

Neuralstem, Inc.
Form 10-K
March 31, 2009

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, 2008.

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)

20850
(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 | 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

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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 o No

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

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a 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 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 NYSE Amex on such date, was approximately \$42,611,966

The number of shares outstanding of Registrant's common stock, \$0.01 par value at March 13, 2009 was 33,751,300.

DOCUMENTS INCORPORATED BY REFERENCE

None.

SUBSEQUENT EVENTS

On February 20, 2009 we announced our spinal cord stem cell trial to treat ALS was on clinical hold and that the FDA has provided us with specific comments, questions and recommendations for modifications to our trial protocol. The FDA has asked for additional information regarding our product manufacturing process and pre-clinical studies, as well as our novel clinical delivery injection device and technique. We believe we can provide this information in an expeditious manner. We are evaluating various modifications to the protocol and eligibility criteria for patients in the trial proposed by the FDA, as well as slight changes to the timing of the surgeries. The FDA had extensive 'non hold' comments, requests for information, and recommendations. These items concerned issues that will need to be addressed for final product manufacturing and testing. We expect to reach agreement with the FDA on all matters so that our application can be approved and the trial commenced.

NEURALSTEM, INC

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2008

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- the accuracy of our estimates and projections;
- our ability to fund our short-term and long-term financing 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

We are a biotechnology company focused on developing and commercializing human neural stem cell technology in the emerging field of regenerative medicine. We are headquartered in Rockville Maryland.

Our History

We began operations in 1996 and were incorporated in 1997 in the state of Maryland. In 2001 we re-incorporated in the state of Delaware. From 1997 to 2003, our research focused on:

- “Genomics,” which is the study of genes and their functions;
- “Drug Discovery,” which consists of the identification of molecules with desired biological effects that have promise as new therapeutic drugs; and
- “Cell Therapy,” which consists of therapies in which cells are administered to patients in order to repair damaged or depleted tissues.

In 2001, we were paid a licensing fee of \$7.5 million by Gene Logic, Inc., payable over three years, to create a database using our technology. Also, in 2001, we received a United States Defense Department contract to do drug screening using the cells derived from our technology in the amount of \$2.5 million over 18 months. Finally, during this period, we pursued our own research into transplanting cells derived from our technology to cure disease. We reached a high of roughly 50 employees in early 2000, mostly involved in the infrastructure involved with the Gene Logic/genomics and drug discovery programs.

In late 2000 and early 2001, as a result of the decline in biotech funding and the accompanying devaluation of the genomics industry, our genomics program was no longer commercially viable. Additionally, in late 2002, the Department of Defense cancelled the program which funded our drug discover efforts. As a result, by the end of 2003, we made the strategic decision to lay off our employees involved in the genomic and drug discovery programs and focus entirely on the transplantation of neural stem cells to treat diseases in patients.

We spent 2004 restructuring our capitalization and creating an “outsourced” model of product development by having our research conducted at various universities and research labs and having all other functions outsourced. In November of 2004 we completed a ten-for-three reverse stock split.

In 2005, we continued to operate under this model, with all accounting, facility, manufacturing, transplantation experimentation and regulatory functions outsourced, under the supervision of Richard Garr, our President, Chief Executive Officer, and general counsel and Dr. Karl Johe, our Chairman and Chief Scientific Officer.

Overview

Starting in 2004, we refocused our research efforts to concentrate primarily in the field of Cell Therapy. Specifically, we are focused on the development and commercialization of treatments based on transplanting human neural stem cells.

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base of our research and development efforts in the area of neural stem cell research, and related technologies. 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 successful development and commercialization of products for use in treatment of a wide array of neurodegenerative conditions and in regenerative repair of acute disease. We are focused on leveraging our key assets, including our intellectual property, our scientific team, our facilities and our capital, to accelerate the advancement of our stem cell technologies. In addition, we are pursuing strategic collaborations with members of academia.

Regenerative Medicine is a young and emerging field. There can be no assurances that our intellectual property portfolio will ultimately produce viable commercialized products and processes. Even if we are able to produce a commercially viable product, there are strong competitors in this field and our product may not be able to successfully compete against them.

All of our research efforts to date are at the level of basic research or in the pre-clinical stage of development. On December 18, 2008 we filed our first Investigational New Drug Application (“IND”) with the U.S. Food and Drug Administration (“FDA”) to begin a clinical trial to treat amyotrophic lateral sclerosis (“ALS” or “Lou Gehrig’s Disease”). On February 20, 2009, the FDA provided us with specific comments, questions and recommendations for modification to the protocol submitted in our IND. The trial is currently on clinical hold. We are in the process of analyzing the notice and the FDA’s comments and recommendations.

The Field of Regenerative Medicine

The emerging field of treatment called "regenerative medicine" or "cell therapy" refers to treatments that are founded on the concept of 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.

Stem Cell Therapy Background

Cells maintain normal physiological function in healthy individuals by secreting or metabolizing substances, such as sugars, amino acids, neurotransmitters and hormones, which are essential to life. When cells are damaged or destroyed, they no longer produce, metabolize or accurately regulate those substances. Cell loss or impaired cellular functions are leading causes of degenerative diseases, and some of the specific substances or proteins that are deficient in some of these diseases have been identified. Although administering these substances or proteins has some advantages over traditional pharmaceuticals, such as specificity, there is no existing technology that can deliver them precisely to the sites of action, under the appropriate physiological regulation, in the appropriate quantity, nor for the duration required to cure the degenerative condition. Cells, however, may do all this naturally. Thus, where failing cells are no longer producing needed substances or proteins or where there has been irreversible tissue damage or organ failure, transplantation of stem or progenitor cells may enable the generation of new functional cells, thus potentially restoring organ function and the patient's health.

Stem cells have two defining characteristics: (i) they produce mature cells which make up particular organs; and (ii) they self renew — that is, some of the cells developed from stem cells are themselves new stem cells, thus permitting the process to continue again and again. Stem cells are known to exist for a number of systems of the human body, including the blood and immune system, the central and peripheral nervous systems (including the brain), the skin, bone, and even hair. They are thought to exist for many others, including the liver and pancreas endocrine systems, gut, muscle, and heart. Stem cells are responsible for organ regeneration during normal cell replacement and, to a greater or lesser extent, after injury.

Stem cells are rare and only available in limited supply, whether from the patients themselves or from donors. Also, cells can often be obtained only through significant surgical procedures. Therefore, in order to develop stem cell therapeutics, three key challenges must be overcome: (i) identification of stem or progenitor cells of a particular organ and testing them for therapeutic potential; (ii) creation of processes to enable use of these rare cells in clinical applications, such as expanding and banking them in sufficient quantities to transplant into multiple patients; and (iii) demonstration of the safety and efficacy of these potential therapeutics in human clinical trials.

The Potential of Our Tissue-Derived Stem Cell-Based Therapy

We believe that, if successfully developed, stem cell therapeutics have the potential to provide a broad therapeutic approach comparable in importance to traditional pharmaceuticals and genetically engineered biologics. With respect to the human neural stem cells, we have developed proprietary and reproducible processes to identify, isolate, expand, purify¹ and control cell differentiation in mature functioning human neurons² and glia³ and bank human neural stem cells derived from brain tissue. Because the cells are purified normal human neural stem cells, they may be better suited for transplantation and may provide a safer and more effective alternative to therapies that are based on cells derived from cancer cells, animal derived cells or cells derived from an unpurified mix of many different cell types.

Potential Markets

We believe that, if successfully developed, neural stem cell-based therapies have the potential to treat a broad range of diseases and injuries of the CNS. We believe the potential application of our technologies given our current research focus includes developing neural cell therapies to treat Parkinson's disease, ALS, and injuries to the spinal cord.

We believe the potential markets for regenerative medicine 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 and represent potential target markets for our proposed products:

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| Medical Condition | Number of Patients * |
|-------------------------------|----------------------|
| Parkinson's Disease | 1 million |
| Spinal-cord injuries | 0.25 million |
| Amyotrophic Lateral Sclerosis | 0.03 million |

*These estimates are based on the estimates published by the following organizations as of April 2006; the Parkinson's Disease Foundation, the Parkinson's Action Network, the Foundation for Spinal Cord Injury Prevention, Care and Cure, and the Amyotrophic Lateral Sclerosis Association.

1 Purification of our cells is the process whereby we separate “raw” donor tissue into our cells. During the process, we monitor the division of the neural stems cells and remove or “weed out” any cells which have failed to divide after a predetermined period of time. We repeat this process 3 to 4 times until the cells remaining have been “purified” in our estimation.

2 Neurons are a major class of cells in the nervous system. Neurons are sometimes called nerve cells, though this term is technically imprecise since many neurons do not form nerves. In vertebrates, they are found in the brain, the spinal cord and in the nerves and ganglia of the peripheral nervous system, and their primary role is to process and transmit neural information. One important characteristic of neurons is that they have excitable membranes which allow them to generate and propagate electrical signals.

3 Glia cells, commonly called neuroglia or simply glia, are non-neuronal cells that provide support and nutrition, maintain homeostasis, form myelin, and participate in signal transmission in the nervous system. In the human brain, glia are estimated to outnumber neurons by as much as 50 to 1.

Our Technology

Our technology is the ability to isolate human neural stem cells from most areas of the developing human brain and spinal cord. Our technology includes the ability to grow neural stem cells into physiologically relevant human neurons of all types. Our two issued core patents entitled “Isolation, Propagation, and Directed Differentiation of Stem Cell from Embryonic and Adult Central Nervous System of Mammals” and “In Vitro Generation of Differentiated Neurons from Cultures of Mammalian Multi-potential CNS Stem Cell” contain claims which cover the process of deriving the cells and the cells created from such process.

Our technology is the ability to isolate human neural stem cells from most areas of the human brain and spinal cord and to grow them into physiologically relevant human neurons of all types. Our core patents entitled:

- Isolation, Propagation, and Directed Differentiation of Stem Cell from Embryonic and Adult Central Nervous System of Mammal; and
- In Vitro Generation of Differentiated Neurons from Cultures of Mammalian Multi-potential CNS Stem Cell

contain claims which cover the details of this process and the culture of cells created. What differentiates our stem cell technology from others is that our patented processes do not require us to “push” the cells towards a certain fate by adding specific growth factors. Our cells actually “become” the type of cell they are fated to be. We believe this process and the resulting cells create a technology platform that allows for the efficient isolation and ability to produce, in commercially reasonable quantities, neural stem cells.

Our technology allows for cells to grow in cultured dishes, also known as “in vitro” growth, without mutations or other adverse events that would compromise their usefulness. We believe this provides two distinct advantages:

- First, the growth or expansion of the cells in vitro occurs while the cells are still in their “stem cell” or blank state which allows for the creation of commercially reasonable quantities of neural stem cells. Once a sufficient number of blank cells have been grown, our technology allows us to program or differentiate the cells into either neurons or glia; and
- Secondly, we have the ability to sample the cells while still in vitro in order to confirm that the cells are differentiating in the desired cell type.

Although not the focus of our business, our technology also has ancillary uses with respect to drug development. Our ability to grow and differentiate neural cells in vitro, gives us the ability to analyze the potential biological effects of molecules on these cells. This has resulted in the identification of a group of small molecule compounds with the potential to enhance the survival of the endogenous cells residing in the hippocampus⁴ region on the brain.

Business Strategy

We are seeking to develop and commercialize stem cell therapeutics to treat, and possibly cure, a range of human diseases. Our strategy has been to identify, isolate and patent important human neural stem and progenitor cells derived from human tissue with therapeutic and commercial importance; to develop techniques which enable the expansion and banking of those cells; and then to take them into clinical development as transplantable therapeutics.

A central element of our business strategy is to obtain patent protection for the compositions, processes and uses of these multiple types of cells that would make the commercial development of neural stem cell therapeutics financially feasible. We have obtained rights to certain inventions relating to stem cells and progenitor through our own research

and from academic collaborators. We expect to continue to expand our search for, and to seek to acquire rights from third parties where relevant, and to further develop our intellectual property positions with respect to both in-house research and through research conducted at commercial and scholarly institutions.

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. Our efforts to date 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 research which 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 institutes pursuant to the terms and conditions of our standard material transfer agreement.

The terms of our standard material transfer agreement require us to provide our research partner or collaborator with access to our technology or “research materials,” which are comprised of our neurological stem cells, for a specific pre-defined purpose. As part of the agreement, we agree to provide sufficient research materials and technical assistance to accomplish the purpose of the program. The determination of sufficiency is determined at our sole discretion. As part of these agreements, we are entitled to certain reporting rights and the right to have patentable discoveries presented to us prior to publication in order for us to file applicable patents. In the event we choose to file a patent, we will either be responsible for all filing and maintenance fees or we will split the fees with our research partner depending on the type of patent to be filed. The agreements also provide for us to receive a fully paid up, royalty free, non-exclusive license to any inventions made by our partner with respect to our technologies and their interest in any intellectual property jointly developed and first right to negotiate an exclusive license. The agreements also provide confidentiality between the parties. Generally each party is responsible for its own expense, there are no milestone payment or royalty payment requirements and the duration of these agreements is for a three year term which can be terminated by either party by providing 90 days written notice. Also, these agreements may require us to pay for certain costs and expenses incurred in connection with the research.

4 The hippocampus region of the brain plays a part in memory and navigation. We believe that this ability to enhance the survival rate of the endogenous cells may result in the development of drugs or compounds that could be used to treat a variety of central nervous system diseases.

Examples of such projects include:

University of California San Diego, San Diego, CA: In May of 2002, we initiated a research project with the University of California in San Diego for the purpose of researching the applicability of our technology to the treatment of Ischemic Spastic Paraplegia and traumatic spinal cord injury. The project is ongoing. The research yielded findings that contributed to our filing of patent entitled Transplantation of Human Cells for Treatment of Neurological Disorders.

Johns Hopkins University, School of Medicine, Baltimore, MD: In March of 2001 we initiated a research project with Johns Hopkins University, School of Medicine for the purpose of researching the applicability of our technology to the treatment of Amyotrophic Lateral Sclerosis and traumatic spinal cord injury. The project is ongoing. The research yielded findings that contributed to our filing of patent entitled Transplantation of Human Cells for Treatment of Neurological Disorders.

University of Southern Florida, Tampa, FL: In September of 2005 we initiated a research project with the University of Southern Florida for the purpose of researching the applicability of our technology to the treatment of Parkinson's Disease. The project is ongoing.

University of Central Florida, Orlando, FL: In March of 2006 we initiated a research project with the University of Central Florida for the purpose of researching the applicability of our technology to the treatment of spinal cord injuries. The project is ongoing.

University of Pennsylvania whereby we have entered into an agreement with the university to assist us in developing "A Feasibility and Safety Study of human Spinal Stem Cell Transplantation for the Treatment of Ischemic Spastic Paraplegia Due to Spinal Cord Ischemia.

Albany Molecular Research, Inc., whereby we have contracted with Albany to assist us in manufacturing small molecule neurogenesis treatment using "Good Manufacturing Practice procedures.

Ricera Biosciences, LLC, whereby we have entered into an agreement whereby Ricera will assist us in performing toxicity tests on small molecule neurogenesis treatments.

China Medical University & Hospital of Taiwan, to collaborate on Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's disease) with Dr. Shinn-Zong Lin, MD, PhD as principle investigator.

Albert-Ludwigs-University in Freiburg, Germany, to collaborate on the treatment of Huntington's disease.

The foregoing is not exhaustive and is only meant to provide a brief overview of the types of projects we are undertaking with third parties.

Manufacturing

We currently manufacture our cells both in-house and on an outsource basis. 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 to be used in pre-clinical works, and which are accordingly subject to higher FDA requirements, to Charles River Laboratories, Inc., of Wilmington, Massachusetts. The Charles River facility has the capacity to be used for cell processing under the FDA determined Good Manufacturing Practices (GMP) in quantities sufficient for our current pre-trial and anticipated future clinical trial

needs. We believe the facility has sufficient capacity to provide for our needs in both the near to intermediate term. We have no quantity or volume commitment with Charles River Laboratories and our cells 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 4 patents and 13 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 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 | I S O L A T I O N , P R O P O G A T I O N , A N D D I R E C T E D D I F F E R E N T I A T I O N O F S T E M C E L L S F R O M C E N T R A L N E R V O U S S Y S T E M O F M A M M A L S |
| 2343571 | CA | 9/20/1999 | N/A | N/A | S T A B L E N E U R A L S T E M C E L L L I N E S |
| 99948396.9 | EP | 9/20/1999 | N/A | N/A | S T A B L E N E U R A L S T E M C E L L L I N E S |
| 2000-574224 | JP | 9/20/1999 | N/A | N/A | S T A B L E N E U R A L S T E M C E L L L I N E S |
| 10/047,352 | US | 1/14/2002 | N/A | N/A | S T A B L E N E U R A L S T E M C E L L S |
| 3790356.4 | EP | 12/5/2003 | N/A | N/A | M E T H O D F O R D I S C O V E R I N G N E U R O G E N I C A G E N T S |
| 10/914,460 | US | 8/9/2004 | N/A | N/A | U S E O F F U S E D I M I D A Z O L E S , A M I N O P Y R I M I D I N E S , I S O N I C O T I N A M I D E S , M I N O M E T H Y L |

| | | | | | PHENOXYPIPERIDINES AND ARYLOXYPIPERIDINES TO PROMOTE AND DETECT ENDOGENOUS NEUROGENESIS |
|-----------------|----|------------|-----|-----|--|
| 11/281,640 | US | 11/17/2005 | N/A | N/A | TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS |
| 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 |

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| | | | | | |
|---------------|----|------------|-----|-----|---|
| 1-2007-501016 | PH | 11/17/2005 | N/A | N/A | TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS |
| 2007122507 | RU | 11/17/2005 | N/A | N/A | TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS |
| 200703490-3 | SG | 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 |
| 11/932,923 | US | 10/31/2007 | N/A | N/A | TRANSPLANTATION OF HUMAN NEURAL CELLS FOR TREATMENT OF NEUROLOGICAL DISORDERS |

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 |
| 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 , PROPOGATION, AND DIRECTED DIFFERENTIATION OF STEM CELLS FROM 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 | I S O L A T I O N , P R O P A G A T I O N A N D D I R E C T E D D I F F E R E N T I A T I O N O F S T E M C E L L S F R O M E M B R Y O N I C A N D A D U L T C E N T R A L N E R V O U S S Y S T E M O F M A M M A L S |
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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 operating in the fields of regenerative medicine, cell therapy, tissue engineering and tissue regeneration. 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.

