Neuralstem, Inc.
Form 10-K
March 14, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015.

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to_____.

Commission File Number 001-33672

NEURALSTEM, INC.

(Exact name of registrant as specified in its charter)

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

Germantown, Maryland
(Address of principal executive offices) (Zip Code)

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

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

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

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

None

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer o		Accelerated filer x
Non-accelerated filer o	(Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). ¨ Yes x 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 $168,902,179.

The number of shares outstanding of Registrant’s common stock, $0.01 par value at March 1, 2016 was **92,044,042**.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement relating to its 2016 annual meeting of shareholders (the “2016 Proxy Statement”) are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2016 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, 2015

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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 related notes included herein. 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.

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, 2015), unless another date is specified.

ITEM 1. BUSINESS

Overview

We are focused on the research, development and commercialization of central nervous system therapies based on our proprietary human neuronal stem cells and our stem-cell derived small molecule compounds. We are headquartered in Germantown, Maryland and have a wholly-owned subsidiary in China, Suzhou Neuralstem Biopharmaceutical Co. Ltd., or Neuralstem China.

Our technology base has produced three primary assets: Our NSI-189 small molecule program, our NSI-566 stem cell therapy program and our novel and proprietary new chemical entity screening platform.

Our patented technology enables the commercial-scale production of multiple types of central nervous system stem cells, which are under development for the potential treatment of central nervous system diseases and conditions. In addition, this ability to generate human neural stem cell lines provides a platform for chemical screening and discovery of novel compounds that Neuralstem believes may stimulate the brain's capacity to generate neurons, potentially reversing pathologies associated with certain central nervous system (CNS) conditions. This proprietary screening platform led to the discovery of NSI-189.

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license one hundred fourteen (114) U.S. and foreign issued patents and forty-seven (47) U.S. and foreign patent applications in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds. At times we have licensed the use of our intellectual property to third parties.

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

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

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

Clinical Programs

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

In January, 2016, we announced a strategic refocusing to concentrate the Company's resources on the NSI-189 small molecule program. As part of this refocusing, the Company announced that it will seek external funding to defray all, or substantially all, of the costs associated with the NSI-566 stem cell therapy program. The Company is in active conversations with a number of sources of funding to achieve this goal and minimize any delay in progressing our stem cell therapy programs.

NSI - 189 (Small Molecule Pharmaceutical Compound).

Major Depressive Disorder (MDD)

Major depressive disorder, or MDD (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. NSI-189 is being developed for the treatment of major depressive disorder and other psychiatric and/or cognitive impairment indications associated with hippocampal atrophy. NSI-189 is the lead compound in our neurogenic small molecule drug platform. We believe that NSI-189 may provide an effective treatment for patients suffering from MDD by promoting synaptogenesis or neurogenesis in the hippocampus.

In February of 2011, we commenced a Phase I clinical trial (Phase Ia portion), NSI-189, at California Clinical Trials, LLC, in Glendale, California. The purpose of the Phase Ia portion of the trial was to evaluate the safety of the drug in healthy volunteers. The Phase Ia portion tested a single oral administration of NSI-189 in 24 healthy volunteers and was completed in October of 2011.

In December of 2011, we received authorization from the FDA to commence the Phase Ib randomized, dose-escalating, placebo controlled clinical trial for the treatment of MDD. The purpose of the Phase Ib portion of the clinical trial was to determine the drug safety and tolerability in three dosages in diagnosed MDD patients. The Phase Ib portion consisted of patients with MDD receiving daily doses for 28 consecutive days with an eight week observation period. The trial was completed in November 2013 and met its primary endpoints of safety and tolerability and showed a promising reduction in depressive and cognitive symptoms across the secondary, explorative endpoints.

In September, 2015 we filed the regulatory and clinical protocol with the Food and Drug Administration (FDA) for a Phase II, multi-site clinical trial in approximately 220 patients. In late February, Neuralstem received the Food and Drug Administration (FDA) approval for the Phase II clinical trial which is expected to enroll the first subject in Q2 of 2016.

In February 2016, the Company received approval from the FDA to commence its Phase 2 Major Depressive Disorder (MDD) trial.

Second Study:

We are exploring the expansion of the NSI-189 program to include a second short-term study. The Company will provide an update in 2016.

NSI - 566 (Stem Cells).

Amyotrophic Lateral Sclerosis (ALS)

Amyotrophic lateral sclerosis, or ALS, is a disease of the nerve cells in the brain and spinal cord that control voluntary muscle movement. In ALS, nerve cells (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. The condition slowly gets worse. When the muscles in the chest area stop working, it becomes hard or impossible to breathe. NSI-566 is under development as a potential treatment for ALS by providing cells designed to nurture and protect the patients' remaining motor neurons; and possibly repair some motor neurons which have not yet died but which are diseased. Neuralstem received orphan designation by the FDA for NSI-566 in ALS.

In January 2010, we commenced the Phase I trial of NSI-566 in ALS at Emory University in Atlanta Georgia. The purpose of the Phase I trial was to evaluate the safety and transplantation technique of our proposed treatment and procedure. The dosing of patients in the Phase I trial, as designed, was completed in August of 2012. We commenced our Phase II clinical trial for ALS in September of 2013. The Phase II dose escalation trial enrolled 15 ambulatory patients in five different dosing cohorts, under an accelerated dosing and treatment schedule. Each patient in the final cohort had two transplants, for a total of 18 surgeries. We have now completed all of the transplantations. The observation period of six months after the last surgery concluded in January 2015. The Phase II 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. In September 2015, nine-month Phase II and combined Phase I and Phase II data on the NSI-566 trial in amyotrophic lateral sclerosis (ALS) was presented at the American Neurological Association Meeting by principal investigator Eva Feldman, MD, PhD, Director of the A. Alfred Taubman Medical Research Institute and Director of Research of the ALS Clinic at the University of Michigan Health. The Company is in discussion with the FDA for planning of a larger registration directed, controlled trial.

In January, 2016, the Company announced that it is in discussions with various governmental, state and non-profit organizations regarding funding grants for a registration directed, controlled trial and that initiation of such a trial would, in part, be dependent upon significant funding from such sources. To date, substantially all of the clinical costs of ALS studies undertaken by the Company have been funded by such grants.

Chronic Spinal Cord Injury

A 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. Chronic spinal cord injury refers to the time after the initial hospitalization. Spinal cord injuries 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 penetrations such as stab or gunshot wounds. In certain instances, SCIs can also be of a non-traumatic origin, as in the case of cancer, infection, intervertebral disc disease, vertebral injury and spinal cord vascular disease. We believe that NSI-566 may provide an effective treatment for chronic spinal cord injury by "bridging the gap" in the spinal cord circuitry created in traumatic spinal cord injury and providing new cells to help transmit the signal from the brain to points at or below the point of injury.

