

Neuralstem, Inc.
Form 10-K
March 30, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2011.

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

Commission File Number 000-1357459

NEURALSTEM, INC.

(Exact name of registrant as specified in its charter)

Delaware
State or other jurisdiction of
incorporation or organization

52-2007292
(I.R.S. Employer
Identification No.)

9700 Great Seneca Highway
Rockville, MD
(Address of principal executive offices) (Zip Code)

20850

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

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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	NYSE Amex

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

None

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller

reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the Company's common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter based upon the closing price of the common stock as reported by the NYSE Amex on such date, was \$64,962,831.

The number of shares outstanding of Registrant's common stock, \$0.01 par value at March 1, 2012 was 53,882,118.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2012 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2011.

SUBSEQUENT EVENTS

On February 10, 2012, the Company completed the offering of 5,200,000 units. The offering resulted in gross proceeds to the Company of \$5,200,000. Net proceeds from the offering, after deducting the placement agent's fee and associated costs and expenses, is estimated to be \$4,910,000.

NEURALSTEM, INC

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2011

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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. Also, any reference to "common share" or "common stock," refers to our \$.01 par value common stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this Annual Report on Form 10-K constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements included in this Annual Report, including those related to our cash, liquidity, resources and our anticipated cash expenditures, as well as any statements other than statements of historical fact, regarding our strategy, future operations, financial position, projected costs, prospects, plans and objectives are forward-looking statements. These forward-looking statements are derived, in part, from various assumptions and analyses we have made in the context of our current business plan and information currently available to us and in light of our experience and perceptions of historical trends, current conditions and expected future developments and other factors we believe are appropriate in the circumstances. You can generally identify forward looking statements through words and phrases such as "believe", "expect", "seek", "estimate", "anticipate", "intend", "plan", "budget", "project", "may likely result", "may be", "may continue" and other similar expressions, although not all forward-looking statements contain these identifying words. We cannot guarantee future results, levels of activity, performance or achievements, and you should not place undue reliance on our forward-looking statements.

Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including the risks described in Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or strategic investments. In addition, any forward-looking statement represents our expectation only as of the day this Annual Report was first filed with the Securities and Exchange Commission ("SEC") and should not be relied on as representing our expectations as of any subsequent date. While we may elect to update forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our expectations change.

When reading any forward-looking statement, you should remain mindful that actual results or developments may vary substantially from those expressed in or implied by such statement for a number of reasons or factors, including but not limited to:

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the success of our research and development activities, the development of a viable commercial product, and the speed with which regulatory authorizations and product launches may be achieved;

- whether or not a market for our product develops, and, if a market develops, the rate at which it develops;

- our ability to successfully sell or license our products;

- our ability to attract and retain qualified personnel to implement our business plan and corporate growth strategies;

- our ability to develop sales, marketing, and distribution capabilities;

- our ability to obtain reimbursement from third party payers for our proposed products if they are developed;

- the accuracy of our estimates and projections;

- our ability to secure additional financing to fund our short-term and long-term financial needs;

- changes in our business plan and corporate strategies; and

- other risks and uncertainties discussed in greater detail in the section captioned “Risk Factors.”

Each forward-looking statement should be read in context with and in understanding of the various other disclosures concerning our company and our business made elsewhere in this Annual Report as well as our public filings with the SEC. You should not place undue reliance on any forward-looking statement. We are not obligated to update or revise any forward-looking statements contained in this Annual Report or any other filing to reflect new events or circumstances unless and to the extent required by applicable law.

ITEM 1. BUSINESS

Overview

We are a development stage company focused on the development and commercialization of treatments for central nervous system disease based on transplanting human neural stem cells and the use of small molecule drugs. We are headquartered in Rockville, Maryland.

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts in the area of neural stem cell research. We own or exclusively license twenty-five (25) issued patents and twenty-nine (29) patent pending applications in the field of regenerative medicine, related to our stem cell technologies as well as our small molecule compounds.

We believe our technology base, in combination with our know-how, and collaborative projects with major research institutions, provide a competitive advantage and will facilitate the development and commercialization of products for use in the treatment of a wide array of neurodegenerative conditions and in regenerative repair of acute disease.

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, our scientific team and our facilities, to advance our technologies. In addition, we are pursuing strategic collaborations with members of academia.

Technology Platforms

Stem Cells

Our technology enables the isolation and large-scale expansion of 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. Our two issued core patents entitled: (i) *Isolation, Propagation, and Directed Differentiation of Stem Cells from Embryonic and Adult Central Nervous System of Mammals*; and (ii) *In Vitro Generation of Differentiated Neurons from Cultures of Mammalian Multipotential CNS Stem Cell* contain claims which cover the process of deriving the cells as well as the cells created from this process.

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 or 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 (“CNS”) including: Alzheimer's disease, Parkinson's disease, Multiple Sclerosis, ALS, depression, and injuries to the spinal cord.