Although not necessarily direct competitors, some of the specialty biotechnology companies include Geron Corporation, Genzyme Corporation, StemCells, Inc., Aastrom Biosciences, Inc. and Viacell, Inc. Some of these companies are well-established and have substantial technical and financial resources compared to us. However, as cell-based products are only just emerging as medical therapies, many of our direct competitors are smaller biotechnology and specialty medical products companies. These smaller companies may become significant competitors through rapid evolution of new technologies. Any of these companies could substantially strengthen their competitive position through strategic alliances or collaborative arrangements with large pharmaceutical or biotechnology companies.

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 stem cell products 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 certain of 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 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

We are presently at the stage of pre-clinical development. On December 18, 2008 we filed our first investigational new drug application (IND) with the FDA to begin a clinical trial to treat amyotrophic ALS or Lou Gehrig's Disease. On February 20, 2009, the FDA provided us with specific comments, questions and recommendations for

modification to the protocol submitted in our IND. The trial is on clinical hold. We are in the process of analyzing the notice and the FDA's comments and recommendations. Prior to marketing our proposed product, we will need to achieve FDA approval. The FDA requirements for our potential products to be marketed in the United States include the following steps:

Preclinical laboratory and animal tests must be conducted. Preclinical tests include laboratory evaluation of the cells and the formulation intended for use in humans for quality and consistency. In vivo studies are performed in normal animals and specific disease models to assess the potential safety and efficacy of the cell therapy product.

An investigational new drug application, or IND, must be submitted to the FDA, and the IND must become effective before human clinical trials in the United States may commence. The IND is submitted to the FDA with the preclinical data, a proposed development plan and a proposed protocol for a study in humans. The IND becomes effective 30 days following receipt by the FDA, provided there are no questions, requests for delay or objections from the FDA. If the FDA has questions or concerns, it notifies the sponsor, and the IND will then be on clinical hold until a satisfactory response is made by the sponsor. In our case, we have received notification from the FDA that our IND is on hold. We are currently analyzing the FDA comments and recommendations.

Adequate and well-controlled human clinical trials must be conducted to establish the safety and efficacy of the product. Clinical trials involve the evaluation of a potential product under the supervision of a qualified physician, in accordance with a protocol that details the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. The protocol for each clinical study must be approved by an independent institutional review board, or IRB, of the institution at which the study is conducted, and the informed consent of all participants must be obtained. The IRB reviews the existing information on the product, considers ethical factors, the safety of human subjects, the potential benefits of the therapy and the possible liability of the institution. The IRB is responsible for ongoing safety assessment of the subjects during the clinical investigation. Clinical development is traditionally conducted in three sequential phases.

- Phase 1 studies for a cell therapy product are designed to evaluate safety in a small number of subjects in a selected patient population by assessing adverse effects, and may include multiple dose levels. This study may also gather preliminary evidence of a beneficial effect on the disease.
- Phase 2 may involve studies in a limited patient population to determine biological and clinical effects of the product and to identify possible adverse effects and safety risks of the product in the selected patient population.
- Phase 3 trials would be undertaken to conclusively demonstrate clinical benefit or effect and to test further for safety within a broader patient population, generally at multiple study sites. The FDA continually reviews the clinical trial plans and results and may suggest changes or may require discontinuance of the trials at any time if significant safety issues arise.

The results of the preclinical studies and clinical studies are submitted to the FDA in the form of a Biological License Application (“BLA”) marketing approval authorization applications. The FDA must approve the applications prior to any commercial sale or practice of the technology or product. Biologic product manufacturing establishments located in certain states also may be subject to separate regulatory and licensing requirements. The testing and approval process will require substantial time, effort and expense. The time for approval is affected by a number of factors, including relative risks and benefits demonstrated in clinical trials, the availability of alternative treatments and the severity of the disease, and animal studies or clinical trials that may be requested during the FDA review period.

Our research and development is based largely on the use of human stem and progenitor cells. The FDA has initiated a risk-based approach to regulating human cell, tissue and cellular and tissue-based products and has published current Good Tissue Practice regulations. As part of this approach, the FDA has published final rules for registration of establishments that engage in the recovery, screening, testing, processing, storage or distribution of human cells, tissues, and cellular and tissue-based products, and for the listing of such products. While the Company believes that it is in compliance with all such practices and regulations; we are not required to register until we apply for licensure from the FDA for our product, subject to successful completion of human trials. In addition, the FDA has published rules for making suitability and eligibility determinations for donors of cells and tissue and for current good tissue practice for manufacturers using them, which have recently taken effect. We cannot now determine the full effects of this regulatory initiative, including precisely how it may affect the clarity of regulatory obligations and the extent of regulatory burdens associated with our stem cell research and the manufacture and marketing of stem cell products.

European and Other Regulatory Approval Approval of a product by regulatory authorities comparable to the FDA in Europe and other countries will likely be necessary prior to commencement of marketing a product in any of these countries. The regulatory authorities in each country may impose their own requirements and may refuse to grant approval, or may require additional data before granting approval, even though the relevant product has been approved by the FDA or another authority. The regulatory authorities in the European Union, or EU, and other developed countries have lengthy approval processes for pharmaceutical products. The process for gaining approval in particular countries varies, but is generally similar to the FDA approval process. In Europe, the European Committee for

Proprietary Medicinal Products provides a mechanism for EU-member states to exchange information on all aspects of product licensing. The EU has established a European agency for the evaluation of medical products, with both a centralized community procedure and a decentralized procedure, the latter being based on the principle of licensing within one member country followed by mutual recognition by the other member countries.

Other Regulations In addition to safety regulations enforced by the FDA, we are also subject to regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act and other present and potential future and federal, state, local, and foreign regulations.

Outside the United States, we will be subject to regulations that govern the import of drug products from the United States or other manufacturing sites and foreign regulatory requirements governing human clinical trials and marketing approval for our products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements vary widely from country to country.

The United States Congress, several states and foreign countries have considered legislation banning or restricting human application of stem cell-based and nuclear transfer based technologies. No assurance can be given regarding future restrictions or prohibitions that might affect our technology and business. In addition, we cannot assure you that future judicial rulings with respect to nuclear transfer technology or human stem cells will not have the effect of delaying, limiting or preventing the use of nuclear transfer technology or stem cell-based technology or delaying, limiting or preventing the sale, manufacture or use of products or services derived from nuclear transfer technology or stem cell-derived material. Any such legislative or judicial development would harm our ability to generate revenues and operate profitably.

For additional information about governmental regulations that will affect our planned and intended business operations, see "Risk Factor" beginning on page 13.

Employees

As of March 13, 2009, we had 8 full-time employees. Of these employees 4 work on Research and development and 4 in administration. We also use the services of numerous outside consultants in business and scientific matters.

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

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. The following important 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 limited operating history and have significantly shifted our operations and strategies since inception.

Since inception in 1996 and through December 31, 2008, we have raised \$61,690,040 of capital and recorded accumulated losses totaling \$57,486,795. On December 31, 2008, we had a working capital surplus of \$3,774,078 and stockholders' equity of \$4,203,245. Our net losses for the two most recent fiscal years have been \$11,830,798 and \$7,063,272 for 2008 and 2007 respectively. We had no revenues for the twelve months ended December 31, 2008.

Our ability to generate revenues and achieve profitability will depend upon our ability to complete the development of our proposed stem cell products, obtain the required regulatory approvals, manufacture, and market and sell our proposed products. In part because of our past operating results, no assurances can be given that we will be able to accomplish any of these goals.

Although we have generated some revenue in prior years, we have not generated any revenue from the commercial sale of our proposed stem cell products. Since inception, we have engaged in several related lines of business and have discontinued operations in certain areas. For example, in 2002, we lost a material contract with the Department of

Defense and were forced to close our principal facility and lay off almost all of our employees in an attempt to focus our development strategy on stem cell technologies. This limited and changing history may not be adequate to enable you to fully assess our current ability to develop and commercialize our technologies and proposed products, obtain approval from the FDA, achieve market acceptance of our proposed products, and respond to competition. No assurances can be given as to exactly when, if at all, we will be able to fully develop, commercialize, market, sell and derive material revenues from our proposed products in development.

We will need to raise additional capital to continue operations.

Historically we have generated limited amounts of cash which are not sufficient to meet current or future operating or capital requirements. We have relied almost entirely on external financing to fund operations. Such financing has historically come primarily from the sale of common stock, and the exercise of investor warrants. As of December 31, 2008, we had cash and cash equivalents on hand of approximately \$5.0 million. Presently, we have a monthly cash burn rate of approximately \$500,000. We will need to raise additional capital to fund anticipated operating expenses and future expansion. Among other things, external financing will be required to cover the further development of our technologies and products and other operating costs. On December 18, 2008, we filed our first IND to commence clinical trials on one of our proposed products. On February 20, 2009 we received notification from the FDA that our IND was on hold pending our submission of additional information and modifications to our IND. In the event the IND is approved, we expect additional cost related to the trials to be phased in slowly over the following 12 months.

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 funds to conduct research and development, establish and conduct clinical and pre-clinical trials and commercial-scale manufacturing arrangements and to provide for marketing and distribution. These funds may not be available on acceptable terms, if at all. If adequate funds are unavailable, we may have to delay, reduce the scope of, or eliminate one or more of our research, development or commercialization programs, which may materially harm our business, financial condition and results of operations.

Our long term capital requirements are expected to depend on many factors, including:

- the continued progress and cost of our research and development programs;
- the progress with pre-clinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the costs of developing sales, marketing and distribution channels and our ability to sell the stem cell products if developed;
- the costs involved in establishing manufacturing capabilities for commercial quantities of our proposed products;
 - competing technological and market developments;
 - market acceptance of our proposed stem cell products;
 - the costs for recruiting and retaining employees and consultants; and
 - the costs for educating and training physicians about our proposed products.

We may expend available resources more rapidly than currently anticipated, resulting in the need for additional funding. We cannot assure you that financing whether from external sources or related parties will be available if needed or on favorable terms. If additional financing is not available when required or is not available on acceptable terms, we may not be able to fund operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures.

Additional financing requirements could result in dilution to existing stockholders.

At present, we are not able to finance our operations through the sale of our products. Accordingly, we will be required to secure additional financing. If we are able to obtain such additional financing, it may be dilutive to current shareholders. We have authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of capital stock, or warrants which may be convertible into any one or more classes or series of capital stock. We are authorized to issue 150,000,000 shares of common stock and 7,000,000 shares of preferred stock. Such securities may generally be issued without the approval or other consent of our stockholders.

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, and 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 U.S. Patent and Trademark Office. Although we prevailed in this particular matter upon re-examination by the patent office, these cases are complex, lengthy and 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 new litigation with StemCells, Inc. which is in its initial stages and any likely outcome is difficult to predict.

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

We anticipate conducting research in countries outside of the United States. A number of our competitors are located in these countries and may be able to get access to 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 FDA approval.

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacture 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. On December 18, 2008, we submitted its first IND, application to the FDA. We cannot assure you when or if such IND application will be granted. Nor can we assure you that if the IND is granted, whether we will successfully complete any clinical trials in connection with such IND application. Further, we cannot yet accurately 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 or our collaborators 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 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 cGTP, 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 Good Manufacturing Practices, or cGMP. Accordingly, we will need to enter into supply agreements with companies that manufacture these components to cGMP 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 will be materially and negatively impacted.

Risks Relating to Our Business

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

We have concentrated our research on stem cell technologies, and 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 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 royalty/licensing fees related to the technology, will be our primary sources of revenues. If we are unable to develop the technologies, investors will likely lose their entire investment.

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.

On December 18, 2008, we submitted our first IND application to the FDA. On February 20, 2009, the FDA provided us with specific comments, questions and recommendations for modification to the protocol submitted in our IND. The trial is on clinical hold. We are in the process of analyzing the notice and the FDA's comments and recommendations. Even if we eventually receive approval from the FDA to commence clinical trials, the outcome of pre-clinical, clinical and product testing of our products is uncertain. If we are unable to satisfactorily complete testing, or if such testing yields unsatisfactory results, we will be unable to commercially produce its proposed products. Before obtaining regulatory approvals for the commercial sale of any potential human products, our products will be subjected to extensive pre-clinical and clinical testing to demonstrate their safety and efficacy in humans. No assurances can be given that the clinical trials will demonstrate the safety and efficacy of such products at all, or to the extent necessary to obtain appropriate regulatory approvals, or that the testing of such products will be completed in a timely manner, if at all, or without significant increases in costs, program delays or both, all of which could harm our ability to generate revenues. In addition, our proposed products may not prove to be more effective for treating disease or injury than current therapies. Accordingly, we may have to delay or abandon efforts to research, develop or obtain regulatory approval to market its proposed products. Many companies involved in biotechnology research and development have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and efficacy of a therapeutic product under development could delay or prevent regulatory approval of the product and could harm our ability to generate revenues, operate profitably or produce any return on an investment.

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 clinical trials will succeed. Even if our product candidates achieve positive results in clinical studies, we will be required to demonstrate through clinical trials that these 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 proceeding 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 reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.

The commencement of clinical testing of our current and potential product candidates may be delayed.

The commencement of clinical trials may be delayed for a variety of reasons, including:

- delays in demonstrating sufficient safety and efficacy in order to obtain regulatory approval to commence clinical trials;

- delays in reaching agreement on acceptable terms with contract research organizations and clinical trial sites;
 - delays in manufacturing quantities of a product candidate sufficient for clinical trials;
 - delays in obtaining approval of an IND from the FDA or similar foreign approvals;
- delays in obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
 - insufficient financial resources.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial. Delays in the commencement of clinical testing of our product candidates could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

There are no assurances that we will be able to submit or obtain FDA approval of a biologics license application.

There can be no assurance that if our clinical trials of any potential product candidate are successfully initiated and completed, we will be able to submit an Biologics License Application (“BLA”) to the FDA or that any BLA we submit will be approved by the FDA in a timely manner, if at all. If we are unable to submit a BLA with respect to any future product candidate, or if any BLA we submit is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject BLAs and requires additional clinical trials, even when product candidates performed well or achieved favorable results in clinical trials. If we fail to commercialize any future product candidate in clinical trials, 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 cell-based therapeutic products is novel, highly regulated, critical to our business, and dependent upon specialized key materials.

The manufacturing of cell-based therapeutic products is a complicated and difficult process, dependent upon substantial know-how and subject to the need for continual process improvements to be competitive. 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, such as GTP, GMP and release testing requirements, is uncertain. Manufacturing irregularities or lapses in quality control could have a serious 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 or are derived from a biological origin. 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 if we are unable to obtain alternatives or alternative sources at all or upon terms that are acceptable to us.

Ethical and other concerns surrounding the use of stem cells may negatively affect regulatory approval or public perception of our product candidates.

The use of stem cells for research and therapy has been the subject of debate regarding related 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 significant 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. At present, the litigation is in its initial stages and any likely outcome is difficult to predict.

We may not be able to obtain third-party patient reimbursement or favorable product pricing.

Our ability to successfully commercialize certain proposed products in the human therapeutic field may depend 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. The Company 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 the current business model.

Our products may not be profitable due to manufacturing costs.

Our products may be significantly more expensive to manufacture than most 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. We hope to substantially reduce manufacturing costs through process improvements, development of new science, increases in manufacturing scale and outsourcing to experienced manufacturers. If we are not successful in these and other initiatives, and depending on the pricing of the product, our profit margins may be significantly less than that of most drugs or therapies on the market today. 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. If we are unable to realize significant profits from our potential product candidates, its business would be materially harmed.

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, of any, will depend on a number of factors, including:

- the clinical efficacy and safety of our proposed products;
- the superiority of our products to alternatives currently on the market;
- the potential advantage of our product over alternative treatment methods; and
- the reimbursement policies of government and third-party payors.

If the health care community does not accept our products for any of the foregoing reasons, or for any other reason, our business would be materially harmed.

We depend on two key employees for our continued operations and future success.

The loss of either of our key executive officers, Richard Garr and Karl Johe, would be detrimental to us.

- We currently do not maintain “key person” life insurance on the life of Mr. Garr. As a result, the Company will not receive any compensation upon the death or incapacity of this key individuals;
- We currently do maintain “key person” life insurance on the life of Mr. Johe. As a result, the Company will receive approximately \$1,000,000 in the event of his death or incapacity.

In addition, we anticipate growth and expansion into areas and activities requiring additional expertise, such as clinical testing, regulatory compliance, manufacturing and marketing, will require the addition of new 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 failure to attract and retain such personnel or to develop such expertise would adversely affect our business.

We have entered into long-term contracts containing significant anti-termination provisions with our key could make future 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 \$1,230,000 per contract and the immediate vesting of all outstanding options and/or warrants held by Messrs. Garr and Johe.

We have no product liability insurance, which may leave us vulnerable to future claims that we will be unable to satisfy.

The testing, manufacturing, marketing and sale of human therapeutic products entails an inherent risk of product liability claims, and we cannot assure you that substantial product liability claims will not be asserted against us. We have no product liability insurance. In the event we are forced to expend significant funds on defending product liability actions, and in the event those funds come from operating capital, we will be required to reduce its business activities, which could lead to significant losses.

We cannot assure you that adequate insurance coverage will be available in the future on acceptable terms.

We have limited commercial insurance policies. Any significant claim would have a material adverse effect on its business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions. We will endeavor to obtain appropriate insurance coverage for insurable risks that we identify. In the event a loss occurs that is not covered, depending on the size of such loss, it could materially affect our business plan or ability to operate.