During the first quarter of 2013, we received authorization from the United States Food and Drug Administration, or FDA, to commence our proposed Phase I clinical trial to treat chronic spinal cord injury. The entire trial will take place at The University of California, San Diego. The trial commenced during the third quarter of 2014 and the first subject was treated in October 2014. The study enrolled four AIS A thoracic-spinal cord injury subjects (motor and sensory complete), one-to-two years post-injury at the time of stem cell treatment. In January, 2016 we reported six month follow-up data on all four subjects. The stem cell treatment demonstrated feasibility and safety; there were no serious adverse events. A self-reported ability to contract some muscles below the level of injury was confirmed via clinical and electrophysiological follow-up examinations in one of the four subjects treated. There was no change in the clinical status of the three other subjects.

To date, substantially all of the clinical costs of this study have been funded by grants arranged through the University of California, San Diego (UCSD).

Motor Deficits Due to Ischemic Stroke

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

In the fourth quarter of 2013 the Company commenced a human clinical trial for treatment of motor deficits due to ischemic stroke. The trial is being conducted by Neuralstem China, at BaYi Brain Hospital in Beijing, China utilizing our spinal cord stem cells. The trial authorization encompasses a combined phase I/II/III design and will test direct injections of NSI-566 into the brain. The Phase I portion of the trial is designed to confirm the maximum safe tolerated dose. To date, we have completed dosing the second of three planned cohorts.

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

Markets

The table below summarizes the potential United States patient populations by indication, for our proposed stem cell and small molecule products:

Medical Condition	**Estimated Number of Patients in United States**	
Small molecule compounds		
Major Depressive Disorder	14.8 million	(1)
Stem cells		
ALS	20,000	(2)
Alzheimer's Disease	5.3 million	(3)
Spinal Cord Injury	240,000 – 337,000	(4)
Stroke	6.5 million	(5)

(1) Anxiety and Depression Association of America (ADAA), website: http://www.adaa.org/about-adaa/press-room/facts-statistics retrieved March 2016

(2) The ALS Association (ALSA), website: http://www.alsa.org/about-als/facts-you-should-know.html retrieved March 2016

(3) Alzheimer's Association (AA), The 2015 Alzheimer's Disease Facts and Figures, website: https://www.alz.org/facts/downloads/facts_figures_2015.pdf retrieved March 2016

(4) National Spinal Cord Injury Statistical Center, Facts and Figures at a Glance. Birmingham, AL: University of Alabama at Birmingham, website: https://www.nscisc.uab.edu/Public/Facts%202015.pdf retrieved March 2016

(5) National Stroke Association (NSA), website: retrieved March 2016 from www.stroke.org **Technology**

Stem Cells.

Our technology enables the isolation and large-scale expansion of regionally specific, human neural stem cells from all areas of the developing human brain and spinal cord, thus enabling the generation of physiologically relevant human neurons of all types. We believe that our stem cell technology will assist the body in producing new cells to replace malfunctioning or dead cells as a way to treat disease and injury. Many significant and currently untreatable human diseases arise from the loss or malfunction of specific cell types in the body. Our focus is the development of effective methods to generate replacement cells from neural stem cells. We believe that replacing damaged, malfunctioning or dead neural cells with fully functional ones may be a useful therapeutic strategy in treating many diseases and conditions of the central nervous system. We own or exclusively license fifty-two (52) and foreign issued patents and thirty-three (33) U.S. and foreign patent applications related to our stem cell technologies.

Small Molecule Pharmaceutical Compounds.

Utilizing our proprietary stem cell derived, screening capability, we have developed and patented a series of small molecule compounds. We believe the low molecular weight organic compounds can efficiently cross the blood/brain barrier. In mice, research indicated that the small molecule compounds both stimulate neurogenesis of the hippocampus and increase its volume. Our collaborators at Massachusetts General Hospital have presented the human data from the MDD trial which showed clinically meaningful and statistically significant improvement in depressive and cognitive scales. We believe the small molecule compounds may assist promoting synaptogenesis or neurogenesis in the human hippocampus documented in indications such as MDD.

Our small molecule compounds are covered by sixty-two (62) exclusively owned U.S. and foreign issued patents and fourteen (14) exclusively owned U.S. and foreign patent applications related to our small molecule compounds.

Research

Substantial resources are devoted to our research programs in order to isolate and develop a series of neural stem cell banks that we believe can serve as a basis for our therapeutic product candidates. Our efforts are directed at developing therapies utilizing our stem cells and small molecule regenerative drug candidates. This research is conducted internally, through the use of third party laboratories and consulting companies under our direct supervision, and through collaboration with academic institutes.

Manufacturing

We currently manufacture our cells both in-house and on an outsourced basis. We outsource the manufacturing of our pharmaceutical compounds to third party manufacturers. We manufacture, in-house, cells that are not required to meet stringent FDA requirements. We use these cells in our research and collaborative programs. During 2015, we are began the process of bringing the manufacturing of our spinal cord stem cells, in-house. We believe this will better assure the availability of our stem cells and to also lead to a reduction in per patient manufacturing costs.

Intellectual Property

Our research and development is supported by our intellectual property. We own or exclusively license one hundred fourteen (114) U.S. and foreign issued patents and forty-seven (47) U.S. and foreign patent applications in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds. Our issued patents have expiration dates ranging from 2016 through 2034. In our opinion the patents expiring in 2016 are not critical to our business.

Our success will likely depend upon our ability to preserve our technologies and operate without infringing the proprietary rights of other parties. However, we may rely on certain proprietary technologies and know-how that are not patentable. We protect our proprietary information, in part, by the use of confidentiality agreements with our employees, consultants and certain of our contractors.

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

In addition to patenting our technologies, we also rely upon trade-secret protection for our confidential and proprietary information and take active measures to control access to that information.

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

consultants, the agreements generally provide that all inventions conceived by the individual or entity in the course of rendering services to us shall be our exclusive property.

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

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

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

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

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multinational pharmaceutical companies, specialty biotechnology

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

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

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

Government Regulation

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

United States Product Development Process

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

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

- Completion of preclinical testing of new pharmaceutical or biological products, generally conducted in the laboratory and in animal studies in accordance with 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 IND application, which must become effective before clinical testing in humans can begin;
- Performance of adequate and well-controlled human clinical trials according to cGMPs and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the product candidate for its intended use;
- Submission to the FDA of a biological license application, or BLA, for any biologic or a new drug application, or NDA, for any new chemical entity drug we seek to market that includes substantive evidence of safety, purity, and

potency, or safety and effectiveness from results of nonclinical testing and clinical trials;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced, packaged and distributed, to assess compliance with cGMPs, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity, and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- Potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA or NDA; and
- FDA review and approval of the NDA, or licensure, of the BLA.