To date we have focused our research efforts on applications involving spinal cord stem cells. We believe we have established “proof of principle” for two important spinal cord applications: ALS, or Lou Gehrig’s disease, and Ischemic Spastic Paraplegia (a painful form of spasticity that may arise as a complication of surgery to repair aortic aneurysms). Of these applications, we have commenced Phase I trials with regard to ALS. We believe that, if successfully developed, stem cell therapeutics have the potential to provide a broad therapeutic approach comparable to traditional pharmaceuticals and genetically engineered biologics.

We intend to treat both chronic and acute spinal cord injury with the same spinal cord stem cells, utilizing the same injection devices we are using for ALS. We, therefore, add to our knowledge about the surgical route of entry for both the ALS patients and the spinal cord injury patients with each patient we treat in the ALS trial.

During 2011, we were selected as the primary subcontractor for a U.S. Department of Defense (“DOD”) contract, awarded to Loma Linda University, to develop human neural stem cell technology for the treatment of cancerous brain tumors. Under the terms of the contract, we may receive up to \$625,000 during the first year. The DOD has three one-year options to continue the program after the first year, based upon milestones. The goal of the program is to have a therapeutic product for the treatment of cancerous brain tumors ready to submit to the FDA by the end of the fourth year (2015). We commenced work on the project during May of 2011.

Pharmaceutical Compounds

We have developed and patented a series of small molecule compounds (low molecular weight organic compounds which can efficiently cross the blood/brain barrier). We believe that these small molecule compounds will stimulate the growth of new neurons in the hippocampus and provide a treatment for depression, and possibly other cognitive impacting diseases. In July of 2009, the U.S. Patent and Trademark Office issued the patent covered by patent application 12/049,922, entitled “Use of Fused Nicotinamides to Promote Neurogenesis,” which claims four chemical entities and any pharmaceutical composition included in them. In October of 2011 we announced that we had received patent allowance for U.S. Patent 8,030,492, entitled: “Compositions to Effect Neuronal Growth.” The claims covered by the patent include both structure and method claims for inducing neurogenesis and the growth of new neurons, both in-vitro and in-vivo.

NSI-189 is the first in a class of compounds that we plan to develop into orally administered drugs for major depressive disorder and other psychiatric disorders which are based on our small molecule technologies. In mice, NSI-189 both stimulates neurogenesis of the hippocampus and increases its volume. Additionally, NSI-189 stimulates neurogenesis of human hippocampus-derived neural stem cells in vitro. We believe NSI-189 may reverse the human hippocampal atrophy seen in major depression and other disorders.

Our small molecule platform results from discoveries made through our ability to generate stable human neural stem cell lines suitable for screening large chemical libraries. Our small molecule platform complements our cell therapy platform, in which brain and spinal cord stem cells are transplanted directly into diseased areas to repair and/or replace diseased or dead cells.

Potential Markets

We believe the potential markets for therapies based on our technologies are large. The table below summarizes the potential United States patient populations which we believe may be amenable to neural cell transplantation or treatment with our pharmaceutical compounds and represent potential target markets for our proposed products:

Medical Condition	Number of Patients	
Stem cells		
ALS	30,000	(1)
Huntington’s disease	15,000	(2)
Multiple Sclerosis	2.5 million	(6)
Parkinson's Disease	1.0 million	(7)
Spinal Cord Injury	250,000	(4)

Stroke	6.5 million	(3)
Small molecule compound		
Alzheimer's disease	4.5 million	(5)
Depression	14.8 million	(5)
Schizophrenia	2.4 million	(5)
Stroke	6.5 million	(3)

- (1) Agency for Toxic Substances and Disease Registry (ATSDR),
- (2) National Institute of the Neurological Disorders and Stroke (NINDS)
- (3) 2005 American Heart Association study
- (4) The University of Alabama National Spinal Cord Injury Statistical Center - March 2002
- (5) National Institute of Health
- (6) National Multiple Sclerosis Society
- (7) Parkinson's Disease Foundation - US only

Clinical Trials

Stem Cells

On September 21, 2009, the U.S. Food and Drug Administration (“FDA”) approved our first Investigational New Drug Application (“IND”) to begin Phase I clinical studies on our treatment for Amyotrophic Lateral Sclerosis (“ALS” or “Lou Gehrig’s disease”). In October of 2011, we announced that after reviewing safety data from the first 12 patients, the FDA granted approval for the trial to advance to transplanting patients in the cervical (upper back) region for the last six patients in the trial. To date, we have treated 14 patients.