Our outsource model depends on third parties to help develop and test its 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 enter into collaborations with third parties in order to further develop the technology and products. In the event we are not able to enter into such relationships in the future, our ability to 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. Also, we currently rely on third parties to assist us with a substantial portion of our research and development. Although our collaborative agreements do not impose any duties or obligations on us other than the licensing of our technology, the failure of any of these third parties may hinder our ability to develop products in a timely fashion. By way of example, our collaboration with John Hopkins University, School of Medicine yielded findings that contributed to our patent application entitled Transplantation of Human Cells for Treatment of Neurological Disorder. Had the collaboration not existed, our ability to apply for such patent would have been greatly hindered.

We intend to rely upon third-party FDA-approved manufacturers for our stem cells.

We currently have no internal manufacturing capability, and will rely extensively on FDA-approved licensees, strategic partners or third party contract manufacturers or suppliers. We currently have an agreement with Charles River Laboratories International, Inc. (“Charles River”) for the manufacturing and storage of our cells. In the event Charles River fails to provide suitable cells, we would be forced to either manufacture the cells ourselves or seek other third party vendors. Should we be forced to manufacture our stem cells, 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.

Our competition includes both public and private organizations and collaborations among academic institutions and large pharmaceutical companies, most of which have significantly greater experience and financial resources than ours.

The biotechnology industry is characterized by intense 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. Although not necessarily direct competitors, companies such as Geron Corporation, Genzyme Corporation, StemCells, Inc., Advanced Cell Technology, Inc., Aastrom Biosciences, Inc. and Viacell, Inc., as well as others, may have substantially greater resources and experience in our fields which put us at a competitive disadvantage.

Risks Relating to Our Common Stock

Our common shares are sporadically or “thinly” traded.

Our common shares have historically been sporadically or “thinly” traded, meaning that the number of persons interested in purchasing our common shares at or near ask prices 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 small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse 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 or non-existent, 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 public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained. Due to these conditions, we can give you no assurance that you will be able to sell your shares at or near ask prices or at all if you need money or otherwise desire to liquidate your shares.

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 a seasoned issuer's. The volatility in our share price is attributable to a number of factors. First, our common shares are sporadically or thinly traded. 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. A seasoned issuer could better absorb sales without a material reduction in share price. Secondly, we are a speculative or "risky" investment due to our limited operating history, lack of significant revenues to date and 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 reporting standard.

The Sarbanes-Oxley Act of 2002, as well as related new rules and regulations implemented by the SEC and the Public Company Accounting Oversight Board, require changes in the corporate governance practices and financial reporting standards for public companies. These new laws, rules and regulations, including compliance with Section 404 of the Sarbanes-Oxley Act of 2002 relating to internal control over financial reporting (“Section 404”), will materially increase the Company's legal and financial compliance costs and make some activities more time-consuming, burdensome and expensive. Additionally, in 2008 the SEC extended the compliance period for non-accredited filers with regard to Section 404(b). Unless further extended, we will be required to include attestation reports in our annual report for year ending on December 31, 2009. We anticipate this will further increase the costs associated with our compliance with the Sarbanes-Oxley Act of 2002.

Any failure to comply with the requirements of the Sarbanes-Oxley Act of 2002, our ability to remediate any material weaknesses that we may identify during our compliance program, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of the periodic management evaluations of our internal controls and, in the case of a failure to remediate any material weaknesses that we may identify, would adversely affect the annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting that are required under Section 404 of the Sarbanes-Oxley Act. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

Any payment of cash dividends is at the sole discretion of our Board of Directors. We have never paid cash dividends nor do we anticipate paying cash dividends in the foreseeable future. Accordingly, any return on investment will be as a result of stock appreciation.

Issuance of additional securities could dilute your proportionate ownership and voting rights.

We are entitled under our amended and restated certificate of incorporation to issue up to 150,000,000 common and 7,000,000 “blank check” preferred shares. As of December 31, 2008, we have issued and outstanding 33,751,300 common shares, 21,880,421 common shares reserved for issuance upon the exercise of current outstanding options and warrants (excluding options and warrants issued under our equity compensation plans), 669,341 common shares reserved for issuance of additional grants under our 2005 incentive stock plan, and 830,000 shares reserved for issuance of grants under our 2007 stock plan. Accordingly, we will be entitled to issue up to 92,868,938 additional common shares and 7,000,000 additional preferred shares. Our board may generally issue those common and preferred shares, or options or warrants to purchase those shares, without further approval by our shareholders based upon such factors as our board of directors may deem relevant at that time. Any preferred shares we may issue shall 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 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 option plans, in order to attract and retain qualified personnel. In the event of issuance, your proportionate ownership and voting rights may be significantly decreased and the value of your investment impacted.

ITEM 2.

PROPERTIES

We currently lease two facilities. Our executive offices and primary research facilities are located at 9700 Great Seneca Highway, Rockville MD, 20850. We lease these facilities consisting of approximately 2,500 square feet for \$8,220 per month. The term of our lease expires on January 31, 2010.

We entered into a lease in 2007 consisting of approximately 900 square feet of research space in San Diego, California at a monthly lease rate of \$3,278. The lease terminates in August of 2009.

The aforesaid properties are in good condition and we believe they will be suitable for our purposes for the next 12 months. There is no affiliation between us or any of our principals or agents and our landlords or any of their principals or agents.

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, other than the following:

- On May 7, 2008, we filed suit against StemCells, Inc., StemCells California, Inc. (collectively “StemCells”) and Neurospheres Holding Ltd., (collectively StemCells and Neurospheres Holding Ltd are referred to as “Plaintiffs”) in U.S. District Court for the District of Maryland, alleging that U.S. Patent No. 7,361,505 (the “‘505 patent”), alleging that the ‘505 patent was exclusively licensed to the Plaintiffs, is invalid, not infringed, and unenforceable. See Civil Action No. 08-1173. On May 13, we filed an Amended Complaint seeking declaratory judgment that U.S. Patent No. 7,155,418 (the “‘418 patent”) is invalid and not infringed and that certain statements made by our CEO are not trade libel or do not constitute unfair competition as alleged by the Plaintiffs. On July 15, 2008, the Plaintiffs filed a Motion to Dismiss for Lack of Subject Matter Jurisdiction, Lack of Personal Jurisdiction, and Improper Venue or in the Alternative to Transfer to the Northern District of California. On August 27, 2008, Judge Alexander Williams, Jr. of the District of Maryland denied StemCells’ Motion to Dismiss, but granted Neurospheres’ motion to dismiss. On September 11, 2008, StemCells filed its answer asserting counterclaims of infringement for the ‘505 patent, the 418 patent, and state law claims for trade libel and unfair competition. On October 1, 2008, Neuralstem filed a motion to dismiss or strike StemCells’ state law trade libel and unfair competition claims. That motion is still pending and it is not known when nor on what basis will this matter be concluded.
- On July 28, 2006, StemCells, Inc., filed suit against Neuralstem, Inc. in the U.S. District Court in Maryland, alleging that Neuralstem has been infringing, contributing to the infringement of, and or inducing the infringement of four patents owned by or exclusively licensed to StemCells relating to stem cell culture compositions, genetically modified stem cell cultures, and methods of using such cultures.

In October 2006, Neuralstem filed a motion to dismiss, or in the alternative for summary judgment, arguing that its preclinical research activities are covered under the “safe harbor” provision of 35 U.S.C. § 271(e)(1) (the “safe harbor” defense’). The parties agreed to stay substantive discovery in the case pending resolution of Neuralstem’s motion to dismiss based on the “safe harbor” defense. While limited discovery was on-going on the “safe harbor” defense, in response to submissions from Neuralstem, the Patent Office ordered reexamination of all four of the patents-in-suit owned by StemCells. In view of the reexamination proceedings, both parties agreed that a stay of the entire lawsuit was warranted. On June 25, 2007, Judge Alexander Williams, Jr. entered an order staying the entire litigation pending the outcome of the reexamination proceedings. It is not known when nor on what basis this matter will be concluded.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II

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

Market Information

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

| | High | Low |
|-------------------|---------|---------|
| 2007: | | |
| First Quarter | \$ 3.95 | \$ 2.25 |
| Second Quarter(1) | \$ 3.45 | \$ 2.20 |
| Third Quarter | \$ 4.17 | \$ 2.75 |
| Fourth Quarter | \$ 3.36 | \$ 2.25 |

2008:

| | | | | |
|----------------|----|------|----|------|
| First Quarter | \$ | 3.58 | \$ | 2.29 |
| Second Quarter | \$ | 2.59 | \$ | 1.31 |
| Third Quarter | \$ | 1.86 | \$ | 1.20 |
| Fourth Quarter | \$ | 2.15 | \$ | 1.01 |

1 On August 27, 2007, our common stock began trading on the NYSE Amex (previously the American Stock Exchange) under the ticker symbol CUR. Prior to such time, our common stock was traded on the Over-the-Counter Bulletin Board. Information for all quotation information prior to August 27, 2007 sets forth the range of high and low prices for our common stock as reported by the NASDAQ website. These prices represent reported transactions that do not include retail markups, markdowns or commissions, and may not necessarily represent actual transactions

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Holders

As of March 16, 2009 our common stock was held by approximately 740 record holders. We believe our actual number of shareholders may be significantly higher as 25,942,945 shares are currently being held in street name.

Dividends

We have not paid any cash dividends to date and have no plans to do so in the immediate future.

Equity Compensation Plan Information

The following table sets forth information with respect to our 2005 & 2007 Stock Plans as of December 31, 2008.

| | (a) Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights | (b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights | (c) Number of Securities Remaining Available or Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) |
|--|---|---|--|
| Equity compensation plans approved by security holders | | | |
| 2005 Stock Plan, as amended | 3,330,659 | \$ 1.19 | 669,341 |
| 2007 Stock Plan | 5,320,000 | 2.46 | 830,000 |
| Equity compensation plans not approved by security holders | | | |
| | N/A | N/A | N/A |
| Total | 8,650,659 | \$ 1.51 | 1,499,341 |

Recent Sales of Unregistered Securities

The following information is given with regard to unregistered securities sold during the preceding three years. The unregistered securities were issued pursuant to section 4(2) of the Securities Act:

- On February 16, 2007, we issued 69,000 common shares to a consultant in connection with the exercise of an option to purchase 69,000 common shares at an exercise price of \$.05 per share.
- On March 15, 2007, we completed the private placement of 2,054,000 units to 15 institutional investors. The units were priced at \$2.50 each and resulted in gross proceeds to the Company of \$5,135,000.00. The units consist of:

1 common stock; and
 ½ common stock purchase warrant.

An aggregate of 2,054,000 common shares and warrants to purchase an additional 1,027,000 common shares were issued. The investors also received certain registration rights with regard to the underlying securities. The exercise price of the warrants is \$3.00. The warrants contain certain provisions providing for an adjustment in the number of common shares underlying the warrants and the exercise price of the warrants in the event of certain dilutive issuances. The warrants have a term of 5 years.

T.R. Winston & Company (TRW) acted as placement agent.

- On March 15, 2007, in connection with the private placement, we issued a warrant to purchase 246,480 common shares at \$3.00 to a placement agent as compensation for its services as placement agent. The warrant contains certain provisions providing for an adjustment in the number of common shares underlying the warrant and the exercise price of the warrant in the event of certain dilutive issuances. The warrant has a term of 5 years.
- On March 27, 2007, we sold an additional 400,000 units for \$1,000,000 pursuant to the terms of our March 15, 2007 private placement. In connection with the sale of such additional units, we paid fees and expenses totaling \$80,300 and issued a warrant to purchase an additional 48,000 common shares at \$3.00 as compensation for acting as placement agent. The units and warrants issued have the same terms as the units and warrants issued on March 15, 2007.
- On April 1, 2007, we granted an officer options to purchase 100,000 common shares. The options vest as follows: (i) 25,000 vest immediately; and (iii) 75,000 vest quarterly over the year. The options have an exercise price of \$3.15 and expire on April 1, 2015.
- On April 12, 2007, pursuant to our adopted director compensation plan, we issued to each of our independent directors options to purchase 20,000 common shares. The options were issued pursuant to our 2005 Stock Plan. The exercise price per share is \$3.30. The options expire on April 12, 2014.

• On June 5, 2007, in exchange for: (i) the acquisition of certain residual rights; and (ii) the cancellation of the Hi Med Technologies, Inc. licensing agreement, we issued Karl Johe, our Chairman and Chief Scientific Officer, warrants to purchase an aggregate of 3,000,000 shares of our common stock at a price per share of \$3.01. The warrants expire 5 years from the date when they become exercisable. Additionally, the warrants will become immediately exercisable upon an event which would result in an acceleration of Mr. Johe's stock options granted under his employment agreement. The warrants vest as follows:

- i. 1,000,000 warrants vest on October 31, 2010; and
- ii. 2,000,000 warrants vest on October 31, 2011.

• On May 16, 2007, pursuant to our adopted director compensation plan, we issued to each of our independent directors options to purchase 15,000 shares of our common stock (5,000 shares per each committee on which they serve). The options were issued pursuant to our 2005 Stock Plan. The exercise price per share is \$3.83 and the options vest quarterly over the year. The options expire on May 16, 2014.

• On September 20, 2007, our Compensation Committee granted Karl Johe, our Chairman and Chief Scientific Officer, an option to purchase an aggregate of 333.333 shares of our common stock at a price per share of \$3.01 pursuant to our 2005 Stock Plan. The option expires 5 years from the date when they become exercisable. Additionally, the option will become immediately exercisable upon an event which would result in an acceleration of Mr. Johe's stock options granted under his employment agreement. The option vests on October 31, 2010 and expires on October 31, 2015.

• On September 26, 2007, we issued 13,000 share of our common stock to a consultant as partial payment for services rendered. The shares were issued in exchange for services valued at \$39,000. We also granted the consultant piggy back registration rights on any registration statement filed by the Company (excluding any registration statement filed on form S-8).

• On October 31, 2007, the Company issued warrants to purchase 1,227,000 shares of common stock at a per share price of \$2.75 to investors who participated in the Company's March 2007 offering which was previously disclosed on the current report filed on Form 8-K with the Securities and Exchange Commission on March 16, 2007. The warrants have a term of 5 years and are substantially identical to those warrants previously issued in the March 2007 offering. The Company agreed to include the common shares underlying the warrants in the Company's next registration statement. The warrants were granted as an inducement for the investors to exercise their prior warrants as well as the waiver of certain anti-dilutive and participation rights provisions contained March 2007 stock purchase agreement and warrants. The Company hereby incorporates by reference the stock purchase agreement and form of warrant contained in the Company's current report filed on Form 8-K on March 16, 2007. The Company relied on the exception from registration provided for in section 4(2) of the Securities Act.

• On November 15, 2007, our Compensation Committee granted an employee options to purchase 15,000 shares of our common stock at a price per share of \$2.71 pursuant to our 2005 Stock Plan. The options are fully vested and expire 10 years from the grant date.

• On December 10, 2007, our Compensation Committee granted an employee options to purchase 50,000 shares of our common stock at a price per share of \$2.00. The options are fully vested and expire on November 15, 2015.

- On January 21, 2008, we granted the following options pursuant to our 2007 Stock Plan:

Karl Johe, Chairman and Chief Science Officer - options to purchase 2.1 million common shares at a price of \$3.66 per share. The options vest over 3.5 years with the vesting period commencing on January 1, 2008 with 700,000

options vesting on each of February 28, 2009, April 30, 2010, and June 30, 2011. The options expire on January 1, 2018. Additionally, the options will become immediately exercisable upon an event which would result in an acceleration of Mr. Johe's stock options granted under his employment agreement.

Richard Garr, Chief Executive Officer and General Council - options to purchase 2.1 million common shares at a price of \$3.66 per share. The options vest over 3.5 years with the vesting period commencing on January 1, 2008 with 700,000 options vesting on each of February 28, 2009, April 30, 2010, and June 30, 2011. The options expire on January 1, 2018. Additionally, the options will become immediately exercisable upon an event which would result in an acceleration of Mr. Garr's stock options granted under his employment agreement.

- On February 19, 2008, we entered into a securities purchase agreement with CJ CheilJedang Corporation (KSE: CJ CheilJedang) for the sale of \$2.5 million of common shares at \$4.063 per share. Pursuant to the agreement, we issued an aggregate of 615,309 common shares to CJ CheilJedang. Please refer to our Current Report filed on form 8-K on February 25, 2008 for a further description of the transaction.

- On April 1, 2008, we granted an officer compensatory options to purchase an aggregate of 1,050,000 common shares at an exercise price of \$2.60. The options vest as follows: (i) 50,000 vest immediately; and (ii) 1,000,000 vest annually over the next three years so that 100% of the options will be vested on April 1, 2011. The options were issued pursuant to our two stock plans as follows: (x) the option to purchase 1,000,000 common shares was issued pursuant to our 2007 Stock Plan; and (y) options to purchase 50,000 common shares were issued pursuant to our 2005 Stock Plan.
- On May 28, 2008, we granted our independent directors options to purchase an aggregate of 120,000 common shares at an exercise price of \$1.32. The grant was made pursuant to our 2007 Stock Plan and in compliance with our non-executive compensation arrangement. The grant consists of: (i) an option purchase 90,000 common shares as compensation for serving on the board of directors; (ii) an option to purchase 10,000 common shares as compensation for serving on our Audit Committee; (iii) an option to purchase 10,000 common shares as compensation for serving on our Compensation Committee; and (iv) an option to purchase 10,000 common shares as compensation for serving on our Governance and Nominating Committee. The options vest quarterly over the grant year and expire 7 years from the date of grant.
- On August 11, 2008, we granted one of our employees options to purchase 200,000. The options vest as follows: (i) 40,000 on the effective date; and (ii) 40,000 on each of August 11, 2009, 2010, 2011 and 2012. The grant was made pursuant to the 2005 Stock Plan. The options have an exercise price of \$1.89 and expire on August 11, 2018.
 - On August 14, 2008, we granted options to purchase an aggregate of 30,000 common shares at an exercise price of \$1.88 to two employees (15,000 each). The grants were made pursuant to our 2005 Stock Plan. The options vest as follows: (i) 15,000 on the granted date; and (ii) 15,000 on August 14, 2009. The options expire on August 14, 2018.
- On November 14, 2008, we granted a consultant a common stock purchase warrant to purchase 50,000 common shares at a price per share of \$2.75. The warrant was issued as partial compensation for services rendered. The warrant expires on November 13, 2013.
- On December 18, 2008, we completed a registered offering of our shares at a price per share of \$1.25. As a result of this transaction, we trigger certain anti-dilution provisions in our outstanding series A, B and C warrants that resulted in the following:
 - (i) the exercise price of 2,093,765 outstanding series A warrants was reduced from \$1.50 to \$1.25;
 - (ii) the exercise price of 2,140,415 outstanding series B warrants was reduced from \$2.00 to \$1.25;
 - (iii) the exercise price of 1,521,480 outstanding series C warrants was reduced from \$2.75 to \$1.25; and
 - (iv) we issued an additional 1,884,672 Series C Warrants with an exercise price of \$1.25.
- On January 5, 2009 we granted a consultant a common stock purchase warrant to purchase 100,000 common shares at a price per share of \$1.64. The warrant has a term of 7 years.