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

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

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

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

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

United States Review and Approval Process

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

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

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

United States Post-Approval Requirements

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

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

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

European, China and Other Regulatory Review and Approval

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

Other Health Care Laws

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

Other Regulations

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

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

Executive Officers

The following sets forth our current executive officers and information concerning their age and background:

Name	Position	Age	Position Since
Richard J. Daly	Chief Executive Officer, President,	54	2016
Karl Johe, Ph.D.	Chief Scientific Officer	55	1996
Jonathan Lloyd Jones	Chief Financial Officer	55	2015

Mr. Richard J. Daly, age 54, has been Chief Executive Officer, President and a director since February of 2016. Mr. Daly has over 25 years of commercial pharmaceutical experience working in positions of progressive responsibility in sales, marketing and operations. From November 2015 until February 2016, Mr. Daly was a managing partner at

Ravine Rock Partners, LLC, a bio-pharmaceutical consulting company. Prior to that, from August 2013 until November 2014, Mr. Daly was the President of U.S. Diabetes, a subsidiary of AstraZeneca Pharmaceutical LP. From October 2011 until November 2012, Mr. Daly was a founding partner, board member and investor in SagePath Partners LLC, a commercial outsourcing provider to the pharmaceutical industry. Between July 2008 and October 2011, Mr. Daly was executive vice president of North and South America for Takeda NA, the north American subsidiary of Takeda Pharmaceuticals (TSE: TYO). Since June 2015, Mr. Daly has served on the board of directors and on the Compensation and Commercial Committees for Synergy Pharmaceuticals (NASDAQ: SGYP). Since February 2015, Mr. Daly has also served on the board of directors and on the Compensation Committee of Catalyst Pharmaceuticals (NASDAQ: CPRX). Mr. Daly holds a BS in Microbiology from The University of Notre Dame and an MBA from Northwestern University's Kellogg Graduate School of Management. In evaluating Mr. Daly's specific experience, qualifications, attributes and skills in connection with his appointment to our board, we took into account his prior work with both public and private organizations, including his experience in building biopharmaceutical organizations, his strong business development background and his past experience and relationships in the biopharma and biotech fields.

Dr. Karl Johe, Ph.D., age 55***,*** has been a director, Chairman of the Board and our Chief Scientific Officer since 1996. Dr. Johe has over 15 years of research and laboratory experience. Dr. Johe is the sole inventor of Neuralstem's granted stem cell patents and is responsible for the strategic planning and development of our therapeutic products. Dr. Johe received his Bachelor of Arts Degree in Chemistry and a Master's Degree from the University of Kansas. Dr. Johe received his doctorate from the Albert Einstein College of Medicine of Yeshiva University. From 1993 to January 1997, Dr. Johe served as a Staff Scientist at the Laboratory of Molecular Biology of the National Institute of Neurological Disease and Stroke in Bethesda, Maryland. While holding this position, Dr. Johe conducted research on the isolation of neural stem cells, the elucidation of mechanisms directing cell type specification of central nervous system stem cells and the establishment of an in vitro model of mammalian neurogenesis. In evaluating Dr. Johe's specific experience, qualifications, attributes and skills in connection with his appointment to our board, we took into account his extensive experience in international science and business communities. Dr. Johe is also multilingual.

Mr. Jonathan Lloyd Jones, ACA, MBA, age 55***,*** has been our Chief Financial Officer since May of 2015. Mr. Lloyd Jones has over 30 years of experience in finance and corporate development. Mr. Lloyd Jones was previously the Chief Financial Officer of Juniper Pharmaceuticals, Inc. (formerly Columbia Pharmaceuticals) (NASDAQ: JNP) from 2013 to 2014 and served as the Chief Financial Officer and Vice President of Corporate Development at TetraLogic Pharmaceuticals, Inc. (NASDAQ: TLOG) from 2011 to 2012. Prior to that, Mr. Lloyd Jones served as an independent consultant for bio-tech companies from 2010 to 2011. Mr. Lloyd Jones served as Vice President, Finance for TransMolecular, Inc., a privately held bio-tech company from 2006 to 2010. From 1996 to 2006, Mr. Lloyd Jones held positions of increasing seniority at Genzyme, Inc. (now Sanofi-Aventis) (NYSE: ADR) most recently, as Senior Director of Corporate Development. Mr. Lloyd Jones is a member of the Institute of Chartered Accountants in England & Wales. He received his bachelor of science in business studies from the University of Bradford in England (1981), and a master of business administration with a dual major in strategic management and finance from The Wharton School of the University of Pennsylvania.

Employees

As of January 31, 2016, we had thirty three (33) full-time employees. Of these full-time employees, twenty five (25) work on research and development and clinical operations eight (8) 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.

In addition to announcing material financial information through our investor relations website, press releases, SEC filings and public conference calls and webcasts, we also intend to use the following social media channels as a means of disclosing information about the company, its services and other matters and for complying with our disclosure obligations under Regulation FD:

· Neuralstem’s Twitter Account (https://twitter.com/Neuralstem_Inc)

· Neuralstem’s Facebook Page (https://www.facebook.com/Neuralstem)

· Neuralstem's Company Blog (http://neuralstem.com/neuralstem-ceo-blog)

· Neuralstem's Google+ Page (https://plus.google.com/u/0/b/104875574397171789280/104875574397171789280/posts)

· Neuralstem's LinkedIn Company Page (http://www.linkedin.com/company/neuralstem-inc-)

· Neuralstem Asia's Tencent Weibo Account (http://t.qq.com/neuralstem)

The information we post through these social media channels may be deemed material. Accordingly, investors should monitor these accounts and the blog, in addition to following the company's press releases, SEC filings and public conference calls and webcasts. This list may be updated from time to time.

We have not incorporated by reference into this report the information in, or that can be accessed through, our website or social media channels, 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 may not be able to continue as a going concern if we do not obtain additional financing by June 2016.

The Company has incurred losses since its inception and has not demonstrated an ability to generate revenues from sales or services. These factors create substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern.

The ability of the Company to continue as a going concern is dependent on generating cash from the sale of its common stock and/or obtaining debt financing.

Our cash and cash equivalents balance at December 31, 2015 was approximately $12,234,000. Based on our current expected level of operating expenditures, we expect to be able to fund our operations for the next five to six months from that date. Our ability to continue as a going concern is wholly dependent upon obtaining sufficient financing to fund our operations. Management has discussed various financing options with financial institutions and believes that it will receive cash adequate to fund operations through December 31, 2016 however, there can be no assurance the Company will be successful in these efforts.

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

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

Our auditors' report on our December 31, 2015 financial statements expressed an opinion that our capital resources as of the date of their Audit Report were not sufficient to sustain operations or complete our planned activities for the upcoming year unless we raised additional funds. Accordingly, our current cash level raises substantial doubt about our ability to continue as a going concern past June 2016. If we do not obtain additional funds by such time, we may no longer be able to continue as a going concern and will cease operation which means that our shareholders may lose their entire investment.

Risks Relating to Our Stage of Development and Capital Structure

We have a history of losses.

Since inception in 1996 and through December 31, 2015, we have accumulated losses totaling approximately $171,959,000. On December 31, 2015, we had a working capital surplus of approximately $7,006,000 and stockholders' equity of approximately $4,967,000. Our net losses for the three most recent fiscal years have been approximately $20,904,000, $22,629,000, and $19,832,000 for 2015, 2014, and 2013, respectively. Although from 2013 through 2015 we recognized revenue as a result of us providing subcontractor services and the licensing of our intellectual property, 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, 2015, we had cash, cash equivalents and short-term investments on hand of approximately $12,234,000. 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 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 will need to raise additional capital to pay our indebtedness as it comes due.