On August 22, 2010, we filed our second IND for our proposed Phase I clinical trials for chronic spinal cord injury. In October of 2010, we were notified that our IND for spinal cord injury had been placed on clinical hold. At the time, the FDA provided us with specific comments, questions and recommendations for modifications to our trial protocol as contained in our IND application. We expect to revisit this IND with the FDA with a review of the long term human safety data from our ALS trial as well as some additional long term animal safety data that was generated for the next phase of the ALS trial. We anticipate the study, if approved and commenced, will be a multi-site study in the United States. It is still too early to predict when the trial will be approved to move forward.

Pharmaceutical Compounds

In February of 2011, we commenced a Phase Ia clinical trial of our drug compound, NSI-189, which is being developed for the treatment of major depressive disorder and other psychiatric indications. NSI-189 is the lead compound in our neurogenerative small molecule drug platform. The Phase Ia trial tested a single oral administration of NSI-189 in healthy volunteers. In October of 2011, we completed the Phase Ia portion of the trial. In December of 2011, we received approval from the FDA to commence the Phase Ib portion of the trial. The Phase Ib portion consists of patients with Major Depressive Disorder (“MDD”) receiving daily doses for 28 consecutive days. We plan on commencing the Phase Ib portion of the trial by the end of the first quarter of 2012. It is still too early in the trials to make any determination as to its level of success, if any.

Our Research and Programs

We have devoted substantial resources to our research programs to isolate and develop a series of neural stem cell banks that we believe can serve as a basis for therapeutic products as well as to developing our pharmaceutical compounds. Our efforts have been directed at methods to identify, isolate and culture large varieties of stem cells of the human nervous system, and to develop therapies utilizing these stem cells. This research is conducted both internally and through the use of third party laboratory consulting companies under our direct supervision. In addition to the research that we conduct internally or under our direct supervision, we conduct research and development through research collaborations. These collaborations, or programs, are undertaken with both commercial and scholarly institutions and universities.

Manufacturing and Operating Strategy

We generally employ an outsourcing strategy where we outsource our Good Laboratory Practices (“GLP”) preclinical development activities and Good Manufacturing Practices (“GMP”) manufacturing and clinical development activities to contract research organizations (“CRO”) and contract manufacturing organizations (“CMO”) as well as all non-critical corporate functions. Manufacturing is also outsourced to organizations with approved facilities and manufacturing practices. This outsource model allows us to better manage cash on hand and minimize non-vital expenditures. It also allows for us to operate with relatively fewer employees and lower fixed costs than that required by our competitors.

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. We outsource all the manufacturing and storage of our stem cells and pharmaceuticals compound to be used in pre-clinical works, and which are accordingly subject to higher FDA requirements, to Charles River Laboratories, Inc., of Wilmington,

Massachusetts (stem cells) and Albany Molecular Resources, Inc. AMRI (small molecule). Both the Charles River and AMRI facilities have the capacity to be used for manufacturing under the FDA determined GMP standards in quantities sufficient for our current and anticipated pre-trial and clinical trial needs. We have no quantity or volume commitment with either Charles River Laboratories or AMRI and our cells and pharmaceutical compounds are ordered and manufactured on an as needed basis.

Products & Marketing

Because of the early stage of our programs, we have yet to identify any specific product and we have not yet addressed questions of channels of distribution and marketing of potential future products.

Our Intellectual Property

Our research and development is supported by our intellectual property. We currently own or have exclusive licenses to 25 patents and 29 patent applications pending worldwide in the field of regenerative medicine and cell therapy.

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.

The following table identifies the issued and pending patents we own or exclusively license that we believe currently support our technology platform.

Patents Pending

Number	Country	Filing Date	Issue Date	Expiration Date	Title
2257068	CA	5/7/1997	N/A	N/A	ISOLATION, PROPOGATION, AND DIRECTED DIFFERENTIATION OF STEM CELLS FROM CENTRAL NERVOUS SYSTEM OF MAMMALS
99948396.9	EP	9/20/1999	N/A	N/A	STABLE NEURAL STEM CELL LINES
2010-254952	JP	9/20/1999	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
3790356.4	EP	12/5/2003	N/A	N/A	METHOD FOR DISCOVERING NEUROGENIC AGENTS
200580039450	CN	11/17/2005	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
5851748.3	EP	11/17/2005	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
2613/CHENP/2007	IN	11/17/2005	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
183092	IL	11/17/2005	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
2007-543219	JP	11/17/2005	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
10-2007-7012097	KR	11/17/2005	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL

DISORDERS

1-2007-501016	PH	11/17/2005	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
1-2007-01216	VN	11/17/2005	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEURODEGENERATIVE CONDITIONS
20073078	NO	11/17/2005	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
11/852,922	US	9/10/2007	N/A	N/A	METHOD FOR DISCOVERING NEUROGENIC AGENTS

