

STEMCELLS INC  
Form 10-K  
March 16, 2009

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

**Form 10-K**

- 1** **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**
- 2** **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**COMMISSION FILE NUMBER 0-19871**

**STEMCELLS, INC.**

*(Exact name of Registrant as specified in its charter)*

**A Delaware Corporation**  
*(State or other jurisdiction  
of incorporation or organization)*  
**3155 PORTER DRIVE**  
**PALO ALTO, CA**  
*(Address of principal offices)*

**94-3078125**  
*(I.R.S. Employer  
Identification No.)*  
**94304**  
*(zip code)*

**Registrant's telephone number, including area code:**

**(650) 475-3100**

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

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
Common Stock, \$0.01 par value	Nasdaq Global Market
Junior Preferred Stock Purchase Rights	

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

**None**

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. (Check one):

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 Exchange Act). Yes ☐ No ☒

Aggregate market value of common stock held by non-affiliates at June 30, 2008: \$99,692,070 Inclusion of shares held beneficially by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management policies of the registrant, or that such person is controlled by or under common control with the Registrant.

Common stock outstanding at March 5, 2009: 95,543,083 shares.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the registrant's 2009 Annual Meeting of Stockholders to be filed with the Commission pursuant to Regulation 14A are incorporated by reference in Part III of this report.

### FORWARD LOOKING STATEMENTS

THIS REPORT CONTAINS FORWARD-LOOKING STATEMENTS AS DEFINED UNDER THE FEDERAL SECURITIES LAWS. ACTUAL RESULTS COULD VARY MATERIALLY. FACTORS THAT COULD CAUSE ACTUAL RESULTS TO VARY MATERIALLY ARE DESCRIBED HEREIN AND IN OTHER DOCUMENTS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. READERS SHOULD PAY PARTICULAR ATTENTION TO THE CONSIDERATIONS DESCRIBED IN THE SECTION OF THIS REPORT ENTITLED MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS AS WELL AS ITEM 1A UNDER THE HEADING RISK FACTORS.

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## NOTE REGARDING REFERENCES TO OUR COMMON STOCK

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Throughout this Form 10-K, the words we, us, our, and StemCells refer to StemCells, Inc., including StemCells California, Inc., a wholly-owned subsidiary, and the owner or licensee of most of our intellectual property. Common stock refers to StemCells, Inc., common stock, \$.01 par value.

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**PART I**

**Item 1. BUSINESS**

**Overview**

StemCells, Inc. is engaged in the discovery and development of cell-based therapeutics to treat damage to, or degeneration of, major organ systems. Our aim is to restore or support organ function, improve patients' lives and reduce the substantial health care costs associated with these diseases and disorders by identifying and developing stem and progenitor cells as potential therapeutic agents. We currently have two product development programs at the Company: (i) our CNS Program, which is developing applications for our proprietary human neural stem cell and (ii) our Liver Program, which is developing applications for our proprietary human liver engrafting cells.

In our CNS Program, we are focused on developing applications for our HuCNS-SC<sup>®</sup> product candidate (purified human neural stem cells) for disorders of the central nervous system (CNS). Our HuCNS-SC product candidate is in clinical development for two indications. In January 2009, we completed a six patient Phase I clinical trial to evaluate the safety and preliminary efficacy of HuCNS-SC cells as a treatment for infantile and late infantile neuronal ceroid lipofuscinosis (NCL), two forms of a group of disorders often referred to as Batten disease. We expect to complete data analysis and to report the results of this trial in mid 2009. In December 2008, we received authorization from the US Food and Drug Administration (FDA) to initiate a Phase I clinical trial of our HuCNS-SC cells in a second indication, Pelizaeus-Merzbacher Disease (PMD), a fatal myelination disorder in the brain. We expect the PMD trial to begin in 2009 and that it will take 12-18 months to complete. In addition, our HuCNS-SC cells are in preclinical development for spinal cord injury and retinal disorders.

In our Liver Program, we are in preclinical development with our human liver engrafting cells (hLEC). We have settled on a process to isolate and purify hLEC, and we plan to seek the necessary approvals to initiate a clinical study to evaluate hLEC as a potential cellular therapy, with the initial indication likely to be liver-based metabolic disorders. We are also conducting research to see if hLEC can be made resistant to the hepatitis C virus.

Many degenerative diseases are caused by the loss of normal cellular function in a particular organ. When cells are damaged or destroyed, they no longer produce, metabolize or accurately regulate substances, such as sugars, amino acids, neurotransmitters, and hormones, which are essential to life. Although traditional pharmaceuticals and genetically engineered biologics may have some utility in addressing a degenerative condition, there is no technology existing today that can deliver these essential substances precisely to the sites of action, under the appropriate physiological regulation, in the appropriate quantity, or for the duration required to cure the degenerative condition. Cells, however, can do all this naturally. Thus, transplantation of stem or progenitor cells may prevent the loss of, or even generate new, functional cells and potentially maintain or restore organ function and the patient's health.

We believe that, if successfully developed, our cell technologies will create the basis for therapies that would address a number of conditions with significant unmet medical needs. Many neurodegenerative diseases involve the failure of an organ that cannot be transplanted, such as the brain or spinal cord. Many liver diseases, such as hepatitis, can be addressed by a liver transplant, but transplantable livers are in very limited supply. We estimate that degenerative conditions of the central nervous system (CNS) and the liver together affect more than 35 million people in the United States and account for nearly \$200 billion annually in health care costs.<sup>1</sup>

On March 1, 2009, we entered into an asset purchase agreement with Stem Cell Sciences Plc ( "SCS" ) to acquire substantially all of the operating assets and liabilities of SCS (the proposed "Acquisition" ). The Acquisition is subject to

the approval of the stockholders of SCS and other customary closing conditions, and is expected to

<sup>1</sup> This estimate is based on information from the Alzheimer's Association, the Alzheimer's Disease Education & Referral Center (National Institute on Aging), the National Parkinson Foundation, the National Institutes of Health's National Institute on Neurological Disorders and Stroke, the Foundation for Spinal Cord Injury Prevention, Care & Cure, the Travis Roy Foundation, the Centers for Disease Control and Prevention, the Wisconsin Chapter of the Huntington's Disease Society of America, the American Liver Foundation, and the Cincinnati Children's Hospital Medical Center.

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close shortly after the SCS extraordinary general meeting scheduled for March 27, 2009. Upon the closing of this Acquisition, we will acquire (i) expertise and infrastructure for providing cell-based assays for drug discovery and screening; (ii) additional cell technologies relating to embryonic stem cells, induced pluripotent stem cells (iPS cells), and tissue-derived (adult) stem cells; (iii) a patented gene insertion technology with potential utility in drug screening and for applications in cell and gene therapy; (iv) a portfolio of over twenty patent families claiming a range of technologies relevant to cell processing, reprogramming and manipulation and gene targeting; and (v) the SC Proven® media formulation and reagent business of SCS, including its iSTEM®, 2i, 3i, Passaid™, HEScGRO™, and EScGRO™ proprietary media. In recent years, the pharmaceutical industry has shown an increasing interest in the use of cell-based assays in their drug discovery research. Following the closing of this Acquisition, we plan to leverage our expertise in cell biology to pursue non-therapeutic applications of our cell technologies, such as cell-based assays for drug discovery and screening. This additional investment is intended to position us to diversify and pursue near-term commercialization opportunities while continuing to develop our cell-based therapeutic products.

### **The Potential of Our Tissue-Derived Cell-Based Therapeutics**

We are focused on identifying and purifying tissue-derived stem and progenitor cells for use in homologous therapy. Tissue-derived stem cells are developmentally pre-programmed to become the mature functional cells of the organ from which they were derived. We believe that homologous use of purified, unmodified tissue-derived cells (for example, use of brain-derived neural stem cells for treatment of CNS disorders and liver-derived cells for treatment of liver disorders) is the most direct way to provide for engraftment and differentiation into functional cells, and should minimize the risk of transplantation of unwanted cell types.

To our knowledge, no one has developed an effective therapy for replacing lost or damaged tissues from the human nervous system. Replacement of tissues in other areas of the human body is mainly limited to those few cases, such as bone marrow or peripheral blood cell transplants, where transplantation of the patient's own cells is now feasible. In a few additional areas, including the liver, transplantation of donor organs is now used, but is limited by the scarcity of organs available through donation. More recently, investigators have isolated subpopulations of cells from a specific organ, such as hepatocytes from the liver or islet cells from the pancreas, which have been transplanted into patients with a measure of success. However, these types of cell transplants are also limited both by the quality of harvested cells and the availability of suitable organs.

Stem cells are rare and only available in limited supply. They have two defining characteristics: (i) they produce all of the mature cells making up the particular organ 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 occur again and again. Because of this self-renewal property, we believe that cell-based therapeutics may facilitate the return to proper function of the impaired organ or system potentially for the life of the patient. To date four human stem cells have been identified and characterized in vivo: the hematopoietic stem cell, the mesenchymal stem cell, the neural stem cell, and the embryonic stem cell. Many researchers believe stem cells exist in other organ systems, including the liver, pancreas endocrine system, and the heart. Stem cells can produce all the mature functional cell types found in normal organs. Progenitor cells are cells that have already developed from the stem cells, but can still produce one or more mature cell types within an organ. We use cells derived from donated fetal or adult tissue sources, which are supplied to us in compliance with all applicable state and federal regulations. We are not involved in any activity directed toward human cloning, nor do we have any plans to start such activities. Upon completion of the Acquisition of the business of SCS, we intend to continue the development of embryonic stem cells and iPS cells as potential research tools. While we are not currently developing embryonic stem cells for therapeutic use, we may in the future explore their applicability as cell-based therapeutic products.

In order to develop cell-based therapeutics, three key challenges must be overcome: (i) identifying the stem or progenitor cells of a particular organ and testing them for therapeutic potential; (ii) creating 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, or purifying them for use in direct transplantation; and (iii) demonstrating the safety and efficacy of these potential therapeutics in human clinical trials. With respect to our HuCNS-SC product candidate, we believe we have (i) identified and characterized the human neural stem cell and (ii) developed proprietary and reproducible processes to purify, expand and bank these cells; we are currently at the stage of demonstrating safety and efficacy of our HuCNS-SC product candidate in human clinical trials.

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### **Business Strategy**

Our strategy is to identify multiple types of human stem and progenitor cells with therapeutic and commercial importance; to develop techniques and processes either to reproducibly purify these cells for direct transplant or to enable the expansion and banking of these cells; to take them into clinical development and ultimately, to commercialize them as cell-based therapeutic products.

We believe that patent protection will be available to the first to identify and isolate any of the finite number of different types of human stem and progenitor cells, and the first to define methods to culture such cells, making the commercial development of cell-based treatments for currently intractable diseases financially feasible. Thus, a central element of our business strategy is to obtain patent protection for the compositions, processes and uses of these multiple types of cells. We have obtained rights to certain inventions relating to stem cells and progenitor cells from academic institutions. We expect to continue to expand our search for, and to seek to acquire rights from third parties relating to, new stem and progenitor cells.

### **Research and Development Programs**

#### *Overview*

The following table summarizes the current status of, and the anticipated initial indications for, our two product development programs. A more detailed discussion of each of these follows the table.

<b>Program Description and Objective</b>	<b>Status</b>
<i>CNS Program</i>	
Cell-based therapeutics to restore or preserve function to central nervous system tissue by protecting, repairing or replacing dysfunctional or damaged cells. Initial indications are lysosomal storage diseases that affect the CNS, such as NCL, and disorders in which deficient myelination plays a central role, such as PMD.	<p><i>Neuronal Ceroid Lipofuscinosis (also known as Batten disease)</i></p> <p>Six-patient Phase I clinical trial completed in January 2009. Results expected to be reported in mid 2009.</p> <p>Demonstrated <i>in vivo</i> proof of principle by showing in a mouse model for infantile NCL that transplanted HuCNS-SC cells can:</p> <ul style="list-style-type: none"> <li>continuously produce the enzyme that is deficient in infantile NCL</li> <li>protect host neurons from death</li> <li>extend the lifespan of the HuCNS-SC transplanted mice</li> </ul>

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**Program Description and Objective**

**Status**

*Spinal Cord Injury:*

***CNS Program***

Many neurodegenerative diseases involve the failure of central nervous system tissue (i.e., the brain, spinal cord and eye) due to the loss of functional cells. Our CNS Program is initially focusing on developing clinical applications to prevent the loss of, or restore function to, neural cells affected by genetic disorders such as neuronal ceroid lipofuscinosis and certain other lysosomal storage diseases; diseases in which deficient myelination plays a central role, such as Pelizaeus-Merzbacher Disease or cerebral palsy; traumatic insults to the brain or spinal cord; and disorders in which retinal degeneration play a central role, such as age-related macular degeneration or retinitis pigmentosa. These disorders affect a significant number of people in the United States and there currently are no effective long-term therapies for them.

Our lead product candidate, HuCNS-SC cells, is a purified composition of normal human neural stem cells. As such, we believe it is better suited for transplantation and should provide a safer and more effective alternative to therapies that are based on cells derived from cancer cells, animal-derived cells or are an unpurified mix of cell types. Furthermore, our HuCNS-SC cells can be directly transplanted, unlike embryonic stem cells, which require a prerequisite differentiation step prior to administration in order to preclude teratoma formation (tumors of multiple differentiated cell types). Our preclinical research has shown *in vivo* that HuCNS-SC cells engraft, migrate, differentiate into neurons and glial cells, and survive for as long as one year with *no sign* of tumor formation or adverse effects; moreover, the HuCNS-SC cells were still producing progeny cells at the end of the test period. These findings show that our neural stem cells, when transplanted, act like normal stem cells, suggesting the possibility of a continual replenishment of normal human neural cells.

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We hold a substantial portfolio of issued and allowed patents in the neural field. See Patents, Proprietary Rights and Licenses, below.

### *Neuronal Ceroid Lipofuscinosis (NCL; also known as Batten disease).*

Neuronal ceroid lipofuscinosis (NCL), which is often referred to as Batten disease, is a neurodegenerative disease that affects infants and young children. Two forms of NCL – infantile and late infantile – are caused by the deficiency of a lysosomal enzyme. Infantile and late infantile NCL are brought on by inherited genetic mutations in the *CLN1* gene, which codes for palmitoyl-protein thioesterase 1 (PPT1) and in the *CLN2* gene, which codes for tripeptidyl peptidase I (TPP-I), respectively. As a result of these mutations, the relevant enzyme is either defective or missing, leading to the accumulation of cellular waste product in various cell types. This accumulation eventually interferes with normal cellular and tissue function, and leads to seizures and progressive loss of motor skills, sight and mental capacity. Today, NCL is always fatal.

In January 2009, we completed a six-patient Phase I clinical trial at Oregon Health & Science University Doernbecher Children's Hospital to evaluate the safety and preliminary efficacy of our HuCNS-SC product candidate as a treatment for infantile and late infantile NCL. This trial was an open label study with two dose levels. Under the trial protocol, patients received immunosuppression for one year following transplantation of the HuCNS-SC cells. In addition to evaluating the safety of HuCNS-SC cells, the trial is also evaluating the ability of the cells to affect the progression of the disease. We expect to complete data analysis and to report the trial results in mid 2009. We believe this clinical trial was the first FDA-approved trial to use purified human neural stem cells as a potential therapeutic agent.

Our preclinical data demonstrate that HuCNS-SC cells, when transplanted in a mouse model of infantile NCL, engraft, migrate throughout the brain, produce the missing PPT1 enzyme, measurably reduce the toxic storage material in the brain, and protect host neurons so that more of them survive. In addition, we have shown that the lifetime of the mice transplanted with HuCNS-SC cells is extended compared to the control group. We have also demonstrated *in vitro* that HuCNS-SC cells produce TPP-I, the enzyme that is deficient in late infantile NCL.

### *Other Lysosomal Storage Diseases.*

NCL, or Batten disease, is one of a group of approximately 46 lysosomal storage diseases (LSDs). All LSDs are caused by defective or missing proteins involved in lysosomal function and some LSDs can be treated by enzyme replacement therapies. Examples of enzyme replacement products already approved are Cerezyme<sup>™</sup> for Gaucher disease, Fabryzyme<sup>™</sup> for Fabry disease, Myozyme<sup>®</sup> for Pompe disease, Aldurazyme<sup>™</sup> for MPS I, and Naglazyme<sup>™</sup> for MPS VI. All of these approved products, however, address LSDs which primarily affect peripheral organs and not the central nervous system. About half of the lysosomal storage diseases, however, do primarily affect the central nervous system; enzyme replacement therapy is not currently a practical treatment option for this subset of LSDs because enzymes are typically too large to cross the blood-brain barrier. We believe that transplanting HuCNS-SC cells directly into the CNS may have the potential to treat some LSDs that affect the CNS by supplying missing enzymes to the brain. In addition to infantile and late infantile NCL, we have found that HuCNS-SC cells can produce the relevant enzyme in a number of other LSDs that affect the CNS.

### *Pelizaeus-Merzbacher Disease (PMD).*

Pelizaeus-Merzbacher Disease, a rare, degenerative, central nervous system disorder, is one of a group of genetic disorders known as leukodystrophies. Leukodystrophies involve abnormal growth of the myelin sheath which is the fatty substance – or insulator – on nerve fibers in the brain and spinal cord. PMD is most commonly caused by a genetic mutation that affects an important protein found in myelin, proteolipid protein (PLP). PMD is most frequently diagnosed in early childhood and is associated with abnormal eye movements, abnormal muscle function, and in some

cases, seizures. The disease form in early infancy is referred to as connatal PMD and diagnosis in later childhood is most typically associated with the classic form. The neurological course of both forms is marked by progressive deterioration resulting in premature death.