We have a substantial level of debt. As of December 31, 2015, we had approximately $8,335,000 in aggregate principal amount long-term indebtedness outstanding. Under our amended loan and security agreement, we were required to make monthly interest only payments through September 2015; and are required to make monthly interest and principal payments of approximately $435,000 per month from October 2015 through March 2017 and make a balloon payment for the remaining principal in April 2017. As security for such indebtedness, we have pledged substantially all of our assets, including our intellectual property. If we are unable to make the required payments, or if we fail to comply with the various requirements and covenants of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity and require immediate repayment and lead to potential foreclosure on the assets securing the debt. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition. Additionally, our amended loan and security agreement governing our $10 million loan also contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and limitations on waivers and amendments to certain agreements, our organizational documents, and documents relating to debt that is subordinate to our obligations under the credit facility. Our failure to comply with the covenants in the amended loan and security agreement could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt and potential foreclosure on the assets securing the debt. If we are unable to refinance or repay our indebtedness as it becomes due, including upon an event of default, we may become insolvent and be unable to continue operations.

Risks Relating to Our Business

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

Our business is significantly dependent on our product candidates which are currently at different phases of pre-clinical and clinical development. The process to approve our product candidates is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If we are not successful in developing our product candidates, we will have invest 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. 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, $19,000, and $110,000 for the years ended December 31, 2015, 2014, and 2013, 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 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 therapy is experimental, highly invasive and is required to be performed by highly experienced neurosurgeons who have received special training. We cannot guarantee consistent and safe performance of the device or the surgical procedure. A surgery related adverse event may result in a clinical hold and may have long-term and damaging effects on our ability to complete development of the stem cell therapy programs, including the completion of any ongoing or planned clinical trials. Even if one or more of our programs is successful and receives marketing approval from a regulatory authority, due to the specialized nature of the device and surgical procedure, there may not be sufficient train surgeons to administer our therapy.

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

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

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

Our inability to manufacture and store our stem cells in-house that are used in our products 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. Additionally, as part of our business plan, we are developing in-house manufacturing capabilities but there can be no assurance that such capabilities will be successfully developed or if developed, be sufficient to meet our demands. And delays in the development of such in-house manufacturing capabilities could adversely affect our plans.

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

We are currently in clinical trials for NSI-566 and NSI-189, two of our proposed products, with regard to multiple indications. Although we have commenced a number of trials, the ultimate outcome of the trials is uncertain. If we are unable to satisfactorily complete such trials, or if such trials yield unsatisfactory results, we may be unable to obtain regulatory approval for and commercialize our proposed products. No assurances can be given that our clinical trials will be completed or result in successful outcomes. A number of events, including any of the following, could delay the completion of our planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

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

- failure of our third-party contractors to meet their contractual obligations to us in a timely manner.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, 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.

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

Our research and development expenses are subject to uncertainty.

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

- competition from companies that have substantially greater assets and financial resources than we have;

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

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

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

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

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

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

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

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

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

The manufacturing of stem cell-based therapeutic products is novel and dependent upon specialized key materials.

The manufacturing of stem cell-based therapeutic products is a complicated and difficult process, dependent upon substantial know-how and subject to the need for continual process improvements. We depend almost exclusively on third party manufacturers to supply our cells. In addition, our suppliers' ability to scale-up manufacturing to satisfy the various requirements of our planned clinical trials is uncertain. Manufacturing irregularities or lapses in quality control could have a material adverse effect on our business. 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.

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

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

We may not be able to obtain necessary licenses to third-party patents and other rights.

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

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

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

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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 key employees and consultants for our continued operations and future success.

We are highly dependent on our chief executive officer, chief scientific officer 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 these key employees or consultants could adversely affect our opportunities and materially harm our future prospects. In addition, we anticipate growth and expansion into areas and activities requiring additional expertise, such as clinical testing, regulatory compliance, manufacturing and marketing. We anticipate the need for additional management personnel as well as the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our present and planned activities, and there can be no assurance that we will be able to attract and retain the qualified personnel necessary for the development our business.

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

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

Our competition has significantly greater experience and financial resources.

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

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

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

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

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

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

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

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 pre-clinical and clinical works, and which are subject to higher FDA requirements, to Charles River Laboratories, Inc., of Wilmington,

Massachusetts (stem cells) and Albany Molecular Resources, Inc. (small molecule). Failure by our contract manufacturer to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously hurt our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic and unannounced inspections by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs, GTPs and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

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

- the third parties do not successfully carry out their contractual duties;

- the third parties fail to meet FDA and other regulatory obligations or expected deadlines;
- we replace a third party for any reason; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

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

Risks Relating to Intellectual Property

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

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

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

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

Risks Relating to Our Common Stock

The market price for our common shares is particularly volatile.

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

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

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

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

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

We have never paid cash dividends nor do we anticipate paying cash dividends in the foreseeable future. Accordingly, any return on your investment will be as a result of stock appreciation if any. Additionally, we are prohibited from paying any cash dividends under the terms of our loan and security agreement.

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

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

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

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

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

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

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

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

We are entitled under our certificate of incorporation to issue up to 300,000,000 shares of common stock and 7,000,000 “blank check” shares of preferred stock. Shares of our blank check preferred stock provide our board of directors with broad authority to determine voting, dividend, conversion, and other rights. As of December 31, 2015 we have issued and outstanding 92,005,705 shares of common stock and we have 39,537,741 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, 2015, we had no shares of preferred stock issued and outstanding. Accordingly, we are entitled to issue up to 168,456,555 additional shares of common stock and 7,000,000 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. Moreover, we cannot assure you that FDA approvals for any products developed by us will be granted on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals could have a material adverse effect on the marketing of our products and our ability to generate product revenue.

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

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

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

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

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

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

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

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

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

regulatory approval. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for those of our product candidates involved will be harmed, and our prospects for profitability will be significantly impaired.

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

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

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

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

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

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of 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. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Even if any of our drug candidates receives marketing approval, as greater numbers of patients use a drug following its approval, an increase in the incidence of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval

clinical trials could result in a number of potentially significant negative consequences, including:

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

We currently operate two facilities located in the United States and one facility located in China. Our corporate offices and primary research facilities are located in Germantown, Maryland, where we license approximately 3,100 square feet. This license provides for monthly payments of approximately $10,200 per month with the term expiring on December 31, 2016.

In 2015, we entered into a lease consisting of approximately 3,100 square feet of research space in San Diego, California. This lease provides for current monthly payments of approximately $11,000 and expires on August 31, 2018.

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.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable

PART II

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

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "CUR." The following table sets forth, for the periods indicated, the high and low sale prices for our common stock.

	High	Low
2015		
First Quarter	$3.92	$1.78
Second Quarter	$2.39	$1.46
Third Quarter	$2.02	$1.02
Fourth Quarter	$1.35	$0.98
2014		
First Quarter	$4.80	$2.76
Second Quarter	$4.81	$2.96
Third Quarter	$4.25	$2.67
Fourth Quarter	$3.39	$2.12

Holders

As of February 28, 2016 our common stock was held by approximately 326 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 our loan and security agreement.