8106303.1	HK	6/5/2008	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEURODEGENERATIVE CONDITIONS
12/404,841	US	3/16/2009	N/A	N/A	METHODS OF TREATING ISCHEMIC SPASTICITY
12/424,238	US	4/15/2009	N/A	N/A	STABLE NEURAL STEM CELL LINES
12/710,097	US	2/22/2010	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEURODEGENERATIVE CONDITIONS
PCT/US2010/046537	PCT	8/24/2010	N/A	N/A	SYNTHESIS OF A NEUROSTIMULATIVE PIPERAZINE
12010502167	PH	9/23/2010	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEURODEGENERATIVE CONDITIONS
90/009,567	US	1/19/2010	N/A	N/A	STABLE NEURAL STEM CELL LINES
2011131830	RU	7/28/2011	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
13/192/972	US	7/28/2011	N/A	N/A	METHODS FOR TREATING AND/OR REVERSING NEURODEGENERATIVE DISEASES AND/OR DISORDERS
PCT/US2011/045732	PCT	7/28/2011	N/A	N/A	METHODS FOR TREATING AND/OR REVERSING NEURODEGENERATIVE DISEASES AND/OR DISORDERS
13/269,507	US	10/07/2011	N/A	N/A	COMPOSITIONS TO EFFECT NEURONAL GROWTH
2012/20641	JP	2/2/2012	N/A	N/A	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
PCT/US2009/39451 (1)	PCT	4/3/2009	N/A	N/A	SPINAL PLATFORM AND METHOD FOR DELIVERING A THERAPEUTIC AGENT TO A SPINAL CORD TARGET
12/913,527 (1)	US	7/1/2009	N/A	N/A	FLOATING SPINAL CANNULA AND METHOD OF USE
PCT/US2009/49427 (1)	PCT	7/1/2009	N/A	N/A	FLOATING SPINAL CANNULA AND METHOD OF USE

(1) Neuralstem holds the exclusive worldwide license to patent rights.

Patents Issued

Number	Country	Filing Date	Issue Date	Expiration Date	Title
5,753,506	US	9/25/1996	5/19/1998	9/25/2016	ISOLATION PROPAGATION AND DIRECTED DIFFERENTIATION OF STEM CELLS FROM EMBRYONIC AND ADULT CENTRAL NERVOUS SYSTEM OF MAMMALS
6,040,180	US	5/7/1997	3/21/2000	5/7/2017	IN VITRO GENERATION OF DIFFERENTIATED NEURONS FROM CULTURES OF MAMMALIAN MULTIPOTENTIAL CNS STEM CELLS
6,284,539	US	10/9/1998	9/4/2001	10/9/2018	METHOD FOR GENERATING DOPAMINERGIC CELLS DERIVED FROM NEURAL PRECURSORS
7,544,511	US	1/14/2002	6/9/2009	9/20/19	STABLE NEURAL STEM CELL LINES
7,560,553	US	3/17/2008	7/14/2009	8/9/2024	USE OF FUSED NICOTINAMIDES TO PROMOTE NEUROGENESIS
755849	AU	9/20/1999	4/3/2003	9/20/2019	STABLE NEURAL STEM CELL LINES
915968	EP	5/7/1997	7/25/2007	5/7/2017	ISOLATION, PROPAGATION AND DIRECTED DIFFERENTIATION OF STEM CELLS FROM EMBRYONIC AND ADULT CENTRAL NERVOUS SYSTEM OF MAMMALS
915968	ES	5/7/1997	7/25/2007	5/7/2017	ISOLATION, PROPAGATION AND DIRECTED DIFFERENTIATION OF STEM CELLS FROM EMBRYONIC AND ADULT CENTRAL NERVOUS SYSTEM OF MAMMALS
915968	FR	5/7/1997	7/25/2007	5/7/2017	ISOLATION, PROPAGATION AND DIRECTED DIFFERENTIATION OF STEM CELLS FROM EMBRYONIC AND ADULT CENTRAL NERVOUS SYSTEM OF MAMMALS
915968	GB	5/7/1997	7/25/2007	5/7/2017	ISOLATION, PROPAGATION AND DIRECTED DIFFERENTIATION OF STEM CELLS FROM EMBRYONIC AND ADULT CENTRAL NERVOUS SYSTEM OF MAMMALS
915968	IE	5/7/1997	7/25/2007	5/7/2017	ISOLATION, PROPAGATION AND DIRECTED DIFFERENTIATION OF STEM CELLS FROM

EMBRYONIC AND ADULT CENTRAL NERVOUS
SYSTEM OF MAMMALS

915968 SE 5/7/1997 7/25/2007 5/7/2017
ISOLATION, PROPAGATION AND DIRECTED
DIFFERENTIATION OF STEM CELLS FROM
EMBRYONIC AND ADULT CENTRAL NERVOUS
SYSTEM OF MAMMALS

915968 CH 5/7/1997 7/25/2007 5/7/2017
ISOLATION, PROPAGATION AND DIRECTED
DIFFERENTIATION OF STEM CELLS FROM
EMBRYONIC AND ADULT CENTRAL NERVOUS
SYSTEM OF MAMMALS