In December 2008, the FDA approved our Investigational New Drug application (IND) to initiate a Phase I clinical trial of our HuCNS-SC product candidate for PMD. We expect to begin enrolling patients in this trial in

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2009 and that the trial will take twelve to eighteen months to complete. In our preclinical research, we have shown that HuCNS-SC cells differentiate into oligodendrocytes, the myelin producing cells, and produce myelin. We have transplanted HuCNS-SC cells into the brain of the mutant shiverer mouse, which is deficient in myelin, and shown widespread engraftment of human cells that matured into oligodendrocytes, and that the human oligodendrocytes myelinated the mouse axons.

### *Other Myelin Disorders.*

Loss of myelin characterizes conditions such as multiple sclerosis, cerebral palsy and certain genetic disorders (for example, Krabbe's disease and metachromatic leukodystrophy), and also plays a role in certain spinal cord indications. Based on our preclinical data showing that HuCNS-SC cells differentiate into oligodendrocytes and that these oligodendrocytes myelinate host axons, we believe our HuCNS-SC product candidate may have applicability to myelin disorders. In addition, in collaboration with Dr. Stephen Back at the Oregon Health & Science University, we are attempting to detect human myelin production by HuCNS-SC cells using magnetic resonance imaging.

### *Spinal Cord Injury.*

Stem cells may have the potential to treat various spinal cord indications. Using a mouse model of spinal cord injury, our collaborators, Drs. Aileen Anderson and Brian Cummings of the Reeve-Irvine Center at the University of California, have shown that HuCNS-SC cells have the potential to protect and regenerate damaged nerves and nerve fibers, and that injured mice transplanted with our human neural stem cells showed improved motor function compared to control animals. Inspection of the spinal cords from the treated mice showed significant levels of human neural cells derived from the transplanted stem cells. Some of these cells were oligodendrocytes, the specialized neural cell that forms the myelin sheath around axons, while others had become neurons and showed evidence of synapse formation, a requirement for proper neuronal function. Drs. Anderson and Cummings then selectively ablated the human cells, and found that the functional improvement was lost, thus demonstrating that the human cells had played a direct role in the functional recovery of the transplanted mice. We are continuing preclinical development on our HuCNS-SC product candidate for various spinal cord indications.

### *Retinal Disorders.*

The retina is a thin layer of neural cells that lines the back of the eye and is responsible for converting external light into neural signals; loss of function in retinal cells leads to impairment or loss of vision. The most common forms of retinal degeneration are age-related macular degeneration and retinitis pigmentosa. Published studies have shown that in a well-established animal model of retinal degeneration, the Royal College of Surgeons (RCS) rat, human neural stem cells protect retinal function and thereby preserve vision. In the RCS model, a genetic mutation causes dysfunction of the retinal pigmented cells, which leads to progressive loss of the photoreceptors and ultimately, loss of visual function. These studies indicate that our HuCNS-SC cells could have potential clinical application as a treatment for retinal degeneration.

In January 2008, we entered into a research collaboration with Oregon Health & Science University Casey Eye Institute to evaluate engraftment and potential applicability of our HuCNS-SC cells in retinal disorders. In November 2008, we presented preclinical results showing that transplanting our HuCNS-SC cells prevented visual impairment in the RCS rat. In the study, our collaborators at the Casey Eye Institute, Drs. Raymond Lund and Peter Francis, transplanted HuCNS-SC cells into one eye of 21-day-old RCS rats while keeping the opposite eye as the control, and demonstrated that the HuCNS-SC cells survived the transplants and engrafted, and the eyes transplanted with the cells showed preservation of the photoreceptors and stabilization of visual function. We are continuing preclinical studies of our HuCNS-SC cells as a potential treatment for retinal disorders.

*Other Neural Collaborations.*

We have established a number of research collaborations to assess both the *in vitro* potential of the HuCNS-SC cells and the effects of transplanting HuCNS-SC cells into preclinical animal models, including a collaboration with researchers at the Stanford University School of Medicine to evaluate our human neural stem cells in animal models

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of stroke. The results of these studies demonstrate the targeted migration of the cells toward the stroke lesion and differentiation toward the neuronal lineage. Another study with researchers at Stanford's School of Medicine demonstrated that HuCNS-SC cells labeled with magnetic nanoparticles could non-invasively track the survival and migration of human cells within the brain. In addition, we concluded an NIH-funded collaboration with Dr. George A. Carlson of the McLaughlin Research Institute to investigate the role of Alzheimer's plaques in neuronal cell death in Alzheimer's disease. Under the collaboration, Dr. Carlson transplanted HuCNS-SC cells into mouse models of Alzheimer's disease and the cells showed robust engraftment in an environment riddled with Alzheimer's plaques.

## ***Liver Program***

According to the American Association for the study of Liver Diseases website, approximately 25 million Americans are afflicted with liver-related disease each year. To our knowledge there currently are no effective, long-term treatments for many of these. Liver stem or progenitor cells may be useful in the treatment of some of these diseases, such as hepatitis, liver failure, blood-clotting disorder, cirrhosis, and liver cancer. A source of defined human cells capable of engraftment and substantial liver regeneration could provide a cellular therapy or cell-based therapeutic product available to a wider patient base than whole liver transplants.

We have identified and isolated a cell population that we call human liver engrafting cells (hLEC) which can be derived from all types of human livers, including those that would not otherwise be used for liver transplantation. When tested *in vitro*, hLEC demonstrate essential liver enzymatic functions, such as detoxification (cytochrome P450) and conversion of toxic ammonia to urea. When transplanted into immunodeficient mice with a metabolic defect, hLEC engraft and show basic function of hepatocytes. Specifically, hLEC produce the human protein deficient in this animal model as well as human albumin and alpha-1-antitrypsin and the engrafted human cells store glycogen and form structural elements for bile and drug excretion from the liver.

In September 2007, we entered into a research collaboration with Belgium's Université Catholique de Louvain (UCL) and the UCL-affiliated Cliniques Universitaires Saint Luc to further the development of hLEC as a potential cell-based liver therapy. We plan to seek the necessary approvals to initiate a clinical study to evaluate hLEC as a potential cellular therapy, with the initial indication likely to be a liver-based metabolic disorder characterized by an enzyme deficiency.

We hold a portfolio of issued and allowed patents in the liver field. See Patents, Proprietary Rights and Licenses, below.

## **Manufacturing**

We have made considerable investments in our manufacturing operations. We believe we have the ability to process cells suitable for use in our ongoing and planned research and development activities and clinical trials.

## **Marketing**

Because of the early stage of our stem and progenitor cell programs, we have not yet addressed questions of channels of distribution and marketing of potential future products.

## **Patents, Proprietary Rights and Licenses**

We believe that proprietary protection of our inventions will be critical to our future business. We vigorously seek out intellectual property that we believe might be useful in connection with our products, and have an active program of protecting our intellectual property. We may also from time to time seek to acquire licenses to important externally



developed technologies.

We have exclusive or non-exclusive rights to a portfolio of patents and patent applications related to various stem and progenitor cells and methods of deriving and using them. These patents and patent applications relate to compositions of matter, methods of obtaining such cells, and methods for preparing, transplanting and utilizing such cells. As of December 31, 2008, our U.S. patent portfolio included approximately 50 issued or allowed U.S. patents from over 25 separate patent families. Three of our U.S. patents issued in 2008: (i) U.S. Patent No. 7,361,505,

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(ii) U.S. Patent No. 7,344,857, and (iii) U.S. Patent No. 7,381,561. These new patents have further strengthened our already extensive patent portfolio, which, we believe, gives us a competitive advantage, especially in the emerging field of neural stem cells, because our patents broadly cover methods for identification, isolation, expansion, and transplantation of neural stem cells as well as their use in drug discovery and testing.

We also have foreign counterparts to a majority of our U.S. patents and applications; a substantial number of these have issued in various countries, making a total of over 150 granted or allowed non-U.S. patents as of December 31, 2008.

Among our significant U.S. patents are:

U.S. Patent No. 5,968,829, entitled Human CNS Neural Stem Cells, which covers our composition of matter for human CNS stem cells;

U.S. Patent No. 7,361,505, entitled Multipotent neural stem cell compositions, which covers human neural stem cells derived from any tissue source, including embryonic, fetal, juvenile, or adult tissue;

U.S. Patent No. 7,153,686, entitled Enriched Central Nervous System Stem Cell and Progenitor Cell Populations, and Methods for Identifying, Isolating and Enriching such Populations, which claims the composition of matter of various antibody-selected neural stem cell populations;

U.S. Patent No. 6,777,233, entitled Cultures of Human CNS Neural Stem Cells, which discloses a neural stem cell culture with a doubling rate of 5 to 10 days;

U.S. Patent No. 6,497,872, entitled Neural transplantation using proliferated multipotent neural stem cells and their progeny, which covers transplanting any neural stem cells or their differentiated progeny, whether the cells have been cultured in suspension or as adherent cells, for the treatment of any disease;

U.S. Patent No. 6,468,794, entitled Enriched central nervous system stem cell and progenitor cell populations, and methods for identifying, isolating and enriching for such populations, which covers the identification and purification of the human CNS stem cell;

U.S. Patent Nos. 6,238,922 and 7,049,141, both entitled Use of collagenase in the preparation of neural stem cell cultures, which describe methods to advance the in vivo culture and passage of human CNS stem cells that result in a 100-fold increase in CNS stem and progenitor cell production after 6 passages;

U.S. Patent No. 5,851,832, entitled In Vitro growth and proliferation of multipotent neural stem cells and their progeny, which covers our methods for selecting the human CNS cell cultures containing central nervous system stem cells, for compositions of human CNS cells expanded by these methods, and for use of cells derived from these cultures in human transplantation;

U.S. Patent No. 6,294,346, entitled Use of multipotent neural stem cells and their progeny for the screening of drugs and other biological agents, which describes the use of human neural stem cells as a tool for screening the effects of drugs and other biological agents on such cells, such as small molecule toxicology studies;

U.S. Patent No. 7,211,404, entitled Liver engrafting cells, assays, and uses thereof, which covers the isolation and use of an enriched population of hepatic liver engrafting cells; and

U.S. Patent No. 7,381,261, entitled Enriched central nervous system stem cell and progenitor cell populations, and methods for identifying, isolating and enriching for such populations, which covers the use of additional monoclonal antibodies for the prospective isolation of rare cells from human neural tissue.

We also rely upon trade-secret protection for our confidential and proprietary information, know-how, and we take active measures to control access to this information. We believe that our know-how will also provide a significant competitive advantage.

Our policy is to require our employees, consultants and significant scientific collaborators and sponsored researchers to execute confidentiality agreements upon the commencement of any employment or consulting relationship with us. These agreements generally provide that all confidential information developed or made

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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.

### ***Licenses with Research Institutions***

We have entered into a number of research-plus-license agreements with academic organizations, including The Scripps Research Institute (Scripps), the California Institute of Technology (Cal Tech) and the Oregon Health & Science University (OHSU). The research components of these agreements have been concluded and have resulted in a number of licenses for resultant technology. Under these license agreements, we are typically subject to obligations of due diligence and the requirement to pay royalties on products that use patented technology licensed under these agreements. The license agreements with these institutions relate largely to stem or progenitor cells or to processes and methods for the isolation, identification, expansion, or culturing of stem or progenitor cells. Generally speaking, these license agreements will terminate upon expiration, revocation or invalidation of the patents licensed to us, unless governmental regulations require a shorter term. They also will terminate earlier if we breach our obligations under the agreement and do not cure the breach or if we declare bankruptcy. We can terminate these license agreements at any time upon notice.

Pursuant to the terms of our license agreement with Cal Tech, we must pay \$10,000 upon the issuance of the first patent in each family licensed to us under the relevant agreement and \$5,000 on the first anniversary of the issuance of each such patent, payable in cash or common stock at our option. We have paid \$60,000 on account of these patents through December 31, 2008; the \$10,000 due in 2008 was paid in common stock (6,924 shares). These amounts are creditable against royalties we must pay under the license agreements. The maximum royalties that we will have to pay to Cal Tech will be \$2 million per year, with an overall maximum of \$15 million. Once we pay the \$15 million maximum royalty, the licenses will become fully paid and irrevocable. In August 2002 we acquired an additional license from Cal Tech to different technology, pursuant to which we issued 27,535 shares of our common stock with a market value of approximately \$35,000; we have also issued 9,535 shares of our common stock with a market value of approximately \$15,000 to Cal Tech on the issuance of two patents covered under this additional license.

In 2008 we terminated our license agreements with Scripps.

### ***Licenses with Commercial Entities***

#### ***NeuroSpheres, Ltd.***

In March 1994, we entered into a contract research and license agreement with NeuroSpheres, Ltd., which was clarified in a license agreement dated as of April 1, 1997. Under the agreement as clarified, we obtained an exclusive patent license from NeuroSpheres in the field of transplantation, subject to a limited right of NeuroSpheres to purchase a nonexclusive license from us, which right was not exercised and has expired. We have developed additional intellectual property relating to the subject matter of the license. We entered into an additional license agreement with NeuroSpheres as of October 30, 2000, under which we obtained an exclusive license in the field of non-transplant uses, such as drug discovery and drug testing and clarified our rights under NeuroSpheres patents for generating cells of the blood and immune system from neural stem cells. Together, our rights under the licenses are exclusive for all uses of the technology. We made up-front payments to NeuroSpheres of 65,000 shares of our common stock in October 2000 and \$50,000 in January 2001, and we will make additional cash payments when milestones are achieved under the terms of the October 2000 agreement. In addition, in October 2000 we reimbursed NeuroSpheres for patent costs amounting to \$341,000. Milestone payments, payable at various stages in the development of potential products, would total \$500,000 for each product that is approved for market. In addition,

beginning in 2004, annual payments of \$50,000 became due, payable by the last day of the year and fully creditable against royalties due to NeuroSpheres under the October 2000 Agreement. Our agreements with NeuroSpheres will terminate at the expiration of all patents licensed to us, but can terminate earlier if we breach our obligations under the agreement and do not cure the breach, or if we declare bankruptcy.

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On July 9, 2008, we amended our 1997 and 2000 license agreements with NeuroSpheres. Six of the patents covered by the license agreements are the basis of our patent infringement suits against Neuralstem. Under the terms of the amendment, we agreed to pay all reasonable litigation costs, expenses and attorney's fees incurred by NeuroSpheres in the declaratory judgment suit between us and Neuralstem. In return, we are entitled to off-set all litigation costs incurred in that suit against amounts that would otherwise be owed under the license agreements, such as annual maintenance fees, milestones and royalty payments.

### *ReNeuron Limited*

In July 2005, we entered into an agreement with ReNeuron Limited, a wholly owned subsidiary of ReNeuron Group plc, a listed UK corporation (collectively referred to as ReNeuron). As part of the agreement, we granted ReNeuron a license that allows ReNeuron to exploit their c-mycER conditionally immortalized adult human neural stem cell technology for therapy and other purposes. We received shares of ReNeuron common stock, as well as a cross-license to the exclusive use of ReNeuron's technology for certain diseases and conditions, including lysosomal storage diseases, spinal cord injury, cerebral palsy, and multiple sclerosis. The agreement also provides for full settlement of any potential claims that either we or ReNeuron might have had against the other in connection with any putative infringement of certain of each party's patent rights prior to the effective date of the agreement. In July and August 2005 we received approximately 8,836,000 ordinary shares of ReNeuron common stock (net of approximately 104,000 shares that were transferred to NeuroSpheres), and subsequently, in 2006 and 2007, as a result of certain anti-dilution provisions in the agreement, we received approximately 1,261,000 more shares, net of approximately 18,000 shares that were transferred to NeuroSpheres. In February 2007, we sold 5,275,000 shares for net proceeds of approximately \$3,077,000. In the first quarter of 2009, we sold in aggregate, approximately 2,900,000 more shares and received net proceeds of approximately \$512,000. As of March 10, 2009, we held approximately 1,922,000 shares of ReNeuron as marketable equity securities. See Note 2 Financial Instruments ReNeuron and Note 15 Subsequent Events in Part II, Item 8 of this Form 10-K and Quantitative and Qualitative Disclosures about Market Risk in Part I, Item 7A of this Form 10-K for further information.

### *Stem Cell Therapeutics Corp.*

In August 2006, we entered into an agreement with Stem Cell Therapeutics Corp. (SCT), a Canadian corporation listed on the Toronto Stock Exchange, granting it a non-exclusive, royalty-bearing license to use several of our patents for treating specified diseases of the central nervous system; the grant does not include any rights to cell transplantation. SCT granted us a royalty-free non-exclusive license to certain of its patents for research and development and a royalty-bearing non-exclusive license for certain commercial purposes. SCT paid an up-front license fee; the license also provides for other payments including annual maintenance, milestones and royalties.

### *Other Commercial Licenses*

In 2002, we issued a license to BioWhittaker, Inc. for the exclusive right to make, sell and distribute one of our proprietary cells for the research market only. BioWhittaker was acquired by Cambrex Corporation, and the relevant Cambrex division was subsequently acquired by Lonza Group. This license is not expected to generate material revenue.

In 2003, we issued a non-exclusive license to StemCell Technologies, Inc. to make, use and sell certain proprietary mouse and rat neural stem cells and in 2004, we issued a non-exclusive license culture media for all mammalian neural stem cells.

We issued a non exclusive license to R&D Systems to make, use and sell certain stem cell expansion kits, also for the research market. These licenses are not expected to generate material revenue.

## **Competition**

In most instances, the targeted indications for our initial products in development have no effective long-term therapies at this time. However, we do expect that our initial products will have to compete with a variety of therapeutic products and procedures. Other pharmaceutical and biotechnology companies currently offer a number of pharmaceutical products to treat lysosomal storage diseases, neurodegenerative and liver diseases, and other

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diseases for which our technologies may be applicable. 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. The market for therapeutic products that address degenerative diseases is large and competition is intense. Many companies have significant products approved or in development that could be competitive with our potential products. We expect competition to increase.

