the various requirements of our planned clinical trials is uncertain. Additionally, many of the materials that we use to prepare our cell-based products are highly specialized, complex and available from only a limited number of suppliers. The loss of one or more of these sources would likely delay our ability to conduct planned clinical trials and otherwise adversely affect our business.

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

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

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of our product candidates or other materials necessary to conduct our clinical trials;
- delays in obtaining regulatory agency agreement for the conduct of our clinical trials;
- lower than anticipated enrollment and retention rate of subjects in clinical trials;

serious and unexpected side effects experienced by patients in our clinical trials which are related to the use of our product candidates; or  
failure of our third-party contractors to meet their contractual obligations to us in a timely manner.

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

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

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

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

We outsource the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. For

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

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

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

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

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

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

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

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

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

Our products may be significantly more expensive to manufacture than other drugs or therapies currently on the market today due to a fewer number of potential manufacturers, greater level of needed expertise and other general market conditions affecting manufacturers of our proposed products. Even if we are able to receive approval for the

reimbursement of our proposed products the amount of reimbursement may be significantly less than the manufacturing costs of our products. Additionally, other market factors may limit the price which we can charge for our proposed products while still being competitive. Accordingly, even if we are successful in developing our proposed products, we may not be able to charge a high enough price for us to earn a profit.

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

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

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

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

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

We have entered into employment agreements with Mr. Daly 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 or resign under certain conditions. These provisions will make the replacement of these employees very costly and could cause difficulty in effecting any required changes in management or a change in control.



***Our competition has significantly greater experience and financial resources.***

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

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

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

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

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

to complete the research in-house.

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

Product liability claims could result in substantial litigation costs and damage awards against us. We attempt to mitigate this risk by obtaining and maintaining appropriate insurance coverage. Historically, we have obtained liability insurance that covers our clinical trials. If we begin commercializing products, we will need to increase our insurance coverage. We may not be able to obtain insurance on acceptable terms, if at all, and the policy limits on our insurance policies may be insufficient to cover our potential liabilities.

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

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

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

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

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

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

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

## **Risks Relating to Intellectual Property**

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

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

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

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

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

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

## **Risks Relating to Our Common Stock**

***The market price for our common shares is particularly volatile.***

The market for our common shares is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than those of a seasoned issuer. The volatility in our share price is attributable to a number of factors. Mainly however, we are a speculative or “risky” investment due to our limited operating history, lack of significant revenues to date and the uncertainty of FDA approval. By way of example, on July 25, 2017, we announced that our Phase 2 clinical trial of NSI-189 in MDD failed to achieve statistical significance on its primary endpoint. As a result of this announcement, the market price of our common stock decreased substantially. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Additionally, in the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management’s attention and resources.

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.

***If we are unable to satisfy NASDAQ maintenance requirements, our common stock may be delisted from NASDAQ, which could impair the liquidity and the value of our common stock.***

Continued listing on NASDAQ generally requires that we meet certain listing maintenance requirements. If we are unable to satisfy NASDAQ’S continued listing requirements, our common stock may be delisted from NASDAQ. In such event, trading in our common stock would likely take place on the over-the-counter market on the “OTC Markets” or the “OTC Bulletin Board.” Consequently, the liquidity of our common stock could be impaired, not only in the number of shares of common stock which could be bought and sold, but also through delays in the timing of transactions, a reduction in security analysts and new media coverage and lower prices for our common stock than might otherwise be obtained. While the shares of our common stock meet current NASDAQ listing requirements and are currently listed on The Nasdaq Capital Market, there can be no assurance that we will meet the criteria for continued listing.

While we continue to monitor our compliance with the requirements for continued listing on The Nasdaq Capital Market, we cannot assure you that we will not fail to satisfy one of the criteria in the future. If that were to occur, NASDAQ may take steps to delist our common stock. A delisting would likely have a negative effect on the price of our common stock and would likely impair your ability to sell or purchase our common stock if and when you wish to do so. In the event of a delisting, we cannot assure you that any action we take to restore listing would be successful. Even if successful, we cannot assure you that any such action would stabilize the market price of our common stock, improve the liquidity of our common stock, or prevent our future non-compliance with NASDAQ listing requirements. Further, if we were to be delisted from The Nasdaq Capital Market, our common stock would no longer be recognized as a “covered security” and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from NASDAQ could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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

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

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

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

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

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

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

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

- our board of directors is divided into three classes, with each class serving for a staggered three-year term, which prevents stockholders from electing an entirely new board of directors at an annual meeting;
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors and propose matters to be brought before an annual meeting of our stockholders may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
-

our board of directors may, without stockholder approval, issue series of preferred stock, or rights to acquire preferred stock, that could dilute the interest of, or impair the voting power of, holders of our common stock or could also be used as a method of discouraging, delaying or preventing a change of control.

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

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



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

We are entitled under our certificate of incorporation to issue up to 300,000,000 shares of common stock and 7,000,000 “blank check” shares of preferred stock. Shares of our blank check preferred stock provide our board of directors with broad authority to determine voting, dividend, conversion, and other rights. As of December 31, 2017, we have issued and outstanding 15,160,014 shares of common stock and we have 10,794,028 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, 2017, we had 1,000,000 shares of preferred stock issued and outstanding. Accordingly, we are entitled to issue up to 274,045,958 additional shares of common stock and 6,000,000 additional shares of “blank check” preferred stock. Our board may generally issue those common and preferred shares, or convertible securities to purchase those shares, without further approval by our shareholders. Any preferred shares we may issue will have such rights, preferences, privileges and restrictions as may be designated from time-to-time by our board, including preferential dividend rights, voting rights, conversion rights, redemption rights and liquidation provisions. It is likely that we will be required to issue a large amount of additional securities to raise capital in order to further our development and marketing plans. It is also likely that we will be required to issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our various stock plans. The issuance of additional securities may cause substantial dilution to our shareholders.

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

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

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

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

the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

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

We are not permitted to market our product candidates in the United States until we receive approval of a BLA or NDA from the FDA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a

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

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

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

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

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

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

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

***If side effects are identified during the time our drug candidates are in development or after they are approved and on the market, we may choose 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 contradictions;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

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

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

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

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

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

the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;

federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

the federal physician sunshine requirements under the ACA, which require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and

HIPAA, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information.

In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing



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

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

#### **ITEM 1B.UNRESOLVED STAFF COMMENTS**

None

#### **ITEM 2.PROPERTIES**

We currently operate one facility located in the United States and one facility located in China. Our corporate offices and primary research facilities are located in Germantown, Maryland, where we lease approximately 1,500 square feet. This lease provides for monthly payments of approximately \$5,600 per month with the term expiring on December 31, 2018.

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. In May 2017, we ceased-use of this property and recognized a loss of approximately \$92,000 representing the present value of the expected remaining net payments due under such lease and the costs to vacate the property. The loss is included in research and development expense on our statements of operations for the year ended December 31, 2017. We are currently exploring opportunities to sub-lease the unused research space.

We lease a research facility in People's Republic of China. This lease expires on September 30, 2018 and has monthly lease payments of approximately \$3,200.

### **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 MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS 5. 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 have been retroactively adjusted, where applicable, to reflect the 1:13 reverse stock split that was effective on January 9, 2017.

|                | High   | Low    |
|----------------|--------|--------|
| 2017           |        |        |
| First Quarter  | \$6.19 | \$2.83 |
| Second Quarter | \$6.60 | \$2.91 |
| Third Quarter  | \$6.20 | \$0.99 |
| Fourth Quarter | \$3.09 | \$0.88 |

|                |         |        |
|----------------|---------|--------|
| 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 |

### Holders

As of February 28, 2018, our common stock was held by approximately 268 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, 2017.

| Plan Category  | Number of Securities<br>to be Issued upon<br>Exercise of<br>Outstanding<br>Options and Rights | Weighted-Average<br><b>Exercise Price<br/>for Outstanding<br/>Options and<br/>Rights</b> | Number of Securities<br>Remaining<br>Available for<br>Future Issuance<br>under Equity<br>compensation Plans<br>(Excluding<br>Securities Reflected<br>in Column (a)) |
|--|---|--|---|
| (a)  | (b)   | (c)  |   |
| Equity compensation plans approved by security holders     |   |  |   |
| 2005 Stock Plan, as amended and restated                   | 20,386  | \$ 26.30   | -   |
| 2007 Stock Plan  | 456,279   | \$ 40.31   | -   |
| 2010 Equity Compensation Plan                              | 1,217,108   | \$ 13.65   | 431,263   |
| Equity compensation plans not approved by security holders |   |  |   |
| Inducement Plan  | 211,539   | \$ 8.97  | 250,000   |
| Total  | 1,905,312   | \$ 19.65   | 681,263   |

### 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, 2017, 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:

- In March 2017, we issued warrants to purchase 230,770 shares of common stock. The warrants have an exercise price of \$5.80 per share and a term of one year. The warrants were issued as an inducement for the exercise of 692,309 outstanding warrants resulting in gross proceeds of approximately \$2,250,000.