Equity Compensation Plan Information

The following table sets forth information with respect to our equity compensation plans as of December 31, 2015.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options and Rights (a)	Weighted-Average Exercise Price for Outstanding Options and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders			
2005 Stock Plan, as amended and restated	580,000	$ 1.23	-
2007 Stock Plan	5,886,318	$ 3.17	115,105
2010 Equity Compensation Plan	10,787,536	$ 1.27	2,516,686
Equity compensation plans not approved by security holders	N/A	N/A	N/A
Total	17,253,853	$ 2.08	2,631,791

Performance Graph

The following graph compares total stockholder returns of Neuralstem, Inc. for the period commencing on December 31, 2010 and ending on December 31, 2015, to four indices: The total return for our stock and for each index assumes an initial investment of $100 and the reinvestment of dividends, although we have never declared dividends on Neuralstem stock, and is based on the returns of the component companies weighted according to their capitalizations as of the end of each quarterly period. The stock price performance included in this graph is not necessarily indicative of future stock price performance. For the period represented, we traded on the NYSE MKT from December 31, 2010 to July 10, 2015. On July 13, 2015, we commended trading on the NASDAQ Capital Market under the symbol “CUR”.

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 February of 2015, we issued a total of 19,206 shares of common stock upon the cashless exercise of 44,000 outstanding common stock purchase warrants. The warrants had an average exercise price of $2.13.

- In July 2015, we issued one of our legal advisors a common stock purchase warrant to purchase 150,000 shares of our common stock at an exercise price of $1.87 per share in exchange for certain legal work. The warrant vests monthly over one year from the grant date, has a term of 5 years and will expire on June 30, 2020. Any vested portion of the warrant can be exercised after 6 months from the issuance date on a cashless basis at any time that the shares underlying the warrant are not subject to a registration statement. The warrant provides for an adjustment to the purchase price and number of shares underlying the warrant upon stock dividends and splits. The warrant does not contain any price protection provisions with regard to subsequent financings.

- On February 15, 2016, as an inducement to Mr. Daly’s employment, we granted an inducement option to purchase 2,750,000 shares of Common Stock. The option has a term of ten (10) years, and vests as follows: (i) 687,500 options vest on the six (6) month anniversary of the grant date, (ii) 687,500 options vest on the one (1) year anniversary of the grant date and the remaining 1,375,000 options vesting quarterly over the subsequent three (3) year period such that the option will be fully vested on the four (4) year anniversary of the grant date.

2016 fundraising placeholder

ITEM 6. SELECTED FINANCIAL DATA

	Year Ended December 31,				
Statement of Operations Data:	2015	2014	2013	2012	2011
Revenues	$10,417	$18,833	$110,000	$407,708	$390,625
Total operating expenses	$19,166,945	$17,454,682	$12,633,941	$10,564,164	$13,381,095
Operating loss	$(19,156,528)	$(17,435,849)	$(12,523,941)	$(10,156,456)	$(12,990,470)
Interest expense	$(1,816,206)	$(1,620,776)	$(1,394,274)	$(2,699)	$(821)
Warrant issuance and modification expense	$-	$(3,109,850)	$(5,017,156)	$-	$-
Gain (loss) from change in fair value adjustment of warrant obligations	$-	$(334,133)	$(965,329)	$-	$161,809
Loss on debt extinguishment	$-	$(445,787)	$-	$-	$-
Litigation settlement	$-	$250,000	$838	$3,484	$-
Net loss	$(20,903,901)	$(22,628,744)	$(19,831,862)	$(10,121,517)	$(12,518,527)
Net loss per share - basic and diluted	$(0.23)	$(0.26)	$(0.27)	$(0.17)	$(0.26)

	As of December 31,				
Balance Sheet Data:	2015	2014	2013	2012	2011
Cash and equivalents	$4,716,533	$12,518,980	$16,846,052	$7,443,773	$2,352,013
Short-term investments	$7,517,453	$15,007,478	$-	$-	$-
Working capital	$7,005,612	$24,153,087	$11,682,987	$5,896,454	$590,385
Total assets	$15,048,264	$29,844,075	$19,413,536	$8,750,079	$4,086,177
Long-term debt, net of discount	$8,026,550	$8,786,482	$7,697,331	$-	$-
Fair value of derivative instruments	$-	$-	$1,417,527	$-	$-
Total stockholders' equity	$4,967,278	$17,719,336	$8,418,199	$6,972,633	$1,659,818

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 2016.

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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, 2015 to the comparable period of 2014 and (ii) year ended December 31, 2014 to the comparable period of 2013.

- *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 development and commercialization of treatments based on human neuronal stem cells and the development and commercialization of treatments using small molecule compounds. We are headquartered in Germantown, Maryland and have a wholly-owned subsidiary in China.

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts. We own or exclusively license one hundred fourteen (114) U.S. or foreign issued patents and forty-seven (47) U.S. and foreign patent applications in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds. At times, we have licensed the use of our intellectual property to third parties.

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

We have not derived any revenue or cash flows from the sale or commercialization of our products. In the past, we have derived limited revenue from the licensing of certain intellectual property to third parties and from consulting fees. As a result, we have incurred annual operating losses since inception and expect to continue to incur substantial operating losses in the future. Therefore, we are dependent upon external financing and revenue from collaborative research arrangements with sponsors to finance our operations. We have no such collaborative research arrangements at this time and there can be no assurance that such financing or partnering revenue will be available when needed or on terms acceptable to us.

Before we can derive revenue or cash inflows from the commercialization of any of our proposed product candidates, we will need to: (i) conduct substantial testing of our proposed products, (ii) undertake pre-clinical and clinical testing for specific disease indications; and (iii), obtain required regulatory approvals. These steps are risky, expensive and time consuming.

Trends & Outlook

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

In the first quarter of 2013 and the third quarter of 2012, we licensed the use of certain of our intellectual property to third parties. During the years ended December 31, 2015, 2014, and 2013 , we recognized approximately $10,000, $19,000, and $110,000 of revenue, respectively, related to up-front payments and ongoing fees under these licenses.

On a long-term basis, we anticipate that our revenue will be derived primarily from licensing fees and sales of our cell based therapy and small molecule compounds. 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 contractor and personnel expenses associated with clinical trials and regulatory submissions; costs associated with preclinical activities such as proof of principle for new indications; toxicology studies; costs associated with cell processing and process development; facilities-related costs and supplies. Clinical trial expenses include payments to research organizations, contract manufacturers, clinical trial sites, consultants and laboratories for testing clinical samples.

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.

For a further description of these clinical trials, see the section of this report entitled "*Clinical Programs*" contained in Item 1. Of this Annual Report.

We expect that research and development expenses, which include expenses related to our ongoing clinical trials, will increase in the future, as funding allows and we proceed into our anticipated Phase II trials. To the extent that it is practical, we will continue to outsource much of our efforts, including product manufacture, proof of principle and pre-clinical testing, toxicology, tumorigenicity, dosing rationale, and development of clinical protocol and IND applications. This approach allows us to use the best expertise available for each task and permits staging new research projects to fit available cash resources.

In June 2010 we formed a wholly owned subsidiary in the People's Republic of China. This subsidiary primarily: (i) conducts pre-clinical research with regard to proposed stem cells therapies, and (ii) oversees our approved future clinical trials in China, including the current trial to treat motor deficits due to ischemic stroke. Through December 31, 2015 this subsidiary has incurred expenses of approximately $796,000.

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, legal fees, facilities and other external general and administrative services.