Competition for any stem and progenitor cell products that we may develop may be in the form of existing and new drugs, other forms of cell transplantation, ablative and simulative procedures, medical devices, and gene therapy. We believe that some of our competitors are also trying to develop stem and progenitor cell-based technologies. 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.

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 is 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.

We expect that all of these products will compete with our potential stem and progenitor cell-based products based on efficacy, safety, cost, and intellectual property positions. While we believe that these will be the primary competitive factors, other factors include, in certain instances, obtaining marketing exclusivity under the Orphan Drug Act, availability of supply, manufacturing, marketing and sales expertise and capability, and reimbursement coverage.

## **Government Regulation**

Our research and development activities and the future manufacturing and marketing of our potential products are, and will continue to be, subject to regulation for safety and efficacy by numerous governmental authorities in the United States and other countries.

### ***U.S. Regulations***

In the United States, pharmaceuticals, biologicals and medical devices are subject to rigorous regulation by the U.S. Food and Drug Administration (FDA). The Federal Food, Drug and Cosmetic Act, the Public Health Service Act, applicable FDA regulations, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, labeling, storage, export, record keeping, approval, marketing, advertising, and promotion of our potential products. Product development and approval within this regulatory framework takes a number of years and involves significant uncertainty combined with the expenditure of substantial resources. In addition, many jurisdictions, both federal and state, have restrictions on the use of fetal tissue.



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### *FDA Marketing Approval*

The steps required before our potential products may be marketed in the United States include:

<b>Steps</b>	<b>Considerations</b>
1. Preclinical laboratory and animal tests	Preclinical tests include laboratory evaluation of the cells and the formulation intended for use in humans for quality and consistency. <i>In vivo</i> studies are performed in normal animals and specific disease models to assess the potential safety and efficacy of the cell therapy product.
2. Submission of an Investigational New Drug (IND) application	The IND is a regulatory document submitted to the FDA with preclinical and manufacturing 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 the sponsor responds satisfactorily. In general an IND must become effective before U.S. human clinical trials may commence.
3. Human clinical trials	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 (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 I, II and III. Phase I studies for a 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.



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<b>Steps</b>	<b>Considerations</b>
	<p>Phase II studies typically involve a larger, but still limited, patient population to determine biological and clinical effects of the investigational product and to identify possible adverse effects and safety risks of the product in the selected patient population.</p> <p>Phase III studies are undertaken to demonstrate clinical benefit or effect in a statistically significant manner and to test further for safety within a broader patient population, generally at multiple study sites.</p> <p>The FDA continually reviews the clinical trial plans and results and may suggest changes or may require discontinuance of any trial at any time if significant safety issues arise.</p>
4. Submission of a Biologics Licensing Application (BLA)	The results of the preclinical studies and clinical studies are submitted to the FDA in an application for marketing approval authorization.
5. Regulatory Approval	<p>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. Additional animal studies or clinical trials may be requested during the FDA review period, which might add to that time. FDA approval of the application(s) is required prior to any commercial sale or shipment of the therapeutic product. Biologic product manufacturing facilities located in certain states also may be subject to separate regulatory and licensing requirements.</p>
6. Post-marketing studies	<p>After receiving FDA marketing approval for a product for an initial indication, further clinical trials may be required to gain approval for the use of the product for additional indications. The FDA may also require post-marketing testing and surveillance to monitor for adverse effects, which could involve significant expense, or the FDA may elect to grant only conditional approvals subject to collection of post-marketing data. In addition, the recently enacted FDA Amendments Act of 2007 provides the FDA with expanded authority over drug products after approval, including the authority to require post-approval studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluation and mitigation strategies approved by the FDA.</p>

*FDA Manufacturing Requirements*

Among the conditions for product licensure is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the FDA's current good manufacturing practice (GMP) requirements. Even after a product's licensure approval, its manufacturer must comply with GMP on a continuing basis, and what constitutes GMP may change as the state of the art of manufacturing changes. Domestic manufacturing facilities are subject to regular FDA inspections for GMP compliance, which are normally held at least every two years. Foreign manufacturing facilities are subject to periodic FDA inspections or inspections by

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the foreign regulatory authorities. Domestic manufacturing facilities may also be subject to inspection by foreign authorities.

### *Orphan Drug Act*

The Orphan Drug Act provides incentives to drug manufacturers to develop and manufacture drugs for the treatment of diseases or conditions that affect fewer than 200,000 individuals in the United States. Orphan drug status can also be sought for treatments for diseases or conditions that affect more than 200,000 individuals in the United States if the sponsor does not realistically anticipate its product becoming profitable from sales in the United States. We may apply for orphan drug status for certain of our therapies. Under the Orphan Drug Act, a manufacturer of a designated orphan product can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity in the United States for that product for the orphan indication. While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same compound for the same indication, it would not prevent other compounds or products from being approved for the same use including, in some cases, slight variations on the originally designated orphan product.

### *FDA Human Cell and Tissue Regulations*

Our research and development is based 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 (HCT/P) products and has published current Good Tissue Practice (GTP) regulations. As part of this approach, the FDA has published final rules for registration of establishments that recover, process, store, label, package, or distribute HCT/P products or that screen or test the donor of HCT/P products, and for the listing of such products. In addition, the FDA has published rules for determining the suitability of donors of cells and tissue, the eligibility of the cells and tissues for clinical use and for current good tissue practice for manufacturers using them, which came into effect in May 2005. We have adopted policies and procedures to comply with these regulations.

### *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 foreign, federal, state, and local regulations.

### *International Law*

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. In particular, the European Union (EU) is revising its regulatory approach to biotechnology products, and representatives from the United States, Japan and the EU are in the process of harmonizing and making more uniform the regulations for the registration of pharmaceutical products in these three markets. This process increases uncertainty over regulatory requirements in our industry. Furthermore, human stem and progenitor cells may be regulated in the EU and other countries as transplant material or as a somatic cell therapy medicinal product, depending on the processing, indication and country.

### **Environment**

We have made, and will continue to make, expenditures for environmental compliance and protection. Expenditures for compliance with environmental laws have not had, and are not expected to have, a material effect on our capital

expenditures, results of operations or competitive position.

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### **Reimbursement and Health Care Cost Control**

Reimbursement for the costs of treatments and products such as ours from government health administration authorities, private health insurers and others, both in the United States and abroad, is a key element in the success of new health care products. Significant uncertainty often exists as to the reimbursement status of newly approved health care products.

The revenue and profitability of some health care-related companies have been affected by the continuing efforts of governmental and third party payors to contain or reduce the cost of health care through various means. Payors are increasingly attempting to limit both coverage and the levels of reimbursement for new therapeutic products approved for marketing by the FDA, and are refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. In certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, there have been a number of federal and state proposals to implement government control over health care costs.

### **Employees**

As of December 31, 2008, we had 55 full-time employees, 16 of whom have Ph.D., M.D. or D.V.M. degrees. 43 full-time employees work in research and development and laboratory support services. No employees are covered by collective bargaining agreements.

### **Scientific Advisory Board**

Members of our Scientific Advisory Board provide us with strategic guidance in regard to our research and product development programs, as well as assistance in recruiting employees and collaborators. Each Scientific Advisory Board member has entered into a consulting agreement with us. These consulting agreements specify the compensation to be paid to the consultant and require that all information about our products and technology be kept confidential. All of the Scientific Advisory Board members are employed by employers other than us and may have commitments to, or consulting or advising agreements with, other entities that limit their availability to us. The Scientific Advisory Board members have generally agreed, however, for so long as they serve as consultants to us, not to provide any services to any other entities that would conflict with the services the member provides to us. We are entitled to terminate the arrangements if we determine that there is such a conflict. Members of our Scientific Advisory Board offer consultation on specific issues encountered by us as well as general advice on the directions of appropriate scientific inquiry for us. In addition, the Scientific Advisory Board members assist us in assessing the appropriateness of moving our projects to more advanced stages. The following persons are members of our Scientific Advisory Board:

Irving L. Weissman, M.D., Chairman of our Scientific Advisory Board, is the Virginia and Daniel K. Ludwig Professor of Cancer Research, Professor of Pathology and Professor of Developmental Biology at Stanford University, Director of the Stanford University Institute for Stem Cell Biology and Regenerative Medicine, and Director of the Stanford Comprehensive Cancer Center, all in Stanford, California. Dr. Weissman's lab was responsible for the discovery and isolation of the first ever mammalian tissue stem cell, the hematopoietic (blood-forming) stem cell. Dr. Weissman was responsible for the formation of three stem cell companies, SyStemix, Inc., StemCells, Inc. and Cellerant, Inc. Dr. Weissman co-discovered the mammalian and human hematopoietic stem cells and the human neural stem cell. He has extended these stem cell discoveries to cancer and leukemia, discovering the leukemic stem cells in human and mouse acute or blast crisis myeloid leukemias, and has enriched the cancer stem cells in several human brain cancers as well as human head and neck squamous cell carcinoma. Past achievements of Dr. Weissman's laboratory include identification of the states of development between stem cells and mature blood cells, the discovery and molecular isolation and

characterization of lymphocyte and stem cell homing receptors, and identification of the states of thymic lymphocyte development. His laboratory at Stanford has developed accurate mouse models of human leukemias, and has shown the central role of inhibition of programmed cell death in that process. He has also established the evolutionary origins of pre-vertebrate stem cells, and identified and cloned the transplantation genes that prevent their passage from one organism to another. Dr. Weissman has



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been elected to the National Academy of Science, the Institute of Medicine of the National Academies, the American Academy of Arts and Sciences, the American Society of Microbiology, and several other societies. He has received the Kaiser Award for Excellence in Preclinical Teaching, the Pasarow Foundation Award for Cancer Research, the California Scientist of the Year (2002), the Kovalenko Medal of the National Academy of Sciences, the Elliott Joslin Medal for Diabetes Research, the de Villiers Award for Leukemia Research, the Irvington Award for Immunologist of the Year, the Bass Award of the Society of Neurosurgeons, the New York Academy of Medicine Award for Medical Research, the Alan Cranston Award for Aging Research, the Linus Pauling Award for Biomedical Research, the E. Donnall Thomas Award for Hematology Research, the van Bekkum Award for Stem Cell Research, the Outstanding Investigator Award from the National Institutes of Health, Robert Koch Award for research in the hemopoietic system, and many other awards.

David J. Anderson, Ph.D., is Roger W. Sperry Professor of Biology, California Institute of Technology, Pasadena, California and Investigator, Howard Hughes Medical Institute. His laboratory was the first to isolate a multipotent, self-renewing, stem cell for the peripheral nervous system, the first to identify instructive signals that promote the differentiation of these stem cells along various lineages, and the first to accomplish a direct purification of peripheral neural stem cells from uncultured tissue. Dr. Anderson's laboratory also was the first to isolate transcription factors that act as master regulators of neuronal fate. More recently, he has identified signals that tell a neural stem cell to differentiate to oligodendrocytes, the myelinating glia of the central nervous system, as well as factors for astrocyte differentiation. Dr. Anderson is a co-founder of the Company and was a founding member of the scientific advisory board of the International Society for Stem Cell Research. Dr. Anderson also serves on the scientific advisory board of Allen Institute for Brain Science. He has held a presidential Young Investigator Award from the National Science Foundation, a Sloan Foundation Fellowship in Neuroscience, and has been Donald D. Matson lecturer at Harvard Medical School. He has received the Charles Judson Herrick Award from the American Association of Anatomy, the 1999 W. Alden Spencer Award in Neurobiology from Columbia University, and the Alexander von Humboldt Foundation Award. Dr. Anderson has been elected to the National Academy of Science and is a member of the American Academy of Arts and Sciences.

Fred H. Gage, Ph.D., is Professor, Laboratory of Genetics, The Salk Institute for Biological Studies, La Jolla, California and Adjunct Professor, Department of Neurosciences, University of California, San Diego, California. Dr. Gage's lab was the first to discover Neurogenesis in the adult human brain. His research focus is on the development of strategies to induce recovery of function following central nervous system damage. Dr. Gage is a co-founder of StemCells and of BrainCells, Inc., and a member of the scientific advisory board of each. Dr. Gage also serves on the Scientific Advisory Board of Ceregene, Inc, and he is a founding member of the scientific advisory board of the International Society for Stem Cell Research. Dr. Gage has been the recipient of numerous awards, including the 1993 Charles A. Dana Award for Pioneering Achievements in Health and Education, the Christopher Reeves Medal, the Decade of the Brain Medal, the Max-Planck research Prize, and the Pasarow Foundation Award. Professor Gage is a member of the Institute of Medicine, a member of the National Academy of Science, and a Fellow of the American Academy of Arts and Science.

## **Available Information**

The following information can be obtained free of charge through our website at <http://www.stemcellsinc.com> or by sending an e-mail message to [irpr@stemcellsinc.com](mailto:irpr@stemcellsinc.com):

our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to these reports as soon as reasonably practicable after such material is electronically filed with the Securities and Exchange Commission;

our policies related to corporate governance, including StemCells Code of Conduct and Ethics and Procedure for Submission of Complaints; and

the charters of the Audit Committee, the Compensation & Stock Option Committee and the Corporate Governance & Nominating Committee of our Board of Directors.

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The public may read and copy any material we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington D.C., 20549. The public may obtain information on the operations of the Public Reference Room by calling the SEC at 1- 800-SEC-0330. The SEC maintains an Internet site, <http://www.sec.gov>, which contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

### **Item 1A. RISK FACTORS**

*This annual report of Form 10-K contains forward looking statements that involve risks and uncertainties. Our business, operating results, financial performance, and share price may be materially adversely affected by a number of factors, including but not limited to the following risk factors, any one of which could cause actual results to vary materially from anticipated results or from those expressed in any forward-looking statements made by us in this annual report of Form 10-K or in other reports, press releases or other statements issued from time to time. Additional factors that may cause such a difference are set forth elsewhere in this annual report of Form 10-K.*

#### **Risks Related to our Business**

***Any adverse development relating to our HuCNS-SC product candidate, such as a significant clinical trial failure, could substantially depress our stock price and prevent us from raising additional capital.***

At present our ability to progress as a company is significantly dependent on a single product candidate, our HuCNS-SC cells (purified human neural stem cells), and on early stage clinical trials. Any clinical, regulatory or other development that significantly delays or prevents us from completing any of our trials, any material safety issue or adverse side effect to any study participant in any of these trials, or the failure of these trials to show the results expected would likely depress our stock price significantly and could prevent us from raising the substantial additional capital we will need to further develop our cellular technologies. Moreover, any material adverse occurrence in our first clinical trials could substantially impair our ability to initiate clinical trials to test our HuCNS-SC cells in other potential indications. This, in turn, could adversely impact our ability to raise additional capital and pursue our planned research and development efforts in both our CNS and Liver Programs.

***We have limited capital resources and we may not obtain the significant additional capital needed to sustain our research and development efforts.***

We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, acquire businesses, technologies and intellectual property rights which may be important to our business, continue preclinical and clinical testing of our investigative products, pursue regulatory approvals, acquire capital equipment, laboratory and office facilities, establish production capabilities, maintain and enforce our intellectual property portfolio, and support our general and administrative expenses and other working capital requirements. In addition, if we complete the acquisition of the operating subsidiaries and related assets of Stem Cell Sciences, we will require additional capital resources to continue to develop and grow our business. We rely on cash reserves and proceeds from equity and debt offerings, proceeds from the transfer, license, lease, or sale of our intellectual property rights, equipment, facilities, or investments, and government grants and funding from collaborative arrangements, if obtainable, to fund our operations.

We intend to pursue opportunities for additional fundraising in the future through equity or debt financings, corporate alliances or combinations, grants or collaborative research arrangements, or any combination of these. However, external financing in the current financial environment may be particularly difficult, and the source, timing and availability of any future fundraising will depend principally upon market conditions, interest rates and, more

specifically, on progress in our research, preclinical and clinical development programs. Funding may not be available when needed at all or on terms acceptable to us. While we actively manage our programs and resources in order to conserve cash between fundraising opportunities, our existing capital resources may not be sufficient to fund our operations beyond the next twelve months. If we exhaust our cash reserves and are unable to realize adequate additional fundraising, we may be unable to meet operating obligations and be required to initiate bankruptcy proceedings or delay, scale back or eliminate some or all of our research and product development programs.

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***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 technology is at an early stage of discovery and development, and we may fail to develop any commercially acceptable or profitable products.***

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 have yet to develop any products that have been approved for marketing, and we do not expect to become profitable within the next several years, but rather expect to incur additional and increasing operating losses. Before commercializing any medical product, we will need to obtain regulatory approval from the FDA or from equivalent foreign agencies after conducting extensive preclinical studies and clinical trials that demonstrate that the product candidate is safe and effective. Except for the NCL trial we completed at Oregon Health & Science University (OHSU), we have had no experience conducting human clinical trials. We expect that none of our cell-based therapeutic product candidates will be commercially available for several years, if at all.

While the FDA has approved our IND to initiate a Phase I clinical trial for PMD, there can be no assurance that this clinical trial will be initiated, be completed or result in a successful outcome.

There can be no assurance that our Phase I clinical trial of our proprietary HuCNS-SC product candidate in NCL will result in a successful outcome. We may elect to delay or discontinue other studies or clinical trials based on unfavorable results. Any product developed from, or based on, cellular technologies may fail to:

survive and persist in the desired location;

provide the intended therapeutic benefit;

engraft into existing tissue in the desired manner; or

achieve therapeutic benefits equal to, or better than, the standard of treatment at the time of testing.