69737949.3 DE 5/7/1997 7/25/2007 5/7/2017
ISOLATION, PROPAGATION AND DIRECTED
DIFFERENTIATION OF STEM CELLS FROM
EMBRYONIC AND ADULT CENTRAL NERVOUS
SYSTEM OF MAMMALS

132324	SG	11/17/2005	11/30/2009	11/17/2025	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
7,858,628	US	7/9/2009	12/29/2010	7/9/2029	USE OF FUSED NICOTINAMIDES TO PROMOTE NEUROGENESIS
8,058,434	US	11/04/2010	11/15/2011	11/04/2030	COMPOSITIONS TO EFFECT NEURONAL GROWTH
8,030,492	US	11/04/2010	10/04/2011	11/04/2030	COMPOSITIONS TO EFFECT NEURONAL GROWTH
2343571	CA	9/20/1999	1/03/2012	9/20/2019	STABLE NEURAL STEM CELL LINES
4709382	JP	9/20/1999	3/25/2011	9/20/2019	STABLE NEURAL STEM CELL LINES
7,691,629	US	11/17/2005	4/6/2010	11/17/2025	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
204356	IL	11/17/2005	12/28/2011	11/17/2025	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
2434636	RU	11/17/2005	11/27/2011	11/17/2025	TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS
8,092,495 (1)	US	4/3/2009	12/21/2011	4/3/2029	SPINAL PLATFORM AND METHOD FOR DELIVERING A THERAPEUTIC AGENT TO A SPINAL CORD TARGET
7,833,217 (1)	US	7/1/2009	11/16/2010	7/1/2029	FLOATING SPINAL CANNULA AND METHOD OF USE

(1) Neuralstem holds the exclusive worldwide license to patent rights.

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 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 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 to determine priority of invention, which could result in substantial uncertainties and cost for us, 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 expected 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 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 technical, research and development, financial and sales and marketing resources significantly greater than ours. In addition, certain smaller biotech companies have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages. 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 to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before we do.

The diseases and medical conditions we are targeting have no effective long-term therapies. Nevertheless, we expect that our technologies and products will compete with a variety of therapeutic products and procedures offered by major pharmaceutical companies. Many pharmaceutical and biotechnology companies are investigating new drugs and therapeutic approaches for the same purposes, which 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, when and if successfully developed, will 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, and gene therapy. We believe that some of our competitors are also trying to develop similar stem cell-based technologies. We expect that all of these products will compete with our potential product candidates based on efficacy, safety, cost and intellectual property positions. We may also face competition from companies that have filed patent applications relating to the use of genetically modified cells to treat disease, disorder or injury. In the event our therapies should require the use of such genetically modified cells, we may be required to seek licenses from these competitors in order to commercialize certain of our proposed products, and such licenses may not be granted or be extremely expensive.

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 patients 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. We anticipate that many, if not all, of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical testing and other approval procedures of the FDA and similar regulatory authorities in European and other countries. Various governmental statutes and regulations also, govern, or influence testing, manufacturing, safety, labeling, storage and recordkeeping related to such products and their marketing. The process of obtaining these 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.

FDA Approval Process

Prior to commencement of clinical studies involving humans, preclinical testing of new pharmaceutical products is generally conducted on animals in the laboratory to evaluate the potential efficacy and safety of the product candidate. The results of these studies are submitted to the FDA as part of an IND application, which must become effective before clinical testing in humans can begin. Typically, human clinical evaluation involves a time-consuming and costly three-phase process. In Phase I, clinical trials are conducted with a small number of people to assess safety and to evaluate the pattern of drug distribution and metabolism within the body. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. (In some cases, an initial trial is conducted in diseased patients to assess both preliminary efficacy and preliminary safety and patterns of drug metabolism and distribution, in which case it is referred to as a Phase I/II trial.) In Phase III, large-scale, multi-center, comparative trials are conducted with patients afflicted with a target disease in order to provide enough data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend, or terminate the testing based upon the data which have been accumulated to that point and its assessment of the risk/benefit ratio to the patient. All adverse events must be reported to the FDA. Monitoring of all aspects of the study to minimize risks is a continuing process.

The results of the preclinical and clinical testing on non-biologic drugs and certain diagnostic drugs are submitted to the FDA in the form of a New Drug Application (“NDA”) for approval prior to commencement of commercial sales. In the case of vaccines or gene and cell therapies, the results of clinical trials are submitted as a Biologics License Application (“BLA”). In responding to an NDA/BLA submission, the FDA may grant marketing approval, may request additional information, may deny the application if it determines that the application does not provide an adequate basis for approval, and may also refuse to review an application that has been submitted if it determines that the application does not provide an adequate basis for filing and review. There can be no assurance that approvals will be granted on a timely basis, if at all, for any of our proposed products.