In April 2017, we issued warrants to purchase 51,283 shares of common stock. The warrants have an exercise price of \$5.80 per share and a term of one year. The warrants were issued as an inducement for the exercise of 153,847 outstanding warrants resulting in gross proceeds of approximately \$500,000.

In the first and second quarters of 2017, we sold an aggregate of 10,887 shares of common stock to certain members of our management. The average price for the shares was \$4.59 based on the closing price of our common stock on each respective purchase date. The sales resulted in gross proceeds of \$50,000.

In July 2017, we issued one of our outside advisors a common stock purchase warrant to purchase 11,539 shares of our common stock at an exercise price of \$5.79 per share as partial compensation for services. The warrant vests monthly over one year from the grant date, has a term of 5 years and will expire on June 30, 2022.

#### **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 2018.
- *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, 2017 to the comparable period of 2016.
- *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 neural stem cells and our small molecule compounds with the ultimate goal of gaining approval from the FDA, and its international counterparts, to market and commercialize such therapies. We are headquartered in Germantown, Maryland.

Our technology has produced three primary assets: our NSI-189 small molecule program, our NSI-566 stem cell therapy program and our novel and proprietary 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 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. We believe our technology 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.

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 10 U.S. issued and pending patents and over 70 foreign issued and pending patents related to our stem cell technologies for use in treating disease and injury. We own over 15 U.S. issued and pending patents and over 70 foreign issued and pending patents related to our small molecule compounds.

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 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**

### ***Revenue***

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

We have historically generated minimal revenue from the licensing of our intellectual property to third parties.

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



### ***Research and Development Expenses***

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

We focus on the development of 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 as we proceed later stage clinical trials.

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

In August 2017, we were awarded a Small Business Innovation Research ("SBIR") grant by the National Institutes of Health ("NIH") to evaluate in preclinical studies the potential of NSI-189, a novel small molecule compound, for the prevention and treatment of diabetic neuropathy. The award of approximately \$1 million will be paid over a two-year period, if certain conditions are met as mid-term. Proceeds from such award will be recorded as contra-research and development expenses.

### ***General and Administrative Expenses***

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

## Critical Accounting Policies

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

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

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

***Use of Estimates*** - Our financial statements prepared in accordance with U.S. GAAP require us to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Specifically, we have estimated the expected economic life and value of our patent technology, our net operating loss carryforward and related valuation allowance for tax purposes the fair value of our liability classified warrants and our share-based compensation expenses related to employees, directors, consultants and investment banks. Actual results could differ from those estimates.

***Long Lived Intangible Assets*** - Our long lived intangible assets consist of our intellectual property patents including primarily legal fees associated with the filings and in defense of our patents. The assets are amortized on a straight-line basis over the expected useful life which we define as ending on the expiration of the patent group. These assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We assess this recoverability by comparing the carrying amount of the asset to the estimated undiscounted future cash flows to be generated by the asset. If an asset is deemed to be impaired, we estimate the impairment loss by determining the excess of the asset's carrying amount over the estimated fair value. These determinations use assumptions that are highly subjective and include a high degree of uncertainty. During the years ended December 31, 2017 and 2016, no significant impairment losses were recognized.



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

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

## Comparison of Our Results of Operations for the Years Ended December 31, 2017 and 2016

### Revenue

During each of the years ended December 31, 2017 and 2016, we recognized revenue of \$10,000 related to ongoing fees pursuant to certain licenses of our intellectual property to third parties. In addition, in 2017 we recognized \$250,000 of milestone-based revenue related to a settlement of a prior patent infringement case.

### Operating Expenses

Operating expenses for 2017 and 2016 were as follows:

|                                   | Year Ended December 31, |              | Increase (Decrease) |      |
|-----------------------------------|-------------------------|--------------|---------------------|------|
|                                   | 2017                    | 2016         | \$                  | %    |
| Operating Expenses                |                         |              |                     |      |
| Research & development costs      | \$8,096,095             | \$13,155,887 | \$(5,059,792)       | -38% |
| General & administrative expenses | 5,471,010               | 7,497,202    | (2,026,192)         | -27% |
| Total expense                     | \$13,567,105            | \$20,653,089 | \$(7,085,984)       | -34% |

### Research and Development Expenses

The decrease of approximately \$5,060,000 or 38% in research and development expenses was primarily attributable to a \$2,328,000 decrease in our personnel, facility and other expenses due to our ongoing corporate restructuring and cost reduction efforts, a \$2,147,000 decrease in costs related to our completed NS-189 Phase 2 clinical trial and a \$677,000 decrease in non-cash share-based compensation expense.

*General and Administrative Expenses*

The decrease of approximately \$2,026,000 or 27% in general and administrative expenses was primarily attributable to \$1,165,000 decrease in payroll and related expenses due to our ongoing corporate restructuring and cost reduction efforts and a \$999,000 decrease in our non-cash share-based compensation expense partially offset by a \$196,000 increase in fees for outsourced service providers and consultants.

*Other income (expense)*

Other expense, net totaled approximately \$2,359,000 and \$438,000 for the years ended December 31, 2017 and 2016, respectively. Other expense, net in 2017 consisted of approximately \$1,470,000 of non-cash losses related to the change in the fair value of our liability classified stock purchase warrants, \$564,000 of expense related to the issuance of inducement warrants, \$243,000 of expense related to the liability classified warrants issued in conjunction with our August 2017 capital raise and \$159,000 of interest expense related primarily to our long-term debt, partially offset by \$70,000 of interest income.

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 liability classified stock purchase warrants, 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 \$660,000 of gain related to the change in the fair value adjustment of our liability classified stock purchase warrants and approximately \$59,000 of interest income.

### ***Impact of the Tax Cuts and Jobs Act of 2017***

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

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

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

### **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 \$11.7 million as at December 31, 2017. On August 1, 2017, we closed a public offering of 3,000,000 shares of common stock and 2,250,000 common stock purchase warrants at a public purchase price of \$2.00 per share and accompanying warrant. We received gross proceeds of \$6.0 million and approximately \$5.4 million of net proceeds from this offering.

Based on our expected operating cash requirements, we anticipate our average monthly cash burn rate will decrease and our current cash and investments on hand will be sufficient to fund our operations, into the first quarter of 2019. As explained in the notes to our financial statements and in the report of our independent registered public accounting

firm for the year ended December 31, 2017 there is substantial doubt about our ability to continue as a going concern.

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

### *Cash Flows – 2017 compared to 2016*

|   | Year Ended December 31, |                | Increase (Decrease) |        |
|---|-------------------------|----------------|---------------------|--------|
|   | 2017                    | 2016           | \$                  | %      |
| Cash and cash equivalents                 | \$6,674,940             | \$15,194,949   | \$(8,520,009 )      | -56 %  |
| Short term investments                    | 5,000,000               | 5,000,000      | -                   | 0 %    |
| Total cash and short term investments     | \$11,674,940            | \$20,194,949   | \$(8,520,009 )      | -42 %  |
| Net cash used in operating activities     | \$(13,416,162)          | \$(15,616,108) | \$2,199,946         | -14 %  |
| Net cash provided by (used in) investing  | \$(94,046 )             | \$2,356,339    | \$(2,450,385 )      | -104 % |
| Net cash provided by financing activities | \$4,990,778             | \$23,738,728   | \$(18,747,950)      | -79 %  |

The decrease in our cash, cash equivalents and short-term investments was primarily due to our cash used in operations and for the payment of our long-term debt partially offset by proceeds from our equity financing and the exercise of common stock purchase warrants.

#### *Net Cash Used in Operating Activities*

The decrease in our use of cash in operating activities of approximately \$2,200,000 was due to a decrease in our operating loss adjusted for certain non-cash items, including share-based compensation and changes in the fair value of liability classified warrants, partially offset by payments of accrued bonuses and accounts payable in 2017. Cash used in operating activities for the year ended December 31, 2017, of approximately \$13,416,000 reflects our \$15,666,000 loss for the period adjusted for certain non-cash items including: (i) \$1,770,000 of stock based compensation, (ii) 806,000 of expenses related to issuance of liability classified warrants and warrant inducement expenses and (iii) \$1,470,000 related to the change in fair value of our liability classified warrants coupled with \$2,149,000 of net cash inflows related to changes in our operating assets and liabilities.