In addition, our products may cause undesirable side effects. Results of preclinical research in animals may not be indicative of future clinical results in humans.

Ultimately if regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would be unable to commercialize our products, and our business and results of operations would be harmed. Even if we do succeed in developing products, we will face many potential obstacles such as the need to develop or obtain manufacturing, marketing and distribution capabilities. Furthermore, because transplantation of cells is a new form of therapy, the marketplace may not accept any products we may develop.

Moreover, because our cell-based therapeutic products will be derived from tissue of individuals other than the patient (that is, they will be non-self or allogeneic transplant products), patients will likely require the use of immunosuppressive drugs. While immunosuppression is now standard in connection with allogeneic transplants of

various kinds, such as heart or liver transplants, long-term maintenance on immunosuppressive drugs can result in complications such as infection, cancer, cardiovascular disease, and renal dysfunction. An immunosuppression regimen was used with our therapeutic product candidate in our Phase I clinical trial for NCL, and is included in the proposed trial protocol for our planned PMD trial.

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***Our success will depend in large part on our ability to develop and commercialize products that treat diseases other than neuronal ceroid lipofuscinosis (Batten disease) and Pelizeaus-Merzbacher Disease (PMD).***

Although we have initially focused on evaluating our neural stem cell product for the treatment of infantile and late infantile NCL (Batten disease) and for Pelizeaus-Merzbacher Disease, these diseases are rare and the markets for treating these diseases are small. Accordingly, even if we obtain marketing approval for our HuCNS-SC product candidate for infantile and late infantile NCL or for PMD, in order to achieve profitability, we will likely need to obtain approval to treat additional diseases that present more significant market opportunities.

***Acquisitions of companies, businesses or technologies may substantially dilute our stockholders and increase our operating losses.***

We may make acquisitions of businesses, technologies or intellectual property rights or otherwise modify our business model in ways we believe to be necessary, useful or complementary to our current product development efforts and cell-based therapeutics business. For example, on March 2, 2009, we announced that we entered into an agreement to acquire the operating subsidiaries and certain other related assets of Stem Cell Sciences. Any such acquisition or change in business activities may require assimilation of the operations, products or product candidates and personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. Acquisitions may not provide the intended technological, scientific or business benefits and could disrupt our operations and divert our limited resources and management's attention from our current operations, which could harm our existing product development efforts. We have agreed to issue 2,650,000 shares of our common stock in the acquisition of the assets of Stem Cell Sciences, and we would likely issue equity securities to pay for any other future acquisitions. The issuance of equity securities for an acquisition could be substantially dilutive to our stockholders. In addition, our results of operations may suffer because of acquisition-related costs or the post-acquisition costs of funding the development of an acquired technology or product candidates or operation of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets. Any investment made in, or funds advanced to, a potential acquisition target could also significantly adversely affect our results of operation and could further reduce our limited capital resources. Any acquisition or action taken in anticipation of a potential acquisition or other change in business activities could substantially depress the price of our stock.

***We have payment obligations resulting from real property owned or leased by us in Rhode Island, which diverts funding from our cell-based therapeutics research and development.***

Prior to our reorganization in 1999 and the consolidation of our business in California, we carried out our former encapsulated cell therapy programs in Lincoln, Rhode Island, where we also had our administrative offices. Although we have vacated the Rhode Island facilities, we remain obligated to make lease payments and payments for operating costs for our former science and administrative facility, which we have leased through June 30, 2013. These costs, before sub-tenant rental income, amounted to approximately \$1,825,000 in 2008; our rent payments will increase over the term of the lease, and our operating costs may increase as well. In addition to these costs of our former science and administrative facility, we are obligated to make debt service payments and payments for operating costs of approximately \$440,000 per year for our former encapsulated cell therapy pilot manufacturing facility, which we own. We have currently subleased a portion of the science and administrative facility, and we are seeking to sublease the remaining portion, but we cannot be sure that we will be able to keep any part of the facility subleased for the duration of our obligation. We are currently seeking to sublease the pilot manufacturing facility, but may not be able to sublease or sell the facility in the future. These continuing costs significantly reduce our cash resources and adversely affect our ability to fund further development of our cellular technologies. In addition, changes in real estate market conditions and assumptions regarding the length of time it may take us to either fully sublease, assign or sell our remaining interest in the our former research facility in Rhode Island may have a significant impact on and cause large

variations in our quarter to quarter results of operations. In 1999, in connection with exiting our former research facility in Rhode Island, we created a reserve for the estimated lease payments and operating expenses related to it. The reserve is periodically re-evaluated and adjusted based on assumptions relevant to real estate market conditions and the estimated time until we can either, fully sublease, assign or sell our remaining interests in the property. At December 31, 2008, the reserve was \$5,513,000. For the year 2008, we incurred \$1,293,000 in operating expenses net of sub-tenant income for this facility. Expenses for this facility will



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fluctuate based on changes in tenant occupancy rates and other operating expenses related to the lease. Even though it is our intent to sublease, assign, sell, or otherwise divest ourselves of our interests in the facility at the earliest possible time, we cannot determine with certainty a fixed date by which such events will occur. In light of this uncertainty, based on estimates, we will periodically re-evaluate and adjust the reserve, as necessary, and we may make significant adverse adjustments to the reserve in the future.

***We may be unable to obtain partners to support our cell-based therapeutic product development efforts when needed to commercialize our technologies.***

Equity and debt financings alone may not be sufficient to fund the cost of developing our cellular technologies, and we may need to rely on partnering or other arrangements to provide financial support for our cellular discovery and development efforts. In addition, in order to successfully develop and commercialize our technologies, we may need to enter into various arrangements with corporate sponsors, pharmaceutical companies, universities, research groups, and others. While we have engaged, and expect to continue to engage, in discussions regarding such arrangements, we have not reached any agreement, and we may fail to obtain any such agreement on terms acceptable to us. Even if we enter into such arrangements, we may not be able to satisfy our obligations under them or renew or replace them after their original terms expire. Furthermore, these arrangements may require us to grant rights to third parties, such as exclusive marketing rights to one or more products, may require us to issue securities to our collaborators and may contain other terms that are burdensome to us or result in a decrease in our stock price.

***If we are unable to protect our patents and proprietary rights, our business, financial condition and results of operations may be materially harmed.***

We either own or exclusively license a number of patents and pending patent applications related to various stem and progenitor cells, including human neural stem cell cultures, as well as methods of deriving and using them. The process of obtaining patent protection for products such as those we propose to develop is highly uncertain and involves complex and continually evolving factual and legal questions. The governmental authorities that consider patent applications can deny or significantly reduce the patent coverage requested in an application either before or after issuing the patent. For example, under the procedures of the European Patent Office, third parties may oppose our issued European patents during the relevant opposition period. These proceedings and oppositions could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us, and the outcome might not be favorable to us. In the United States, third parties may seek to invalidate or render unenforceable issued patents through a U.S. PTO reexamination process or through the courts; currently two of our patents are the subject of a reexamination proceeding and six of our patents are the subject of litigation. In addition, changes to the laws protecting intellectual property rights could adversely impact the perceived or actual value of our Company. Consequently, we do not know whether any of our pending applications will result in the issuance of patents, whether any of our issued patents will be invalidated or restricted, whether any existing or future patents will provide sufficient protection or significant commercial advantage, or whether others will circumvent these patents, whether or not lawfully. In addition, our patents may not afford us adequate protection from competing products. Moreover, because patents issue for a limited term, our patents may expire before we can commercialize a product covered by the issued patent claims or before we can utilize the patents profitably. Some of our most important patents begin to expire in 2015.

If we learn of third parties who infringe our patent rights, we may decide to initiate legal proceedings to enforce these rights. Patent litigation, including the pending litigation to which we are a party, is inherently unpredictable and highly risky and may result in unanticipated challenges to the validity or enforceability of our intellectual property, antitrust claims or other claims against us, which could result in the loss of these intellectual property rights. Litigation proceedings can be very time-consuming for management and are also very costly and the parties we bring actions against may have significantly greater financial resources than our own. We may not prevail in these proceedings and

if we do not prevail we could be liable for damages as well as the costs and attorney fees of our opponents.

Proprietary trade secrets and unpatented know-how are also important to our research and development activities. We cannot be certain that others will not independently develop the same or similar technologies on their own or gain access to our trade secrets or disclose such technology or that we will be able to meaningfully protect

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our trade secrets and unpatented know-how. We require our employees, consultants and significant scientific collaborators and sponsored researchers to execute confidentiality agreements upon the commencement of an employment or consulting relationship with us. These agreements may, however, fail to provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer or disclosure of such information or technology.

***If we are unable to obtain necessary licenses to third-party patents and other rights, we may not be able to commercially develop our expected products.***

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

We are aware of intellectual property rights held by third parties that relate to products or technologies we are developing. For example, some aspects of our cell-based therapeutic product candidates involve the use of growth factors, antibodies and other reagents that may, in certain cases, be the subject of third party rights. Before we commercialize any product using these growth factors, antibodies or reagents, we may need to obtain license rights from third parties or use alternative growth factors, antibodies and reagents that are not then the subject of third party patent rights. We currently believe that the commercialization of our products as currently planned will not infringe these third party rights, or, alternatively, that we will be able to obtain necessary licenses or otherwise use alternative non-infringing technology. However, third parties may nonetheless bring suit against us claiming infringement. If we are unable to prove that our technology does not infringe their patents, or if we are unable to obtain necessary licenses or otherwise use alternative non-infringing technology, we may not be able to commercialize any products.

We have obtained rights from companies, universities and research institutions to technologies, processes and compounds that we believe may be important to the development of our products. These licensors, however, may cancel our licenses or convert them to non-exclusive licenses if we fail to use the relevant technology or otherwise breach these agreements. Loss of these licenses could expose us to the risk that our technology infringes the rights of third parties. We can give no assurance that any of these licenses will provide effective protection against our competitors.

***We compete with companies that have significant advantages over us.***

The market for therapeutic products to treat diseases of, or injuries to, the central nervous system (CNS) is large and competition is intense. The majority of the products currently on the market or in development are small molecule pharmaceutical compounds, and many pharmaceutical companies have made significant commitments to the CNS field. We believe cellular therapies, if proven safe and effective, will have unique properties that will make them desirable over small molecule drugs, none of which currently replace damaged tissue. However, any cell-based therapeutic to treat diseases of, or injuries to, the CNS is likely to face intense competition from the small molecule sector, biologics, as well as medical devices. We expect to compete with a host of companies, some of which are privately owned and some of which have resources far greater than ours.

In the liver field, there are no broad-based therapies for the treatment of liver disease at present. The primary therapy is liver transplantation, which is limited by the availability of matched donor organs. Liver-assist devices, when and if they become available, could also be used to help patients while they await suitably matched organs for

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transplantation. Liver transplantation may remain the standard of care even if we successfully develop a cellular therapy. In addition, new therapies may become available before we successfully develop a cell-based therapy for liver disease.

***Development of our technologies is subject to, and restricted by, extensive government regulation, which could impede our business.***

Our research and development efforts, as well as any ongoing or 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 or continue 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 and progenitor cells obtained from human tissue, including fetal tissue. The U.S. federal and state governments and other jurisdictions impose restrictions on the acquisition and use of fetal tissue, including those incorporated in federal Good Tissue Practice, or GTP, regulations. These regulatory and other constraints could prevent us from obtaining cells and other components of our products in the quantity or 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 GMP. Accordingly, we will need to enter into supply agreements with companies that manufacture these components to GMP standards.

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, and refusal of the government to enter into supply contracts or fund research, or delay in approving or refusal to approve new drug applications.

***We are dependent on the services of key personnel.***

We are highly dependent on the principal members of our management and scientific staff and some of our outside consultants, including the members of our scientific advisory board, our chief executive officer, our vice presidents, and the heads of key departments or functions within the company. Although we have entered into employment agreements with some of these individuals, they may terminate their agreements at any time. In addition, our operations are dependent upon our ability to attract and retain additional qualified scientific and management personnel. We may not be able to attract and retain the personnel we need on acceptable terms given the competition for experienced personnel among pharmaceutical, biotechnology and health care companies, universities and research institutions.

***Our activities involve hazardous materials and experimental animal testing; improper handling of these animals and materials by our employees or agents could expose us to significant legal and financial penalties.***

Our research and development activities involve the controlled use of test animals as well as hazardous chemicals and potentially hazardous biological materials such as human tissue. Their use subjects us to

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environmental and safety laws and regulations such as those governing laboratory procedures, exposure to blood-borne pathogens, use of laboratory animals, and the handling of biohazardous materials. Compliance with current or future laws and regulations may be expensive and the cost of compliance could adversely affect us.

Although we believe that our safety procedures for using, handling, storing, and disposing of hazardous and potentially hazardous materials comply with the standards prescribed by California and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident or of any violation of these or future laws and regulations, state or federal authorities could curtail our use of these materials; we could be liable for any civil damages that result, the cost of which could be substantial; and we could be subjected to substantial fines or penalties. In addition, any failure by us to control the use, disposal, removal, or storage, or to adequately restrict the discharge, or to assist in the cleanup, of hazardous chemicals or hazardous, infectious or toxic substances could subject us to significant liability. Any such liability could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations. Moreover, an accident could damage our research and manufacturing facilities and operations and result in serious adverse effects on our business.

***The development, manufacturing and commercialization of cell-based therapeutic products expose us to product liability claims, which could lead to substantial liability.***

By developing and, ultimately, commercializing medical products, we are exposed to the risk of product liability claims. Product liability claims against us could result in substantial litigation costs and damage awards against us. We have obtained liability insurance that covers our clinical trials, and we will need to increase our insurance coverage if and when we begin commercializing products. We may not be able to obtain insurance on acceptable terms, if at all, and the policy limits on our insurance policies may be insufficient to cover our liability.

***The manufacture of cell-based therapeutic products is novel, highly regulated, critical to our business, and dependent upon specialized key materials.***

The proliferation and manufacture of cell-based therapeutic products are complicated and difficult processes, dependent upon substantial know-how and subject to the need for continual process improvements to be competitive. Our manufacturing experience is limited and the technologies are comparatively new. In addition, our 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 disruptions may occur and despite efforts to regulate and control all aspects of manufacturing, the potential for human or system failure remains. 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 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.

***Because health care insurers and other organizations may not pay for our products or may impose limits on reimbursements, our ability to become profitable could be adversely affected.***

In both domestic and foreign markets, sales of potential products are likely to depend in part upon the availability and amounts of reimbursement from third-party health care payor organizations, including government agencies, private health care insurers and other health care payors, such as health maintenance organizations and self-insured employee plans. There is considerable pressure to reduce the cost of therapeutic products. Government and other third party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of

reimbursement for new therapeutic products and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA or other relevant authority has not granted marketing approval. Moreover, in some cases, government and other third party payors have refused to provide reimbursement for uses of approved products for disease indications for which the FDA or other relevant authority has granted marketing approval. Significant uncertainty exists as to the reimbursement status of newly approved health care products or novel therapies such as ours. Even if we obtain regulatory approval to market our products, we can give no assurance that reimbursement will be provided by such payors at all or without substantial delay or,



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if such reimbursement is provided, that the approved reimbursement amounts will be sufficient to enable us to sell products we develop on a profitable basis. Changes in reimbursement policies could also adversely affect the willingness of pharmaceutical companies to collaborate with us on the development of our cellular technologies. In certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. We also expect that there will continue to be a number of federal and state proposals to implement government control over health care costs. Efforts to change regulatory and reimbursement standards are likely to continue in future legislative sessions. We do not know what legislative proposals federal or state governments will adopt or what actions federal, state or private payors for health care goods and services may take in response to such proposals or legislation. We cannot predict the effect of government control and health care reimbursement practices on our business.

***Ethical and other concerns surrounding the use of stem or progenitor-based cell therapy may negatively affect regulatory approval or public perception of our product candidates, which could reduce demand for our products or depress our stock price.***

The use of stem cells for research and therapy has been the subject of debate regarding related ethical, legal and social issues. Although these concerns have mainly been directed to the use of embryonic stem cells, which we presently do not use, the distinction between embryonic and non-embryonic stem cells is frequently overlooked; moreover, our use of human stem or progenitor cells from fetal sources might raise these or similar concerns. Also, upon completion of the Acquisition of the assets of Stem Cell Sciences, we intend to continue the development of embryonic stem cells and iPS cells as potential research tools, and we may in the future explore their applicability as cell-based therapeutic products. 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. Also, existing regulatory constraints on the use of embryonic stem cells may in the future be extended to use of fetal stem cells, and these constraints might prohibit or restrict us from conducting research or from commercializing products. Existing and potential U.S. government regulation of embryonic 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 face of the competition among pharmaceutical, biotechnology and health care companies, universities and research institutions for what may become a shrinking class of qualified individuals.

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

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

## **Risks Related to the Securities Market**

***Our stock price has been, and will likely continue to be, highly volatile, which may negatively affect our ability to obtain additional financing in the future.***

The market price per share of our common stock has been and is likely to continue to be highly volatile due to the risks and uncertainties described in this section of this Annual Report on Form 10-K, as well as other factors, including:

our ability to develop and test our technologies;

our ability to patent or obtain licenses to necessary technologies;

conditions and publicity regarding the industry in which we operate, as well as the specific areas our product candidates seek to address;

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competition in our industry;

economic and other external factors or other disasters or crises;

price and volume fluctuations in the stock market at large that are unrelated to our operating performance; and

comments by securities analysts, or our failure to meet market expectations.

Over the two-year period ended December 31, 2008, the trading price of our common stock as reported on the Nasdaq Global Market ranged from a high of \$3.63 to a low of \$0.66 per share. As a result of this volatility, an investment in our stock is subject to substantial risk. Furthermore, the volatility of our stock price could negatively impact our ability to raise capital or acquire businesses or technologies.