ITEM 6.

SELECTED FINANCIAL DATA

We are not required to provide the information as to selected financial data as we are considered a smaller reporting company.

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 (MD&A) is provided in addition to the accompanying consolidated financial statements and notes to assist readers in understanding our results of operations, financial condition, and cash flows. MD&A is organized as follows:

- Overview. Discussion of our business and overall analysis of financial and other highlights affecting the company 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 our operating segments and outlook for 2009.
- 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 2008 to 2007.
- Liquidity and Capital Resources. An analysis of changes in our balance sheets and cash flows, and discussion of our financial condition including the credit quality of our investment portfolio and potential sources of liquidity.

The various sections of this MD&A contain a number of forward-looking statements. Words such as “expects,” “goals,” “plans,” “believes,” “continues,” “may,” and variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements that refer to projections of our future financial performance, our anticipated growth and trends in our businesses, and other characterizations of future events or circumstances are forward-looking statements. Such statements are based on our current expectations and could be affected by the uncertainties and risk factors described throughout this filing and particularly in the “Overview” and “Trends & Outlook” section (see also “Risk Factors” in Part I, Item 1A of this Form 10-K). Our actual results may differ materially.

Overview

Neuralstem is focused on the development and commercialization of treatments based on transplanting human neural stem cells.

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 four (4) issued patents and twelve (12) patent pending applications in the field of regenerative medicine and related technologies. We believe our technology base, in combination with our know-how, and collaborative projects with major research institutions provides a competitive advantage and will facilitate the successful development and commercialization of products for use in the treatment of a wide array of neurodegenerative conditions and in regenerative repair of acute disease.

Regenerative medicine is a young and emerging field. There can be no assurances that our intellectual property portfolio will ultimately produce viable commercialized products and processes. Even if we are able to produce a commercially viable product, there are strong competitors in this field and our product may not be able to successfully compete against them.

All of our research efforts to date are at the pre-clinical stage of development. We are focused on leveraging our key assets, including our intellectual property, our scientific team, our facilities and our capital, to accelerate the advancement of our stem cell technologies. In addition, we are pursuing strategic collaborations with members of academia. We are headquartered in Rockville, Maryland.

In addition to our core tissue based technology we have begun developing a Small-Molecule compound. The company has performed preliminary in vitro and in vivo tests on the compound with regard to neurogenesis. Based on the results of these tests we have applied for a U.S. patent on the compound.

Technology

Our technology is the ability to isolate human neural stem cells from most areas of the developing human brain and spinal cord and our technology includes the ability to grow them into physiologically relevant human neurons of all types. Our two issued core patents entitled: (i) Isolation, Propagation, and Directed Differentiation of Stem Cell from Embryonic and Adult Central Nervous System of Mammals ; and (ii) In Vitro Generation of Differentiated Neurons from Cultures of Mammalian Multi-potential CNS Stem Cell contain claims which cover the process of deriving the cells and the cells created from such process.

What differentiates our stem cell technology from others is that our patented processes do not require us to “push” the cells towards a certain fate by adding specific growth factors. Our cells actually “become” the type of cell they are fated to be. We believe this process and the resulting cells create a technology platform that allows for the efficient isolation and ability to produce, in commercially reasonable quantities, neural stem cells from the human brain and spinal cord.

Our technology allows for cells to grow in cultured dishes, also known as in vitro growth, without mutations or other adverse events that would compromise their usefulness.

Research

We have devoted substantial resources 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 therapeutic products. Our efforts to date 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.

Trends & Outlook

Revenue: Our revenue was previously derived primarily from grant reimbursements and licensing fees. As our focus is now on pre-clinical work in anticipation of entering clinical trials in 2009, we are not concentrated on increasing revenue.

Long-term, we anticipate that our revenue will be derived primarily from licensing fees and the sale of our cell therapy products. At present, we are in our pre-clinical stage of development and as a result, we cannot accurately predict when or if we will be able to produce a product for commercialization. Accordingly, we cannot accurately estimate if or when we will begin generating revenue from such sources.

Research & Development Expense: Our research and development expenses consist primarily of costs associated with pre-clinical research, exclusively in the field of human neural stem cell therapies and regenerative medicine, related to our clinical cell therapy candidates. These expenses represent both pre-clinical development costs and costs associated with non-clinical support activities such as quality control and regulatory processes. The cost of our research and development personnel is the most significant category of expense. However, we also incur expenses with third parties, including license agreements, third-party contract services, sponsored research programs and consulting expenses.

We do not segregate research and development costs by project because our research is focused exclusively on human stem cell therapies as a unitary field of study. Although we have different areas of focus for our research, these areas are completely intertwined and have not yet matured to the point where they are separate and distinct projects. The intellectual property, scientists and other resources dedicated to these efforts are not separately allocated to individual projects, but rather are conducting our research on an integrated basis.

We expect that research and development expenses will continue to increase in the foreseeable future as we add personnel, expand our pre-clinical research (animal surgeries, manufacturing of cells, and in vitro characterization of cells which includes testing and cell quality control), begin clinical trial activities, increase our regulatory compliance capabilities, and ultimately begin manufacturing.

In 2006 we retained Quintiles, Inc. to assist with regulatory compliance, preparation of our first investigational new drug (IND) application, and patient enrollment for our first human trial. While recruitment for the trial cannot commence until we have received an FDA approved protocol, much of the infrastructure required must be developed and in place well in advance. For instance, we can begin to identify, contact, and educate prospective patients as well as the treatment community prior to commencing these trials.

The amount of monetary increases stemming from increased personnel and expenses as we move from pre-clinical to clinical state is difficult to predict due to the uncertainty inherent in the timing and extent of progress in our research programs, and initiation of clinical trials. In addition, the results from our basic research and pre-clinical trials, as well as the results of trials of similar therapeutics underdevelopment by others, will influence the number, size and duration of planned and unplanned trials. As our research efforts mature, we will continue to review the direction of our research based on an assessment of the value of possible commercial applications emerging from these efforts. Based on this continuing review, we expect to establish discrete research programs and evaluate the cost and potential for cash inflows from commercializing products, partnering with others in the biotechnology industry, or licensing the technologies associated with these programs to third parties.

On December 18, 2008 we filed our IND with the FDA to begin a clinical trial to treat ALS or Lou Gehrig's Disease. On February 20, 2009, the FDA provided us with specific comments, questions and recommendations for modification to the protocol submitted in our IND. The trial is on clinical hold. We are in the process of analyzing the notice and the FDA's comments and recommendations. We believe that it is not possible at this stage to provide a meaningful estimate of the total cost to complete our ongoing projects, including clinical trials, and bring any proposed products to market. The use of human stem cells as a therapy is an emerging area of medicine, and it is not known what clinical trials will be required by the FDA in order to gain marketing approval. The costs to complete such clinical trials could vary substantially depending upon the projects selected for development, the number of clinical trials required and the number of patients needed for each study. At a minimum, we estimate that a trial for an individual indication such as ALS will require at least 10 to 12 patients at an estimated cost of \$100,000 per patient. It is possible that the completion of these studies could be delayed for a variety of reasons, including difficulties in enrolling patients, delays in manufacturing, incomplete or inconsistent data from the pre-clinical or clinical trials, and difficulties evaluating the trial results. Any delay in completion of a trial would increase the cost of that trial, which would harm our operating results. Due to these uncertainties, we cannot reasonably estimate the size, nature, nor timing of the costs to complete, or the amount or timing of the net cash inflows from our current activities. Until we obtain further relevant pre-clinical and clinical data, we will not be able to estimate our future expenses related to these programs or when, if ever, and to what extent, we will receive cash inflows from resulting products.

General and Administrative Expenses: Our general and administrative ("G&A") expenses consist of the general costs, expenses and salaries for the operation and maintenance of our business. We anticipate that general and administrative expenses will increase as we progress from pre-clinical to a clinical phase.

We anticipate G&A expenses related to our core business will increase at a slower rate than that of similar companies making such transition due in large part to our outsourcing model.

Critical Accounting Policies

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. 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 1 of the Notes to Financial Statements 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 accounting principles generally accepted in the United States, 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 financial statements:

Use of Estimates—our financial statements have been prepared in accordance with accounting principles generally accepted in the United States and, accordingly, require management 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, our management has estimated the expected economic life and value of our licensed technology, our net operating loss for tax purposes and our stock option and warrant expenses related to compensation to employees and directors, consultants and investment banks. Actual results could differ from those estimates.

Revenue Recognition—our revenues, to date, has been derived primarily from providing treated samples for gene expression data from stem cell experiments and from providing services as a subcontractor under federal grant programs. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery of goods and services has occurred, the price is fixed and determinable, and collection is reasonably assured.

Intangible and Long-Lived Assets—we follow SFAS No. 144, "Accounting for Impairment of Disposal of Long-Lived Assets," which established a "primary asset" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell. During the period ended December 31, 2008 no impairment losses were recognized.

Research and Development Costs—Research and development costs consist of expenditures for the research and development of patents and technology, which are not capitalizable and charged to operations when incurred. Our research and development costs consist mainly of payroll and payroll related expenses, research supplies and costs incurred in connection with specific research grants.

Stock Based Compensation—The Company accounts for equity instruments issued to non-employees in accordance with EITF 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services." Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed.

Beginning in 2006, we adopted SFAS No. 123R "Share Based Payment" which superseded APB Opinion No. 25. SFAS No. 123R requires compensation costs related to share-based payment transactions to be recognized in the financial statements. We recognized \$4,632,847 and \$1,575,120 in Stock-based compensation expense for the years ended December 31, 2008 and 2007, respectively.

Results of Operations

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future due to the occurrence of material recurring and nonrecurring events.

Revenue

Revenue totaled \$0 in 2008 and \$306,057 in 2007.

| | | | Change in 2008 Versus 2007 | |
|---------|------|-------------|----------------------------------|--------|
| | 2008 | 2007 | \$ | % |
| Revenue | \$ | -\$ 306,057 | \$ (306,057) | (100)% |

The decrease in revenue in 2008 as compared to 2007 was attributable to us having completed all work on our grants. We do not anticipate any revenues for 2009.

Operating Expenses

Operating expense totaled \$11,831,973 in 2008 and \$6,673,629 in 2007.

| | 2008 | 2007 | Change in 2008 Versus 2007 | |
|---|----------------------|---------------------|----------------------------------|------------|
| | | | \$ | % |
| Operating Expenses | | | | |
| Research & development | \$ 6,513,349 | \$ 3,440,129 | \$ 3,073,220 | 89% |
| General, selling & administrative expense | 5,252,863 | 3,201,443 | 2,051,420 | 64% |
| Depreciation and amortization | 65,761 | 32,057 | 33,704 | 105% |
| Total expense | \$ 11,831,973 | \$ 6,673,629 | \$ 5,158,344 | 77% |

Research and Development Expenses

Research and development expenses totaled \$6,513,349 in 2008, as compared to \$3,440,129 in 2007. The increase of \$3,073,220, or 89%, from 2007 to 2008 was primarily attributable to an increase in stock-based compensation expense. The remainder of the increase in 2008 was due to the costs of completing the application to the FDA to move our tissue based products into clinical trials and other operating expenses.

General and Administrative Expenses

G&A expenses totaled \$5,252,863 in 2008, compared with \$3,201,443 in 2007. The increase of approximately \$2,051,420, or 64%, from 2007 to 2008 was primarily attributable to increased litigation expenses and a \$1.2 million increase in stock-based compensation expense.

Depreciation and Amortization

Depreciation and amortization expenses totaled \$65,761 in 2008, compared with \$32,057 in 2007. The increase of \$33,706 or 105% from 2007 to 2008 was primarily attributed to additional capital expenditures in R&D and G&A.

Other Income (Expense)

Other income (expense) totaled \$39,806 in 2008, compared with \$193,451 in 2007.

| | 2008 | 2007 | Change in 2008 Versus 2007 | |
|---------------------------------------|-----------------|-------------------|----------------------------------|--------|
| | | | \$ | % |
| Nonoperating income (expense): | | | | |
| Interest | \$ 39,806 | \$ 194,753 | \$ (154,947) | (80)% |
| Interest expense | — | (1,302) | 1,302 | (100)% |
| Warrant modification expense | (38,631) | — | (38,631) | 100% |
| Total nonoperating income | \$ 1,175 | \$ 193,451 | \$ (192,276) | |

Interest Income

Interest income totaled \$39,806 in 2008 compared to \$194,753 in 2007. The decrease in 2008 as compared to 2007 of 154,947 was as a result of lower cash balances and interest rates.

Interest Expense

Interest expense was \$0 in 2008 and \$1,302 in 2007. The decrease in 2008 as compared to 2007 was attributable to the pay off of a loan balance in 2007.

Warrant Modification Expense

The Company had a warrant modification expense of \$38,631 in 2008. Details of the transaction are in Note 2 to the financial statements.

Liquidity and Capital Resources

Since our inception, we have financed our operations through the private placement of our securities, the exercise of investor warrants, and to a lesser degree from grants. Our currently monthly cash burn rate is \$500,000. In the next several months we expect the monthly burn rate to drop below \$400,000. We anticipate that our available cash and expected income will be sufficient to finance most of our current activities for at least the next 12 months from December 31, 2008, although certain activities and related personnel may need to be reduced.

On December 18, 2008, we filed our first IND with the FDA. In the event the FDA approves our IND, we expect additional costs related to the trial this year of about \$350,000. Assuming approval of the IND, 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, 2008. We cannot assure you that public or private financing or grants will be available on acceptable terms, if at all. 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.

| | 2008 | 2007 | Change in 2008 Versus 2007 | |
|---|----------------|----------------|----------------------------------|-------|
| | | | \$ | % |
| At December 31: | | | | |
| Cash and cash equivalents | \$ 4,903,279 | \$ 7,403,737 | \$ (2,500,458) | (34)% |
| Year ended December 31: | | | | |
| Net cash used in operating activities | \$ (6,860,039) | \$ (4,001,368) | \$ 2,858,671 | 71% |
| Net cash used in investing activities | (193,630) | (229,627) | (35,998) | 16% |
| Net cash provided by financing activities | 4,553,211 | 9,827,691 | (5,274,480) | (54)% |

Total cash and cash equivalents was \$4,903,279 at December 31, 2008, compared with \$7,403,737 at December 31, 2007. The decrease in our cash and cash equivalents of \$2,500,458 or 34%, from December 31, 2007 to December 31, 2008 was a consequence of the ramp-up of our operations activity to complete our IND applications

Net Cash Used in Operating Activities

In our operating activities we used \$6,860,039 in cash in 2008 and \$4,001,368 in cash in 2007. The increase of \$2,858,671 in cash used in operating activities in 2008 as compared to 2007 was primarily attributable to a consequence of the ramp-up of our operations activity to complete our IND applications.

Net Cash Used in Investing Activities

In our investment activities we used \$193,630 in cash in 2008 and \$229,627 in cash in 2007. The decrease from 2007 to 2008 of \$35,997 for net cash used in investing activities was due to a decrease in our investment in property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$4,553,211 in 2008 as compared to \$9,827,691 in 2007.

Listed below are key financing transactions entered into by us in the last two years. Also, please refer to the section of this Annual Report entitled "Recent Sale of Unregistered Securities" for a further description of the following transactions:

¶ In March of 2007 we completed the private placement of \$6,135,000 of our units consisting of: (i) one share of common stock; and (ii) one half class C warrant. The units were priced at \$2.50.

¶ In October of 2007 warrant holders holding approximately 1,227,000 of our class C warrants exercised their warrants. As an inducement for the exercise, we issued those warrant holders who exercised their warrants a replacement class C warrant.

- In February of 2008, we sold a strategic purchaser \$2,500,000 of our common stock.

On December 18, 2008, we sold \$2,000,000 of common stock pursuant to our shelf registration statement on Form S-3.

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 grants. We have a shelf registration statement which was declared effective on September 29, 2008 and covers up to approximately \$25,000,000 of our securities that could be available for financings. On December 18, 2008, we filed a Prospectus Supplement announcing that we entered into a securities purchase agreement under which we sold \$2,000,000 of common shares pursuant to such shelf registration. Accordingly, we may issue an additional \$23,000,000 pursuant to the shelf registration statement.

The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, on 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are not required to provide the information as to selected financial data as we are considered a smaller reporting company.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Neuralstem, Inc. as of December 31, 2008 and 2007, and the related statements of operations, stockholders' equity and cash flows for the years ended December 31, 2008 and 2007. Neuralstem, Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. Neuralstem, Inc. is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of Neuralstem, Inc.'s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Neuralstem, Inc. as of December 31, 2008 and 2007, and the results of its operations and its cash flows for the years ended December 31, 2008 and 2007 in conformity with accounting principles generally accepted in the United States of America.

/s/ Stegman & Company

Baltimore, Maryland
March 30, 2009

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Neuralstem, Inc.