#### *Net Cash Used in Investing Activities*

For the year ended December 31, 2017 cash used in investing activities was comprised of costs related to our patent assets and fixed asset purchases. For the year ended December 31, 2016 we received, net of purchases, approximately \$2.5 million from the maturity of some of our short-term investments.

#### *Net Cash Provided by Financing Activities*

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

For the year ended December 31, 2016, cash provided by financing activities consisted primarily of approximately \$28.1 million, net from our financings in May and December 2016 partially offset by \$4,570,000 of payments of our long-term debt.

#### *Future Liquidity and Needs*

We have incurred significant operating losses and negative cash flows since inception. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment,



laboratory and office facilities, establishment of production capabilities, for general and administrative expenses and other working capital requirements. We rely on cash balances and the proceeds from the offering of our securities, exercise of outstanding warrants and grants to fund our operations.

We intend to pursue opportunities to obtain additional financing in the future through the sale of our securities and additional research grants. On June 23, 2017, our shelf registration statement (Registration No. 333-218608), which replaced our prior expiring shelf registration statement, was declared effective by the SEC. Under such replacement shelf registration statement, we can offer and sell up to \$100 million of our securities. Through December 31, 2017 we have sold and reserved for issuance upon exercise of outstanding equity-linked instruments approximately \$10.5 million of securities.

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

***Off-balance Sheet Arrangements***

None.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

Not Applicable.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

### ***Opinion on the Consolidated Financial Statements***

We have audited the accompanying consolidated balance sheets of Neuralstem, Inc. and subsidiary (the “Company”) as of December 31, 2017 and 2016, and the related consolidated statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

### ***Substantial Doubt about the Company’s Ability to Continue as a Going Concern***

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

### ***Basis for Opinion***

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

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

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

/s/ Dixon Hughes Goodman LLP

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

**Baltimore, Maryland**

**April 2, 2018**

Neuralstem, Inc.

## Consolidated Balance Sheets

|   | December 31,<br>2017 | 2016          |
|---|----------------------|---------------|
| <b>ASSETS</b>   |                      |               |
| <b>CURRENT ASSETS</b>   |                      |               |
| Cash and cash equivalents   | \$6,674,940          | \$15,194,949  |
| Short-term investments  | 5,000,000            | 5,000,000     |
| Trade and other receivables   | 312,802              | 10,491        |
| Current portion of related party receivable, net of discount  | 58,784               | 53,081        |
| Prepaid expenses  | 402,273              | 646,195       |
| Total current assets  | 12,448,799           | 20,904,716    |
| Property and equipment, net   | 172,886              | 269,557       |
| Patents, net  | 883,462              | 990,153       |
| Related party receivable, net of discount and current portion   | 365,456              | 424,240       |
| Other assets  | 13,853               | 15,662        |
| Total assets  | \$13,884,456         | \$22,604,328  |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                      |               |
| <b>CURRENT LIABILITIES</b>  |                      |               |
| Accounts payable and accrued expenses   | \$875,065            | \$2,343,936   |
| Accrued bonuses   | 418,625              | 852,963       |
| Current portion of long-term debt, net of fees and discount   | -                    | 3,705,787     |
| Other current liabilities   | 220,879              | 430,738       |
| Total current liabilities   | 1,514,569            | 7,333,424     |
| Warrant liabilities   | 3,852,882            | 3,921,917     |
| Other long term liabilities   | 1,876                | 18,209        |
| Total liabilities   | 5,369,327            | 11,273,550    |
| Commitments and contingencies (Note 9)  |                      |               |
| <b>STOCKHOLDERS' EQUITY</b>   |                      |               |
| Preferred stock, 7,000,000 shares authorized, \$0.01 par value; 1,000,000 shares issued and outstanding in both 2017 and 2016                         | 10,000               | 10,000        |
| Common stock, \$0.01 par value; 300 million shares authorized, 15,160,014 and 11,032,858 shares issued and outstanding in 2017 and 2016, respectively | 151,600              | 110,329       |
| Additional paid-in capital  | 217,050,174          | 204,239,837   |
| Accumulated other comprehensive income  | 2,631                | 3,905         |
| Accumulated deficit   | (208,699,276)        | (193,033,293) |
| Total stockholders' equity  | 8,515,129            | 11,330,778    |
| Total liabilities and stockholders' equity  | \$13,884,456         | \$22,604,328  |

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

Consolidated Statements of Operations and Comprehensive Loss

|  | Year Ended December 31, |                |
|--|-------------------------|----------------|
|  | 2017                    | 2016           |
| Revenues   | \$260,000               | \$16,246       |
| Operating expenses:  |                         |                |
| Research and development costs   | 8,096,095               | 13,155,887     |
| General and administrative expenses  | 5,471,010               | 7,497,202      |
| Total operating expenses   | 13,567,105              | 20,653,089     |
| Operating loss   | (13,307,105)            | (20,636,843)   |
| Other income (expense):  |                         |                |
| Interest income  | 70,269                  | 58,835         |
| Interest expense   | (159,066 )              | (1,141,297 )   |
| Gain on related party settlement   | -                       | 458,608        |
| Gain (loss) from change in fair value of liability classified warrants       | (1,470,174 )            | 660,253        |
| Fees related to issuance of liability classified warrants and other expenses | (799,907 )              | (474,167 )     |
| Total other income (expense)   | (2,358,878 )            | (437,768 )     |
| Net loss   | \$(15,665,983)          | \$(21,074,611) |
| Net loss per common share - basic and diluted                                | \$(1.20 )               | \$(2.53 )      |
| Weighted average common shares outstanding - basic and diluted               | 13,064,422              | 8,345,992      |
| Comprehensive loss:  |                         |                |
| Net loss   | \$(15,665,983)          | \$(21,074,611) |
| Foreign currency translation adjustment                                      | (1,274 )                | 834            |
| Comprehensive loss   | \$(15,667,257)          | \$(21,073,777) |

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

## Consolidated Statements of Changes In Stockholders' Equity

|   | Preferred<br>Stock<br>Shares | Preferred<br>Stock<br>Amount | Common<br>Stock Shares<br>(See Note 2) | Common<br>Stock<br>Amount | Additional<br>Paid-In Capital | Accumulated<br>Other<br>Comprehensive<br>Income<br>(Loss) | Accumulated<br>Deficit | Total<br>Stockholders'<br>Equity |
|---|------------------------------|------------------------------|--|---------------------------|-------------------------------|---|------------------------|----------------------------------|
| Balance at<br>January 1,<br>2016  | -                            | -                            | 7,077,362                              | 70,774                    | 176,852,115                   | 3,071   | (171,958,682)          | 4,967,278                        |
| Share based<br>payments   | -                            | -                            | -                                      | -                         | 3,445,539                     | -   | -                      | 3,445,539                        |
| Issuance of<br>common<br>stock for<br>RSU and<br>option<br>exercises<br>net of<br>forfeited<br>shares for<br>exercise<br>price and<br>payment of<br>taxes | -                            | -                            | 4,250                                  | 43                        | (43 )                         | -   | -                      | -                                |
| Issuance of<br>preferred<br>stock,<br>common<br>stock and<br>warrants<br>from capital<br>raises, net  | 1,000,000                    | 10,000                       | 3,951,246                              | 39,512                    | 23,942,226                    | -   | -                      | 23,991,738                       |
| Foreign<br>currency<br>translation<br>adjustments   | -                            | -                            | -                                      | -                         | -                             | 834   | -                      | 834                              |
| Net loss  |                              |                              |  |                           |                               |   | (21,074,611 )          | (21,074,611)                     |
| Balance at<br>December<br>31, 2016  | 1,000,000                    | \$ 10,000                    | 11,032,858                             | \$ 110,329                | \$ 204,239,837                | \$ 3,905  | \$ (193,033,293)       | \$ 11,330,778                    |
| Share<br>rounding<br>adjustment<br>relating to  | -                            | -                            | 6,537                                  | 65                        | (65 )                         | -   | -                      | -                                |



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|  |           |           |            |            |                |          |                 |              |
|--|-----------|-----------|------------|------------|----------------|----------|-----------------|--------------|
| 1:13 reverse stock split   |           |           |            |            |                |          |                 |              |
| Share based payments   | -         | -         | -          | -          | 1,769,964      | -        | -               | 1,769,964    |
| Issuance of common stock and inducement warrants for warrant exercises |           |           | 1,013,464  | 10,134     | 7,801,843      |          |                 | 7,811,977    |
| Issuance of common stock for RSU exercises                             | -         | -         | 4,939      | 49         | (49 )          | -        | -               | -            |
| Issuance of common stock and warrants from capital raises, net         | -         | -         | 3,022,387  | 30,224     | 3,239,443      | -        | -               | 3,269,667    |
| Issuance of restricted stock awards                                    |           |           | 79,829     | 799        | (799 )         |          |                 | -            |
| Foreign currency translation adjustments                               | -         | -         | -          | -          | -              | (1,274)  | -               | (1,274 )     |
| Net loss   |           |           |            |            |                |          | (15,665,983 )   | (15,665,983) |
| Balance at December 31, 2017   | 1,000,000 | \$ 10,000 | 15,160,014 | \$ 151,600 | \$ 217,050,174 | \$ 2,631 | \$(208,699,276) | \$ 8,515,129 |

See accompanying notes to consolidated financial statements

Neuralstem, Inc.