***We are contractually obligated to issue shares in the future, diluting the interest of current stockholders.***

As of December 31, 2008, there were outstanding warrants to purchase 11,599,828 shares of our common stock, at a weighted average exercise price of \$2.05 per share, outstanding options to purchase 8,340,530 shares of our common stock, at a weighted average exercise price of \$2.32 per share, and outstanding restricted stock units for 1,650,000 shares of our common stock. In March 2009, we entered into an asset purchase agreement with Stem Cell Sciences Plc ( "SCS" ) to acquire substantially all of the operating assets and liabilities of SCS (the "Acquisition" ). The Acquisition is subject to customary closing conditions, including the approval of the stockholders of SCS, and is expected to close shortly after the SCS extraordinary general meeting scheduled for March 27, 2009. As partial consideration for the operating assets and liabilities to be acquired, we will issue to SCS 2,650,000 shares of our common stock. Moreover, we expect to issue additional options to purchase shares of our common stock to compensate employees, consultants and directors, and may issue additional shares to raise capital, to acquire other companies or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of diluting the interest of current stockholders.

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

None

### **Item 2. PROPERTIES**

We entered into a 5-year lease, as of February 1, 2001, for a 40,000 square foot facility, located in the Stanford Research Park in Palo Alto, California. This facility includes space for animals as well as laboratories, offices and a suite designed to be used to manufacture materials for clinical trials. Effective July 1, 2006, under an agreement that extends the lease through March 31, 2010, we leased the remainder of the building, adding approximately 27,500 square feet to our leased premises. We have a space-sharing agreement with Stanford University for part of the animal facility not needed for our own use.

We continue to lease the following facilities in Lincoln, Rhode Island obtained in connection with our former encapsulated cell technology: our former research laboratory and corporate headquarters building which contains 62,500 square feet of wet labs, specialty research areas and administrative offices held on a lease agreement that goes through June 2013, as well as a 21,000 square-foot pilot manufacturing facility and a 3,000 square-foot cell processing facility financed by bonds issued by the Rhode Island Industrial Facilities Corporation. We have subleased small portions of the 62,500 square foot facility, amounting to approximately 21 percent of the total space. We are actively seeking to sublease, assign or sell our remaining interests in these properties.

**Item 3. *LEGAL PROCEEDINGS***

In July 2006, we filed suit against Neuralstem, Inc., in the Federal District Court for the District of Maryland, alleging that Neuralstem's activities violate claims in four of the patents we exclusively licensed from NeuroSpheres. Neuralstem has filed a motion for dismissal or summary judgment in the alternative, citing Title 35, Section 271(e)(1) of the United States Code, which says that it is not an act of patent infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information to the FDA. Neuralstem argues that because it does not have any therapeutic products on the market yet, the activities complained of fall within the protection of Section 271(e)(1) — that is, basically, that the suit is premature. This

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issue will be decided after discovery is complete. Subsequent to filing its motion to dismiss, in December 2006, Neuralstem petitioned the U.S. Patent and Trademark Office (PTO) to reexamine two of the patents in our infringement action against Neuralstem, namely U.S. Patent No. 6,294,346 (claiming the use of human neural stem cells for drug screening) and U.S. Patent No. 7,101,709 (claiming the use of human neural stem cells for screening biological agents). In April 2007, Neuralstem petitioned the PTO to reexamine the remaining two patents in the suit, namely U.S. Patent No. 5,851,832 (claiming methods for proliferating human neural stem cells) and U.S. Patent No. 6,497,872 (claiming methods for transplanting human neural stem cells). These requests were granted by the PTO and, in June 2007, the parties voluntarily agreed to stay the pending litigation while the PTO considers these reexamination requests. In October 2007, Neuralstem petitioned the PTO to reexamine a fifth patent, namely U.S. Patent No. 6,103,530, which claims a culture medium for proliferating mammalian neural stem cells. In April 2008, the PTO upheld the 832 and 872 patents, as amended, and issued Notices of Intent to Issue an *Ex Parte* Reexamination Certificate for both. In August 2008, the PTO upheld the 530 patent, as amended, and issued a Notice of Intent to Issue an *Ex Parte* Reexamination Certificate. The remaining two patents are still under review by the PTO.

In May 2008, we filed a second patent infringement suit against Neuralstem and its two founders, Karl Johe and Richard Garr. In this suit, which we filed in the Federal District Court for the Northern District of California, we allege that Neuralstem's activities infringe claims in two patents we exclusively license from NeuroSpheres, specifically U.S. Patent No. 7,361,505 (claiming composition of matter of human neural stem cells derived from any source material) and U.S. Patent No. 7,115,418 (claiming methods for proliferating human neural stem cells). In addition, we allege various state law causes of action against Neuralstem arising out of its repeated derogatory statements to the public about our patent portfolio. Also in May 2008, Neuralstem filed suit against us and NeuroSpheres in the Federal District Court for the District of Maryland seeking a declaratory judgment that the 505 and 418 patents are either invalid or are not infringed by Neuralstem and that Neuralstem has not violated California state law. In August 2008, the California court transferred our lawsuit against Neuralstem to Maryland for resolution on the merits. We anticipate that the Maryland District Court will consolidate these actions in some manner prior to trial.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****(a) Market price and dividend information**

Our stock is traded on the Nasdaq Global Market under the symbol STEM. The quarterly ranges of high and low bid prices per share for the last two fiscal years as reported by Nasdaq are shown below:

	High	Low
<b><u>2008</u></b>		
First Quarter	\$ 1.90	\$ 1.00
Second Quarter	\$ 1.75	\$ 1.11
Third Quarter	\$ 1.43	\$ 1.00
Fourth Quarter	\$ 2.48	\$ 0.66

**2007**

First Quarter	\$ 3.63	\$ 2.36
Second Quarter	\$ 3.09	\$ 2.27
Third Quarter	\$ 2.45	\$ 1.90
Fourth Quarter	\$ 2.53	\$ 1.40

No cash dividends have been declared on our common stock since our inception.

**Table of Contents****PERFORMANCE GRAPH**

We show below the cumulative total return to our stockholders during the period from December 31, 2003 through December 31, 2008<sup>2</sup> in comparison to the cumulative return on the Standard & Poor's 500 Index and the Amex Biotechnology Index during that same period.

The stock price performance shown on the graph below is not necessarily indicative of future stock price performance.

	<b>December 31, 2003</b>	<b>December 31, 2004</b>	<b>December 31, 2005</b>	<b>December 31, 2006</b>	<b>December 31, 2007</b>	<b>December 31, 2008</b>
StemCells, Inc.	\$ 100.00	\$ 213.64	\$ 174.24	\$ 133.84	\$ 75.76	\$ 68.69
S&P 500 Index	\$ 100.00	\$ 108.99	\$ 112.26	\$ 127.55	\$ 132.06	\$ 81.23
Amex Biotechnology Index	\$ 100.00	\$ 111.05	\$ 138.93	\$ 153.9	\$ 160.48	\$ 132.05

The information under Performance Graph is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any filing of StemCells, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this 10-K and irrespective of any general incorporation language in those filings.

**(b) Approximate Number of Holders of Common Stock**

As of February 27, 2009, there were approximately 590 holders of record of our common stock and the closing price per share of our common stock on the Nasdaq Global Market was \$1.56.

The number of record holders is based upon the actual number of holders registered on the books of our transfer agent at such date and does not include holders of shares in street names or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

**(c) Recent Sales of Unregistered Securities (last three years ending December 31, 2008)**

We issued the following unregistered securities in 2008:

In September 2008, we issued 6,924 shares of common stock to the California Institute of Technology (Cal Tech) for payment of annual fees of \$5,000 for each of two patent families to which we hold a license from

<sup>2</sup> Cumulative total returns assumes a hypothetical investment of \$100 on December 31, 2003.

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Cal Tech, payable in cash or stock at our choice. We elected to pay these fees in stock. The shares were issued in a transaction not involving any public offering pursuant to Section 4(2) of the Securities Act of 1933, as amended.

We issued the following unregistered securities in 2007:

In June 2007, we issued 3,865 shares of common stock to the California Institute of Technology (Cal Tech) for payment of annual fees of \$5,000 for each of two patent families to which we hold a license from Cal Tech, payable in cash or stock at our choice. We elected to pay these fees in stock. The shares were issued in a transaction not involving any public offering pursuant to Section 4(2) of the Securities Act of 1933, as amended.

We issued the following unregistered securities in 2006:

In August 2006, we issued 3,848 shares of common stock to the California Institute of Technology (Cal Tech) as payment of annual fees of \$5,000 for each of two patent families to which we hold a license from Cal Tech, payable in cash or stock at our choice. We elected to pay these fees in stock. The shares were issued in a transaction not involving any public offering pursuant to Section 4(2) of the Securities Act of 1933, as amended.

**Equity Compensation Plan Information**

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2008.

Plan Category	Equity Compensation Plan Information		
	Number of Securities to be Issued Upon	Weighted-Average	Number of Securities Remaining Available for
	Exercise of Outstanding Stock Options, Warrants and Rights	Exercise Price of Outstanding Stock Options, Warrants and Rights	Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders(1)	9,990,530	\$ 1.93	4,571,429

(1) Consists of stock options issued to employees and directors, restricted stock units issued to employees and stock options issued as compensation to consultants for consultation services. These stock options and restricted stock units were issued under our 1992 Equity Incentive Plan, Directors Stock Option Plan, StemCells, Inc. Stock Option Plan, or our 2001, 2004 and 2006 Equity Incentive Plans.





**Table of Contents****Item 6. *SELECTED FINANCIAL DATA***

The following selected financial and operating data are derived from our audited consolidated financial statements. The selected financial and operating data should be read in conjunction with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation and the consolidated financial statements and notes thereto contained elsewhere in this Form 10-K.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except per share amounts)				
Consolidated Statements of Operations					
Revenue from licensing agreements and grants	\$ 232	\$ 57	\$ 93	\$ 206	\$ 141
Research and development expenses(1)	17,808	19,937	13,600	8,226	7,844
General and administrative expenses(1)	8,296	7,927	7,154	5,540	4,870
Wind-down expenses(2)	866	783	709	2,827	2,827
Write down for other than temporary impairment of marketable securities(3)	2,083				
Loss on change in fair value of warrant liability(4)	937				
License & settlement agreement income, net(5)		551	103	3,736	
Gain on sale of marketable securities		716			
Net loss	(29,087)	(25,023)	(18,948)	(11,738)	(15,330)
Basic and diluted loss per share	\$ (0.35)	\$ (0.31)	\$ (0.25)	\$ (0.18)	\$ (0.31)
Shares used in computing basic and diluted loss per share amounts	82,716	79,772	74,611	63,643	49,606

	December 31,				
	2008	2007	2006	2005	2004
	(In thousands)				
Consolidated Balance Sheets					
Cash and cash equivalents	\$ 30,043	\$ 9,759	\$ 51,795	\$ 34,541	\$ 41,060
Marketable securities	4,182	29,847	7,266	3,721	
Total assets	41,230	48,283	66,857	44,839	47,627
Accrued wind-down expenses(2)	5,513	6,143	6,750	7,306	5,528
Fair value of warrant liability(4)	8,440				
Long-term debt, including capital leases	867	1,034	1,145	1,351	1,646
Stockholders' equity	21,809	35,212	54,376	32,376	36,950

- (1) Effective January 1, 2006, we adopted Statement of Financial Accounting Standards 123 (revised 2004) (SFAS 123R), *Share-Based Payment*, in accordance with the provisions of SFAS 123R, we elected to adopt the standard using the modified prospective method. SFAS 123R requires us to recognize in operating expenses, the fair value of our stock-based compensation awards. See Note 7 *Stock-Based Compensation* in the Notes to the

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Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

- (2) Relates to wind-down expenses in respect of our Rhode Island facility. See Note 8 Wind-down and exit costs in the Notes to the Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.
- (3) Relates to the impairment of our marketable equity securities (shares of ReNeuron) determined to be other than temporary. See Note 2 Financial Instruments in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.
- (4) Relates to the fair value of warrants issued as part of our financing in November 2008. See Note 10 Warrant Liability in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.
- (5) Relates to an agreement with ReNeuron. See Note 2 Financial Instruments in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

**Table of Contents****Item 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

This report contains forward looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act that involve substantial risks and uncertainties. Such statements include, without limitation, all statements as to expectation or belief and statements as to our future results of operations; the progress of our research, product development and clinical programs; the need for, and timing of, additional capital and capital expenditures; partnering prospects; costs of manufacture of products; the protection of, and the need for, additional intellectual property rights; effects of regulations; the need for additional facilities; and potential market opportunities. Our actual results may vary materially from those contained in such forward-looking statements because of risks to which we are subject, including uncertainty as to whether the U.S. Food and Drug Administration (FDA) or other regulatory authorities will permit us to proceed with clinical testing of proposed products despite the novel and unproven nature of our technologies; the risk that our clinical trials or studies could be substantially delayed beyond their expected dates or cause us to incur substantial unanticipated costs; uncertainties in our ability to obtain the capital resources needed to continue our current research and development operations and to conduct the research, preclinical development and clinical trials necessary for regulatory approvals; the uncertainty regarding our ability to obtain a corporate partner or partners, if needed, to support the development and commercialization of our potential cell-based therapeutics products; the uncertainty regarding the outcome of our clinical trials or studies we may conduct; the uncertainty regarding the validity and enforceability of our issued patents; the uncertainty whether any products that may be generated in our cell-based therapeutics programs will prove clinically safe and effective; the uncertainty whether we will achieve revenue from product sales or become profitable; uncertainties regarding our obligations with respect to our former encapsulated cell therapy facilities in Rhode Island; obsolescence of our technologies; competition from third parties; intellectual property rights of third parties; litigation risks; and other risks to which we are subject. All forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the cautionary statements and risk factors set forth in *Risk Factors* in Part I, Item 1A of this Form 10-K.

**Overview*****The Company***

Our research and development (R&D) programs are focused on identifying and developing potential cell-based therapeutics which can either restore or support organ function. Since we relocated our corporate headquarters and research laboratories to California in 1999 our R&D efforts have primarily been directed at refining our methods for identifying, isolating, culturing, and purifying the human neural stem cell and human liver engrafting cells (hLEC) and developing these as potential cell-based therapeutics for the central nervous system (CNS) and the liver, respectively. In our CNS Program, our HuCNS-SC<sup>®</sup> product candidate (purified human neural stem cells) is in clinical development for two indications. In January 2009, we completed a six patient Phase I clinical trial to evaluate the safety and preliminary efficacy of HuCNS-SC<sup>®</sup> cells as a treatment for infantile and late infantile neuronal ceroid lipofuscinosis (NCL), two forms of a group of disorders often referred to as Batten disease. We expect to complete data analysis and to report the trial results in mid 2009. In December 2008, the FDA approved our IND to initiate a Phase I clinical trial of HuCNS-SC cells in a second indication, Pelizaeus-Merzbacher Disease (PMD), a fatal myelination disorder in the brain. We expect the PMD trial to begin enrolling patients in 2009 and that the trial will take 12-18 months to complete. In addition, our HuCNS-SC cells are in preclinical development for spinal cord injury and retinal disorders. In our Liver Program, we are in preclinical development with our human liver engrafting cells (hLEC) and we plan to seek the necessary approvals to initiate a clinical study to evaluate hLEC as a potential cellular therapy, with the initial indication likely to be liver-based metabolic disorders. See *Overview Research and Development Programs* in the Business Section of Part I, Item 1 of this Form 10-K for a brief description of our

significant research and development programs. We have also conducted research on several other cell types and in other areas, which could lead to other possible product candidates, process improvements or further research activities.

We have not derived any revenue or cash flows from the sale or commercialization of any products except for license revenue for certain of our patented cells and media for use in research. As a result, we have incurred annual operating losses since inception and expect to incur substantial operating losses in the future. Therefore, we are

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dependent upon external financing from equity and debt offerings and revenue from collaborative research arrangements with corporate sponsors to finance our operations. We have no such collaborative research arrangements at this time and there can be no assurance that such financing or partnering revenue will be available when needed or on terms acceptable to us.

Before we can derive revenue or cash inflows from the commercialization of any of our therapeutic product candidates, we will need to: (i) conduct substantial *in vitro* testing and characterization of our proprietary cell types, (ii) undertake preclinical and clinical testing for specific disease indications; (iii) develop, validate and scale-up manufacturing processes to produce these cell-based therapeutics, and (iv) pursue required regulatory approvals. These steps are risky, expensive and time consuming.

Overall, we expect our R&D expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future product candidates. However, expenditures on R&D programs are subject to many uncertainties, including whether we develop our product candidates with a partner or independently. We cannot forecast with any degree of certainty which of our current product candidates will be subject to future collaboration, when such collaboration agreements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. In addition, there are numerous factors associated with the successful commercialization of any of our cell-based therapeutics, including future trial design and regulatory requirements, many of which cannot be determined with accuracy at this time given the stage of our development and the novel nature of stem cell technologies. The regulatory pathways, both in the United States and internationally, are complex and fluid given the novel and, in general, clinically unproven nature of stem cell technologies. At this time, due to such uncertainties and inherent risks, we cannot estimate in a meaningful way the duration of, or the costs to complete, our R&D programs or whether, when or to what extent we will generate revenues or cash inflows from the commercialization and sale of any of our product candidates. While we are currently focused on advancing each of our product development programs, our future R&D expenses will depend on the determinations we make as to the scientific and clinical prospects of each product candidate, as well as our ongoing assessment of the regulatory requirements and each product candidate's commercial potential. If we are successful in completing the Acquisition of the business of SCS, we would expect our expenses and expenditures to increase.