Balance Sheets

| | December 31, 2008 | December 31, 2007 |
|--|----------------------|----------------------|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$ 4,903,279 | \$ 7,403,737 |
| Prepaid expenses | 136,287 | 130,719 |
| Total current assets | 5,039,566 | 7,534,456 |
| Property and equipment, net | 163,930 | 136,920 |
| Intangible assets, net | 212,265 | 111,406 |
| Other assets | 52,972 | 43,271 |
| Total assets | \$ 5,468,733 | \$ 7,826,053 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable and accrued expenses | \$ 1,265,488 | \$ 1,016,699 |
| LONG-TERM LIABILITIES - | — | — |
| Total liabilities | 1,265,488 | 1,016,699 |
| STOCKHOLDERS' EQUITY | | |
| Common stock, \$0.01 par value, 150 million shares authorized, 33,751,300 and 31,410,566 shares outstanding in 2008 and 2007 | 337,513 | 314,106 |
| Additional paid-in capital | 61,352,527 | 52,151,245 |
| Accumulated deficit | (57,486,795) | (45,655,997) |
| Total stockholders' equity | 4,203,245 | 6,809,354 |
| Total liabilities and stockholders' equity | \$ 5,468,733 | \$ 7,826,053 |

See notes to financial statements.

Neuralstem, Inc.

Statements of Operations

| | Years | |
|--|--------------------|----------------|
| | Ended December 31, | 2007 |
| | 2008 | 2007 |
| Revenues | \$ — | \$ 306,057 |
| Operating expenses: | | |
| Research and development | 6,513,349 | 3,440,129 |
| General, selling and administrative expenses | 5,252,863 | 3,201,443 |
| Depreciation and amortization | 65,761 | 32,057 |
| | 11,831,973 | 6,673,629 |
| Operating loss | (11,831,973) | (6,367,572) |
| Nonoperating income (expense): | | |
| Interest income | 39,806 | 194,753 |
| Interest expense | - | (1,302) |
| Warrant modification expense | (38,631) | — |
| Non-operating income | 1,175 | 193,451 |
| Net loss | (11,830,798) | (6,174,121) |
| Deemed dividend – Repriced Warrants | — | (889,151) |
| Net loss attributable to common shareholders | \$ (11,830,798) | \$ (7,063,272) |
| Net loss per share, basic and diluted | \$ (0.37) | \$ (0.24) |
| Average number of shares of common stock outstanding | 32,114,365 | 29,012,858 |

See notes to financial statements.

Neuralstem, Inc.

Statements of Cash Flows

| | Years ended December 31, | |
|--|--------------------------|----------------|
| | 2008 | 2007 |
| Cash Flows From Operating Activities: | | |
| Net loss | \$ (11,830,798) | \$ (6,174,121) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 65,761 | 32,055 |
| Stock and warrant based compensation | 4,632,847 | 1,575,120 |
| Warrant Modification Expense | 38,631 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses | (5,568) | (97,871) |
| Other assets | (9,701) | (1,288) |
| Accounts payable and accrued expenses | 248,789 | 664,737 |
| Net cash used in operating activities | (6,860,039) | (4,001,368) |
| Cash Flows From Investing Activities: | | |
| Capital outlay for intangible assets | (116,921) | (95,721) |
| Purchase of property and equipment | (76,709) | (133,906) |
| Net cash used in investing activities | (193,630) | (229,627) |
| Cash Flows From Financing Activities: | | |
| Issuance of common stock | 4,553,211 | 9,856,036 |
| Payments on notes payable | | (28,345) |
| Net cash provided by financing activities | 4,553,211 | 9,827,691 |
| Net (decrease) increase in cash and cash equivalents | (2,500,458) | 5,596,696 |
| Cash and cash equivalent, beginning of period | 7,403,737 | 1,807,041 |
| Cash and cash equivalent, end of period | \$ 4,903,279 | \$ 7,403,737 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for interest | \$ | —\$ 1,302 |
| Supplemental schedule of non cash investing and financing activities: | | |
| Issuance shares of common stock to satisfy common stock payable commitment | | |
| conversion of 6,254,402 shares of preferred stock to 14,182,399 shares of common stock | - | 150,000 |

See notes to financial statements.

Neuralstem, Inc.

Statements
of Shareholders' Equity

For the years ended December 31, 2008 and 2007

NEURALSTEM, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

For the period from January 1, 2007 through December 31, 2008

| | Common Stock Shares | Common Stock Amount | Common Stock Payable | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity |
|--|---------------------------|---------------------------|----------------------------|----------------------------------|------------------------|----------------------------------|
| Balance at January 1, 2007 | 26,011,605 | \$ 260,116 | \$ 150,000 | \$ 39,734,878 | \$ (38,592,725) | \$ 1,552,269 |
| Issuance of common stock for satisfaction of common stock payable | 300,000 | 3,000 | (150,000) | 147,000 | | - |
| Issuance of common stock related to exercise of warrants, between \$0.05-\$0.50 exercise price per share | 169,000 | 1,690 | | 51,760 | | 53,450 |
| Issuance of common stock related to exercise of warrants related to Private Placement Offering, between \$0.05 and \$3.00 exercise price per share | 2,475,961 | 24,760 | | 4,161,597 | - | 4,186,356 |
| Issuance of common stock related to Private Placement Offering, net of \$520,400 in offering related expenses, \$2.50 per share | 2,454,000 | 24,540 | | 5,590,060 | | 5,614,600 |
| Vesting of officer/directors stock options | - | - | | 1,530,576 | | 1,530,576 |
| Vesting of warrants for 19,789 shares of common stock, \$2.33 fair value per share | - | - | | 46,224 | | 46,224 |
| On October 26, 2007, the Company agreed to reduce | - | | | 889,151 | (889,151) | - |

the exercise price of the warrants issued in connection with the Company's March 2007 offering by \$.25 per share. As a result of the discounted exercise price we recorded a deemed dividend charge of \$889,151 for the warrants that were so exercised.

| | | | | | | |
|---|------------|------------|---|---------------|-----------------|--------------|
| Net loss | - | - | - | (6,174,121) | (6,174,121) | |
| Balance at December 31, 2007 | 31,410,566 | \$ 314,106 | - | \$ 52,151,245 | \$ (45,655,997) | 6,809,354 |
| Exercise of Warrants to purchase Common Stock (\$1.50 to \$2.00 per share), net of offering costs of \$20,889 | 125,425 | 1,254 | | 209,957 | | 211,211 |
| Issuance of common stock through private placement (\$4.06 per share). | 615,309 | 6,153 | | 2,493,847 | | 2,500,000 |
| Issuance of common stock through private placement (\$1.25 per share), net of offering costs of \$158,000 | 1,600,000 | 16,000 | | 1,826,000 | | 1,842,000 |
| Share Based Payment – Employee Compensation | | | | 4,632,847 | | 4,632,847 |
| Warrant Modification Expense | | | | 38,631 | | 38,631 |
| Net loss for 2008 | | | | (11,830,798) | | (11,830,798) |
| Balance at December 31, 2008 | 33,751,300 | \$ 337,513 | - | \$ 61,352,527 | \$ (57,486,795) | \$ 4,203,245 |

See notes to financial statements.

NEURALSTEM, INC.

NOTES TO FINANCIAL STATEMENTS

Note 1. Nature of Business and Significant Accounting Policies

Nature of business:

Neuralstem, Inc. (“Company”) is a biopharmaceuticals company that is utilizing its proprietary human neural stem cell technology to create a comprehensive platform for the treatment of central nervous system diseases. The Company will commercialize this technology as a tool for use in the next generation of small-molecule drug discovery and to create cell therapy biotherapeutics to treat central nervous system diseases for which there are no cures. The Company was founded in 1997 and currently occupies lab and office space in Rockville, Maryland.

Inherent in the Company’s business are various risks and uncertainties, including its limited operating history, the fact that Neuralstem’s technologies are new and may not allow the Company or its customers to develop commercial products, regulatory requirements associated with drug development efforts and the intense competition in the genomics industry. The Company’s success depends, in part, upon successfully raising additional capital, prospective product development efforts, the acceptance of the Company’s solutions by the marketplace, and approval of the Company’s solutions by various governmental agencies.

A summary of the Company’s significant accounting policies is as follows:

Basis of Presentation

These financial statements have been prepared on the basis that the Company will continue as a going concern. Such assertion contemplates the significant losses recognized to date and the challenges we anticipate with respect to obtaining near-term funding under prevailing and forecasted economic conditions. The Company continues to be fully committed and has the capacity to continue to provide necessary capital and liquidity to fund continuing operations. The Company plans to accomplish this through the reduction of expenditures in the near-term.

Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

For the Statements of Cash Flows, all highly liquid investments with maturity of three months or less are considered to be cash equivalents.

Property and Equipment

Property and equipment is stated at cost and depreciated on a straight-line basis over the estimated useful lives ranging from three to eight years. Expenditures for maintenance and repairs are charged to operations as incurred.

Recoverability of Long-Lived Assets and Identifiable Intangible Assets

Long-lived assets and certain identifiable intangible assets to be held and used are reviewed for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Long-lived assets and certain identifiable intangible assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

Fair Value of Financial Instruments

The fair values of financial instruments are estimated based on market rates based upon certain market assumptions and information available to management. The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values. These financial instruments include cash, accounts payable and notes payable. Fair values were assumed to approximate carrying values for cash and payables due to the short-term nature or that they are payable on demand.

Revenue Recognition

To date, revenue has been derived primarily from providing treated samples for gene expression data from stem cell experiments and from providing services under a federal grant program approximating \$306,057 in 2007. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery of goods and services has occurred, the price is fixed and determinable, and collection is reasonably assured.

Research and Development

Research and development costs are charged to operations when incurred.

Income taxes

Income taxes are provided for using the liability method of accounting in accordance with SFAS No. 109 "Accounting for Income Taxes." A deferred tax asset or liability is recorded for all temporary differences between financial and tax reporting. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax basis. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effect of changes in tax laws and rates on the date of enactment.

Significant New Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") 157, "Fair Value Measurements." SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those years. The implementation of SFAS 157 did not have a material impact on our financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). FIN 48 clarifies when tax benefits should be recorded in financial statements, requires certain disclosure of uncertain tax matters and indicates how any tax reserves should be classified in a balance sheet. On January 1, 2007, the Company adopted FIN 48. We have determined that adoption of FIN 48 did not have any impact on our financial condition or results of operations. It is our policy to recognize interest and penalties related to unrecognized tax liabilities within income tax expense in the statements of operations.

In February 2007, the FASB issued SFAS 159, "The Fair Value Option for Financial Assets and Liabilities." SFAS 159 permits entities to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This pronouncement is effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. The implementation of SFAS 159 did not have a material impact on our financial position or results of operations.

In June 2007, the FASB ratified a consensus opinion reached by the Emerging Issue Task Force ("EITF") on EITF Issue 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities." The guidance in EITF Issue 07-3 requires use to defer and capitalize nonrefundable advance payments made for goods or services to be use in research and developments activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the

services expected to be performed, we would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. Early adoption is not permitted. Retrospective application of EITF Issue 07-3 is also not permitted. The impact of applying this consensus did not have material effect on our research and development contractual arrangements entered into on or after December 15, 2007.

In December 2007, the FASB ratified a consensus reached by the EITF on Issue 07-1, "Accounting for Collaborative Arrangements." The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and its terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for us January 1, 2008 and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The adoption of EITF 07-1 did not have a material impact on our financial statements.

In December 2007, the FASB issued SFAS 141, Revised 2007 (SFAS 141R), "Business Combinations." SFAS 141R's objective is to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after December 15, 2008. We do not expect the implementation of SFAS 141R to have a material impact on our financial statements.

In December 2007, the FASB issued SFAS 160, "Noncontrolling Interests in Consolidated Financial Statements." SFAS 160's objective is to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 shall be effective for fiscal years and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not expect the implementation of SFAS 160 to have a material impact on our financial statements.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities - an Amendment of FASB Statement No. 133 ." This Statement amends and expands the disclosure requirements of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities ." The Statement requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of and gains and losses on derivative instruments, and disclosures about credit-risk-related contingent features in derivative agreements. This Statement is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company does not expect that the adoption of this Statement will have a material impact on its financial position, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162, "The Hierarchy of Generally Accepted Principles ." This statement identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles ("GAAP") in the United States. The Statement is directed to entities rather than auditors because entities are responsible for the selection of accounting principles for financial statements that are presented in conformity with GAAP. This Statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles ." The Company does not expect that the adoption of this Statement will have a material impact on its financial position, results of operations or cash flows.

In June 2008, the FASB ratified the consensus reached on EITF Issue No. 07-5, "Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity's Own Stock" (Issue 07-5). This Issue provides guidance for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock. Issue 07-5 applies to any freestanding financial instrument or embedded feature that has all the characteristics of a derivative under paragraphs 6-9 of Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities," (SFAS 133) for purposes of determining whether that instrument or embedded feature qualifies for the first part of the scope exception under paragraph 11(a) of SFAS 133. Issue 07-5 also applies to any freestanding financial instrument that is potentially settled in an entity's own stock, regardless of whether the instrument has all the characteristics of a derivative under paragraphs 6-9 of SFAS 133, for purposes of determining whether the instrument is within the scope of EITF Issue 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," (Issue 00-19) which provides accounting guidance for instruments that are indexed to, and potentially settled in, the issuer's own stock. Issue 07-5 is effective for fiscal years beginning after December 15, 2008. Early application is not permitted by entities that have previously adopted an alternative accounting policy. We are currently evaluating the requirements of Issue 07-5 and have not yet determined its effect, if any, on our financial statements.

Stock - Based Compensation

We have granted stock-based compensation awards to employees and board members. Awards may consist of common stock, or stock options. Our stock options and warrants have lives of five to ten years.. The stock options or warrants vest either upon the grant date or over varying periods of time. The stock options we grant provide for option exercise prices equal to or greater than the fair market value of the common stock at the date of the grant.

During the year ended December 31, 2008 we granted 5,600,000 options. In the year ended December 31, 2007 we granted 718,333 options. We accrue related compensation expenses as our options vest in accordance with SFAS123(R), Share-Based Payment. We recognized \$4,632,847 and \$1,575,120 stock-based compensation expense during the year ended December 31, 2008 and 2007, respectively, from the vesting of stock options.

A summary of stock option activity during the year ended December 31, 2008 and related information is included in financial statements footnote 2.

Comprehensive Loss

Statement of Financial Accounting Standard (SFAS) No. 130“Reporting Comprehensive Income,” requires the presentation of comprehensive income or loss and its components as part of the financial statements. For the years ended December 31, 2008 and 2007, the Company’s net loss reflects comprehensive loss and, accordingly, no additional disclosure is required.

Note 2. Stockholders' Equity

Preferred and Common Stock

The authorized stock of the Company consists of 7,000,000 shares of preferred stock with a par value of \$0.01 and 150,000,000 shares of common stock with par value of \$0.01. The preferred stock is divided into A, B, and C Series. None of these shares have been issued.

During the year ended December 31, 2007, the Company sold 2,454,000 shares of common stock for a total consideration of \$5,614,600 (net of offering expenses of \$511,300) through a Limited Offering Memorandum. Each Unit sold consisted of one share of common stock, ½ Warrant to Purchase A share of Common Stock at \$3.00 per share. In addition we gave the underwriter, T.R. Winston & Co 294,280 \$3.00 warrants. These warrants have a life of 5 years.

During the year ended December 31, 2007, the Company also converted 2,644,961 warrants into common shares raising \$4,245,436 net of \$327,202 in expenses. In conjunction with one large conversion we issued and additional 1,227,000 \$2.75 warrants with a five year life.

During the year ended December 31, 2008, the Company sold 2,215,309 shares of common stock for a total consideration of \$4,342,000 (net of offering expenses of \$158,000). During the year ended December 31, 2008 the Company also converted 125,425 warrants to purchase Common Stock into common shares, raising \$211,211 net of \$20,889 in expenses.

Stock Options

In 1997, the Company adopted a stock incentive plan (the Plan) to provide for the granting of stock awards, such as stock options and restricted common stock to employees, directors and other individuals as determined by the Board of Directors. The Company reserved 2.7 million shares of common stock for issuance under the Plan. At December 31, 2002, 816,084 options were outstanding with 216,040 options exercisable. During 2003, the Company reduced operations and terminated employment with all employees. The Plan was discontinued, terminating all options outstanding.

- On April 12, 2007, pursuant to our adopted director compensation plan, we issued to each of the independent directors options to purchase 20,000 common shares. The options were issued pursuant to our 2005 Stock Plan. The exercise price per share is \$3.30. The options expire on April 12, 2014.
- On April 1, 2007, we granted an officer options to purchase 100,000 common shares. The options vest as follows: (i) 25,000 vest immediately; and (iii) 75,000 vest quarterly over the year. The options have an exercise price of \$3.15 and expire on April 1, 2015. These options have a value of \$118,284.
- On May 16, 2007, pursuant to our adopted director compensation plan, we issued to each of the independent directors options to purchase 15,000 shares of our common stock (5,000 shares per each committee on which they serve). The options were issued pursuant to our 2005 Stock Plan. The exercise price per share is \$3.83 and the options vest quarterly over the year. The options expire on May 16, 2014.
- On September 20, 2007, our Compensation Committee granted Karl Johe, our Chairman and Chief Scientific Officer, options to purchase an aggregate of 333.333 shares of our common stock at a price per share of \$3.01 pursuant to our 2005 Stock Plan. The options expire 5 years from the date when they become exercisable. Additionally, the options will become immediately exercisable upon an event which would result in an acceleration

of Mr. Johe's stock options granted under his employment agreement. The options vest on October 31, 2010. The Options have a value of \$570,478.

- On November 15, 2007, our Compensation Committee granted an employee options to purchase an aggregate of 14,000 shares of our common stock at a price per share of \$2.71 pursuant to our 2005 Stock Plan. The options expire 10 years from the grant date. The options are fully vested and have a value of \$11,509.
- On December 15, 2007, our Compensation Committee granted a consultant options to purchase an aggregate of 50,000 shares of our common stock at a price per share of \$2.00 pursuant to our 2005 Stock Plan. The options expire in 2015. The options are fully vested and have a value of \$54,898.
- On January 21, 2008, we granted the following options pursuant to our 2007 Stock Plan:

Karl Johe, Chairman and Chief Science Officer - options to purchase 2.1 million common shares at a price of \$3.66 per share. The options vest over 3.5 years with the vesting period commencing on January 1, 2008 with 700,000 options vesting on each of February 28, 2009, April 30, 2010, and June 30, 2011. The options expire on January 1, 2018. Additionally, the options will become immediately exercisable upon an event which would result in an acceleration of Mr. Johe's stock options granted under his employment agreement.