## Consolidated Statements of Cash Flows

|   | For the Year Ended December 31, |                |
|---|---------------------------------|----------------|
|   | 2017                            | 2016           |
| Cash flows from operating activities:   |                                 |                |
| Net loss  | \$(15,665,983)                  | \$(21,074,611) |
| Adjustments to reconcile net loss to cash used in operating activities:                 |                                 |                |
| Depreciation and amortization   | 289,208                         | 337,508        |
| Share based compensation expenses   | 1,769,964                       | 3,445,539      |
| Amortization of deferred financing fees and debt discount                               | 59,781                          | 347,491        |
| Change in fair value of liability classified warrants                                   | 1,470,174                       | (660,253 )     |
| Warrant inducement expense  | 563,744                         | -              |
| Expenses related to issuance of liability classified warrants                           | 242,676                         | 466,541        |
| Loss on disposal of fixed assets  | 8,128                           | 10,284         |
| Changes in operating assets and liabilities:  |                                 |                |
| Trade and other receivables   | (302,311 )                      | 26,825         |
| Related party receivable  | 53,081                          | (477,321 )     |
| Prepaid expenses  | 297,298                         | 513,156        |
| Other assets  | 1,855                           | 55,663         |
| Accounts payable and accrued expenses   | (1,522,917 )                    | 879,076        |
| Accrued bonuses   | (434,338 )                      | 691,601        |
| Other current liabilities   | (230,189 )                      | (21,672 )      |
| Other long term liabilities   | (16,333 )                       | (155,935 )     |
| Net cash used in operating activities   | (13,416,162)                    | (15,616,108)   |
| Cash flows from investing activities:   |                                 |                |
| Purchases of short-term investments   | (5,000,000 )                    | (5,000,000 )   |
| Maturity of short-term investments  | 5,000,000                       | 7,517,453      |
| Patent costs  | (82,645 )                       | (63,026 )      |
| Purchase of property and equipment  | (11,401 )                       | (98,088 )      |
| Net cash provided by investing activities   | (94,046 )                       | 2,356,339      |
| Cash flows from financing activities:   |                                 |                |
| Proceeds from issuance of common stock from warrants exercised, net of issuance costs   | 3,225,176                       | -              |
| Proceeds from sale of common stock, preferred stock and warrants, net of issuance costs | 5,510,840                       | 28,118,962     |
| Payments of long-term debt  | (3,765,568 )                    | (4,569,540 )   |
| Proceeds from short term notes payable  | 346,863                         | 313,483        |
| Payments of short term notes payable  | (326,533 )                      | (124,177 )     |
| Net cash provided by financing activities   | 4,990,778                       | 23,738,728     |
| Effects of exchange rates on cash   | (579 )                          | (543 )         |

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|  |              |               |
|--|--------------|---------------|
| Net increase (decrease) in cash and cash equivalents | (8,520,009 ) | 10,478,416    |
| Cash and cash equivalents, beginning of year         | 15,194,949   | 4,716,533     |
| Cash and cash equivalents, end of year               | \$6,674,940  | \$ 15,194,949 |

See accompanying notes to consolidated financial statements.

**Neuralstem, Inc.**

**Consolidated Statements of Cash Flows**

|  | For the Year Ended<br>December 31, |            |
|--|------------------------------------|------------|
|  | 2017                               | 2016       |
| Supplemental cash flow information:  |                                    |            |
| Cash paid for interest   | \$ 118,257                         | \$ 990,857 |
| 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   |

See accompanying notes to consolidated financial statements.

**NEURALSTEM, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1. Organization and Business and Financial Condition**

Nature of business

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

Neuralstem is a clinical stage biopharmaceutical company that is utilizing its proprietary human neural stem cell technology to create a comprehensive platform of therapies for the treatment of central nervous system diseases. The Company has utilized this technology as a tool for small-molecule drug discovery and to create cell therapy biotherapeutics to treat central nervous system diseases. The Company was founded in 1997 and currently has laboratory and office space in Germantown, Maryland and laboratory facilities in the People’s Republic of China. Our operations to date have 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.

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.

Liquidity and Going Concern

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

In making this assessment the Company performed a comprehensive analysis of its current circumstances including: its financial position at December 31, 2017, its cash flow and cash usage forecasts for the period covering one-year from the issuance date of this Annual Report on Form 10-K, its current capital structure including outstanding warrants and other equity-based instruments.

Our cash, cash equivalents and short-term investments balance at December 31, 2017 was approximately \$11.7 million. On August 1, 2017, we closed a public offering of 3,000,000 shares of common stock and 2,250,000 common stock purchase warrants at a public offering price of \$2.00 per share and accompanying warrant. We received gross proceeds of \$6.0 million and approximately \$5.4 million of net proceeds from this offering.

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 first quarter of 2019. The inability to secure additional capital by such date may raise substantial doubt about our ability to continue as a going concern. Accordingly, we will require additional capital to further develop our pre-clinical and clinical development programs. To continue to fund our operations and the development of our product candidates, we anticipate raising additional cash through the private and public sales of equity or debt securities, collaborative arrangements, licensing agreements or a combination thereof. Although management believes that such funding sources will be available, there can be no assurance that any such collaborative or licensing arrangements will be entered into or that financing will be available to us when needed in order to allow us to continue our operations, or if available, on terms acceptable to us. If we do not raise sufficient 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.

### **Use of Estimates**

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

### Fair Value Measurements

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

### Foreign Currency Translation

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

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

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

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

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

### Revenue



Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. Revenue for upfront payments under our license agreements is recognized over the license period. Revenue for payments related to customer development milestones or sales royalties is recognized when milestones are achieved.

### Research and Development

Research and development costs are expensed as they are incurred. Research and development expenses consist primarily of costs associated with the pre-clinical development and clinical trials of our product candidates. For the year ended December 31, 2017, we recorded approximately \$41,000 of cost reimbursements from our SBIR grant as an offset to research and development expenses.

### Income (Loss) per Common Share

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

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

For all periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses; accordingly, diluted loss per share is the same as basic loss per share for the years ended December 31, 2017 and 2016. A total of approximately 10.2 and 8.7 million potential dilutive shares have been excluded in the calculation of diluted net income per share for the years ended December 31, 2017 and 2016, respectively as their inclusion would be anti-dilutive.

#### Share-Based Compensation

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

#### Intangible and Long-Lived Assets

We assess impairment of our long-lived assets using a "primary asset" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. No significant impairment losses were recognized during the years ended December 31, 2017 or 2016.

#### Income Taxes

We account for income taxes using the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. We also recognize a tax benefit from uncertain tax positions only if it is "more likely than not" that the position is sustainable based on its technical merits. Our policy is to recognize interest and penalties on uncertain tax positions as a component of income tax expense.

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

#### Significant New Accounting Pronouncements

*Recently Adopted Guidance*

In November 2015, the FASB issued *ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes*. This ASU eliminates the requirement for separate presentation of current and non-current portions of deferred tax. Subsequent to adoption, all deferred tax assets and deferred tax liabilities are presented as non-current on the balance sheet. The ASU became effective for us on January 1, 2017 and had no material effect on our consolidated financial statements.

In March 2016, the FASB issued *ASU No. 2016-09, Improvements to Employee Share Based Payment Accounting*. This guidance simplifies the accounting for and financial statement disclosure of share-based compensation awards, consisting of changes in the accounting for excess tax benefits and tax deficiencies, and changes in the accounting for forfeitures associated with share-based awards, among other things. The ASU became effective for us on January 1, 2017. We no longer record estimate forfeitures on share-based awards and, instead, record forfeitures as they occur. This adoption had no material effect on our consolidated financial statements.