Given the early stage of development of our product candidates, any estimates of when we may be able to commercialize one or more of these products would not be meaningful. Moreover, any estimate of the time and investment required to develop potential products based upon our proprietary HuCNS-SC and hLEC technologies will change depending on the ultimate approach or approaches we take to pursue them, the results of preclinical and clinical studies, and the content and timing of decisions made by the FDA and other regulatory authorities. There can be no assurance that we will be able to develop any product successfully, or that we will be able to recover our development costs, whether upon commercialization of a developed product or otherwise. We cannot provide assurance that any of these programs will result in products that can be marketed or marketed profitably. If certain of our development-stage programs do not result in commercially viable products, our results of operations could be materially adversely affected.

## ***Significant Events***

In January 2008, we completed enrollment and dosing of a six-patient Phase I clinical trial of our HuCNS-SC product candidate as a treatment for infantile and late infantile neuronal ceroid lipofuscinosis (NCL) at Oregon Health & Science University (OHSU) Doernbecher Children's Hospital.

In January 2008, we entered into a research collaboration with the OHSU Casey Eye Institute to evaluate our HuCNS-SC product candidate as a potential treatment for retinal degeneration, a leading cause of blindness.

In April 2008, the U.S. Patent and Trademark Office issued U.S. Patent Number 7,361,505 with broad claims covering human neural stem cells derived from any tissue source, including embryonic, fetal, juvenile, or adult tissue. The 505 patent is exclusively licensed to us.

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In June 2008, U.S. Patent and Trademark Office issued U.S. Patent Number 7,381,561 claiming the use of additional monoclonal antibodies for the prospective isolation of rare cells from human neural tissue, such as our HuCNS-SC product candidate. The 561 patent is assigned to us.

In September 2008, Stewart Craig, Ph.D. joined us as Senior Vice President, Development and Operations, with responsibility for process design and engineering, GMP manufacturing operations, regulatory affairs, quality assurance, facilities and supply chain management. Dr. Craig has over twenty-five years of experience in the biotechnology sector, the last 15 of which have been in the cell therapy field.

In October 2008, we were awarded a \$305,000 grant from the National Institute of Diabetes and Digestive and Kidney Diseases to research and develop a potential cell-based therapeutic for liver disease arising from infection by the hepatitis C virus. This grant will fund work over the next year to investigate whether our human liver engrafting cells can be made resistant to infection by the hepatitis C virus.

In November 2008, we reported that our HuCNS-SC cells, when transplanted into a well-established animal model, can protect the retina from progressive degeneration and prevent the loss of visual function. Retinal degeneration leads to loss of vision in diseases such as age-related macular degeneration and retinitis pigmentosa.

In November 2008, we raised approximately \$20 million in gross proceeds through the sale of approximately 13.8 million units at \$1.45 per unit. Each unit consisted of one share of common stock and a warrant to purchase 0.75 shares of common stock at an exercise price of \$2.30 per share. We received total proceeds, net of offering expenses and placement agency fees, of approximately \$18.6 million.

In December 2008, the FDA approved our IND to initiate a clinical trial of our HuCNS-SC product candidate to treat Pelizaeus-Merzbacher Disease (PMD), a fatal brain disorder that mainly affects young children. This Phase I trial, which is designed to evaluate the safety and preliminary efficacy of HuCNS-SC cells as a treatment for PMD, is expected to begin enrolling patients in 2009.

In January 2009, we completed the six-patient Phase I clinical trial of our HuCNS-SC product candidate as a treatment for infantile and late infantile NCL.

In March 2009, we entered into an asset purchase agreement with Stem Cell Sciences Plc ( SCS ) to acquire substantially all of the operating assets and liabilities of SCS (the proposed Acquisition ). The Acquisition is subject to the approval of the stockholders of SCS and other customary closing conditions, and is expected to close shortly after the SCS extraordinary general meeting scheduled for March 27, 2009.

## **Critical Accounting Policies and the Use of Estimates**

The accompanying discussion and analysis of our financial condition and results of operations are based on our Consolidated Financial Statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these Consolidated Financial Statements requires management to make estimates, assumptions, and judgments that affect the reported amounts in our Consolidated Financial Statements and accompanying notes. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and we have established internal controls related to the preparation of these estimates. Actual results and the timing of the results could differ materially from these estimates.

## ***Warrant Liability***



We account for our warrants in accordance with Emerging Issues Task Force Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock* (EITF 00-19), which defines how freestanding contracts that are indexed to and potentially settled in a company's own stock should be measured and classified. The general concept under EITF 00-19 is that contracts that could require net-cash settlement should be classified as assets or liabilities and contracts that only provide for settlement in shares should be classified as equity. In order for a contract to be classified as equity, each of the specific conditions enumerated in EITF 00-19 must be met; these conditions are intended to identify situations in which net cash

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settlement could be forced upon the issuer. As part of our November 2008 financing, we issued warrants with a five year term to purchase 10,344,828 shares of our common stock at \$2.30 per share. In accordance with EITF 00-19, we are required to classify the fair value of the warrants issued as a liability, with subsequent changes in fair value to be recorded as income (loss) on change in fair value of warrant liability. The fair value of the warrants is determined using the Black-Scholes-Merton (Black-Scholes) option pricing model and is affected by changes in inputs to that model including our stock price, expected stock price volatility and contractual term. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability. The estimated fair value of our warrant liability at December 31, 2008, was approximately \$8,440,000.

***Stock-Based Compensation***

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004) (SFAS 123R), *Share-Based Payment*, which revises SFAS 123, *Accounting for Stock-Based Compensation*, and supersedes Accounting Principles Board Opinion 25, *Accounting for Stock Issued to Employees*. SFAS 123R requires us to recognize expense related to the fair value of our stock-based compensation awards, including employee stock options and restricted stock units. Under the provisions of SFAS 123R, employee stock-based compensation is estimated at the date of grant based on the award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period. The Black-Scholes option-pricing model requires the use of certain assumptions, the most significant of which are our estimates of the expected volatility of the market price of our stock, the expected term of the award, and the risk-free interest rate. Our estimate of the expected volatility is based on historical volatility. The expected term represents the period during which our stock-based awards are expected to be outstanding. In 2008 we estimated this amount based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations. Our estimate of the risk-free interest rate is based on U.S. Treasury debt securities with maturities close to the expected term of the option as of the date of grant. As required under SFAS 123R, we review our valuation assumptions at each grant date and, as a result, our assumptions in future periods may change. For the year ended December 31, 2008, employee stock-based compensation expense was approximately \$3,755,000. As of December 31, 2008, total compensation cost related to unvested stock options and restricted stock units not yet recognized was approximately \$5,207,000, which is expected to be recognized as expense over a weighted-average period of 2.1 years.

***Wind-down expenses***

In connection with our wind-down of our research and manufacturing operations in Lincoln, Rhode Island, and the relocation of our corporate headquarters and remaining research laboratories to California in October 1999, we provided a reserve for our estimate of the exit cost obligation in accordance with EITF 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Including Certain Costs Incurred in a Restructuring)*. The reserve reflects estimates of the ongoing costs of our former research and administrative facility in Lincoln, which we hold on a lease that terminates on June 30, 2013. We are seeking to sublease, assign, sell, or otherwise divest ourselves of our interest in the facility at the earliest possible time, but we cannot determine with certainty a fixed date by which such events will occur, if at all.

In determining the facility exit cost reserve amount, we are required to consider our lease payments through the end of the lease term and estimate other relevant factors such as facility operating expenses, real estate market conditions in Rhode Island for similar facilities, occupancy rates, and sublease rental rates projected over the course of the leasehold. We re-evaluate the estimate each quarter, taking into account changes, if any, in each of the underlying factors. The process is inherently subjective because it involves projections into time from the date of the estimate through the end of the lease and it is not possible to determine any of the factors except the lease payments with

certainty over that period.

Management forms its best estimate on a quarterly basis, after considering actual sublease activity, reports from our broker/realtor about current and predicted real estate market conditions in Rhode Island, the likelihood of new subleases in the foreseeable future for the specific facility and significant changes in the actual or projected operating expenses of the property. We discount the projected net outflow over the term of the lease to arrive at the

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present value, and adjust the reserve to that figure. The estimated vacancy rate for the facility is an important assumption in determining the reserve because changes in this assumption have the greatest effect on estimated sublease income. In addition, the vacancy rate estimate is the variable most subject to change, while at the same time it involves the greatest judgment and uncertainty due to the absence of highly predictive information concerning the future of the local economy and future demand for specialized laboratory and office space in that area. The average vacancy rate of the facility over the last six years (2003 through 2008) was approximately 74%, varying from 62% to 89%. As of December 31, 2008, based on current information available to management, the vacancy rate is projected to be approximately 78% for 2009, and approximately 70% from 2010 through the end of the lease. These estimates are based on actual occupancy as of December 31, 2008, predicted lead time for acquiring new subtenants, historical vacancy rates for the area and assessments by our broker/realtor of future real estate market conditions. If the assumed vacancy rate for 2010 to the end of the lease had been five percentage points higher or lower at December 31, 2008, then the reserve would have increased or decreased by approximately \$178,000. Similarly, a 5% increase or decrease in the operating expenses for the facility from 2008 on would have increased or decreased the reserve by approximately \$118,000, and a 5% increase or decrease in the assumed average rental charge per square foot would have increased or decreased the reserve by approximately \$54,000. Management does not wait for specific events to change its estimate, but instead uses its best efforts to anticipate them on a quarterly basis.

For the year ended December 31, 2008, we recorded actual expenses against this reserve net of subtenant income of approximately \$1,293,000. Based on management's evaluation of the factors mentioned above, and particularly the projected vacancy rates described above, we adjusted the reserve to \$5,513,000 at December 31, 2008 by recording an additional \$866,000 as wind-down expenses for the year ended December 31, 2008.

***Income Taxes***

We account for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes* (SFAS 109) and FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*, as amended by FASB Staff Position No. 48-1 (FIN 48). Under SFAS 109 and FIN 48, we must recognize deferred tax assets and liabilities for expected future tax consequences of temporary differences between the carrying amounts and tax bases of assets and liabilities. Income tax receivables and liabilities, and deferred tax assets and liabilities, are recognized based on the amounts that more likely than not would be sustained upon ultimate settlement with taxing authorities.

Developing our provision for income taxes and analyzing our tax positions requires significant judgment and knowledge of federal and state income tax laws, regulations and strategies, including the determination of deferred tax assets and liabilities and, any valuation allowances that may be required for deferred tax assets.

We assess the likelihood of realizing our deferred tax assets to determine whether an income tax valuation allowance is required. Based on such evidence that can be objectively verified, we determine whether it is more likely than not that all or a portion of the deferred tax assets will be realized. The main factors that we consider include:

- cumulative losses in recent years;
- income/losses expected in future years; and
- the applicable statute of limitations.

Tax benefits associated with uncertain tax positions are recognized in the period in which one of the following conditions is satisfied: (1) the more likely than not recognition threshold is satisfied; (2) the position is ultimately settled through negotiation or litigation; or (3) the statute of limitations for the taxing authority to examine and

challenge the position has expired. Tax benefits associated with an uncertain tax position are reversed in the period in which the more likely than not recognition threshold is no longer satisfied.

We concluded that the realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

**Table of Contents*****Contingencies***

We are currently involved in certain legal proceedings. See Note 9, Commitments and Contingencies, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on these matters.

***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, including without limitation the receipt and payment of recurring and nonrecurring licensing payments, the initiation or termination of research collaborations, the on-going expenses to lease and maintain our Rhode Island facilities, other than temporary impairment of our financial assets, changes in estimated fair value of our warrant liability, and the increasing costs associated with operating our California facility and expanding our operations.

***Revenue***

Revenue totaled approximately \$232,000 in 2008, \$57,000 in 2007, and \$93,000 in 2006.

			<b>Change in 2008 Versus 2007</b>		<b>Change in 2007 Versus 2006</b>	
	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>\$ %</b>	<b>\$ %</b>	
Revenue						
Licensing agreements and grants	\$ 231,730	\$ 56,722	\$ 92,850	\$ 175,008 309%	\$ (36,128) (39)%	

The increase in licensing and grant revenue in 2008 as compared to 2007 was primarily attributable to the receipt of a \$150,000 milestone payment under a license agreement. In addition, in October 2008, we were awarded a \$305,000 grant from the National Institute of Diabetes and Digestive and Kidney Diseases to research and develop a potential cell-based therapeutic for liver disease arising from infection by the hepatitis C virus. The award is a Phase I grant under the Small Business Innovation Research (SBIR) Program of the National Institutes of Health. We recognized approximately \$26,000 as grant revenue in 2008. The decrease in licensing and grant revenue in 2007 as compared to 2006 was primarily attributable to the completed draw down in 2006 of a \$464,000 Small Business Technology Transfer Grant for studies in Alzheimer's disease that was awarded in September 2004. The grant supported joint work with Dr. George A. Carlson of the McLaughlin Research Institute (MRI) in Great Falls, Montana. We received and recognized approximately \$38,000 in 2006, as grant revenue for this study.

***Operating Expenses***

Operating expense totaled approximately \$26,970,000 in 2008, \$28,648,000 in 2007, and \$21,464,000 in 2006.

			<b>Change in 2008 Versus 2007</b>		<b>Change in 2007 Versus 2006</b>	
	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>\$ %</b>	<b>\$ %</b>	

Operating Expenses							
Research & development	\$ 17,808,009	\$ 19,937,426	\$ 13,600,433	\$ (2,129,417)	(11)%	\$ 6,336,993	47%
General & administrative	8,295,554	7,927,443	7,154,042	368,111	5%	773,401	11%
Wind-down expenses	866,199	783,022	709,209	83,177	11%	73,813	10%
Total operating expenses	\$ 26,969,762	\$ 28,647,891	\$ 21,463,684	\$ (1,678,129)	(6)%	\$ 7,184,207	33%

### *Research and Development Expenses*

Our R&D expenses consist primarily of salaries and related personnel expenses, costs associated with clinical trials and regulatory submissions; costs associated with preclinical activities such as toxicology studies; costs associated with cell processing and process development; certain patent-related costs such as licensing; facilities-

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related costs such as depreciation; lab equipment and supplies. Clinical trial expenses include payments to vendors such as clinical research organizations, contract manufacturers, clinical trial sites, laboratories for testing clinical samples and consultants. Cumulative R&D costs incurred since we refocused our activities on developing cell-based therapeutics (fiscal years 2000 through 2008) were approximately \$92 million. Over this period, the majority of these cumulative costs were related to: (i) characterization of our proprietary HuCNS-SC cell, (ii) expenditures for toxicology and other preclinical studies, preparation and submission of applications to regulatory agencies to conduct clinical trials and obtaining regulatory clearance to initiate such trials, all with respect to our HuCNS-SC cells, (iii) preclinical studies and development of our human liver engrafting cells; and (iv) costs associated with cell processing and process development.

We use and manage our R&D resources, including our employees and facilities, across various projects rather than on a project-by-project basis for the following reasons. The allocations of time and resources change as the needs and priorities of individual projects and programs change, and many of our researchers are assigned to more than one project at any given time. Furthermore, we are exploring multiple possible uses for each of our proprietary cell types, so much of our R&D effort is complementary to and supportive of each of these projects. Lastly, much of our R&D effort is focused on manufacturing processes, which can result in process improvements useful across cell types. We also use external service providers to assist in the conduct of our clinical trials, to manufacture certain of our product candidates and to provide various other R&D related products and services. Many of these costs and expenses are complementary to and supportive of each of our programs. Because we do not have a development collaborator for any of our product programs, we are currently responsible for all costs incurred with respect to our product candidates.

R&D expense totaled approximately \$17,808,000 in 2008, as compared to \$19,937,000 in 2007 and \$13,600,000 in 2006. At December 31, 2008, we had 43 full-time employees working in research and development and laboratory support services as compared to 49 at December 31, 2007 and 35 at December 31, 2006.

*2008 versus 2007.* The decrease in R&D expenses of approximately \$2,129,000, or 11%, in 2008 as compared to 2007 was primarily attributable to a decrease in external services of approximately \$2,833,000; these external services were mainly related to manufacturing and testing of our cells and to clinical trial expenses. The decrease in clinical trial expenses was due mainly to the completion of enrollment and dosing of our six-patient Phase I clinical trial in January 2008. The decrease in R&D expenses was also attributable to a decrease in business travel expenses of approximately \$197,000. These decreased R&D expenses were partially offset by an increase in other operating expenses primarily attributable to (i) an increase in share based compensation expense of \$263,000, and (ii) an increase in other operating expenses of approximately \$638,000, primarily attributable to supplies.

*2007 versus 2006.* The increase in R&D expenses of approximately \$6,337,000, or 47%, in 2007 as compared to 2006 was primarily attributable to the expansion of our operations in cell processing and clinical development. A portion of our cell processing and clinical operations are performed by external service providers, so external services and clinical trial costs were approximately \$3,954,000 of the increase in R&D expenses. The increase in R&D expenses was also due to an increase in personnel costs of approximately \$1,442,000, of which approximately \$206,000 was attributable to stock-based compensation expense. The remainder of the increase in R&D expenses in 2007 was due to increases in supplies, rent, and other operating expenses.

*General and Administrative Expenses*

General and administrative (G&A) expenses totaled approximately \$8,296,000 in 2008, compared with \$7,927,000 in 2007 and \$7,154,000 in 2006.

*2008 versus 2007.* The increase in G&A expenses of approximately \$369,000, or 5%, in 2008 as compared to 2007 was primarily attributable to an increase in share-based compensation expense of \$431,000. In addition, operating



expenses for our vacant pilot manufacturing facility in Rhode Island increased by approximately \$524,000 due to the loss of tenant income to offset operating expenses. These increased expenses were partially offset by a decrease in external fees of \$399,000, including legal and recruiting fees, and a decrease in other operating expenses of approximately \$187,000.