European, China and Other Regulatory 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 (EU), 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 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 "Risk Factors."

Executive Officers

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

Name	Position	Age	Position Since
I. Richard Garr	Chief Executive Officer, President, General Counsel	59	1996
Karl Johe, Ph.D.	Chief Scientific Officer	51	1996
John Conron	Chief Financial Officer	61	4/1/2007

Mr. I. Richard Garr, JD, age 59, has been a director and our Chief Executive Officer since 1996. Mr. Garr was previously an attorney with Beli, Weil & Jacobs, the B&G Companies, and Circle Management Companies. Mr. Garr is a graduate of Drew University (1976) and the Columbus School of Law, The Catholic University of America (1979). Additionally, he was a founder and current Board member of the First Star Foundation, a children's charity focused on abused children's issues; a founder of The Starlight Foundation Mid Atlantic chapter, which focuses on helping seriously ill children; and is a past Honorary Chairman of the Brain Tumor Society. In evaluating Mr. Garr's specific experience, qualifications, attributes and skills in connection with his appointment to our board, we took into account his broad experience in Neural Stem Cells. He is among the longest serving executives in the field.

Mr. Karl Johe, Ph.D., age 51, 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. Mr. Johe is also multilingual.

Mr. John Conron, age 61, has served as our Chief Financial Officer since April 1, 2007. Mr. Conron, a Certified Public Accountant, has over 30 years of experience in the field of corporate finance. Since 2003, Mr. Conron has been consulting early stage companies by providing critical outsource CFO functions such as implementation of accounting systems, creation and monitoring of internal controls, Sarbanes Oxley compliance, audit preparation, financial modeling and strategic planning. Prior to his work as a consultant, Mr. Conron worked for Cyberstar, Inc., a wholly owned subsidiary of Loral Space & Communications, Inc., where he held the position of CFO from 2000 to 2003. Mr. Conron joined Cyberstar from Transworld Telecommunications, Inc., a Qualcomm spin-off which offered telecommunication services in Russia, where he served as CFO. Mr. Conron also served as CFO and on the board of directors of Mercury Communications in London. Mercury was the European subsidiary of Cable & Wireless.

Employees

As of March 1, 2012, we had 14 full-time employees and 2 full time independent contractors. Of these employees, 10 work on research and development and 6 in administration. We also use the services of numerous outside consultants in business and scientific matters.

Our Corporate Information

We are incorporated in the state of Delaware. Our principal executive offices are located at 9700 Great Seneca Highway, Rockville, Maryland 20850, and our telephone number is (301) 366-4960. Our website is located at www.neuralstem.com. We have not incorporated by reference into this Annual Report the information in, or that can be accessed through, our website, and you should not consider it to be a part of this Annual 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

9700 Great Seneca Highway,

Rockville, Maryland 20850

Attn: Chief Financial Officer

Tel: (301) 366-4841

ITEM 1A. RISK FACTORS

Below are 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 us, our business and the value of our securities. The following factors, among others, could cause our actual business, financial condition and future results to differ materially from those contained in forward-looking statements made in this Annual Report or presented elsewhere by management from time to time.

Risks Relating to Our Stage of Development

We have a history of losses.

Since inception in 1996 and through December 31, 2011, we have raised \$100,132,476 of capital and recorded accumulated losses totaling \$98,472,658. On December 31, 2011, we had a working capital surplus of \$590,385 and stockholders' equity of \$1,659,818. Our net losses for the three most recent fiscal years have been \$12,518,527, \$18,387,300 and \$10,364,363, for 2011, 2010 and 2009, respectively. In August of 2011, we were selected as the primary subcontractor for a DOD contract, awarded to Loma Linda University, to develop its human neural stem cell technology for the treatment of cancerous brain tumors. We have recognized revenue related to this contract of \$390,625 for year ended December 31, 2011. In November 2010, we were awarded three federal grants, totaling \$733,438 through the Patient Protection and Affordable Care Act. These are the only revenues for the years ended December 31, 2011 and 2010. We had no revenue for the year ended December 31, 2009. We do not anticipate generating any revenue from the sales of our products during 2011.

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 financed our operations through the sale of our securities, the exercise of investor warrants, and to a lesser degree from grants and research contracts. Currently, our monthly cash burn rate is

approximately \$1,000,000. The burn rate is expected to drop to \$700,000 in the second quarter as we bring our accounts payable current. We estimate that we will have sufficient cash and cash equivalents to finance our current operations, pre-clinical and clinical work for at least 12 months from December 31, 2011. We cannot assure you that we will be able to secure additional financing after such time. Several factors will affect our ability to raise additional funding, including, but not limited to, the volatility of our common shares and general market conditions. We anticipate that our available cash and expected income will be sufficient to finance our current activities for at least the next 12 months from December 31, 2011, although certain activities and related personnel may need to be reduced.