Richard Garr, Chief Executive Officer and General Council - options to purchase 2.1 million common shares at a price of \$3.66 per share. The options vest over 3.5 years with the vesting period commencing on January 1, 2008 with 700,000 options vesting on each of February 28, 2009, April 30, 2010, and June 30, 2011. The options expire on January 1, 2018. Additionally, the options will become immediately exercisable upon an event which would result in an acceleration of Mr. Garr's stock options granted under his employment agreement.

- On April 1, 2008, we granted an officer compensatory options to purchase an aggregate of 1,050,000 common shares at an exercise price of \$2.60. The options vest as follows: (i) 50,000 vest immediately; and (ii) 1,000,000 vest annually over the next three years so that 100% of the options will be vested on April 1, 2011. The options were issued pursuant to our two stock plans as follows: (x) the option to purchase 1,000,000 common shares was issued pursuant to our 2007 Stock Plan; and (y) option to purchase 50,000 common shares was issued pursuant to our 2005 Stock Plan.
- On May 28, 2008, we granted independent directors options to purchase an aggregate of 120,000 common shares at an exercise price of \$1.32. The grant was made pursuant to our 2007 Stock Plan and in compliance with our non-executive compensation arrangement. The grant consists of: (i) an option purchase 90,000 common shares as compensation for serving on the board of directors; (ii) an option to purchase 10,000 common shares as compensation for serving on our Audit Committee; (iii) an option to purchase 10,000 common shares as compensation for serving on our Compensation Committee; and (iv) an option to purchase 10,000 common shares as compensation for serving on our Governance and Nominating Committee. The options vest quarterly over the grant year and expire 7 years from the date of grant.
- On August 14, 2008, we granted options to purchase an aggregate of 30,000 common shares at an exercise price of \$1.88 to two employees (15,000 each). The grants were made pursuant to our 2005 Stock Plan. The options vest as follows: (i) 15,000 on the granted date; and (ii) 15,000 on August 14, 2009. The options expire on August 18, 2018.
- On August 14, 2008, we granted one of our employees options to purchase 200,000. The grant is effective as of August 11, 2008, the employee's start date. The options vest as follows: (i) 40,000 on the effective date; and (ii) 40,000 on each of August 11, 2009, 2010, 2011 and 2012. The grant was made pursuant to the 2005 Stock Plan. The options have an exercise price of \$1.89 and expire on August 14, 2018.

During the twelve months ended December 31, 2008, we granted 5,600,000 options and in the similar period ended December 31, 2007, we granted 718,333 options. We recorded related compensation expenses as our options vest in accordance with the Statement of Financial Accounting Standards ("SFAS") 123(R), "Share-Based Payment." We recognized \$4,632,847 and \$1,575,120 in share-based compensation expense during the twelve months ended December 31, 2008 and 2007, respectively, from the vesting of stock options or warrants.

| A summary of stock option activity during the twelve months ended December 31, 2008 and related information is included in the table below: | Number of Options | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value |
|---|-------------------|---------------------------------|--|---------------------------|
| Outstanding at January 1, 2007 | 2,432,326 | 0.66 | 7.5 | |
| Granted | 718,333 | 3.04 | | |
| Exercised | - | | | - |
| Forfeited | - | | | - |
| Outstanding at January 1, 2008 | 3,150,659 | \$ 1.19 | 6.8 | \$ |
| Granted | 5,600,000 | 3.34 | 9.3 | |

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| | | | | |
|----------------------------------|-----------|---------|-----|--------------|
| Exercised | - | - | - | - |
| Forfeited | - | - | - | - |
| Outstanding at December 31, 2008 | 8,750,659 | \$ 2.55 | 8.2 | \$ 2,799,600 |
| Exercisable at December 31, 2008 | 2,322,326 | \$ 1.11 | 6.7 | \$ 2,070,000 |

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| Range of Exercise Price | Outstanding Options | Expiration Dates |
|-------------------------|---------------------|------------------|
| \$0.5 - 2.00 | 2,800,000 | 2015 - 2018 |
| \$ 2.01 - 3.00 | 1,065,000 | 2017 - 2018 |
| \$3.01 - 4.00 | 4,818,275 | 2012 - 2018 |
| \$4.01 - 8.00 | 62,042 | 2011 - 2015 |
| \$8.01 - higher | 5,342 | 2010 - 2011 |
| | 8,750,659 | |

Share-based compensation included in the statements of operations for the twelve months ended December 31, 2008 and 2007 was as follows:

| | Twelve Months Ended December 30, | |
|--|----------------------------------|--------------|
| | 2008 | 2007 |
| Research and development costs | \$ 3,024,537 | \$ 1,167,172 |
| General, selling and administrative expenses | 1,608,310 | 407,948 |
| Total | \$ 4,632,847 | \$ 1,575,120 |

Stock Warrants

During the year ended December 31, 2007 the company issued the following warrants:

- On March 15, 2007, we completed a private placement through T.R. Winston & Company, LLC of 2,054,000 units to 15 institutional investors. The units were priced at \$2.50 each and resulted in gross proceeds to the Company of \$5,135,000.00. The units consist of:

1 common stock; and

½ common stock purchase warrant.

An aggregate of 2,054,000 common shares and warrants to purchase an additional 1,027,000 common shares were issued. The units were priced at \$2.50 each and resulted in gross proceeds to the Company of \$5,135,000.00. The investors also received certain registration rights with regard to the underlying securities. The exercise price of the warrants is \$3.00.

- On March 15, 2007, in connection with the private placement of the same date, the Company paid fees and expenses totaling \$431,000.00 and issued a warrant to purchase 246,480 common shares at \$3.00 to our placement agent.
 - On March 27, 2007, we sold an additional 400,000 warrants to purchase an additional 200,000 common shares were issued for \$1,000,000 pursuant to our March 15, 2007 private placement. In connection with the

sale of such additional units, we paid fees and expenses totaling \$80,300 and issued a warrant to purchase an additional 48,000 common shares at \$3.00 to our placement agent.

- On April 1, 2007, we issued warrants for 100,000 shares of our common stock to a consultant as payment for services rendered. The warrants have an exercise price of \$3.20 and vest over 18 months. The warrants are valued \$124,525.
- On June 5, 2007, in exchange for: (i) the acquisition of certain residual rights; and (ii) the cancellation of the Hi Med Technologies, Inc. licensing agreement, we issued Karl Johe, our Chairman and Chief Scientific Officer, warrants to purchase an aggregate of 3,000,000 shares of our common stock at a price per share of \$3.01. The warrants expire 5 years from the date when they become exercisable. Additionally, the warrants will become immediately exercisable upon an event which would result in an acceleration of Mr. Johe's stock options granted under his employment agreement. The warrants vest as follows:
 - i. 1,000,000 warrants vest on October 31, 2010; and
 - ii. 2,000,000 warrants vest on October 31, 2011.

- On October 31, 2007, the Company issued warrants to purchase 1,227,000 shares of common stock at a per share price of \$2.75 to investors who participated in the Company's March 2007 offering which was previously disclosed on the current report filed on Form 8-K with the Securities and Exchange Commission on March 16, 2007. The warrants have a term of 5 years and are substantially identical to those warrants previously issued in the March 2007 offering. The Company agreed to include the common shares underlying the warrants in the Company's next registration statement. The warrants were granted as an inducement for the investors to exercise their prior warrants as well as the waiver of certain anti-dilutive and participation rights provisions contained March 2007 stock purchase agreement and warrants. The Company hereby incorporates by reference the stock purchase agreement and form of warrant contained in the Company's current report filed on Form 8-K on March 16, 2007. The Company relied on the exception from registration provided for in section 4(2) of the Securities Act.
- On November 14, 2008, we granted a consultant common stock purchase warrants to purchase 50,000 common shares at a price per share of \$2.75. The warrant was issued as partial compensation for services rendered. The warrant expires on November 13, 2013.
- On December 18, 2008, we completed a registered offering of our shares at a price per share of \$1.25. As a result of this transaction we issued:
 - o 112,000 placement agent warrants to purchase common stock at a price per share of \$2.52. The warrants expire December 16, 2013.
 - o 1,884,672 Series C Warrants to purchase common stock at a price per share of \$1.25. The warrants expire October 31, 2012.

Warrants to purchase common stock were issued to certain officers, stockholders and consultants.

| | Number of Warrants | Weighted- Average Exercise Price |
|----------------------------------|-----------------------|---|
| Outstanding at January 1, 2007 | 8,148,602 | \$ 1.90 |
| Issued | 5,752,480 | \$ 2.95 |
| Exercised | (2,692,567) | \$ (1.61) |
| Forfeited | - | |
| Outstanding at December 31, 2007 | 11,208,515 | \$ 2.44 |
| Issued | 2,046,672 | \$ 1.30 |
| Exercised | (125,425) | \$ 1.68 |
| Forfeited | - | |
| Outstanding at December 31, 2008 | 13,129,762 | \$ 2.27 |
| Exercisable at December 31, 2008 | 10,129,762 | \$ 2.05 |

The following table summarizes information about stock warrants at December 31, 2008 of which 10,129,762 are currently exercisable:

| Exercise Price | Outstanding Warrants | Expiration Date |
|----------------|----------------------|-----------------|
| \$0.50 | 320,000 | 2010 |
| \$1.10 | 782,005 | 2011 |
| \$1.25 | 3,111,672 | 2012 |
| \$1.25 | 294,480 | 2012 |
| \$1.50 | 2,131,265 | 2011 |
| \$1.50 | 112,000 | 2013 |
| \$2.00 | 2,228,340 | 2011 |
| \$2.00 | 100,000 | 2016 |
| \$2.75 | 50,000 | 2013 |
| \$3.01 | 1,000,000 | 2015 |
| \$3.01 | 2,000,000 | 2016 |
| \$5.00 | 1,000,000 | 2016 |
| | 13,129,762 | |

Warrant Modification Expense

In November 2008 we extended the lives of warrants for 320,000 shares of common stock with a strike price of \$.50 for two years. The warrants had been issued earlier in the decade in exchange for extinguishment of debt. The warrants were due to expire in November 2008. As a result of the term change we recorded a Warrant Modification Expense charge of \$38,631 for the warrants that were modified.

Valuation and Expense Information Under SFAS 123R

On January 1, 2006, we adopted SFAS 123R, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees service providers, and directors, including employee stock options and warrant awards.

The following table summarizes the stock-based compensation expense related to share-based payment awards under SFAS 123R for the year ended December 31, 2008 and 2007 which was allocated as follows:

| | Year Ended December 31, 2008 | Year Ended December 31, 2007 |
|---|---------------------------------|------------------------------------|
| Research and development | \$ 3,024,537 | \$ 1,167,172 |
| General and administrative | 1,608,310 | 407,948 |
| Stock-based compensation expense included in operating expenses | \$ 4,632,847 | \$ 1,575,120 |

The fair value of options granted in fiscal years 2008 and 2007 reported above have been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

| | 2008 | 2007 |
|-------------------------------|---------------|----------------|
| Dividend yield | 0% | 0% |
| Expected volatility range | 46% to 82% | 47% to 82% |
| Risk-free interest rate range | 1.22 to 4.96% | 3.09% to 4.96% |
| Expected life | 2 to 6.5 yrs | 2 to 6.5 yrs |

We have not used the historical volatility of our stock since we began public trading in December 2006 and consequently do not have sufficient trading history to forecast volatility for the expected life of our options. Instead to estimate expected volatility we use a market capitalization weighted average of the historical trading of other companies in our industry. The expected term of options is two years beyond the vesting date. This is an estimate based on management's judgment and corresponds with its experience with Equity Warrants. The risk-free interest rate is based on the Daily Treasury Yield Curve Rates as published by the US Treasury for the expected term in effect on the date of grant. We grant options under our equity plans to employees, non-employee directors, and consultants for whom the vesting period is between immediate and 4.5 years.

As stock-based compensation expense recognized in the statements of operations for the years ended December 31, 2008 and December 31, 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures but at a minimum, reflects the grant-date fair value of those awards that actually vested in the period. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based management judgment.

Based on the Black Scholes option-pricing model, the weighted average estimated fair value of employee stock options granted during the year ended December 31, 2008 was \$3.34 per share.

Earnings Per Share

Net loss per share is calculated in accordance with SFAS No. 128, "Earnings Per Share." The weighted-average number of common shares outstanding during each period is used to compute basic loss per share. Diluted loss per share is

computed using the weighted average number of shares and dilutive potential common shares outstanding. Dilutive potential common shares are additional common shares assumed to be exercised. All stock options have been excluded from the calculation because the effect would be anti-dilutive.

Common stock payable for 300,000 unissued shares of common stock at December 31, 2006

During the year ended December 31, 2006, the Company received \$150,000 related to exercise of warrants for 300,000 shares of common stock at \$0.50 per share. As of December 31, 2006, the Company had not issued any of the 300,000 shares of common stock. However, the 300,000 shares of common stock have been included in the net loss per share computation in the accompanying statements of operations. The Company issued these shares in February 2007.

Note 3. Property and Equipment

The major classes of property and equipment consist of the following:

| | 2008 | 2007 |
|--|------------|------------|
| Furniture and Fixtures | \$ 14,400 | \$ 5,289 |
| Computers and office equipment | 43,273 | 39,181 |
| Lab equipment | 196,036 | 132,530 |
| | \$ 253,709 | \$ 177,000 |
| Less accumulated depreciation and amortization | (89,779) | (40,080) |
| Property and equipment, net | \$ 163,930 | \$ 136,920 |

Depreciation expense for the years ended December 31, 2008 and 2007 was \$49,699 and \$32,057, respectively. In 2007 we retired \$1,139,411 of fully depreciated equipment that was no longer being used by the company.

Note 4. Intangible Assets

The Company holds patents related to its stem cell research. Patent filing costs were capitalized and are being amortized over the life of the patents. The company has determined that the intangibles purchased have a seventeen year useful life. The provisions of SFAS No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets" are followed in determining if there is any impairment. The Company determined that no impairment to the assigned values had occurred. The Company's intangible assets and accumulated amortization consisted of the following at December 31, 2008 and 2007:

| | 2008 | | 2007 | |
|--------------------|------------|--------------------------|------------|--------------------------|
| | Gross | Accumulated Amortization | Gross | Accumulated Amortization |
| Patent filing fees | \$ 243,004 | \$ (30,739) | \$ 126,083 | \$ (14,677) |

Amortization expense for the years ended December 31, 2008 and 2007 was \$16,062 and \$8,120, respectively.

Note 5. Income Taxes

We did not provide any current or deferred U.S. federal income tax provision or benefit for any of the periods presented because we have experienced operating losses since inception. We provided a full valuation allowance on the net deferred tax asset, consisting of net operating loss carryforwards, because management has determined that it is more likely than not that we will not earn income sufficient to realize the deferred tax assets during the carryforward period.

The tax effects of significant temporary differences representing deferred tax assets as of December 31, 2008 and 2007:

| | 2008 | 2007 |
|-----------------------------------|---------------|---------------|
| Net operating loss carry-forwards | \$ 15,563,878 | \$ 12,795,157 |
| Valuation allowance | (15,563,878) | (12,795,157) |
| Net deferred tax asset | \$ - | \$ - |

At December 31, 2008, the Company has net operating loss carryforwards of approximately \$38.9 million. The Company has also reported certain other tax credits, the benefit of which has been deferred. The Company's NOL carryforwards and credits will begin to expire in the tax year 2012. The timing and manner in which these net operating loss carryforwards and credits may be utilized in any year by the Company will be limited to the Company's ability to generate future earnings and also may be limited by certain provision of the U.S. tax code.

Note 6. Commitments and Contingencies

We currently lease three facilities. Our executive offices and primary research facilities are located at 9700 Great Seneca Highway, Rockville MD, 20850. We lease these facilities consisting of approximately 2,500 square feet for \$8,220 per month. The term of our lease expires on January 31, 2010

We entered into a lease in 2007 to secure approximately 900 square feet of research space in San Diego, California at a monthly lease rate of \$3,278 . The lease expires in August of 2009.

We entered into a lease in February 2008 to secure an additional two rooms for research purposes in San Diego, California at a monthly lease rate of \$6,000. The lease expired in February of 2009. The Company then extended the lease an additional year for one room at \$4,000 per month. That lease expires in February of 2010.

The Company recognized \$180,356 and \$251,997 in rent expense for the years ended December 31, 2008 and 2007, respectively.

On November 1, 2005, the Company amended and extended its employment agreements dated January 1, 1997 with Richard Garr and Karl Johe for an additional seven (7) years which includes a base salary of \$240,000 per year for each officer. On July 28, 2005, the Company granted both Mr. Garr and Mr. Johe stock options for 1,200,000 shares of the Company's common stock each vesting annually over a four year period with an exercise price of \$0.50 per share. Termination prior to full term on the contracts would cost the Company \$240,000 per year unserved, or as much as \$1,230,000 per contract, and immediate vesting of all outstanding options.

On July 28, 2006, StemCells, Inc., filed suit against Neuralstem, Inc. in the U.S. District Court in Maryland, alleging that Neuralstem has been infringing, contributing to the infringement of, and or inducing the infringement of four patents owned by or exclusively licensed to StemCells relating to stem cell culture compositions, genetically modified stem cell cultures, and methods of using such cultures.