Critical Accounting Policies

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

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

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

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

Long Lived Intangible Assets - Our long lived intangible assets consist of our intellectual property patents including primarily legal fees associated with the filings and in defense of our patents. The assets are amortized on a straight-line basis over the expected useful life which we define as ending on the expiration of the patent group. These assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. We assess this recoverability by comparing the carrying amount of the asset to the

estimated undiscounted future cash flows to be generated by the asset. If an asset is deemed to be impaired, we estimate the impairment loss by determining the excess of the asset's carrying amount over the estimated fair value. These determinations use assumptions that are highly subjective and include a high degree of uncertainty. During the years ended December 31, 2015, 2014 and 2013, no significant impairment losses were recognized.

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

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

Comparison of Our Results of Operations for the Year Ended December 31, 2015 and 2014

Revenue

We did not generate any revenues from the sale of our proposed products in 2015 or 2014. During 2015 and 2014, we recognized revenue of approximately $10,000 and $19,000, respectively related to the licensing of certain of our intellectual properties to third parties. The revenue in 2015 and 2014 consisted solely of ongoing, annual license fees.

Operating Expenses

Operating expenses for 2015 and 2014 were as follows:

	Year Ended December 31,		Increase (Decrease)	
	2015	2014	$	%
Operating Expenses				
Research & development costs	$12,637,278	$8,361,559	$4,275,719	51 %
General & administrative expenses	6,529,667	9,093,123	(2,563,456)	-28%
Total expense	$19,166,945	$17,454,682	$1,712,263	10 %

Research and Development Expenses

Our research and development expenses consist primarily of contractor and personnel expenses associated with clinical trials and regulatory submissions; costs associated with preclinical activities such as proof of principle for new indications; toxicology studies; costs associated with cell processing and process development; facilities-related costs and supplies. Clinical trial expenses include payments to research organizations, contract manufacturers, clinical trial sites, consultants and laboratories for testing clinical samples.

The increase of approximately $4,276,000 or 51% in research and development expenses was primarily attributable to a $924,000 increase in payroll and related expense due to increased salaries and headcount and a $3,443,000 increase in project and lab expenses.. These increased expenses are all related to a ramping up of our pre-clinical and clinical trial efforts and are expected to continue into subsequent periods.

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, legal fees, facilities and other external general and administrative services.

The decrease of approximately of approximately $2,563,000 or 28% in general and administrative expenses was primarily attributable to

a $1,794,000 decrease in non-cash stock based compensation related to a consultant achieving a performance based milestone which resulted in a term extension of certain common stock purchase warrants in the previous year, and

$1,443,000 decrease in legal, consulting and other external advisory fees. This was partially offset by an increase of $494,000 increase in payroll and related expenses due to current year headcount increases.

Other income (expense)

Other expense totaled approximately $1,747,000 and $5,193,000 in the years ended December 31, 2015 and 2014, respectively. This reduction of expense was primarily the result of the non-recurrence of a warrant modification expense in 2014 of $3,110,000.

Comparison of Our Results of Operations for the Year Ended December 31, 2014 and 2013

Revenue

We did not generate any revenues from the sale of our proposed products in 2014 or 2013. During 2014 and 2013, we recognized revenue of approximately $19,000 and $110,000, respectively related to the licensing of certain of our intellectual properties to third parties. The revenue in 2013 included up-front fees for new licenses while the revenue recognized in 2014 consisted solely of ongoing, annual license fees.

Operating Expenses

Operating expenses for 2014 and 2013 were as follows:

	Year Ended December 31,		Increase (Decrease)	
	2014	2013	$	%
Operating Expenses				
Research & development costs	$8,361,559	$7,285,752	$1,075,807	15%
General & administrative expenses	9,093,123	5,348,189	3,744,934	70%
Total expense	$17,454,682	$12,633,941	$4,820,741	38%

Research and Development Expenses

Our research and development expenses consist primarily of contractor and personnel expenses associated with clinical trials and regulatory submissions; costs associated with preclinical activities such as proof of principle studies for new indications; toxicology studies; costs associated with cell processing and process development; facilities-related costs and supplies. Clinical trial expenses include payments to research organizations, contract manufacturers, clinical trial sites, consultants and laboratories for testing clinical samples.

The increase of approximately $1,076,000 or 15% in research in development expenses was primarily attributable to a $674,000 increase in payroll and related expense due to increased headcount, a $140,000 increase in project and lab expenses and a $112,000 increase in travel and related expense due to our clinical trial activities. These increased expenses are all related to a ramping up of our pre-clinical and clinical trial efforts and are expected to continue into subsequent periods.

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, legal fees, facilities and other external general and administrative services.

The increase of approximately $3,745,000 or 70% in general and administrative expenses was primarily attributable to a $1,953,000 increase in non-cash stock based compensation expense primarily related to a consultant achieving a performance based milestone which resulted in a term extension of certain common stock purchase warrants, a $1,010,000 increase in legal and professional fees related to patent, litigation and other corporate matters, a $554,00

increase in consulting fees primarily related to new business development efforts and a $236,000 increase in payroll and related expenses due to current year headcount increases.

Other income (expense)

Other expense totaled approximately $5,193,000 and $7,308,000 in the years ended December 31, 2014 and 2013, respectively. Other expense in 2014 consisted primarily of a $3,110,000 expense related to our extension of certain common stock purchase warrants, $1,621,000 of interest expense primarily related to our long-term debt, a $446,000 loss on our debt amendment transaction, and a $334,000 expense related to the change in fair value of the Company's warrant liabilities partially offset by approximately $250,000 of income from a milestone payment from a legal settlement.

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. In February and March of 2015, we issued 812,423 shares of common stock at an average price of $3.77 per share generating gross proceeds of approximately $3,064,000 and net proceeds of approximately $2,932,000 ($3.61 per share) after deducting commissions and fees of approximately $132,000.

Our independent registered public accounting firm has included an explanatory paragraph with respect to our ability to continue as a going concern in its report on our consolidated financial statements for the year ended December 31, 2015. The presence of the going concern explanatory paragraph may suggest that we may not have sufficient liquidity or minimum cash levels to operate the business.

Our Cash and Cash Equivalent balances of approximately $12.2 million as at December 31, 2015 are only sufficient to fund operations through June, 2016. 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. Management is in ongoing discussions regarding various financing options with financial institutions and believes that it will receive cash adequate to fund operations through December 31, 2016. We cannot assure you that we will be able to secure such additional financing 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 – 2015 compared to 2014

	Year Ended December 31,		Increase (Decrease)	
	2015	2014	$	%
Cash and cash equivalents	$4,716,533	$12,518,980	$(7,802,447)	-62 %
Short term investments	7,517,453	15,007,478	(7,490,025)	-50 %
Total cash and short term investments	$12,233,986	$27,526,458	$(15,292,472)	-56 %
Net cash used in operating activities	$(18,931,665)	$(11,706,688)	$(7,224,977)	62 %
Net cash provided by (used in) investing	$7,246,441	$(15,563,826)	$22,810,267	-147%
Net cash provided by financing activities	$3,887,189	$22,944,425	$(19,057,236)	-83 %

The decrease in our cash and short term investments was primarily due to our use of cash in operating activities of approximately $18,932,000, partially offset by the proceeds from sales of stock and from the exercise of warrants.