*Unadopted Guidance*

In May 2014, the Financial Accounting Standards Board (“FASB”) issued *Accounting Standard Update (“ASU”), No. 2014-09, Revenue from Contracts with Customers*. This ASU consists of a comprehensive revenue recognition standard that will supersede nearly all existing revenue recognition guidance under U.S. GAAP. The issuance of ASU No. 2015-14 in August 2015 delays the effective date of the standard to interim and annual periods beginning after December 15, 2017. Either full retrospective adoption or modified retrospective adoption is permitted. In addition to expanded disclosures regarding revenue, this pronouncement may impact timing of recognition in some arrangements with variable consideration or contracts for the sale of goods or services. During 2017, the Company evaluated its existing revenue arrangements and determined that the adoption of the new guidance will not impact its current revenue recognition policies and will not result in any changes to its consolidated financial statements.

In February 2016, the FASB issued *ASU, No. 2016-02, Leases*. This ASU consists of a comprehensive lease accounting standard. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets. We have not yet begun to evaluate the specific impacts of this guidance.

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

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

In July 2017, the FASB issued *ASU No. 2017-11, I. Accounting for Certain Financial Instrument with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of the ASU simplifies the accounting for certain equity-linked financial instruments and embedded features with down round features that reduce the exercise price when the pricing of a future round of financing is lower (“down round protection”). Current accounting guidance provides that instruments with down round protection be classified as derivative liabilities with changes in fair value recorded through earnings. The updated guidance provides that instruments with down round protection are no longer precluded from being classified as equity. This guidance is effective for fiscal years beginning after December 15, 2018 and early adoption is permitted. This guidance must be applied retrospectively. While the Company has not completed its assessment of the new guidance, adoption may have a material effect to our financial statements resulting from the way we currently account for certain of our equity-linked securities that have down round features.

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

### **Note 3. Fair Value Measurements**

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

*Level 1* – inputs are based upon unadjusted quoted prices for identical instruments traded in active markets.

*Level 2* – inputs are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques (e.g. the Black-Scholes model) for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs including interest rate curves, foreign exchange rates, and forward and spot prices for currencies and commodities.

*Level 3* – inputs are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques, including option pricing models and discounted cash flow models.

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

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

At December 31, 2017 and December 31, 2016, we had certain common stock purchase warrants issued in connection with our May 2016 and August 2017 capital raises (See Note 5) that are accounted for as liabilities whose fair value was determined using Level 3 inputs. The following table identifies the carrying amounts of such liabilities:

|  | Level 1 | Level 2 | Level 3     | Total       |
|--|---------|---------|-------------|-------------|
| <b>Liabilities</b>                           |         |         |             |             |
| Liability classified stock purchase warrants | \$ -    | \$ -    | \$3,921,917 | \$3,921,917 |
| Balance at December 31, 2016                 | \$ -    | \$ -    | \$3,921,917 | \$3,921,917 |
| Liability classified stock purchase warrants | \$ -    | \$ -    | \$3,852,882 | \$3,852,882 |
| Balance at December 31, 2017                 | \$ -    | \$ -    | \$3,852,882 | \$3,852,882 |

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

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

The 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:

|                              | Mark-to-market<br>liabilities -<br>stock purchase<br>warrants |
|------------------------------|---|
| Balance at December 31, 2015 | \$ -  |
| Issuance of warrants         | 4,582,170   |
| Change in fair value - gain  | (660,253 )  |
| Balance at December 31, 2016 | \$ 3,921,917  |

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

**Note 4. Debt**

In October 2014, we entered into an agreement to refinance and amend the terms of our March 2013 loan and security agreement. 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 is classified in equity.

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 4,475 shares at an exercise price of \$34.58 per share. The warrant has terms substantially similar to the lender warrant and is classified as equity.

The amended loan was paid off in its entirety in April 2017, pursuant to its terms.

**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, common stock purchase warrants, or common stock options. Our stock options and stock purchase warrants have lives of up to ten years from the grant date. Awards vest either upon the grant date or over varying periods of time. The stock options provide for exercise prices equal to or greater than the fair value of the common stock at the date of the grant. Restricted stock units grant the holder the right to receive fully paid common shares with various restrictions on the holder's ability to transfer the shares. As of December 31, 2017, we have approximately 6.9 million shares of common stock reserved for issuance upon the exercise 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<br>31, |             |
|-------------------------------------|----------------------------|-------------|
|                                     | 2017                       | 2016        |
| Research and development costs      | \$1,091,036                | \$1,767,732 |
| General and administrative expenses | 678,928                    | 1,677,807   |
| Total                               | \$1,769,964                | \$3,445,539 |

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 whose employment was terminated during the first quarter of 2016. 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.

**Stock Options**

A summary of stock option activity and related information for the year ended December 31, 2017 follows:

|                                | Number of<br>Options | Weighted-Average<br>Exercise Price | Weighted-Average<br>Remaining<br>Contractual Life<br>(in years) | Aggregate<br>Intrinsic<br>Value |
|--------------------------------|----------------------|------------------------------------|---|---------------------------------|
| Outstanding at January 1, 2017 | 1,691,987            | \$ 22.60                           | 5.1   | \$-                             |
| Granted                        | 246,982              | \$ 1.92                            |   |                                 |
| Exercised                      | -                    | -                                  |   |                                 |



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|                                  |           |          |     |           |
|----------------------------------|-----------|----------|-----|-----------|
| Forfeited/Expired                | (44,892 ) | \$ 28.67 |     |           |
| Outstanding at December 31, 2017 | 1,894,077 | \$ 19.76 | 4.7 | \$108,000 |
| Exercisable at December 31, 2017 | 1,576,364 | \$ 22.92 | 3.8 | \$-       |

| Range of<br>Exercise Prices | Number of<br>Options<br>Outstanding | Weighted-Average<br>Exercise Price | Weighted-Average<br>Remaining<br>Contractual Life<br>(in years) | Aggregate<br>Intrinsic<br>Value |
|-----------------------------|-------------------------------------|------------------------------------|---|---------------------------------|
| \$1.00 - \$3.50             | 200,000                             | \$ 1.18                            | 9.8   | \$108,000                       |
| \$3.51 - \$13.00            | 758,917                             | \$ 9.42                            | 6.2   | -                               |
| \$13.01 - \$26.00           | 369,830                             | \$ 15.26                           | 3.9   | -                               |
| \$26.01 - \$39.00           | 147,445                             | \$ 32.46                           | 1.7   | -                               |
| \$39.01 - \$56.00           | 417,885                             | \$ 46.96                           | 1.4   | -                               |
|                             | 1,894,077                           | \$ 19.76                           | 4.7   | \$108,000                       |

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, |       |               |       |
|--------------------------|-------------------------|-------|---------------|-------|
|                          | 2017                    |       | 2016          |       |
| Annual dividend          | -                       |       | -             |       |
| Expected life (in years) | 0.3                     | - 6.5 | 5.8           | - 7.3 |
| Risk free interest rate  | 0.80% - 2.22%           |       | 1.34% - 1.75% |       |
| Expected volatility      | 62.2% - 98.0%           |       | 69.0% - 80.2% |       |

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

Options granted in the years ended December 31, 2017 and 2016 had weighted average grant date fair values of \$1.34 and \$5.18, respectively. The total fair value of the options vested during the years ended December 31, 2017 and 2016 was approximately \$302,000 and \$2,643,000, respectively.

Unrecognized compensation cost for unvested stock option awards outstanding at December 31, 2017 was approximately \$926,000 to be recognized over approximately 1.8 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, 2017 follows:

|                                | Number<br>of RSU's | Weighted-Average<br>Grant Date Fair<br>Value |
|--------------------------------|--------------------|--|
| Outstanding at January 1, 2017 | 6,863              | \$ 30.70                                     |
| Granted                        | 9,311              | \$ 5.37                                      |

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|  |          |          |
|--|----------|----------|
| Exercised and converted to common shares | (4,939 ) | \$ 25.99 |
| Forfeited                                | -        | \$ -     |
| Outstanding at December 31, 2017         | 11,235   | \$ 11.77 |
| Exercisable at December 31, 2017         | 6,580    | \$ 16.30 |

The total fair value of the shares vested during the year ended December 2017, was approximately \$25,000. No RSU's were granted or vested during 2016. The total intrinsic value of the outstanding restricted stock units at December 31, 2017 was approximately \$19,000. The total value of all restricted stock units that were converted in the year ended December 31, 2017 was approximately \$23,000.

### Restricted Stock

We have granted restricted stock to certain board members.