We have expended and expect to continue to expend substantial cash in the research, development, clinical and pre-clinical testing of our stem cell technologies with the goal of ultimately obtaining FDA approval to market our proposed 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 operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to our competitive market pressures. If we exhaust our cash reserves and are unable to realize 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.

Additional financing will result in dilution to existing stockholders.

We do not generate any revenue. Accordingly, we will be required to issue our securities in order to secure additional financing. The issuance of additional securities may be dilutive to current shareholders. We are authorized to issue 150,000,000 shares of common stock and 7,000,000 shares of preferred stock. Such securities, as well as derivative securities that are exercisable into common or preferred stock, may generally be issued without the approval or consent of our stockholders. The issuance of such securities may result in substantial dilution to existing shareholders.

Risks Relating to Our Business

Our business is dependent on the successful development of our product candidates.

At present our ability to progress as a company is significantly dependent on our two (2) product candidates currently in Phase I trials. Any clinical, regulatory or other development that significantly delays or prevents us from completing any of our trials, any material safety issue or adverse side effect to any study participant in these trials, or the failure of these trials to show the results expected would likely depress our stock price significantly and could prevent us from raising the additional capital we will need to further develop our technologies. Moreover, any material adverse occurrence in our clinical trials could substantially impair our ability to initiate clinical trials to test our product candidates in other potential indications. This, in turn, could adversely impact our ability to raise additional capital and pursue our planned research and development efforts.

Our business relies on technologies that we may not be able to commercially develop.

We have concentrated the majority of our research on 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 and currently have limited human applications. We cannot guarantee that we will be able to develop our technologies or that such development will result in products with any commercial utility or value. We anticipate that the commercial sale of such products and/or royalty/licensing fees related to the technology, will be our primary sources of revenues. If we are unable to develop our technologies, we may never realize any revenue.

Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of these therapies 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.

Our inability to complete pre-clinical and clinical testing and trials will impair our viability.

We are currently undertaking two (2) sponsored Phase I clinical trials. Although we have commenced the trials, the outcome of the trials is uncertain, and if we are unable to satisfactorily complete such trials, or if such trials yield unsatisfactory results, we will be unable to commercialize our proposed products. No assurances can be given that the clinical trials will be completed or result in a successful outcome. If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would be unable to commercialize our therapeutic products, and our business and results of operations would be materially harmed.

Our proposed products may not have favorable results in clinical trials or receive regulatory approval.

Positive results from pre-clinical studies should not be relied upon as evidence that our clinical trials will succeed. Even if our product candidates achieve positive results in pre-clinical studies, we will be required to demonstrate, through clinical trials, that the 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 would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon our development efforts of any of our product candidates, then we may not be able to generate sufficient revenues to become profitable, and our operations could be materially harmed.

There are no assurances that we will be able to submit or obtain FDA approval of a new drug application or biologics license application in order to market and sell our products.

There can be no assurance that even if the clinical trials of any potential product candidates are successfully initiated and completed, that we will be able to submit a Biologics License Application or New Drug Application to the FDA or that any BLA or NDA we submit will be approved in a timely manner, if at all. If we are unable to submit a BLA and NDA with respect to any future product candidate, 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 in clinical trials. If we fail to commercialize our product candidate, we may be unable to generate sufficient revenues to attain profitability and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

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 reputation and business, which could cause a significant loss of stockholder value. 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. At present, some of our material requirements are single sourced, and the loss of one or more of these sources may adversely affect our business

Our business is subject to ethical and social concerns.

The use of stem cells for research and therapy has been the subject of debate regarding ethical, legal and social issues. Negative public attitudes toward stem cell therapy could result in greater governmental regulation of stem cell therapies, which could harm our business. For example, concerns regarding such possible regulation could impact our ability to attract collaborators and investors. Existing and potential U.S. government regulation of human tissue may lead researchers to leave the field of stem cell research or the country altogether, in order to assure that their careers will not be impeded by restrictions on their work. Similarly, these factors may induce graduate students to choose other fields less vulnerable to changes in regulatory oversight, thus exacerbating the risk that we may not be able to attract and retain the scientific personnel we need in the face of competition among pharmaceutical, biotechnology and health care companies, universities and research institutions for what may become a shrinking class of qualified individuals

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 it. 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. By way of example, in May of 2008, we filed a complaint against StemCells, Inc., alleging that U.S. Patent No. 7,361,505 (the "'505 patent'"), allegedly exclusively licensed to StemCells, Inc., is invalid, not infringed and unenforceable. On the same day, StemCells, Inc. filed a complaint alleging that we had infringed, contributed to the infringement of, and or induced the infringement of two patents owned by or exclusively licensed to StemCells relating to stem cell culture compositions. Please refer to the section of this Annual Report entitled "*Legal Proceedings*" for a further discussion of such litigation.