Net Cash Used in Operating Activities

The increase in cash used in operating activities during 2015 as compared to 2014 was primarily the result increased project and payroll related expenses associated with increased clinical and pre-clinical activities.

Net Cash Used in Investing Activities

The increase in cash received in investing activities during 2015 as compared to 2014 was primarily due to the use of short term investments to fund ongoing operating expenses and reduced investment activities during 2015 compared to 2014.

Net Cash Provided by Financing Activities

Net cash provided by financing activities decreased by approximately $19,057,000 in 2015 compared to 2014. In 2015, we raised approximately $6,005,000 in proceeds from sales of securities and exercise of warrants. In 2014 we raised approximately $19.560,000, net from the sale of our securities pursuant to a registered direct offering and approximately $4,213,000 of net proceeds pursuant to our debt amendment transaction.

Cash Flows – 2014 compared to 2013

	Year Ended December 31,		Increase (Decrease)	
	2014	2013	$	%
Cash and cash equivalents	$12,518,980	$16,846,052	$(4,327,072)	-26 %
Short term investments	15,007,478	-	15,007,478	- %
Total cash and short term investments	$27,526,458	$16,846,052	$10,680,406	63 %
Net cash used in operating activities	$(11,706,688)	$(10,591,617)	$(1,115,071)	11 %
Net cash used in investing activities	$(15,563,826)	$(537,050)	$(15,026,776)	2798 %
Net cash provided by financing activities	$22,944,425	$20,524,702	$2,419,723	12 %

The increase in our cash and short term investments was primarily due to our raising approximately $19,468,000, net through the sale of our common stock and warrants and $4,213,000 net in our debt amendment transaction partially offset by our cash used in operations.

Net Cash Used in Operating Activities

The increase in cash used in operating activities during 2014 as compared to 2013 was primarily the result of a $2,797,000 increase in our net loss partially offset by changes in our operating assets and liabilities.

Net Cash Used in Investing Activities

The increase in our use of cash in investing activities during 2014 as compared to 2013 was primarily due to approximately $15,007,000 of purchases, net of maturities of short term investments using the proceeds from our January 2014 registered direct offering.

Net Cash Provided by Financing Activities

In 2014 we raised approximately $19,468,000, net through the sale of our common stock and warrants, $4,213,000 from our debt amendment transaction and $1,795,000 from exercises of stock purchase warrants. These were partially offset by $1,929,000 of principal payments on our long-term debt and the $426,000 payment of taxes related to stock option exercises.

In 2013 we raised approximately $7,048,000, net through the sale of our common stock and warrants, $7,551,000 from the issuance of long-term debt and $6,108,000 from exercises of stock purchase warrants.

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. We currently have two shelf registration statements that are effective. On June 19, 2014, our shelf registration statement registering the sale of up to $100 million of our securities was declared effective by the SEC. To date, we have not sold any securities under this shelf registration statement. On September 13, 2013, our shelf registration statement (Registration No. 333-190936) registering the sale of up to $50 million of our securities was declared effective by the SEC. To date, through February 29, 2016 we have sold or reserved for sale upon the exercise of outstanding warrants approximately $47.2 million of securities under this shelf registration statement. Additionally, securities sold pursuant to our At the Market Offering Agreement (see below) are being sold pursuant to this registration statement and accordingly, we have reserved the balance of approximately $2.8 million of securities pursuant thereto. We anticipate conducting financing in the future based on our shelf registration statement when and if financing opportunities arise.

In October 2013, we entered into an At the Market Offering Agreement with T.R. Winston & Company as our sales agent pursuant to which we can sell up to $25 million of our common stock. The At the Market Offering Agreement was entered into pursuant to a takedown from our shelf registration statement declared effective on September 13,

2013 (Registration No. 333-190936). To date through December 31, 2015 we have sold 2,202,580 shares under such agreement at an average price per share of $3.16 resulting in gross proceeds of approximately $6,965,000 and net proceeds of approximately $6,665,000 . Future sales under our agreement are limited to approximately $1.8 million which is the amount available under our shelf registration of which the At the Market Offering Agreement is part of.

The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, our progress in our exploratory, preclinical and future clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and/or our capital expenditures or to license our potential products or technologies to third parties.

Contractual Obligations

As of December 31, 2015, our contractual obligations were as follows:

Contractual Obligations	Less than 1 year	1 - 3 Years	3 - 5 Years	More than 5 Years	Total
Operating facility leases	$309,286	$331,412	$ -	$ -	$640,697
Long-term debt	4,569,537	3,765,569	-	-	8,335,106
Total contractual obligations	$4,878,822	$4,096,981	$ -	$ -	$8,975,803

Off-balance Sheet Arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents and short-term investments. Our investment policy, approved by our Board of Directors, limits the amount we may invest in any one type of investment issuer, thereby reducing credit risk concentrations. In addition, our CDs are invested through the Certificate of Deposit Account Registry Service ("CDARS") program which reduces or eliminates our risk related to concentrations of investments above FDIC insurance levels. We limit our credit and liquidity risks through our investment policy and through regular reviews of our portfolio against our policy. Because of the short-term maturities, we do not believe that a one-half percentage point increase or decrease in interest rates would have had a material effect on our interest income.

We are subject to interest rate risk on our long-term debt which contains a floating interest rate based on Wall Street Journal published prime rate. For the year ended December 31, 2015 a one percentage point increase in the prime rate would have increased our interest expense by approximately $188,000.

Our foreign operations in China subject us to changes in foreign exchange rates. Changes in rates for the year ended December 31, 2015 would not have had a material effect as the operations were limited. Future changes to foreign exchange rates could have a material effect on us as our clinical trial activity increases.

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.

Germantown, Maryland

We have audited the accompanying consolidated balance sheets of Neuralstem, Inc. (the "Company") as of December 31, 2015 and 2014, and the consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2015. We also have audited the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over consolidated financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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 and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally

accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Neuralstem, Inc. as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the three year period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, Neuralstem, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

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

/s/ Stegman & Company

Baltimore, Maryland

March 14, 2016

Neuralstem, Inc.