A summary of our restricted stock activity for the year ended December 31, 2017 is as follows:

|                                  | Shares of<br>Restricted<br>Stock | Weighted-Average<br>Grant Date Fair<br>Value |
|----------------------------------|----------------------------------|--|
| Outstanding at January 1, 2017   | -                                | \$ -   |
| Granted                          | 79,829                           | \$ 3.33                                      |
| Vested                           | (29,869 )                        | \$ 3.88                                      |
| Forfeited                        | -                                | \$ -   |
| Outstanding at December 31, 2017 | 49,960                           | \$ 3.00                                      |

The total intrinsic value of the outstanding restricted stock at December 31, 2017 was approximately \$86,000. The total intrinsic value of all restricted stock vested in the year ended December 31, 2017 was approximately \$47,000.

#### Stock Purchase Warrants

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

In May 2016, we issued 1,746,173 common stock purchase warrants in conjunction with our capital raising transactions. Such warrants were classified as liabilities due to the existence of non-standard anti-dilution and certain other conditions contained in the warrants. At December 31, 2017, after giving effect of exercises, 732,709 remain outstanding and are recorded at fair value as mark-to-market liabilities (see Note 3).

In March 2017, we entered into a letter agreement with an investor pursuant to which the investor agreed to exercise certain of their warrants to purchase 692,309 shares of the Company's common stock; such warrants were originally issued on May 6, 2016 in the Company's registered offering and contained a current exercise price of \$3.25 per share. In exchange for and to induce the investor to exercise the warrants, we issued to the investors inducement warrants to purchase 230,771 shares of the Company's common stock.

The inducement warrants are exercisable through March 20, 2018 at an exercise price equal to \$5.80 per share, and contain provisions providing for an adjustment in the underlying number of shares and exercise price in the event of stock splits or dividends, subsequent rights offerings, pro rata distributions, and fundamental transactions. In the event that the shares underlying the inducement warrants are not subject to an effective registration statement at the time of exercise, the inducement warrants may be exercised on a cashless basis at any time after six (6) months from the issuance date. The inducement warrants are classified in equity. The fair value of the inducement warrants of

\$476,084 was expensed as inducement expense in the accompanying consolidated statement of operations for the year ended December 31, 2017.

In April 2017, we executed a similar agreement with a different investor pursuant to which the investor agreed to exercise certain of their stock purchase warrants to purchase 153,847 shares of the Company's common stock; such warrants were originally issued on May 6, 2016 in the Company's registered offering and contained a current exercise price of \$3.25 per share. In exchange for and to induce the investor to exercise the warrants, we issued to the investors an inducement stock purchase warrant to purchase 51,283 shares of the Company common stock at \$5.80 per share (the "Inducement Warrants"). The terms of the Inducement Warrants issued in April 2017 are substantially similar to the terms of the Inducement Warrants issued in March 2017 and are classified in equity. The fair value of the Inducement Warrants of \$87,660 was expensed as inducement expense in the accompanying consolidated statement of operations for the year ended December 31, 2017.

In August 2017, we issued 2,250,000 common stock purchase warrants in conjunction with our capital raise transaction. Such warrants are classified as liabilities due to the existence of certain net cash settlement provisions and certain other conditions contained in the warrants. The warrants are recorded at fair value as mark-to-market liabilities (see Note 3).

A summary of outstanding warrants at December 31, 2017 follows:

| Range of Exercise Prices | Number of Warrants Outstanding | Range of Expiration Dates   |
|--------------------------|--------------------------------|-----------------------------|
| \$2.00 - \$3.90          | 2,994,248                      | May 2021 - August 2024      |
| \$5.79 - \$5.80          | 293,593                        | March 2018 - July 2022      |
| \$12.80- \$12.90         | 39,296                         | January 2022                |
| \$16.20- \$16.30         | 174,544                        | March 2020                  |
| \$18.60- \$19.80         | 12,309                         | March 2018 - June 2018      |
| \$22.10- \$27.90         | 153,755                        | March 2019 - January 2021   |
| \$34.50- \$39.00         | 159,639                        | August 2018 - October 2019  |
| \$39.10- \$39.20         | 230,772                        | October 2020 - October 2021 |
| \$47.30- \$52.20         | 275,897                        | January 2019 - July 2019    |
|                          | 4,334,053                      |                             |

#### Preferred and Common Stock

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

In March and April 2017, we issued 846,156 shares of our common stock upon the exercise of certain outstanding common stock purchase warrants. The warrants were exercised at \$3.25 per share and we received approximately \$2,700,000 in net proceeds. The exercises were pursuant to an inducement agreement entered into with the investors. In conjunction with the exercise we issued certain inducement warrants to the investors. (See "Stock Purchase Warrants" section of Note 5).

In June and July 2017, we issued 167,308 shares of our common stock upon the exercise of certain outstanding common stock purchase warrants. The warrants were exercised at \$3.25 per share and we received approximately \$544,000 in net proceeds.

In August 2017, we completed a public offering of 3,000,000 shares of common stock and 2,250,000 common stock purchase warrants at a public offering price of \$2.00 per each share and common stock purchase warrant. We received aggregate gross proceeds of \$6.0 million and net proceeds of approximately \$5,414,000 from the offering. The warrants allow the holder to purchase one share of common stock, have an exercise price of \$2.00 per share and a term of 7 years. The warrants contain certain cash settlement features and non-standard anti-dilution protection and consequently, are being accounted for as liabilities recorded at fair value each period (See Note 3). The costs directly related to this offering were allocated between the common stock and the liability classified warrants with those being

allocated to the warrants 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 23, 2017 (Registration No. 333-218608).

During the year ended December 31, 2017 we issued 4,939 shares of our common stock upon the conversion of 4,939 outstanding restricted stock units.

## Note 6. Property and Equipment

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

|                                | 2017      | 2016      |
|--------------------------------|-----------|-----------|
| Furniture and fixtures         | \$35,407  | \$35,407  |
| Computers and office equipment | 138,897   | 127,497   |
| Leasehold improvements         | -         | 15,005    |
| Lab equipment                  | 820,507   | 816,419   |
|                                | 994,811   | 994,328   |
| Less accumulated depreciation  | (821,925) | (724,771) |
| Property and equipment, net    | \$172,886 | \$269,557 |

The above includes approximately \$73,000 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, 2017 and 2016, was approximately \$100,000 and \$161,000, 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 9.9 years at December 31, 2017. 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, 2017 and 2016, no significant impairment losses were recognized. The Company's intangible assets and accumulated amortization consisted of the following at December 31, 2017 and 2016:

|                          | 2017        | 2016        |
|--------------------------|-------------|-------------|
| Patent asset             | \$2,028,557 | \$1,950,823 |
| Accumulated amortization | (1,145,095) | (960,670 )  |
| Net intangibles          | \$883,462   | \$990,153   |

Amortization expense for the years ended December 31, 2017 and 2016 was approximately \$189,000 and \$176,000, respectively. The expected average future annual amortization expense over the next five years is approximately \$88,000 based on current balances of our intangible assets.

**Note 8. Income Taxes**

Our provision for income taxes for the years ended December 31, 2017 and 2016 consists of the following:

|                                    | 2017         | 2016        |
|------------------------------------|--------------|-------------|
| Current provision:                 |              |             |
| Federal                            | \$-          | \$-         |
| State                              | -            | -           |
| Foreign                            | -            | -           |
| Total current provision            | -            | -           |
| Deferred provision (benefit):      |              |             |
| Federal                            | (17,837,120) | (5,626,995) |
| State                              | (1,417,482 ) | (1,183,093) |
| Foreign                            | -            | -           |
| Total deferred provision (benefit) | (19,254,602) | (6,810,088) |
| Valuation allowance                | 19,254,602   | 6,810,088   |
| Consolidated income tax provision  | \$-          | \$-         |



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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:

|   | 2017   |    | 2016     |
|---|--------|----|----------|
| Federal statutory rate                      | (34.0  | %) | (34.0 %) |
| State income taxes, net of Federal benefits | (4.1   | %) | (4.2 %)  |
| Stock based compensation                    | 0.2    | %  | 7.6 %    |
| Changes related to 2017 Tax Act             | 155.0  | %  | 0.0 %    |
| Other                                       | 5.8    | %  | (2.6 %)  |
| Valuation allowance                         | (122.9 | %) | 33.2 %   |
| Total                                       | 0.0    | %  | 0.0 %    |

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

|                                    | 2017         | 2016         |
|------------------------------------|--------------|--------------|
| Net operating loss carryforwards   | \$35,610,806 | \$51,249,822 |
| Stock based compensation expense   | 6,764,508    | 10,118,401   |
| Tax credit carryforwards and other | 1,112,286    | 1,373,979    |
|                                    | 43,487,600   | 62,742,202   |
| Valuation allowance                | (43,487,600) | (62,742,202) |
| Net deferred tax assets            | \$-          | \$-          |

The Company had Federal net operating loss (“NOL”) carryforwards of approximately \$146.4 and \$133.6 million at December 31, 2017 and 2016, respectively, which begin expiring in 2018. The Company also has certain Federal tax credit carryforwards that will expire through 2036. The timing and manner in which these net operating loss carryforwards and credits may be used in any year will be limited to the Company’s ability to generate future earnings and also may be limited by certain provisions in the U.S. tax code. The Company has not identified any uncertain tax positions and did not recognize any adjustments for unrecognized tax benefits. The Company remains subject to examination for income tax returns dating back to 2014.