In October 2006, Neuralstem filed a motion to dismiss, or in the alternative for summary judgment, arguing that its preclinical research activities are covered under the “safe harbor” provision of 35 U.S.C. § 271(e)(1) (the “safe harbor” defense’). The parties agreed to stay substantive discovery in the case pending resolution of Neuralstem’s motion to dismiss based on the “safe harbor” defense. While limited discovery was on-going on the “safe harbor” defense, in response to submissions from Neuralstem, the Patent Office ordered reexamination of all four of the patents-in-suit owned by StemCells. In view of the reexamination proceedings, both parties agreed that a stay of the entire lawsuit was warranted. On June 25, 2007, Judge Alexander Williams, Jr. entered an order staying the entire litigation pending the outcome of the reexamination proceedings. It is not known when nor on what basis this matter will be concluded.

In May of 2008, the Company 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. At present, the litigation is in its initial stages and we are unable to predict any likely outcome.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on management’s evaluation (with the participation of our CEO and Chief Financial Officer (CFO)), as of the end of the period covered by this report, our CEO and CFO have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)), are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management Report on Internal Control Over Financial Reporting

Management of Neuralstem, Inc. is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Internal control over financial reporting is a process designed by, or under the supervision of, the Company’s principal

executive and principal financial officers to provide reasonable assurance to the Company's management and board of directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- 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
 - 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 inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. A control system, no matter how well designed and operated, can provide only reasonable, but not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") as a guide. The Company sought in its evaluation to determine whether there were any "significant deficiencies" or "material weakness" in its internal control over financial reporting, or whether it had identified any acts of fraud involving management or other employees. Based on the above evaluation, the Company's chief executive officer and chief financial officer have concluded that as of December 31, 2008, the Company's internal control over financial reporting were effective.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only the management's report in this annual report.

Inherent Limitations on Effectiveness of Controls

Our management, including the CEO and CFO, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

Our board of directors consists of four members. Our bylaws provide for a staggered board consisting of 3 groups. The following sets forth our current directors, information concerning their ages and background, and information concerning their respective groups.

Class III Directors

The following directors are Class III directors and will serve until our 2011 annual meeting:

| Name | Principal Occupation | Age | Director Since |
|-----------------|--|-----|----------------|
| I. Richard Garr | Chief Executive Officer, President, General Counsel and Director of Neuralstem, Inc. | 56 | 1996 |
| Karl Johe, Ph.D | Chief Scientific Officer, Chairman of the Board and Director of Neuralstem, Inc. | 48 | 1996 |

Class II Directors

The following directors are Class II directors and will serve until our 2010 annual meeting:

| Name | Principal Occupation | Age | Director |
|------|----------------------|-----|----------|
|------|----------------------|-----|----------|

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| | | | |
|--------------------|---|----|---------------|
| William Oldaker(1) | Partner at Oldaker, Belair & Witte, LLP Director of Neuralstem, Inc. | 67 | Since 2007 |
|--------------------|---|----|---------------|

(1) Mr. Oldaker qualifies as an independent director within the meaning of the NYSE Amex rules and regulations.

Class I Directors

The following directors are Class I directors and will serve until our 2009 annual meeting:

| Name | Principal Occupation | Age | Director Since |
|------------------|--|-----|-------------------|
| Scott Ogilvie(1) | CEO and President of Gulf Enterprises International, Ltd. Director of Neuralstem, Inc. | 54 | 2007 |

(1) Mr. Ogilvie qualifies as an independent director within the meaning of the NYSE Amex rules and regulations.

Mr. I. Richard Garr, JD, age 56, 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.

Mr. Karl Johe, Ph.D., age 48, 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.

Mr. William Oldaker, age 67, has served on our board of directors since April 12, 2007. Mr. Oldaker is a founder and partner in the Washington, D.C. law firm of Oldaker, Belair & Witte, LLP. Prior to founding the firm in 1993, Mr. Oldaker was a partner in the Washington office of the law firm of Manatt, Phelps and Phillips from 1987 to 1993. In 2004, Mr. Oldaker was a founder of Washington First Bank in Washington, D.C. and serves as a member of the board of directors. He previously served as a director of Century National Bank, from 1982 until its acquisition in 2001. Mr. Oldaker was appointed by President Clinton to serve as a commissioner on the National Bioethics Advisory Commission, a post he held until 2001. He is a member of the Colorado, D.C. and Iowa Bar Associations, the Bar Association for the Court of Appeals, D.C., and the Bar of the United States Supreme Court. He is also a partner in The National Group, a consulting firm.

Mr. Scott V. Ogilvie, age 53, has served on our board of directors since April 12, 2007. Mr. Ogilvie is President and CEO of Gulf Enterprises International, Ltd, (“Gulf”) a company that brings strategic partners, expertise and investment capital to the Middle East and North Africa. He has held this position since August of 2006. Mr. Ogilvie also serves as Chief Operating Officer of CIC Group, Inc., an investment manager, a position he has held for the last five years. He began his career as a corporate and securities lawyer with Hill, Farrer & Burrill, and has extensive public and private corporate board experience in finance, real estate, and technology companies. Mr. Ogilvie currently serves on the board of directors of Neuralstem, Inc. (AMEX:CUR), Innovative Card Technologies, Inc. (NASDAQ:INVC) and Preferred Voice Inc, (OTCDBD:PRFV).

Executive Officers and Significant Employees

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 | 56 | 1996 |
| Karl Johe, Ph.D. | Chief Scientific Officer | 48 | 1996 |
| John Conron | Chief Financial Officer | 58 | 4/1/2007 |

I. Richard Garr – See Bio in the “Directors” section

Karl Johe, Ph.D. – See Bio in the “Directors” section

Mr. John Conron 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.

Family Relationships

There are no family relationships between any director, executive officer, or person nominated or chosen by the registrant to become a director or executive officer.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires our officers, directors, and stockholders owning more than ten percent of our common stock, to file reports of ownership and changes in ownership with the SEC and to furnish us with copies of such reports. Based solely on our review of Form 3, 4 and 5's, the following table provides information regarding any of the reports which were filed late during the fiscal year ended December 31, 2008:

| Name of Reporting Person | Type of Report Filed Late | No. of Transactions Reported Late |
|--------------------------|--|-----------------------------------|
| Richard Garr | Form 4 - Statement of Change in Beneficial Ownership | 1 |
| Karl Johe | Form 4 - Statement of Change in Beneficial Ownership | 1 |
| William Oldaker | Form 4 - Statement of Change in Beneficial Ownership | 2 |
| Scott Ogilvie | Form 4 - Statement of Change in Beneficial Ownership | 2 |

Code of Ethics

We have adopted a "Code of Ethics" that applies to our officer, directors and employees. We have also adopted a "Finance Code of Professional Conduct" that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and any persons who participate in our financial reporting process. A copy of our codes can be viewed on our website at www.neuralstem.com.

The codes incorporate our guidelines designed to deter wrongdoing and to promote honest and ethical conduct and compliance with applicable laws and regulations. The codes also incorporate our expectations of our officers, directors and employees that enable us to provide accurate and timely disclosure in our filings with the SEC and other public communications. In addition, the codes incorporate guidelines pertaining to topics such as complying with applicable laws, rules, and regulations; reporting violations; and maintaining accountability for adherence to the codes.

We intend to disclose future amendments to certain provisions of our codes, or waivers of such provisions on our web site within four business days following the date of such amendment or waiver.

Committees

We have established 3 corporate governance committees comprising of the: (i) Audit Committee; (ii) Compensation Committee; and (iii) Nomination and Corporate Governance Committee.

Audit Committee

We have a designated audit committee in accordance with section 3(a)(58)(A) of the Exchange Act. The members of the Audit Committee are Messrs Ogilvie and Oldaker. The Audit Committee assists our board in fulfilling its responsibility for the oversight of the quality and integrity of our accounting, auditing, and reporting practices, and such other duties as directed by the board. The committee's purpose is to oversee our accounting and financial reporting processes, the audits of our financial statements, the qualifications of our public accounting firm engaged by us as our independent auditor to prepare or issue an audit report on our financial statements, and the performance of our internal audit function and independent auditor. The committee reviews and assesses the qualitative aspects of financial reporting to shareholders, our processes to manage business and financial risk, and compliance with significant applicable legal, ethical, and regulatory requirements. The committee is directly responsible for the appointment (subject to shareholder ratification), compensation, retention, and oversight of our independent auditor.

Our board of directors has determined that Mr. Ogilvie is an "audit committee financial expert" within the meaning of SEC rules. An audit committee financial expert is a person who can demonstrate the following attributes: (1) an understanding of generally accepted accounting principles and financial statements; (2) the ability to assess the general application of such principles in connection with the accounting for estimates, accruals and reserves; (3) experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of

complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the company's financial statements, or experience actively supervising one or more persons engaged in such activities; (4) an understanding of internal controls and procedures for financial reporting; and (5) an understanding of audit committee functions.

Compensation Committee

The Compensation Committee's role is to discharge our boards responsibilities relating to compensation of our executives and to oversee and advise the board of directors on the adoption of policies that govern our compensation and benefit programs. Messrs Ogilvie and Oldaker are the members of the Compensation Committee.

Nomination and Corporate Governance Committee

The Nomination and Corporate Governance Committee reviews and evaluates the effectiveness of our executive development and succession planning processes, as well as provides active leadership and oversight of these processes, and oversight of our corporate governance policies. The Nomination and Corporate Governance Committee also evaluates and recommends nominees for membership on our board of directors and its committees. Messrs Ogilvie and Oldaker are the members of the Nomination Committee.

There has been no change material change to the procedures by which security holders may recommend nominees to our board of directors since we last provided such disclosure in our definitive proxy statement filed with the SEC in connection with our 2008 annual meeting.

Independent Directors

Our board of directors has determined that Messrs Ogilvie and Oldaker are each “independent” as that term is defined by the NYSE Amex. Messrs Ogilvie and Oldaker are the sole members of our: (i) Audit Committee; (ii) Compensation Committee; and (iii) Nomination and Corporate Governance Committee. The Company has determined that both Mr. Ogilvie and Mr. Oldaker are independent directors.

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

Summary Compensation

The following table sets forth information for our most recently completed fiscal year concerning the compensation of (i) the Principal Executive Officer and (ii) all other executive officers of Neuralstem, Inc. who earned over \$100,000 in salary and bonus during the last most recently completed fiscal year ended December 31, 2008 (together the “Named Executive Officers”).

| Name and principal position (a) | Year (b) | Salary (\$)(c) | Bonus (\$)(d) | Stock Awards (\$)(e) | Option Award (\$)(f)(2) | Nonequity Incentive Plan compensation (\$)(g) | Non-qualified deferred compensation earning (\$)(h) | All other Compensation (\$)(i)(1) | Total (\$)(j) |
|---|----------|----------------|---------------|----------------------|-------------------------|---|---|-----------------------------------|---------------|
| I. Richard Garr Chief Executive President, General Counsel (“PEO”) | 2008 | \$ 436,750 | 307,662 | | 3,437,056 | | | 88,523 | \$ 4,269,991 |
| | 2007 | \$ 357,000 | 26,750 | | | | | 33,384 | \$ 417,134 |
| Karl Johe Chief Scientific Officer | 2008 | \$ 427,250 | 343,350 | | 3,437,056 | | | 6,000 | \$ 4,213,656 |
| | 2007 | \$ 345,000(3) | 26,750 | | 570,478(4) | | | | \$ 636,612 |
| John Conron Chief Financial Officer | 2008 | \$ 208,750 | 18,750 | | 1,125,581 | | | 4,500 | \$ 1,357,581 |
| | 2007 | \$ 80,000 | 10,000 | | 315,000 | | | — | \$ 405,000 |

- (1) Includes automobile allowance, perquisites and other personal benefits.
- (2) For additional information regarding the valuation of Option Awards, refer to Note 2 of our financial statements in the section captioned "Stock Options."
- (3) Includes \$321,000 paid pursuant to employment agreement and \$24,000 of 1099 income for certain additional work performed in connection with our grants.
- (4) Includes 333,333 options awarded on September 20, 2007. This item does not include warrants granted in connection with the termination of Hi-Med Licensure Agreement and assignment of intellectual property residual rights.

Employment Agreements and Arrangements and Change-In-Control Arrangements

Employment Agreement with I. Richard Garr

We have a written employment agreement with Mr. Garr, our Chief Executive Officer and General Counsel. Pursuant to the agreement, as in effect, Mr. Garr is entitled to an annual salary of \$407,000 paid monthly of which \$30,000 is paid in connection with Mr. Garr's duties as general counsel. In addition, the agreement provides for certain performance bonuses as determined from time to time by our Compensation Committee. Our Compensation Committee approved a bonus award of up to 85% of Mr. Garr's base salary for the year ending on December 31, 2008 in the event certain objectives are achieved. On February 4, 2009, our Compensation Committee completed its annual performance and compensation review and approved the payment of a performance bonus to Mr. Garr in the amount of \$345,950 (85% of his base compensation for 2008). Mr. Garr has elected to defer his 2008 bonus until such time as we complete a financing. Mr. Garr's employment agreement also provides for a \$500 monthly automobile allowance and the reimbursement of reasonable business expenses. The term of the agreement is until October 31, 2012.

Mr. Garr's employment agreement also provides for severance ("Termination Provisions") in an amount equal to the greater of: (i) the aggregate compensation remaining on his contract; or (ii) \$1,000,000, in the event Mr. Garr is terminated for any reason. In the event of termination, the agreement also provides for the immediate vesting of 100% of stock options granted to Mr. Garr during his term of employment. These termination provisions apply whether employee is terminated for "cause" or "without cause." Additionally, in the event employee voluntarily terminates his employment following a change in control and material reassignment of duties, he will also be entitled to the termination provisions under the contract. In the event of early termination, the Termination Provisions will require us to make a substantial payment to the employee. By way of example, such payments would be approximately as follows:

| Termination Date | Amount of Payment (1) |
|--|-----------------------|
| October 31, 2009 | \$ 1,221,000 |
| October 31, 2010 until the end of Contract | \$ 1,000,000 |

(1)Assumes payment of annual salary of \$407,000 and a monthly automobile allowance of \$500.00. Does not include health benefits, bonuses or increase in annual salary.

Mr. Garr's agreement contains non-solicitation, and confidentiality and non-competition covenants. The agreement may be terminated by either party with or without cause and without prior notice subject to the termination provisions as discussed.

Employment Agreement with Karl Johe, Ph.D.

We have a written employment agreement with Mr. Johe, our Chief Scientific Officer. Pursuant to the agreement, as in effective, Mr. Johe is entitled to an annual salary of \$422,100 paid monthly. In addition, the agreement provides for certain performance bonuses as determined from time to time by our Compensation Committee. Our Compensation Committee approved a bonus award of up to 85% of Mr. Johe's base salary for the year ending on December 31, 2008 in the event certain objectives are achieved. On February 4, 2009, our Compensation Committee completed its annual performance and compensation review and approved the payment of a performance bonus to Mr. Johe in the amount of \$336,600 (85% of his base compensation for 2008 in the amount of \$396,000). Mr. Johe has elected to defer 75% of his 2008 bonus until such time as we complete a financing. Mr. Johe's employment agreement also provides for a \$500 monthly automobile allowance and the reimbursement of reasonable business expenses. The term of the agreement is until October 31, 2012.

Mr. Johe's employment agreement also provides for severance ("Termination Provisions") in an amount equal to the greater of: (i) the aggregate compensation remaining on his contract; or (ii) \$1,000,000, in the event Mr. Johe is terminated for any reason. In the event of termination, the agreement also provides for the immediate vesting of 100% of stock options granted to Mr. Johe during his term of employment. These termination provisions apply whether employee is terminated for "cause" or "without cause." Additionally, in the event employee voluntarily terminates his employment following a change in control and material reassignment of duties, he will also be entitled to the termination provisions under the contract. In the event of early termination, the Termination Provisions will require us to make a substantial payment to the employee. By way of example, such payments would be approximately as follows:

| Termination Date | Amount of Payment (1) |
|------------------|-----------------------|
| October 31, 2009 | \$ 1,226,300 |

October 31, 2010 until the end of Contract

\$ 1,000,000

(1) Assumes payment of annual salary of \$422,100 and a monthly automobile allowance of \$500.00. Does not include health benefits, bonuses or increase in annual salary.

Mr. Johe's agreement contains non-solicitation, and confidentiality and non-competition covenants. The agreement may be terminated by either party with or without cause and without prior notice subject to the termination provisions as discussed.

Employment Agreement with John Conron.

We have a written employment agreement with John Conron, our Chief Financial Officer. Pursuant to the agreement, as in effect, Mr. Conron is entitled to an annual salary of \$225,000. In addition, the agreement provides for certain performance bonuses as determined from time to time by our Compensation Committee. Our Compensation Committee approved a bonus award of up to 35% of Mr. Conron's base salary for the year ending on December 31, 2008 in the event certain objectives are achieved. On February 4, 2009, our Compensation Committee completed its annual performance and compensation review and approved the payment of a performance bonus to Mr. Conron in the amount of \$78,750 (35% of his base compensation for 2008). Mr. Conron has elected to defer his 2008 bonus until such time as we complete a financing. Mr. Conron's employment agreement also provides for a \$500 monthly automobile allowance.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information concerning unexercised options; stock that has not vested; equity incentive; and awards for each Named Executive Officer outstanding as of the end of the last completed fiscal year.

| Name (a) | Number of securities underlying unexercised options (#) (b) | Number of securities underlying unexercised options (#) (c) | Equity incentive plan awards: | | Option exercise price (\$) (e) | Option expiration date (f) | Number of shares or units of stock that have not vested (#) (g) | Market value of shares of units of stock that have not vested (\$) (h) | Equity incentive plan award: Number of un-earned shares, units or other rights that have not vested (#) (i) | Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested (\$) (j) |
|------------------------|--|--|--|-----------------------------------|-----------------------------------|-------------------------------|--|---|--|---|
| | | | Number of securities underlying unexercised options (#) (d) | Option exercise price (\$) (e) | | | | | | |
| I. Richard Garr | | | | | | | | | | |
| | (1) | 900,000 | 300,000 | | \$ 0.50 | 7/28/15 | | | | |
| | (2) | | 2,100,000 | | \$ 3.66 | 1/1/18 | | | | |
| Karl Johe | | | | | | | | | | |
| (3) | (4) | 900,000 | 300,000 | | \$ 0.50 | 7/28/15 | | | | |
| | (5) | | 333,333 | | \$ 3.01 | 10/31/15 | | | | |
| | (6) | | 2,100,000 | | \$ 3.66 | 1/1/18 | | | | |
| John Conron | | | | | | | | | | |
| | (7) | 100,000 | | | \$ 3.15 | 4/1/15 | | | | |
| | (8) | 50,000 | | | \$ 2.60 | 4/1/18 | | | | |
| | (9) | | 1,000,000 | | \$ 2.60 | 4/1/18 | | | | |

(1) On July 28, 2005, we granted our CEO an option to purchase 1,200,000 common shares. The option was granted under our 2005 Stock Plan. The option vests annually over 4 years at a rate of 300,000 per year. The applicable vesting dates are July 28, 2006, 2007, 2008 and 2009. The only vesting condition is Mr. Garr's continued employment.