Consolidated Balance Sheets

	December 31, 2015	2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$4,716,533	$12,518,980
Short term investments	7,517,453	15,007,478
Trade and other receivables	37,316	225,524
Deferred financing fees, current portion	89,562	135,694
Prepaid expenses	1,159,782	274,106
Total current assets	13,520,646	28,161,782
Property and equipment, net	343,200	301,265
Patents, net	1,103,467	1,233,172
Deferred financing fees, net of current portion	9,154	89,143
Other assets	71,797	58,713
Total assets	$15,048,264	$29,844,075
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$1,455,826	$2,504,978
Accrued bonuses	161,362	646,960
Current portion of long-term debt, net of discount	4,634,742	730,012
Other current liabilities	263,104	126,745
Total current liabilities	6,515,034	4,008,695
Long-term debt, net of discount and current portion	3,391,808	8,056,470
Other long term liabilities	174,144	59,574
Total liabilities	10,080,986	12,124,739
Commitments and contingencies (Note 10)		
STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, $0.01 par value; 300 million shares authorized, 92,005,705 and 87,789,679 shares issued and outstanding in 2015 and 2014, respectively	920,057	877,897
Additional paid-in capital	176,002,832	167,890,220
Accumulated other comprehensive income	3,071	6,000
Accumulated deficit	(171,958,682)	(151,054,781)

Total stockholders' equity	4,967,278	17,719,336
Total liabilities and stockholders' equity	$15,048,264	$29,844,075

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,		
	2015	2014	2013
Revenues	$10,417	$18,833	$110,000
Operating expenses:			
Research and development costs	12,637,278	8,361,559	7,285,752
General and administrative expenses	6,529,667	9,093,123	5,348,189
Total operating expenses	19,166,945	17,454,682	12,633,941
Operating loss	(19,156,528)	(17,435,849)	(12,523,941)
Other income (expense):			
Interest income	69,549	67,651	68,000
Interest expense	(1,816,206)	(1,620,776)	(1,394,274)
Warrant modification expense	-	(3,109,850)	(5,017,156)
Loss from change in fair value of derivative instruments	-	(334,133)	(965,329)
Loss on debt extinguisment	-	(445,787)	-
Other expense	(716)	-	-
Litigation settlement	-	250,000	838
Total other income (expense)	(1,747,373)	(5,192,895)	(7,307,921)
Net loss	$(20,903,901)	$(22,628,744)	$(19,831,862)
Net loss per share - basic and diluted	$(0.23)	$(0.26)	$(0.27)
Weighted average common shares outstanding - basic and diluted	90,866,938	87,086,345	72,279,210
Comprehensive loss:			
Net loss	$(20,903,901)	$(22,628,744)	$(19,831,862)
Foreign currency translation adjustment	(2,929)	(1,241)	7,241
Comprehensive loss	$(20,906,830)	$(22,629,985)	$(19,824,621)

See accompanying notes to consolidated financial statements.

Neuralstem, Inc.

Consolidated Statements of Changes In Stockholders' Equity

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at January 1, 2013	68,189,314	$681,893	$114,884,915	$ -	$(108,594,175)	$6,972,633
Share based payments	-	-	1,665,155	-	-	1,665,155
Issuance of common stock for warrant exercises, net of fees of $113,200	5,302,935	53,029	5,979,277	-	-	6,032,306
Issuance of common stock and replacement warrants as inducement for warrant exercises	72,440	724	5,016,432	-	-	5,017,156
Issuance of common stock and warrants for professional services, net of forfeited shares	332,848	3,329	1,503,419	-	-	1,506,748
Issuance of common stock and warrants from capital raises, net of issuance costs of $534,825	3,988,494	39,885	7,008,937	-	-	7,048,822
Foreign currency translation adjustments				7,241		7,241
Net loss	-	-	-	-	(19,831,862)	(19,831,862)
Balance at December 31, 2013	77,886,031	778,860	136,058,135	7,241	(128,426,037)	8,418,199
Share based payments	-	-	4,318,994	-	-	4,318,994
Issuance of common stock for warrant exercises, net of fees of $113,200	805,972	8,060	991,940	-	-	1,000,000
Issuance of common stock and replacement warrants as inducement for warrant exercises	1,947,535	19,476	1,288,515	-	-	1,307,991
Issuance of common stock and warrants for professional services, net of forfeited shares	7,122,022	71,220	19,489,214	-	-	19,560,434
	-	-	1,704,097	-	-	1,704,097

Reclassification of warrant classified as derivative liability						
Modification of executive warrant	-	-	3,109,850	-	-	3,109,850
Issuance of common stock and warrants in conjunction with debt amendment, net	28,119	281	929,475	-	-	929,756
Foreign currency translation adjustments	-	-	-	(1,241)	-	(1,241)
Net loss	-	-	-	-	(22,628,744)	(22,628,744)
Balance at December 31, 2014	87,789,679	877,897	167,890,220	6,000	(151,054,781)	17,719,336
Share based payments	-	-	2,951,367	-	-	2,951,367
Issuance of common stock for warrant exercises net	1,724,606	17,246	3,056,289	-	-	3,073,535
Issuance of common stock for RSU and option exercises net of forfeited shares for exercise price and payment of taxes	1,251,189	12,512	(814,566)	-	-	(802,054)
Issuance of common stock and warrants from capital raises, net	812,423	8,124	2,923,800	-	-	2,931,924
Modification of executive warrant	-	-	-	-	-	-
Issuance of common stock for restricted stock awards	427,808	4,278	(4,278)	-	-	-
Foreign currency translation adjustments	-	-	-	(2,929)	-	(2,929)
Net loss	-	-	-	-	(20,903,901)	(20,903,901)
Balance at December 31, 2015	92,005,705	$920,057	$176,002,832	$ 3,071	$(171,958,682)	$4,967,278

See accompanying notes to consolidated financial statements

Neuralstem, Inc.

Consolidated Statements of Cash Flows

	For the Year Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net loss	$(20,903,901)	$(22,628,744)	$(19,831,862)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	345,460	348,630	244,725
Share based compensation expenses	2,951,367	4,320,073	2,331,401
Amortization of deferred financing fees and debt discount	870,530	829,632	694,175
Warrant modification expense	-	3,109,850	5,017,156
Loss from change in fair value of warrant obligations	-	334,133	965,329
Loss on debt extinguishment	-	445,787	-
Changes in operating assets and liabilities:			
Trade and other receivables	188,208	(215,524)	(6,667)
Prepaid expenses	(840,772)	191,263	125,470
Other assets	(13,998)	6,141	(5,183)
Accounts payable and accrued expenses	(1,045,765)	1,382,447	(116,750)
Accrued bonuses	(485,598)	181,092	3
Other current liabilities	253,427	(2,206)	2,469
Other long term liabilities	(250,624)	(9,262)	(11,883)
Net cash used in operating activities	(18,931,666)	(11,706,688)	(10,591,617)
Cash flows from investing activities:			
Purchases of short-term investments	(7,517,453)	(25,007,478)	-
Maturity of short-term investments	15,007,478	10,000,000	-
Patent costs	(67,312)	(348,455)	(411,688)
Purchase of property and equipment	(176,272)	(207,893)	(125,362)
Net cash provided by (used in) investing activities	7,246,441	(15,563,826)	(537,050)
Cash flows from financing activities:			
Proceeds from issuance of common stock from warrants exercised, net	3,073,535	1,794,865	6,107,842
Proceeds from sale of common stock and warrants, net of issuance costs	2,931,924	19,467,857	7,048,822
Payments of taxes on stock option exercises	(802,054)	(426,212)	-
Proceeds from long-term debt transactions, net of issuance costs	-	4,212,561	7,551,329
Payments of long-term debt	(1,154,150)	(1,929,449)	-
Payment on fees for future financing	(45,000)	-	-
Payments of short term notes payable	(117,068)	(175,197)	(183,291)

Net cash provided by financing activities	3,887,187	22,944,425	20,524,702
Effects of exchange rates on cash	(4,409)	(983)	6,244
Net increase (decrease) in cash and cash equivalents	(7,802,447)	(4,327,072)	9,402,279