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*2007 versus 2006.* The increase in G&A expenses of approximately \$773,000, or 11%, in 2007 as compared to 2006 was primarily attributable to an increase in external services of approximately \$763,000, driven by an increase in legal fees related to patent prosecutions and litigation, and an increase in personnel costs of approximately \$425,000, of which approximately \$211,000 was attributable to an increase in stock-based compensation expense. These increases were partially offset by a decrease in other G&A expenses.

*Wind-down Expenses*

In 1999, in connection with exiting our former research facility in Rhode Island, we created a reserve for the estimated lease payments and operating expenses related to it. The reserve has been re-evaluated and adjusted based on assumptions relevant to real estate market conditions and the estimated time until we could either fully sublease, assign or sell our remaining interests in the property. The reserve was approximately \$5,513,000 at December 31, 2008 and \$6,143,000 at December 31, 2007. Payments net of subtenant income were recorded against this reserve of \$1,293,000 in 2008, \$1,420,000 in 2007, and \$1,295,000 in 2006. We re-evaluated the estimate and adjusted the reserve by recording in aggregate, additional wind-down expenses of \$866,000 in 2008, \$783,000 in 2007, and \$709,000 in 2006. Expenses for this facility will fluctuate based on changes in tenant occupancy rates and other operating expenses related to the lease. Even though it is our intent to sublease, assign, sell, or otherwise divest ourselves of our interests in the facility at the earliest possible time, we cannot determine with certainty a fixed date by which such events will occur. In light of this uncertainty, based on estimates, we will periodically re-evaluate and adjust the reserve, as necessary. See Note 8 Wind-down and exit costs, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

**Other Income (Expense)**

Other expense totaled approximately \$2,349,000 in 2008, compared with other income of approximately \$3,568,000 in 2007 and \$2,422,000 in 2006.

				<b>Change in 2008 Versus 2007</b>		<b>Change in 2007 Versus 2006</b>	
	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
Other income							
(expense):							
License and							
settlement							
agreement, net	\$	\$ 550,467	\$ 103,359	\$ (550,467)	(100)%	\$ 447,108	433%
Realized gain on							
sale of							
marketable							
securities		715,584		(715,584)	(100)%	715,584	*%
Other than							
temporary							
impairment of							
marketable							
securities	(2,082,894)			(2,082,894)	*%		
Change in fair	(937,241)			(937,241)	*%		
value of warrant							

liability							
Interest income	803,095	2,459,820	2,479,740	(1,656,725)	(67)%	(19,920)	(1)%
Interest expense	(109,762)	(123,606)	(143,001)	13,844	(11)%	19,395	(14)%
Other expense, net	(21,943)	(33,899)	(17,644)	11,956	(35)%	(16,255)	92%
Total other income (expense), net	\$ (2,348,745)	\$ 3,568,366	\$ 2,422,454	\$ (5,917,111)	(166)%	\$ 1,145,912	47%

\* Calculation cannot be performed or is not meaningful.

#### *License and Settlement Agreement*

In July 2005, we entered into an agreement with ReNeuron Limited, a wholly owned subsidiary of ReNeuron Group plc, a listed UK corporation (collectively referred to as ReNeuron). As part of the agreement, we granted ReNeuron a license that allows ReNeuron to exploit their c-mycER conditionally immortalized adult human neural stem cell technology for therapy and other purposes. We received shares of ReNeuron common stock, as well as a cross-license to the exclusive use of ReNeuron's technology for certain diseases and conditions, including lysosomal storage diseases, spinal cord injury, cerebral palsy, and multiple sclerosis. The agreement also provides

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for full settlement of any potential claims that either we or ReNeuron might have had against the other in connection with any putative infringement of certain of each party's patent rights prior to the effective date of the agreement. In July and August 2005 we received approximately 8,836,000 ordinary shares of ReNeuron common stock (net of approximately 104,000 shares that were transferred to NeuroSpheres), and subsequently, in 2006 and 2007, as a result of certain anti-dilution provisions in the agreement, we received approximately 1,261,000 more shares, net of approximately 18,000 shares that were transferred to NeuroSpheres. In February 2007, we sold 5,275,000 shares for net proceeds of approximately \$3,077,000. See Note 15 Subsequent Events in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

Other income from the license and settlement agreement totaled approximately \$0 in 2008, \$550,000 in 2007, and \$103,000 in 2006, which was the fair value of the ReNeuron shares we received under such agreement, net of legal fees and the value of the shares that were transferred to NeuroSpheres Ltd., an Alberta corporation from which we have licensed some of the patent rights that are the subject of the agreement with ReNeuron. See Note 2 Financial Instruments ReNeuron License Agreement in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information regarding this transaction.

### *Gain on Sale of Marketable Equity Securities*

The gain on sale of marketable equity securities of approximately \$716,000 in 2007 was attributable to sales of ReNeuron shares. See Note 2 Financial Instruments, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on this transaction.

### *Other than temporary impairment of marketable securities*

As of December 31, 2008, we determined that our investment in ReNeuron shares (marketable equity securities) was impaired and that such impairment was other than temporary. We considered various criteria, including the duration of the impairment and our intent to liquidate all or part of this investment within a reasonably short period of time. For the year ended December 31, 2008, we recorded a loss of \$2,082,894, which is the difference between the investment's carrying value and its quoted market price at that date. No other than temporary impairment was recognized during the years ended December 31, 2007 and 2006. See Note 2 Financial Instruments, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on this transaction.

### *Interest Income*

Interest income totaled approximately \$803,000 in 2008, \$2,460,000 in 2007, and \$2,480,000 in 2006. The decrease in interest income in 2008 as compared to 2007 was primarily attributable to lower average yields and a lower average bank balance in 2008. Interest income in 2007 was relatively flat compared to 2006, as a result of lower average bank balances offset by higher average yields.

### *Interest Expense*

Interest expense was approximately \$110,000 in 2008, \$124,000 in 2007, and \$143,000 in 2006. The decreases in 2008 as compared to 2007 and in 2007 as compared to 2006 were attributable to lower outstanding debt and capital lease balances. See Note 9 Commitment and Contingencies, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

### *Other Expense, net*

Other expense, net for 2008, 2007, and 2006 of approximately \$22,000, \$34,000, and \$18,000 respectively, primarily relate to the payment of state franchise taxes.

**Table of Contents****Liquidity and Capital Resources**

Since our inception, we have financed our operations through the sale of common and preferred stock, the issuance of long-term debt and capitalized lease obligations, revenue from collaborative agreements, research grants, license fees, and interest income.

				Change in 2008 Versus 2007		Change in 2007 Versus 2006	
	2008	2007	2006	\$	%	\$	%
At December 31:							
Cash and highly liquid investments(1)	\$ 34,037,775	\$ 37,645,085	\$ 51,795,529	\$ (3,607,310)	(10)%	\$ (14,150,444)	(27)%
Year ended December 31:							
Net cash used in operating activities	\$ (22,740,421)	\$ (20,856,746)	\$ (16,104,120)	\$ 1,883,475	9%	\$ 4,752,626	29%
Net cash provided by (used in) investing activities	\$ 24,223,629	\$ (27,155,656)	\$ (1,297,124)	\$ 51,379,285	189%	\$ 25,858,532	1994%
Net cash provided by financing activities	\$ 18,800,609	\$ 5,976,042	\$ 34,655,865	\$ 12,824,567	215%	\$ (28,679,823)	(83)%

(1) Cash and highly liquid investments include unrestricted cash, cash equivalents, and short-term and long-term marketable debt securities. Marketable equity securities, which are comprised of 4,821,924 ordinary shares of ReNeuron, are excluded from the amounts above. See Note 2, Financial Instruments, in the Notes to the Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

Total cash and highly liquid investments were approximately \$34,038,000 at December 31, 2008, compared with approximately \$37,645,000 at December 31, 2007, and \$51,796,000 at December 31, 2006. The decrease in our cash and highly liquid investments of approximately \$3,607,000, or 10%, in 2008 as compared to 2007 and \$14,150,000, or 27%, in 2007 as compared to 2006 was primarily attributable to cash used in operating activities; partially offset by cash generated from financing activities.

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

Cash used by operating activities consists of net loss for the year, adjusted for non-cash expenses such as depreciation and amortization and share based compensation, and adjustments for changes in various components of working capital. Cash used in operating activities was approximately \$22,740,000 in 2008, \$20,857,000 in 2007, and

\$16,104,000 in 2006. The increase in cash used in operating activities in 2008 compared to 2007 was primarily attributable to the timing of cash payments and receipts for various operating assets and liabilities such as accounts payable, accrued expenses, and accounts receivable. This increased use of working capital in 2008 was partially offset by a decrease in operating loss in 2008 as compared to 2007. The decrease in operating loss from approximately \$28,591,000 in 2007 to approximately \$26,738,000 in 2008 was primarily attributable to the decrease in R&D expenses in 2008 as compared to 2007. The increase in cash used in 2007 as compared to 2006, was primarily attributable to higher R&D expenses in 2007.

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

The increase of approximately \$51,379,000 for net cash provided by investing activities in 2008 as compared to 2007 was primarily attributable to the maturity of marketable debt securities held to maturity in 2008. In 2008, we received net proceeds of \$23,859,000 from the maturity of marketable debt securities, while in 2007, we invested approximately \$27,862,000 in net purchases of marketable debt securities. In addition, in December 2008, we made a secured loan of £200,000 (approximately \$298,000) to SCS in connection with a potential acquisition transaction. The loan accrues interest at 8% per annum and is repayable on June 23, 2009 if the proposed Acquisition does not close beforehand. The increase of approximately \$25,859,000 for net cash used in investing activities in 2007 as compared to 2006 was almost entirely due to the redeployment of cash held in money market funds (classified as cash equivalents) to marketable debt securities (classified as marketable securities). In February 2007, we sold 5,275,000 ordinary shares of ReNeuron for net proceeds of approximately \$3,075,000. In addition, cash used in

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investing activities in 2007 included a secured loan of \$1,000,000 made to PCT in December 2007. See Note 2, Financial Instruments, in the Notes to the Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on our investing activities.

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

The increase for net cash provided by financing activities of approximately \$12,825,000 in 2008 as compared to 2007 was primarily attributable to the sale in November 2008 of 13,793,104 units to institutional investors at a price of \$1.45 per unit. Each unit consisted of one share of our common stock and a warrant to purchase 0.75 shares of our common stock at an exercise price of \$2.30 per share. We received approximately \$18,637,000, net of offering expenses and placement agency fees. The decrease of approximately \$28,680,000 in 2007 as compared to 2006 was primarily attributable to the sale in April 2006 of 11,750,820 shares of our common stock to institutional investors at a price of \$3.05 per share. We received total proceeds, net of offering expenses and placement agency fees, of approximately \$33,422,000.

Listed below are key financing transactions entered into by us in the last three years:

In November 2008, we sold 13,793,104 units to institutional investors at a price of \$1.45 per unit, for gross proceeds of \$20,000,000. The units, each of which consisted of one share of common stock and a warrant to purchase 0.75 shares of common stock at an exercise price of \$2.30 per share, were offered as a registered direct offering under an effective shelf registration statement previously filed with and declared effective by the Securities and Exchange Commission. We received total proceeds net of offering expenses and placement agency fees of approximately \$18,637,000.

In April 2007, a warrant issued as part of our June 2004 financing was exercised to purchase an aggregate of 575,658 shares of our common stock at \$1.90 per share. We issued 575,658 shares of our common stock and received proceeds of approximately \$1,094,000.

In December 2006, we filed a Prospectus Supplement announcing the entry of a sales agreement with Cantor Fitzgerald & Co (Cantor) under which up to 10,000,000 shares may be sold from time to time under a shelf registration statement. In 2007 and 2008, we sold a total of 2,012,600 shares of our common stock under this agreement at an average price per share of \$2.68 for gross proceeds of approximately \$5,133,000. Cantor is paid compensation equal to 5.0% of the gross proceeds pursuant to the terms of the agreement.

In April 2006, we sold 11,750,820 shares of our common stock to institutional investors at a price of \$3.05 per share, for gross proceeds of approximately \$35,840,000. The shares were offered as a registered direct offering under an effective shelf registration statement previously filed with and declared effective by the Securities and Exchange Commission. We received total proceeds, net of offering expenses and placement agency fees, of approximately \$33,422,000. No warrants were issued as part of this financing transaction.

In March 2006, a warrant issued as part of our June 2004 financing was exercised to purchase an aggregate of 526,400 shares of our common stock at \$1.89 per share. We issued 526,400 shares of our common stock and received proceeds of approximately \$995,000.

In the first quarter of 2009, we sold in aggregate, 3,325,000 shares of our common stock pursuant to the sales agreement we entered into with Cantor, at an average price per share of \$2.10 for gross proceeds of approximately \$6,999,000. Cantor is paid compensation equal to 5.0% of the gross proceeds pursuant to the terms of the agreement.



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 proceeds from equity and debt offerings,

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proceeds from the transfer or sale of our intellectual property rights, equipment, facilities or investments, and government grants and funding from collaborative arrangements, if obtainable, to fund our operations.

We intend to pursue opportunities to obtain additional financing in the future through equity and debt financings, grants and collaborative research arrangements. On June 25, 2008 we filed with the SEC a universal shelf registration statement, declared effective July 18, 2008, which permits us to issue up to \$100 million worth of registered debt and equity securities. Under this effective shelf registration, we have the flexibility to issue registered securities, from time to time, in one or more separate offerings or other transactions with the size, price and terms to be determined at the time of issuance. Registered securities issued using this shelf may be used to raise additional capital to fund our working capital and other corporate needs, for future acquisitions of assets, programs or businesses, and for other corporate purposes. As of March 10, 2009, we had approximately \$71 million under our universal shelf registration statement available for issuing debt or equity securities; approximately \$24 million of this \$71 million has been reserved for the potential exercise of the warrants issued in connection with our November 2008 financing. In July 2008, we deregistered the remaining unissued shares (approximately \$59 million worth of common stock) available under the shelf registration statement we had filed in October 2005. The 2005 shelf permitted the issuance of up to \$100 million of registered shares of common stock. Also in July 2008, we amended our sales agreement with Cantor to allow for sales under our universal shelf registration rather than the 2005 shelf registration.

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. In addition, the decline in economic activity, together with the deterioration of the credit and capital markets, could have an adverse impact on potential sources of future financing.

## ***Commitments***

See Note 9, *Commitments and Contingencies* in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

## ***Off-Balance Sheet Arrangements***

We have certain contractual arrangements that create potential risk for us and are not recognized in our Consolidated Balance Sheets. Discussed below are those off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

## ***Operating Leases***

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance, and minimum lease payments. Some of our leases have options to renew.

We entered into and amended a lease agreement for an approximately 68,000 square foot facility located at the Stanford Research Park in Palo Alto, California. At December 31, 2008, we had a space-sharing agreement covering approximately 10,451 square feet of this facility. We receive base payments plus a proportionate share of the operating expenses based on square footage over the term of the space-sharing agreement. For the year 2009, we expect to receive, in aggregate, approximately \$606,000 as part of the space-sharing agreement. As a result of the above transactions, our estimated net cash outlay for the rent and operating expenses of this facility will be

approximately \$3,244,000 for 2009.

We continue to have outstanding obligations in regard to our former facilities in Lincoln, Rhode Island. In 1997, we had entered into a fifteen-year lease for a scientific and administrative facility (the SAF) in a sale and leaseback arrangement. The lease includes escalating rent payments. For the year 2009, we expect to pay approximately \$1,172,000 in operating lease payments and estimated operating expenses of approximately

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\$625,000, before receipt of sub-tenant income. For the year 2009, we expect to receive, in aggregate, approximately \$212,000 in sub-tenant rent. As a result of the above transactions, our estimated cash outlay net of sub-tenant rent for the SAF will be approximately \$1,585,000 for 2009.

With the exception of leases discussed above, we have not entered into any off balance sheet financial arrangements and have not established any special purpose entities. We have not guaranteed any debts or commitments of other entities or entered into any options on non-financial assets.

See Note 9, Commitments and Contingencies, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

*Indemnification Agreement*

In July 2008, we amended our 1997 and 2000 license agreements with NeuroSpheres. NeuroSpheres is the holder of certain patents exclusively licensed by us, including the six patents that are the basis of our patent infringement suits against Neuralstem. As part of the amendment, we agreed to pay all reasonable litigation costs, expenses and attorney's fees incurred by NeuroSpheres in the declaratory judgment suit between us and Neuralstem. In return, we are entitled to off-set all litigation costs incurred in that suit against amounts that would otherwise be owed under the license agreements, such as annual maintenance fees, milestones and royalty payments. At this time, we cannot estimate the likely total costs of our pending litigation with Neuralstem, given the unpredictable nature of such proceedings, or the total amount we may ultimately owe under the NeuroSpheres license agreements. However, the ability to apply the offsets will run for the entire term of each license agreement. For these reasons, we have chosen to approximate the potential value of the offset receivable by assuming that all litigation charges actually incurred in the declaratory judgment action as of December 31, 2008, will ultimately be offset against royalties owed. Management will reevaluate this assumption on a quarterly basis based on actual costs and other relevant factors.