#### *Impact of the Tax Cuts and Jobs Act of 2017*

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

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

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

#### **Note 9. Commitments and Contingencies**

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We currently operate one facility located in the United States and one facility located in China. Our corporate offices and primary research facilities are located in Germantown, Maryland, where we lease approximately 1,500 square feet. This lease provides for monthly payments of approximately \$5,600 per month with the term expiring on December 31, 2018.

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. In May 2017, we ceased-use of this property and recognized a loss of approximately \$92,000 representing the present value of the expected remaining net payments due under such lease and the costs to vacate the property. The loss is included in research and development expense on our statements of operations for the year ended December 31, 2017. We are currently exploring opportunities to sub-lease the unused research space.

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, 2017 are as follows:

| Year                   | Amount    |
|------------------------|-----------|
| 2018                   | 240,000   |
| 2019                   | 97,000    |
| 2020                   | -         |
| 2021                   | -         |
| 2022 and thereafter    | -         |
| Total minimum payments | \$337,000 |

The Company recognized approximately \$161,000 and \$243,000, in rent expense for the years ended December 31, 2017 and 2016, respectively.

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

The Company is currently obligated under two written employment agreements and a general release agreement. The employment agreements are with our: (i) Chief Executive Officer and (ii) Chief Scientific Officer (“CSO”). Pursuant to the terms of the agreements, our CEO and CSO receive annual salaries of \$410,000 and \$500,000, respectively. The agreements also provide for the payment of severance in the event one of the executives is terminated in certain circumstances and also provide for the acceleration of vesting with regard to outstanding equity awards.

On April 30, 2017, we entered into a separation agreement and release (“Agreement”) with our former Chief Financial Officer. Pursuant to the Agreement, the Company will pay an aggregate of \$315,000 payable in twelve equal monthly installments. At December 31, 2017, \$105,000 of payments remain outstanding.

#### **Note 10. 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 is being amortized through interest income using the effective interest method. The principal amount of \$558,000 remains outstanding at December 31, 2017 and is payable in \$100,000 annual installments with a final payment due July 2022.

#### **Note 11. Subsequent Events**

None

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

None

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

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, 2017 to provide reasonable assurance that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

### **Inherent Limitations Over Internal Controls**

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

- (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and
- (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Management, including the Company's principal executive officer 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, 2017 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP.

### **Changes in Internal Control Over Financial Reporting**

There were no changes in the Company's internal control over financial reporting during the fourth quarter of 2017, 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 2018 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for

our 2018 Annual Meeting of Shareholders (“2018 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 2018 Proxy Statement and is incorporated herein by reference.

## **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item is set forth under the headings “Director Compensation” and “Executive Compensation” of our 2018 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 2018 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 2018 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 2018 Proxy Statement and is incorporated herein by reference.

**PART IV****ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**1. Financial Statements:

## 2. Exhibits:

**INDEX TO EXHIBITS**

| Exhibit<br>No.  | Description  | Filed/<br>Furnished<br>Herewith | Incorporated by Reference |                |            |             |
|-----------------|--|---------------------------------|---------------------------|----------------|------------|-------------|
|                 |  |                                 | Form                      | Exhibit<br>No. | File No.   | Filing Date |
| <u>3.01(i)</u>  | Amended and Restated Certificate of Incorporation of Neuralstem, Inc. filed on 1/5/2017      |                                 | 8-K                       | 3.01(i)        | 001-33672  | 1/6/17      |
| <u>3.02(i)</u>  | Certificate of Designation of Series A 4.5% Convertible Preferred Stock                      |                                 | 8-K                       | 3.01           | 001-33672  | 12/12/16    |
| <u>3.03(ii)</u> | Amended and Restated Bylaws of Neuralstem, Inc. adopted on 11/10/2015                        |                                 | 8-K                       | 3.01           | 001-33672  | 11/16/15    |
| <u>4.01**</u>   | Amended and Restated 2005 Stock Plan adopted on 6/28/07                                      |                                 | 10-QSB                    | 4.2(i)         | 333-132923 | 8/14/07     |
| <u>4.02**</u>   | Non-qualified Stock Option Agreement between Neuralstem, Inc. and Richard Garr dated 7/28/05 |                                 | SB-2                      | /A 4.4         | 333-132923 | 6/21/06     |
| <u>4.03**</u>   | Non-qualified Stock Option Agreement between Neuralstem, Inc. and Karl Johe dated 7/28/05    |                                 | SB-2                      | /A 4.5         | 333-132923 | 6/21/06     |
| <u>4.04**</u>   | Neuralstem, Inc. 2007 Stock Plan   |                                 | 10-QSB                    | 4.21           | 333-132923 | 8/14/07     |
| <u>4.05</u>     | Form of Common Stock Purchase Warrant Issued to Karl Johe on 6/5/07                          |                                 | 10-KSB                    | 4.22           | 333-132923 | 3/27/08     |
| <u>4.06</u>     |  |                                 | 8-K                       | 4.1            | 001-33672  | 12/18/08    |



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Form of Placement Agent Warrant Issued to  
Midtown Partners & Company on 12/18/08

|             |  |       |      |                    |
|-------------|--|-------|------|--------------------|
| <u>4.07</u> | Form of Consultant Common Stock Purchase<br>Warrant issued on 1/5/09 | S-3/A | 10.1 | 333-157079 02/3/09 |
|-------------|--|-------|------|--------------------|

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|               |   |         |            |            |         |
|---------------|---|---------|------------|------------|---------|
| <u>4.08</u>   | Form of Series D, E and F Warrants  | 8-K     | 4.01       | 001-33672  | 7/1/09  |
| <u>4.09</u>   | Form of Placement Agent Warrant   | 8-K     | 4.02       | 001-33672  | 7/1/09  |
| <u>4.10</u>   | Form of Consultant Warrant Issued 1/8/10  | 10-K    | 4.20       | 001-33672  | 3/31/10 |
| <u>4.11</u>   | Form of Replacement Warrant Issued 1/29/10  | 10-K    | 4.21       | 001-33672  | 3/31/10 |
| <u>4.12</u>   | 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 |
| <u>4.13</u>   | 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 |
| <u>4.14</u>   | Form of Warrants dated 6/29/10  | 8-K     | 4.01       | 001-33672  | 6/29/10 |
| <u>4.15**</u> | Amended Neuralstem 2010 Equity Compensation Plan adopted on June 22, 2017   | DEF 14A | Appendix I | 001-33672  | 5/1/17  |
| <u>4.16</u>   | Form of Consultant Warrant issued 10/1/09 and 10/1/10   | S-3     | 4.07       | 333-169847 | 10/8/10 |
| <u>4.17**</u> | 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  |
| <u>4.18**</u> | Form of Restricted Stock Unit Agreement   | S-8     | 4.08       | 333-172563 | 3/1/11  |
| <u>4.19</u>   | Form of Common Stock Purchase Warrant issued pursuant to February 2012 registered offering                                      | 8-K     | 4.01       | 001-33672  | 2/8/12  |
| <u>4.20</u>   | 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  |
| <u>4.21</u>   | Form of Underwriter Warrant issued to Aegis Capital Corp. on 8/20/12  | 8-K     | 4.1        | 001-33672  | 8/17/12 |