(2) On January 21, 2008, we granted our CEO an option to purchase 2,100,000 common shares. The grant has an effective date of January 1, 2008. The option was granted under our 2007 Stock Plan. The option vests at a rate of 700,000 per 14 month period. The applicable vesting dates are February 28, 2009, April 30, 2010, and June 30, 2011. The only vesting condition is Mr. Garr's continued employment.

(3) Outstanding equity awards for Mr. Johe do not include warrants to purchase an aggregate of 3,000,000 common shares that were issued on June 5, 2007. For a further description of the transaction, please refer to the section of this report entitled "Transactions with Related Persons, Promoters and Certain Control Persons."

(4)

On July 28, 2005, we granted our CSO an option to purchase 1,200,000 common shares. The option was granted under our 2005 Stock Plan. The option vests annually over 4 years at a rate of 300,000 per year. The applicable vesting dates are July 28, 2006, 2007, 2008 and 2009. The only vesting condition is Mr. Johe's continued employment.

- (5) On September 20, 2007, we granted our Chairman and Chief Scientific Officer, an option to purchase an aggregate of 333,333 shares of our common stock at a price per share of \$3.01 pursuant to our 2005 Stock Plan. The option expires 5 years from the date when they become exercisable. The option vests on October 31, 2010. The option is immediately exercisable upon an event which would result in an acceleration of Mr. Johe's stock option grants under his employment agreement.
- (6) On January 21, 2008, we granted our CSO an option to purchase 2,100,000 common shares. The grant has an effective date of January 1, 2008. The option was granted under our 2007 Stock Plan. The option vests at a rate of 700,000 per 14 month period. The applicable vesting dates are February 28, 2009, April 30, 2010, and June 30, 2011. The only vesting condition is Mr. Johe's continued employment.
- (7) In April of 2007, we granted our CFO an option to purchase 100,000 common shares pursuant to his employment contract. The option is fully vested as of December 31, 2008.

(8) On April 1, 2008, we granted our CFO an option to purchase 50,000 common shares. The grant was made pursuant to Mr. Conron's employment agreement. The option was fully vested at the grant date.

(9) On April 1, 2008, we granted our CFO an option to purchase 1,000,000 common shares. The option vests at an annual rate of 333,333 per year. The vesting dates are April 1, 2009, 2010 and 2011. The only vesting condition is Mr. Conron's continued employment.

Director Compensation

The following table summarizes the compensation for our board of directors for the fiscal year ended December 31, 2008:

| Name (a) | Fees Earned or Paid in Cash (\$) (b) | Stock Awards (\$) (c) | Option Awards (\$) (d) | Non-Equity Incentive Plan Compensation (\$) (e) | Nonqualified Deferred Compensation Earnings (\$) (f) | All Other Compensation (\$) (g) | Total (\$) (h) |
|------------------------------|--|--------------------------------|---------------------------------|---|---|--|----------------------|
| William Oldaker | | | | | | | |
| Independent Director(1) | 20,000 | | \$ 20,706 | | | | \$ 40,706 |
| Audit Committee(2) | 5,000 | | \$ 2,301 | | | | \$ 7,301 |
| Compensation Committee(2) | 5,000 | | \$ 2,301 | | | | \$ 7,301 |
| Nomination Committee(2) | 5,000 | | \$ 2,301 | | | | \$ 7,301 |
| Scott Ogilvie | | | | | | | |
| Independent Director(1) | 20,000 | | \$ 20,706 | | | | \$ 40,706 |
| Audit Committee(2) | 5,000 | | \$ 2,301 | | | | \$ 7,301 |
| Compensation Committee(2) | 5,000 | | \$ 2,301 | | | | \$ 7,301 |
| Nomination Committee(2) | 5,000 | | \$ 2,301 | | | | \$ 7,301 |

(1) On May 28, 2008, pursuant to our adopted director compensation plan, we issued to each of Messrs Ogilvie and Oldaker options to purchase 45,000 shares of our common stock. The options were issued pursuant to our 2005 Stock Plan. The exercise price per share is \$1.32 and will expire 7 years from the date of grant. The individual grants vest on March 31, 2009.

(2) On May 28, 2008, pursuant to our adopted director compensation plan, we issued to each of Messrs Ogilvie and Oldaker, options to purchase 15,000 shares of our common stock (5,000 shares per each committee on which they serve). The options were issued pursuant to our 2005 Stock Plan. The exercise price per share is \$1.32 and the options vest on March 31, 2009.

Director Compensation Plan

Our Compensation Committee has adopted a formal outsider director compensation plan to assist us in attracting and retaining qualified directors. Under our plan, each eligible director shall receive:

Option Grants

First Year Grant. Upon joining the board, individual will receive options to purchase 45,000 common shares. The options shall vest as follows: (i) 25,000 shall vest on the one month anniversary of joining the Board; and (ii) 20,000 shall vest quarterly over a one year period commencing on the date such Director joins the Board. For purpose of the First Year option grant, all current eligible directors will be considered "First Year" directors and be eligible for such grant;

Annual Grant. Starting on the first year anniversary of service, and each subsequent anniversary thereafter, each eligible director will be granted options to purchase 20,000 shares of common stock. These Annual Grants will vest quarterly during the year; and

Committee Grant. Each Director will receive options to purchase an additional 5,000 shares for each committee on which he or she serves. These Committee Grants will vest quarterly during the year.

The exercise price for the options to be granted to the independent directors shall be the market price of the stock on each applicable grant date. The options shall expire 7 years from the grant date. The option will be granted pursuant to our 2005 Stock Plan.

Cash Compensation

Board Retention Amount. Each director shall receive a \$20,000 annual board retainer. The retainer shall be payable quarterly commencing on January 1, 2008.

Committee Retainer. In addition to the Board Retention Amount, each director serving on a committee shall receive an additional \$5,000 per committee on which he serves.

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

Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding shares authorized for issuance under equity compensation plans approved and not approved by stockholders required by this Item is incorporated by reference from Item 5 of this Annual Report from the section entitled "Equity Compensation Plan Information."

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth, as of March 9, 2009, information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to be the beneficial owner of 5% or more of any class of our voting securities;
- each of our current directors and nominees;
- each of our current named executive officers; and
- all current directors and named executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC. Beneficial ownership means that a person has or shares voting or investment power of a security and includes any securities that person or group has the right to acquire within 60 days after the measurement date. This table is based on information supplied by officers, directors and principal stockholders. Except as otherwise indicated, we believe that each of the beneficial owners of the common stock listed below, based on the information such beneficial owner has given to us, has sole investment and voting power with respect to such beneficial owner's shares, except where community property laws may apply.

| Name and Address of Beneficial Owner(1) | Shares | Common Stock | | Percent of Class(2) |
|---|-----------|---|-----------|---------------------|
| | | Shares Underlying Convertible Securities(2) | Total | |
| Directors and named executive officers | | | | |
| I. Richard Garr | 1,224,084 | 1,600,000 | 2,824,084 | 8.37% |
| Karl Johe, Ph.D | 1,769,484 | 1,600,000 | 3,369,484 | 9.98% |
| Scott Ogilvie | — | 95,000 | 95,000 | *% |
| William Oldaker | 68,400 | 95,000 | 163,400 | *% |
| John Conron | 15,000 | 483,333 | 498,333 | 1.48% |
| All directors and executive officers as a group (5 persons) | 3,076,968 | 3,873,333 | 6,950,301 | 18.471% |
| Beneficial Owners of 5% or more | | | | |
| Merrill Solomon | 2,057,097 | 120,000 | 2,177,097 | 6.45% |

*

Less than one percent.

(1) Except as otherwise indicated, the persons named in this table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them, subject to community property laws where applicable and to the information contained in the footnotes to this table. Unless otherwise indicated, the address of the beneficial owner is c/o Neuralstem, Inc. 9700 Great Seneca Highway, Rockville, MD.

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(2) Pursuant to Rules 13d-3 and 13d-5 of the Exchange Act, beneficial ownership includes any shares as to which a shareholder has sole or shared voting power or investment power, and also any shares which the shareholder has the right to acquire within 60 days, including upon exercise of common shares purchase options or warrant. There are 33,751,300 shares of common stock issued and outstanding as of March 9, 2009.

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

Transactions with Related Persons, Promoters and Certain Control Persons

Summarized below are certain transactions and business relationships between Neuralstem and persons who are or were an executive officer, director or holder of more than five percent of any class of our securities since January 1, 2007 or which have been proposed since December 31, 2008:

- On June 5, 2007, in exchange for: (i) the acquisition of certain residual rights; and (ii) the cancellation of the Hi Med Technologies, Inc. licensing agreement, we issued Karl Johe, our Chairman and Chief Scientific Officer, warrants to purchase an aggregate of 3,000,000 shares of our common stock at a price per share of \$3.01 and expire 5 years from the date when they become exercisable. Additionally, the warrants will become immediately exercisable upon an event which would result in an acceleration of Mr. Johe's stock options granted under his employment agreement. The warrants vest as follows:

- (i) 1,000,000 warrants vest on October 31, 2010; and
- (ii) 2,000,000 warrants vest on October 31, 2011.

In addition to the issuance of the warrants, we also made a one-time cash payment to Mr. Johe in the amount of \$150,000.

- We have paid Merrill Solomon, a 5% shareholder and employee, compensation for 2007 and 2008 at follows:

- (i) 2008 – Salary of \$152,750 and Bonus of \$5,875 for total compensation of \$158,625.
- (ii) 2007 – Salary of \$141,000, Bonus of \$11,750, and Other Compensation of \$26,855 for total compensation of \$179,405

Director Independence

Information regarding director independence required by this Item is incorporated by reference from Item. 10 of this Annual Report from the section entitled "Director Independence."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table summarizes the approximate aggregate fees billed to us or expected to be billed to us by our independent auditors for our 2008 and 2007 fiscal years:

| Type of Fees | 2008 | 2007 |
|-------------------|-----------|-----------|
| Audit Fees | | |
| Stegman & Company | \$ 66,426 | \$ 47,000 |
| Dave Banerjee | 6,000 | 18,152 |

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| | | |
|--------------------|-----------|-----------|
| Audit Related Fees | - | - |
| Tax Fees | | |
| Stegman & Company | 6,000 | 5,500 |
| Dave Banerjee | - | - |
| All Other Fees | | |
| Total Fee's | \$ 78,426 | \$ 70,652 |

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Pre-Approval of Independent Auditor Services and Fees

Our audit committee reviewed and pre-approved all audit and non-audit fees for services provided by Stegman & Company and has determined that the provision of such services to us during fiscal 2008 and in connection with the audit of our 2008 fiscal year financials is compatible with and did not impair independence. It is the practice of the audit committee to consider and approve in advance all auditing and non-auditing services provided to us by our independent auditors in accordance with the applicable requirements of the SEC. Stegman & Company did not provide us with any services, other than those listed above.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements: See "Index to Financial Statements" in Part II, Item 8 of this Form 10-K.
2. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Form 10-K.

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

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

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

SIGNATURES

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

NEURALSTEM, INC

Dated: March 31, 2009

By: /s/ I Richard Garr
I Richard Garr
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the following capacities and on the dates indicated.

| Name | Title | Date |
|---------------------|--|----------------|
| /s/ I. Richard Garr | President, Chief Executive Officer, General Counsel and Director | March 31, 2009 |

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| | | |
|--|--|----------------|
| I. Richard Garr | (Principal executive officer) | |
| /s/ John Conron John Conron | Chief Financial Officer (Principal financial and accounting officer) | March 31, 2009 |
| /s/ Karl Johe Karl Johe | Chairman of the Board and Director | March 31, 2009 |
| /s/ William Oldaker William Oldaker | Director | March 31, 2009 |
| /s/ Scott Ogilvie Scott Ogilvie | Director | March 31, 2009 |

INDEX TO EXHIBITS

| Exhibit No. | Description | Filed Herewith | Form | Incorporated by Reference | | Filing Date |
|-------------|--|----------------|---------|---------------------------|------------|-------------|
| | | | | Exhibit No. | File No. | |
| 3.01(i) | Amended and Restated Certificate of Incorporation of Neuralstem, Inc. filed on 9/29/05 | * | | | | |
| 3.02(i) | Certificate of Amendment to Certificate of Incorporation of Neuralstem, Inc. filed on 5/29/08 | | DEF 14A | Appendix I | 001-33672 | 4/24/08 |
| 3.03(ii) | Amended and Restated Bylaws of Neuralstem, Inc. adopted on July 16, 2007 | | 10-QSB | 3.2(i) | 333-132923 | 8/14/07 |
| 4.01** | Amended and Restated 2005 Stock Plan adopted on June 28, 2007 | | 10-QSB | 4.2(i) | 333-132923 | 8/14/07 |
| 4.02** | Non-qualified Stock Option Agreement between Neuralstem, Inc. and Richard Garr dated July 28, 2005 | | SB-2 | 4.4 | 333-132923 | 6/21/06 |
| 4.03** | Non-qualified Stock Option Agreement between Neuralstem, Inc. and Karl Johe dated July 28, 2005 | | SB-2 | 4.5 | 333-132923 | 6/21/06 |
| 4.04 | Private Placement Memorandum for March 2006 offering | | SB-2 | 4.12 | 333-132923 | 6/21/06 |
| 4.05 | Form of Placement Agent Warrant issued in connection with the March 2006 offering | | SB-2 | 4.13 | 333-132923 | 6/21/06 |
| 4.06 | Form of Series A Warrant (\$1.50) issued in connection with the March 2006 offering | | SB-2 | 4.14 | 333-132923 | 6/21/06 |
| 4.07 | Form of Series B Warrant (\$2.000) issued in connection with the March 2006 offering | | SB-2 | 4.15 | 333-132923 | 6/21/06 |
| 4.08 | Form of Subscription Agreement for March 2006 offering | | SB-2 | 4.16 | 333-132923 | 7/26/06 |

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| | | | | | |
|--------|---|--------|------|------------|---------|
| 4.09 | Form of Securities Purchase Agreement dated March 15, 2007 | 8-K | 4.1 | 333-132923 | 3/16/07 |
| 4.10 | Form of Common Stock Purchase Warrant dated March 15, 2007 (Series C) | 8-K | 4.2 | 333-132923 | 3/16/07 |
| 4.11 | Form of Registration Rights Agreement dated March 15, 2007 | 8-K | 4.3 | 333-132923 | 3/16/07 |
| 4.12** | Neuralstem, Inc. 2007 Stock Plan | 10-QSB | 4.21 | 333-132923 | 8/14/07 |

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| | | | | | |
|---------|--|--------|-------|------------|-----------|
| 4.13 | Form of Common Stock Purchase Warrant Issued to Karl Johe on June 5, 2007 | 10-KSB | 4.22 | 333-132923 | 3/27/08 |
| 4.14 | Form of Registration Rights Agreement entered into on February 19, 2008 between the Company and CJ CheilJedang Corporation | 8-K | 10.20 | 001-33672 | 2/25/08 |
| 4.15 | Form of Placement Agent Warrant Issued to Midtown Partners & Company on December 18, 2008 | 8-K | 4.1 | 001-33672 | 12/18/08 |
| 4.16 | Form of Consultant Common Stock Purchase Warrant issued on January 5, 2009 | S-3/A | 10.1 | 333-157079 | 02/3/2009 |
| 10.01** | Employment Agreement with I. Richard Garr dated January 1, 2007 and amended as of November 1, 2005 | SB-2 | 10.1 | 333-132923 | 6/21/06 |
| 10.02** | Amended terms to the Employment Agreement of I Richard Garr dated January 1, 2008 | * | | | |
| 10.03** | Employment Agreement with Karl Johe dated January 1, 2007 and amended as of November 1, 2005 | SB-2 | 10.1 | 333-132923 | 6/21/06 |
| 10.04** | Amended terms to the Employment Agreement of Karl Johe dated January 1, 2009 | * | | | |
| 10.05 | Licensing Agreement between Neuralstem, Inc. and the Maryland Economic Development Corporation dated February 1, 2004 and amended on March 14, 2004. | SB-2 | 10.5 | 333-132923 | 6/21/06 |
| 10.06 | Lease of Vivarium Room between Neuralstem, Inc. and Perry Scientific dated February 14, 2006 | SB-2 | 10.16 | 333-132923 | 6/21/06 |
| 10.07 | Form of Securities Purchase Agreement entered into between the Company and CJ CheilJedang Corporation on February 19, 2008 | 8-K | 10.19 | 001-33672 | 2/25/08 |
| 14.01 | Neuralstem Code of Ethics | SB-2 | 14.1 | 333-132923 | 6/21/06 |
| 14.02 | Neuralstem Financial Code of Profession Conduct adopted on May 16, 2007 | 8-K | 14.2 | 333-132923 | 6/6/07 |

23 Consent of Independent Registered Public *
Accounting Firm

31.1 Certification of the Principal Executive *
Officer Pursuant to Section 302 of the
Sarbanes-Oxley Act of 2002

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- | | | |
|------|--|---|
| 31.2 | Certification of the Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | * |
| 32.1 | Certification of Principal Executive Officer Pursuant to 18 U.S.C. § 1350 | * |
| 32.2 | Certification of Principal Financial Officer Pursuant to 18 U.S.C. § 1350 | * |

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