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 upon 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 third-party patient reimbursement or favorable product pricing.

Our ability to successfully commercialize our proposed products in the human therapeutic field depends to a significant degree on patient reimbursement of the costs of such products and related treatments. We cannot assure you that reimbursement in the United States or 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. 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 health care 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 our current business model.

Our products may not be profitable due to manufacturing costs.

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 stem cell based products. Accordingly, we may not be able to charge a high enough price for us to make a profit from the sale of our cell therapy products.

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

Our proposed products, 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 drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance will depend on a number of factors, including:

- the clinical efficacy and safety of our proposed products;
- the superiority of our products to alternatives;
- the potential advantages of our products over alternative treatment methods; and
- the reimbursement policies of government and third-party payers.

If the health care community does not accept our products for any reason, our business would 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 employee or consultant could adversely affect our opportunities and materially harm our future prospects. In addition, we anticipate the need for additional management personnel and 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 continue to attract and retain the qualified personnel necessary for the development our business.

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

We have entered into employment agreements with Messrs. Garr and Johe which expire on November 1, 2012. In the event either individual is terminated prior to the full term of their respective contracts, for any reason other than a voluntary resignation, all compensation due to such employee under the terms of the respective agreement shall become due and payable immediately. These provisions will make the replacement of either of these employees very costly and could cause difficulty in effecting a change in control. Termination prior to the full term of these contracts would cost us as much as \$1,000,000 per contract and the immediate vesting of all outstanding options and/or warrants held by Messrs. Garr and Johe.

Our competition may have significantly greater experience and financial resources.

The biotechnology industry is characterized by intense competition. We will 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. Although not necessarily direct competitors, in the event we develop a commercially feasible product, we will compete against companies such as Genzyme Corporation, Aastrom Biosciences, Inc. and Viacell, Inc., as well as others, may have substantially greater resources and experience in our fields.

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

Our strategy for the development, clinical and preclinical testing and commercialization of our proposed products is based 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 would be required to expend considerable 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 our therapies exposes us to product liability claims.

Product liability claims could result in substantial litigation costs and damage awards against us. 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 intend to rely upon third-party FDA-approved manufacturers for our products.

We currently have no internal manufacturing capability and rely extensively on FDA-approved licensees, strategic partners or third party contract manufacturers or suppliers. Should we be forced to manufacture our proposed products, we cannot give you any assurance that we will be able to develop an internal manufacturing capability or procure alternative third party suppliers. Moreover, we cannot give you any assurance that any contract manufacturers or suppliers we procure will be able to supply our product in a timely or cost effective manner or in accordance with applicable regulatory requirements or our specifications.

Risks Relating to Intellectual Property and Government Regulation

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, even though issued, our current and potential future patents will survive such challenges. For example, in 2005 our neural stem cell technology was challenged in the USPTO. Although we prevailed in this particular matter upon re-examination by the patent office, 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. At present, there is litigation with StemCells, Inc., which is further described in the portion of this Annual Report entitled “*Legal Proceedings*.”

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

We anticipate conducting research in countries outside of the United States 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.

Our products may not receive regulatory approval.

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacturing and marketing of pharmaceutical products through lengthy and detailed laboratory, pre-clinical and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these regulations typically takes several years or more and vary substantially based upon the type, complexity and novelty of the proposed product. We are currently undertaking two (2) sponsored Phase I clinical trials. 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 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.

Development of our technologies 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 United States 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 the development and manufacture of the cells and cell lines required for our preclinical and clinical products could substantially delay or prevent us from producing the cells needed to initiate 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.

We base a large part of our research and development on the use of human 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 requirements both before and after approval, if any, 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 permitted to commercialize our products due to regulatory constraints.

Federal, state and local governments and agencies in the United States (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.

Risks Relating to Our Common Stock

Our common shares are “thinly” traded.

Our common shares have historically been “thinly” traded, meaning that the number of persons interested in purchasing our common shares at or near the asking price at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the facts that we are a micro-cap company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community. Even if we came to the attention of such persons, they tend to be risk-adverse and would be reluctant to follow an unproven development stage company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without a material reduction in share price. We cannot give you any assurance that a broader or more active trading market for our common shares will develop or be sustained, or that current trading levels will be sustained. Due to these conditions, you may not be able to sell your shares if you need money or otherwise desire to liquidate your investment.

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 of our share price is attributable to a number of factors. First, there is limited liquidity in the market for our common shares. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our shareholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of our common shares are sold on the market without commensurate demand. Secondly, we are a speculative or “risky” investment due to our limited operating history, lack of significant revenues to date and the uncertainty of future market acceptance for our products if successfully developed. As a consequence of this enhanced risk, more risk-averse 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; government regulations; announcements of significant acquisitions, strategic partnerships or joint ventures; our capital commitments; 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.

We face risks related to compliance with corporate governance laws and financial re