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|               |  |      |      |            |          |
|---------------|--|------|------|------------|----------|
| <u>4.22</u>   | Form of Placement Agent Warrant issued to Aegis Capital Corp. on 9/13/12                                     | 8-K  | 4.1  | 001-33672  | 9/19/12  |
| <u>4.23</u>   | 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) |      |      |            |          |
| <u>4.24</u>   | Form of Lender Warrant issued March 22, 2013   | 8-K  | 4.01 | 001-33672  | 3/27/13  |
| <u>4.25</u>   | Form of Advisor Warrant issued March 22, 2013  | 8-K  | 4.02 | 001-33672  | 3/27/13  |
| <u>4.26</u>   | Form of Warrant issued June of 2013 and July of 2014 to Legal Counsel  | 10-Q | 4.26 | 001-33672  | 8/8/13   |
| <u>4.27</u>   | Form of Warrant issued in September 2013 in connection with Issuer's registered direct offering              | 8-K  | 4.01 | 011-33672  | 9/10/13  |
| <u>4.28</u>   | Form of Warrant issued to strategic advisor in August 2013   | 10-Q | 4.28 | 001-33672  | 11/12/13 |
| <u>4.29</u>   | Form of Investor Warrant issued January 2014   | 8-K  | 4.01 | 001-33672  | 1/6/14   |
| <u>4.30</u>   | Form of Lender Warrant Issued October 28, 2014   | 8-K  | 4.01 | 001-33672  | 10/29/14 |
| <u>4.31**</u> | Inducement Stock Option Plan adopted 2/15/2016   | 8-K  | 4.01 | 001-33672  | 2/19/16  |
| <u>4.32**</u> | Form of Inducement Award Non-Qualified Stock Option Grant pursuant to Inducement Stock Option Plan           | 8-K  | 4.02 | 001-33672  | 2/19/16  |
| <u>4.33</u>   | Form of Common Stock Purchase Warrant From May 2016 Public Offering dated May 6, 2016                        | 8-K  | 4.01 | 001-33672  | 5/4/16   |
| <u>4.34</u>   | Form of Common Stock Purchase Warrant from May 2016 Private Offering Dated May 12, 2016                      | 8-K  | 4.01 | 001-33672  | 5/13/16  |
| <u>4.35</u>   | Form of Series A Preferred Stock Certificate   | 8-K  | 4.01 | 001-33672  | 9/12/16  |
| <u>4.36</u>   | Form of Inducement Warrant issued March 20, 2017 and March 31, 2017  | 8-K  | 4.01 | 001-33672  | 3/20/17  |

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|                |   |        |       |            |         |
|----------------|---|--------|-------|------------|---------|
| <u>4.37</u>    | Form of Common Stock Purchase Warrant from August 2017 Public Offering Dated August 1, 2017                                     | 8-K    | 4.01  | 001-33672  | 7/28/17 |
| <u>10.01**</u> | Employment Agreement with I. Richard Garr dated January 1, 2007 and amended as of November 1, 2005                              | SB-2/A | 10.1  | 333-132923 | 6/21/06 |
| <u>10.02**</u> | Amended terms to the Employment Agreement of I Richard Garr dated January 1, 2008   | 10-K   | 10.02 | 001-33672  | 3/31/09 |
| <u>10.03**</u> | Amended terms to the employment Agreement of I. Richard Garr dated March 1, 2015  | 8-K    | 10.01 | 001-33672  | 3/2/15  |
| <u>10.04**</u> | 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 |
| <u>10.05**</u> | Amended terms to the Employment Agreement of Karl Johe dated January 1, 2009  | 10-K   | 10.04 | 001-33672  | 3/31/09 |
| <u>10.06**</u> | Employment Agreement with Thomas Hazel, Ph.D dated August 11, 2008  | 10-K/A | 10.05 | 001-33672  | 10/5/10 |
| <u>10.07**</u> | Employment Agreement with Richard Daly dated February 15, 2016  | 8-K    | 10.01 | 001-33672  | 2/19/16 |
| <u>10.08</u>   | 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 |
| <u>10.09**</u> | Renewal of I. Richard Garr Employment Agreement dated 7/25/12   | 8-K    | 10.01 | 001-33672  | 7/27/12 |
| <u>10.10**</u> | Renewal of Dr. Karl Johe Employment Agreement dated 7/25/12   | 8-K    | 10.02 | 001-33672  | 7/27/12 |
| <u>10.11**</u> | Renewal of Dr. Tom Hazel Employment Agreement dated 7/25/12   | 8-K    | 10.03 | 001-33672  | 7/27/12 |
| <u>10.12**</u> | Amendment of terms of Karl Johe Employment Agreement dated 9/17/14  | 8-K    | 10.01 | 001-33672  | 9/18/14 |
| <u>10.13</u>   | Loan and Security Agreement dated March 2013  | 8-K    | 10.01 | 001-33672  | 3/27/13 |

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|                |  |      |       |            |          |
|----------------|--|------|-------|------------|----------|
| <u>10.14</u>   | Intellectual Property and Security Agreement dated March 2013  | 8-K  | 10.02 | 001-33672  | 3/27/13  |
| <u>10.15</u>   | At the Market Offering Agreement entered into on October 25, 2013  | 8-K  | 10.01 | 001-33672  | 10/25/13 |
| <u>10.16**</u> | Form of Amendment to Karl Johe Employment Agreement  | 8-K  | 10.01 | 001-33672  | 9/18/14  |
| <u>10.17</u>   | 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 |
| <u>10.18**</u> | Offer Letter Between Neuralstem, Inc. and Jonathan Lloyd Jones   | 8-K  | 10.01 | 001-33672  | 5/11/15  |
| <u>10.19**</u> | General Release and Waiver of Claims with I. Richard Garr dated 3/2/2016   | 8-K  | 10.01 | 001-33672  | 3/4/16   |
| <u>10.20</u>   | Form of Securities Purchase Agreement from May 2016 Private Offering   | 8-K  | 10.01 | 001-33672  | 5/13/16  |
| <u>10.21**</u> | 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  |
| <u>10.22</u>   | Form of Securities Purchase Agreement between Issuer and Tianjin Pharmaceuticals Holdings, Ltd.  | 8-K  | 10.01 | 001-33672  | 9/12/16  |
| <u>10.23**</u> | Form of Securities Purchase Agreement between Issuer and Jonathan Lloyd Jones  | 10-Q | 10.22 | 001-33672  | 11/8/16  |
| <u>10.24</u>   | Form of Securities Purchase Agreement between Issuer and Richard Daly  | 10-Q | 10.23 | 001-33672  | 11/8/16  |
| <u>10.25</u>   | Form of Letter Agreement for Warrant Exercises on March 20, 2017 and March 30, 2017  | 8-K  | 10.01 | 001-33672  | 3/20/17  |
| <u>10.26**</u> | Form of Separation Agreement and Release with Jonathan Lloyd Jones dated April 30, 2017  | 8-K  | 10.01 | 001-33672  | 5/4/17   |
| <u>14.01</u>   | Neuralstem Code of Ethics and Conduct  | *    |       |            |          |
| <u>14.02</u>   | Neuralstem Financial Code of Professional Conduct adopted May 16, 2007   | 8-K  | 14.2  | 333-132923 | 6/6/07   |
| <u>21.02</u>   | Subsidiaries of Registrant   | 10-K | 21.01 | 001-33672  | 3/10/14  |
| <u>23.01</u>   | Consent of Dixon, Hughes, Goodman LLP  | *    |       |            |          |
| <u>31.1</u>    | Certification of the Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | *    |       |            |          |



32.1 Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. § 1350 \*

101.INS XBRL Instance Document \*

101.SCH XBRL Taxonomy Extension Schema \*

101.CAL XBRL Taxonomy Extension Calculation Linkbase \*

101.DEF XBRL Taxonomy Extension Definition Linkbase \*

101.LAB XBRL Taxonomy Extension Label Linkbase \*

101.PRE XBRL Taxonomy Extension Presentation Linkbase \*

\* *Filed herein*

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

## ITEM 16. FORM 10-K SUMMARY

None

## SIGNATURES

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

NEURALSTEM, INC

Dated: April 2, 2018 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          |
|---|--|---------------|
| <u>/s/ Richard J. Daly</u><br>Richard Daly        | President, Chief Executive Officer, and Director (Principal executive officer) | April 2, 2018 |
| <u>/s/ William Oldaker</u><br>William Oldaker     | Director   | April 2, 2018 |
| <u>/s/ Xi Chen</u><br>Xi Chen                     | Director   | April 2, 2018 |
| <u>/s/ Cristina Csimma</u><br>Cristina Csimma     | Director   | April 2, 2018 |
| <u>/s/ Scott V. Ogilvie</u><br>Scott V. Ogilvie   | Director   | April 2, 2018 |
| <u>/s/ Sandford D. Smith</u><br>Sandford D. Smith | Director   | April 2, 2018 |
| <u>/s/ Stanley Westreich</u><br>Stanley Westreich | Director   | April 2, 2018 |