**Contractual Obligations**

In the table below, we set forth our legally binding and enforceable contractual cash obligations:

	<b>Total</b>					<b>Payable</b>	<b>Payable</b>
	<b>Obligations</b>	<b>Payable in</b>	<b>Payable in</b>	<b>Payable in</b>	<b>Payable in</b>	<b>in</b>	<b>in</b>
	<b>at 12/31/08</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>and</b>
							<b>Beyond</b>
Operating lease payments(1)	\$ 8,380,319	\$ 3,536,843	\$ 1,767,304	\$ 1,171,875	\$ 1,171,875	\$ 732,422	\$
Capital lease (equipment)	26,483	19,862	6,621				
Bonds Payable (principal & interest)(2)	1,344,563	244,572	242,559	242,321	240,666	237,593	136,852
	\$ 9,751,365	\$ 3,801,277	\$ 2,016,484	\$ 1,414,196	\$ 1,412,541	\$ 970,015	\$ 136,852

Total  
contractual  
cash  
obligations

- (1) Operating lease payments exclude space-sharing and sub-lease income. See Off-Balance Sheet Arrangements Operating Leases above for further information.
- (2) See Note 9, Commitments and Contingencies in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

Under license agreements with NeuroSpheres, Ltd., we obtained an exclusive patent license covering all uses of certain neural stem cell technology. We made up-front payments to NeuroSpheres of 65,000 shares of our common stock and \$50,000, and will make additional cash payments as stated milestones are achieved. Effective in 2004, we began making annual \$50,000 payments, creditable against certain royalties.

We do not have any material unconditional purchase obligations or commercial commitments related to capital expenditures, clinical development, clinical manufacturing, or other external services contracts at December 31, 2008.

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### **Recent Accounting Pronouncements**

In February 2008, the FASB issued FASB Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-2 delays the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except for certain items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). We are currently evaluating the impact of SFAS 157 on our consolidated financial statements for items within the scope of FSP 157-2, which will become effective beginning with our first quarter of 2009.

In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* (FSP 157-3). FSP 157-3 clarifies the application of SFAS 157, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP shall be effective upon issuance, including prior periods for which financial statements have not been issued. Revisions resulting from a change in the valuation technique or its application shall be accounted for as a change in accounting estimate. Adoption of FSP 157-3 did not have a material impact on our consolidated financial statement.

In April 2008, the FASB issued FSP No. 142-3, *Determination of the Useful Life of Intangible Assets* (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). FSP 142-3 amends paragraph 11(d) of SFAS 142 to require an entity to use its own assumptions about renewal or extension of an arrangement, adjusted for the entity-specific factors in paragraph 11 of SFAS 142, even when there is likely to be substantial cost or material modifications. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, with early adoption prohibited. We do not expect that the adoption of FSP 142-3 on January 1, 2009, will have a material effect on our consolidated financial condition and results of operations.

In December 2007, FASB issued SFAS No. 141R, *Business Combinations* (SFAS 141R). SFAS 141R provides companies with principles and requirements on how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, liabilities assumed, and any non controlling interest in the acquiree as well as the recognition and measurement of goodwill acquired in a business combination. SFAS 141R also requires certain disclosures to enable users of the financial statements to evaluate the nature and financial effects of the business combination. Acquisition costs associated with the business combination will generally be expensed as incurred. SFAS 141R is effective for business combinations occurring in fiscal years beginning after December 15, 2008. Early adoption of SFAS 141R is not permitted. We will be required to apply the guidance in SFAS 141R to any future business combinations effective January 1, 2009.

In June 2008, the FASB issued EITF Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*. EITF Issue No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. EITF Issue No. 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. We do not expect the adoption of EITF Issue No. 07-05 to have a material impact on our consolidated financial statements.

### **Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### **Interest Rate and Credit Risks**

Our interest-bearing assets, or interest-bearing portfolio, consists of cash, cash equivalents, restricted cash, and marketable debt securities. The balance of our interest-bearing portfolio, was approximately \$34,031,000, or 85%, of total assets at December 31, 2008 and \$38,414,000, or 79%, of total assets at December 31, 2007. Interest income earned on these assets was approximately \$803,000 in 2008 and \$2,460,000 in 2007. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. At December 31, 2008, our debt securities were primarily composed of money market accounts comprised of US Treasuries and repurchase

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agreements that are backed by US Treasuries. Generally, corporate obligations must have senior credit ratings of A2/A or the equivalent. See Note 1, Summary of Significant Accounting Policies Financial Instruments and Note 2

Financial Instruments section in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K for further information.

Our long-term debt is comprised of industrial revenue bonds issued by the State of Rhode Island to finance the construction of our pilot manufacturing facility in Rhode Island. See Note 9, Commitments and Contingencies, section in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K for further information.

**Equity Security and Foreign Exchange Risks**

In July 2005, we entered into an agreement with ReNeuron Limited, a wholly owned subsidiary of ReNeuron Group plc, a listed UK corporation (collectively referred to as ReNeuron). As part of the agreement, we granted ReNeuron a license that allows ReNeuron to exploit their c-mycER conditionally immortalized adult human neural stem cell technology for therapy and other purposes. We received shares of ReNeuron common stock, as well as a cross-license to the exclusive use of ReNeuron's technology for certain diseases and conditions, including lysosomal storage diseases, spinal cord injury, cerebral palsy, and multiple sclerosis. The agreement also provides for full settlement of any potential claims that either we or ReNeuron might have had against the other in connection with any putative infringement of certain of each party's patent rights prior to the effective date of the agreement. In July and August 2005 we received approximately 8,836,000 ordinary shares of ReNeuron common stock (net of approximately 104,000 shares that were transferred to NeuroSpheres), and subsequently, as a result of certain anti-dilution provisions in the agreement, we received approximately 1,261,000 more shares, net of approximately 18,000 shares that were transferred to NeuroSpheres. In February 2007, we sold 5,275,000 shares for net proceeds of approximately \$3,077,000. In the first quarter of 2009, we sold in aggregate, approximately 2,900,000 more shares and received net proceeds of approximately \$512,000. As of March 10, 2009, we held approximately 1,922,000 shares of ReNeuron as marketable equity securities.

Changes in market value as a result of changes in market price per share or the exchange rate between the U.S. dollar and the British pound are accounted for under other comprehensive income (loss) if deemed temporary and are not recorded as other income or loss until the shares are disposed of and a gain or loss realized or an impairment is determined to be other than temporary. After considering various criteria, including, the duration of the impairment and our intent to liquidate all or part of this investment within a reasonably short period of time, we determined that the impairment of our investment in ReNeuron was other than temporary. For the year ended December 31, 2008, we recorded, on our Consolidated Statements of Operations under Other Income (expense), a loss of \$2,082,894, which is the difference between the investment's carrying value and its quoted market price at that date.

Company/Stock Symbol	Exchange	Risks	No. of Shares at December 31, 2008	Share Price at December 31, 2008 in GBP(£)	Exchange Rate at December 31, 2008 1 GBP = USD	Market Value in USD at December 31, 2008	Expected Future Cash Flows
ReNeuron Group plc/RENE	AIM (AIM is the London Stock	Lower share price Foreign currency	4,821,924	0.0265	1.4619	\$ 186,803	(1)



Exchange s translation  
Alternative Liquidity  
Investment Bankruptcy  
Market)

- (1) It is our intention to liquidate this investment when we can do so at prices acceptable to us. Although we are not legally restricted from selling the stock, the share price is subject to change and the volume traded has often been very small since the stock was listed on the AIM on August 12, 2005. The performance of ReNeuron Group plc stock since its listing does not predict its future value.

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

**STEMCELLS, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders  
StemCells, Inc.

We have audited the accompanying consolidated balance sheets of StemCells, Inc. (a Delaware corporation) and subsidiary (collectively, the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. These financial statements are the responsibility of the Company's management. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

We also have audited, in accordance with standards of the Public Company Accounting Oversight Board (United States), StemCells, Inc. and subsidiary's internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ GRANT THORNTON LLP

San Francisco, California  
March 11, 2009

**Table of Contents****StemCells, Inc.****Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 30,042,986	\$ 9,759,169
Marketable securities, current	4,181,592	26,696,413
Other receivables	164,204	264,631
Note receivable	298,032	1,000,000
Prepaid assets	645,242	1,032,482
Total current assets	35,332,056	38,752,695
Marketable securities, non current		3,150,971
Property, plant and equipment, net	3,173,468	3,905,404
Other assets, non-current	2,079,278	1,710,829
Intangible assets, net	645,538	762,667
Total assets	\$ 41,230,340	\$ 48,282,566
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,078,123	\$ 1,813,595
Accrued expenses and other liabilities	2,261,245	2,462,252
Accrued wind-down expenses, current	1,420,378	1,374,632
Deferred revenue, current	43,909	43,909
Capital lease obligation, current	18,739	17,530
Deferred rent, current	346,930	290,391
Bonds payable, current	149,167	136,250
Total current liabilities	5,318,491	6,138,559
Capital lease obligation, non-current	6,529	25,269
Bonds payable, non-current	860,000	1,009,166
Fair value of warrant liability	8,439,931	
Deposits and other long-term liabilities	466,211	527,804
Accrued wind-down expenses, non-current	4,092,939	4,768,859
Deferred rent, non-current	90,215	437,144
Deferred revenue, non-current	147,039	163,865
Total liabilities	19,421,355	13,070,666
Commitments and contingencies (Note 9)		
Stockholders' equity:		

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Common stock, \$.01 par value; 250,000,000 shares authorized; issued and outstanding 94,945,603 at December 31, 2008 and 80,681,087 at

December 31, 2007	949,455	806,810
Additional paid-in capital	279,868,802	264,603,711
Accumulated deficit	(259,001,524)	(229,914,747)
Accumulated other comprehensive loss	(7,748)	(283,874)
Total stockholders' equity	21,808,985	35,211,900
Total liabilities and stockholders' equity	\$ 41,230,340	\$ 48,282,566

See Notes to Consolidated Financial Statements.

**Table of Contents****StemCells, Inc.****Consolidated Statements of Operations**

	<b>Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Revenue:			
Revenue from licensing agreements and grants	\$ 231,730	\$ 56,722	\$ 92,850
Operating expenses:			
Research and development	17,808,009	19,937,426	13,600,433
General and administrative	8,295,554	7,927,443	7,154,042
Wind-down expenses	866,199	783,022	709,209
Total operating expenses	26,969,762	28,647,891	21,463,684
Operating loss	(26,738,032)	(28,591,169)	(21,370,834)
Other income (expense):			
License and settlement agreement, net		550,467	103,359
Realized gain on sale of marketable securities		715,584	
Other than temporary impairment of marketable securities	(2,082,894)		
Change in fair value of warrant liability	(937,241)		
Interest income	803,095	2,459,820	2,479,740
Interest expense	(109,762)	(123,606)	(143,001)
Other expense, net	(21,943)	(33,898)	(17,644)
Total other income (expense), net	(2,348,745)	3,568,367	2,422,454
Net loss	\$ (29,086,777)	\$ (25,022,802)	\$ (18,948,380)
Basic and diluted net loss per share	\$ (0.35)	\$ (0.31)	\$ (0.25)
Shares used to compute basic and diluted loss per share	82,716,455	79,772,351	74,611,196

See Notes to Consolidated Financial Statements.

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## StemCells, Inc.

## Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit		
<b>Balances, December 31, 2005</b>	65,396,022	\$ 653,960	\$ 217,919,336	\$ (185,943,565)	\$ (254,147)	\$ 32,375,584
Comprehensive loss						
Net loss				(18,948,380)		(18,948,380)
Change in unrealized gain on securities available-for-sale					3,442,125	3,442,125
Comprehensive loss						(15,506,255)
Issuance of common stock related to equity financing net of issuance cost of \$2,418,467	11,750,820	117,508	33,304,026			33,421,534
Common stock issued for licensing agreements	3,848	38	9,962			10,000
Common stock issued pursuant to employee benefit plan	50,120	501	121,955			122,456
Compensation expense from grant of options and stock (fair value)			2,409,509			2,409,509
Exercise of employee and consultant stock options	319,094	3,191	545,088			548,279
Exercise of warrants	526,400	5,264	989,632			994,896
<b>Balances, December 31, 2006</b>	78,046,304	780,462	255,299,508	(204,891,945)	3,187,978	54,376,003
Comprehensive loss						
Net loss				(25,022,802)		(25,022,802)

Change in unrealized loss on securities available-for-sale				(3,471,852)	(3,471,852)	
Comprehensive loss						(28,494,654)
Issuance of common stock related to equity financing net of issuance cost of \$297,465	1,807,000	18,070	4,816,983			4,835,053
Common stock issued for licensing agreements	3,865	39	9,961			10,000
Common stock issued pursuant to employee benefit plan	73,074	731	172,429			173,160
Compensation expense from grant of options and stock (fair value)			3,008,315			3,008,315
Exercise of employee stock options	175,186	1,752	208,521			210,273
Exercise of warrants	575,658	5,756	1,087,994			1,093,750
<b>Balances, December 31, 2007</b>	80,681,087	806,810	264,603,711	(229,914,747)	(283,874)	35,211,900
Comprehensive loss						
Net loss				(29,086,777)		(29,086,777)
Change in unrealized loss on securities available-for-sale					276,126	276,126
Comprehensive loss						(28,810,651)
Issuance of common stock and warrants, net of issuance cost of \$1,432,539	13,998,704	139,987	11,184,188			11,324,175
Common stock issued for licensing agreements	6,924	69	9,931			10,000
Common stock issued pursuant to employee benefit plan	144,188	1,442	189,724			191,166
Compensation expense from grant of options, restricted			3,754,871			3,754,871



stock units and stock (fair value)									
Exercise of employee and director stock options	114,700	1,147	126,377					127,524	
<b>Balances, December 31, 2008</b>	94,945,603	\$ 949,455	\$ 279,868,802	\$ (259,001,524)	\$	(7,748)	\$	21,808,985	

See Notes to Consolidated Financial Statements.

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## StemCells, Inc.

## Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2008	2007	2006
<b>Cash flows from operating activities:</b>			
Net loss	\$ (29,086,777)	\$ (25,022,802)	\$ (18,948,380)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,186,428	1,174,510	1,044,688
Issue of shares and options in exchange for services	3,946,037	3,181,475	2,531,966
(Gain) loss on disposal of fixed assets		(1,500)	1,573
Non-cash income from license and settlement agreement, net		(550,467)	(103,359)
Gain on sale of marketable securities		(715,584)	
Other than temporary impairment of marketable securities	2,082,894		
Change in fair value of warrant liability	937,241		
Changes in operating assets and liabilities:			
Other receivables	100,427	218,219	(280,931)
Prepaid assets	387,240	86,985	(732,501)
Other assets, net	(358,449)	19,532	56,270
Accounts payable and accrued expenses	(936,479)	1,601,180	554,245
Accrued wind-down expenses	(630,174)	(606,766)	(555,469)
Deferred revenue	(16,826)	10,257	197,517
Deferred rent	(290,390)	(232,198)	105,735
Deposits and other long-term liabilities	(61,593)	(19,587)	24,526
Net cash used in operating activities	(22,740,421)	(20,856,746)	(16,104,120)
<b>Cash flows from investing activities:</b>			
Purchase of marketable debt securities	(4,822,684)	(37,029,744)	
Sales or maturity of marketable debt securities	28,681,708	9,168,183	
Proceeds from sale of marketable equity securities		3,074,654	
Repayment received under note receivable	1,000,000		
Advance made under note receivable	(298,032)	(1,000,000)	
Purchases of property, plant and equipment	(312,988)	(1,319,374)	(1,258,749)
Purchase of intangibles and other assets	(24,375)	(49,375)	(38,375)
Net cash provided by (used in) investing activities	24,223,629	(27,155,656)	(1,297,124)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock, net	18,826,865	4,835,053	33,421,534
Proceeds from the exercise of stock options	127,524	210,273	548,279
Proceeds from the exercise of warrants		1,093,750	994,896

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Proceeds (repayments) of capital lease obligations	(17,531)	42,799	(54,676)
Repayments of bonds payable	(136,249)	(205,833)	(254,168)
Net cash provided by financing activities	18,800,609	5,976,042	34,655,865
Increase (decrease) in cash and cash equivalents	20,283,817	(42,036,360)	17,254,621
Cash and cash equivalents at beginning of year	9,759,169	51,795,529	34,540,908
Cash and cash equivalents at end of the year	\$ 30,042,986	\$ 9,759,169	\$ 51,795,529
Supplemental disclosure of cash flow information:			
Interest paid	\$ 109,762	\$ 123,606	\$ 143,001
Supplemental schedule of non-cash investing and financing activities:			
Stock issued for licensing agreements(1)	\$ 10,000	\$ 10,000	\$ 10,000

- (1) Under terms of a license agreement with the California Institute of Technology (Cal Tech), annual fees of \$5,000 were due on each of two patents to which StemCells holds a license from Cal Tech, payable in cash or stock at our choice. We elected to pay the fees in common stock and issued shares of 6,924 in 2008, 3,865 in 2007 and 3,848 in 2006 to Cal Tech.

See Notes to Consolidated Financial Statements.

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**StemCells, Inc.**

**Notes to Consolidated Financial Statements  
December 31, 2008**

**Note 1. Summary of Significant Accounting Policies**

***Nature of Business***

StemCells, Inc., a Delaware corporation, is a biopharmaceutical company that operates in one segment, the development of novel cell-based therapeutics designed to treat human diseases and disorders.

The accompanying consolidated financial statements have been prepared on the basis that we will continue as a going concern. Since inception, we have incurred annual losses and negative cash flows from operations and have an accumulated deficit of approximately \$259 million at December 31, 2008. We have not derived revenue from the sale of products, and do not expect to receive revenue from product sales for at least several years. We may never be able to realize sufficient revenue to achieve or sustain profitability in the future.

We expect to incur additional operating losses over the foreseeable future. We have limited liquidity and capital resources and must obtain significant additional capital and other resources in order to sustain our product development efforts, to provide funding for the acquisition of technologies and intellectual property rights, preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, general and administrative expenses and other working capital requirements. We rely on our cash reserves, proceeds from equity and debt offerings, proceeds from the transfer or sale of intellectual property rights, equipment, facilities or investments, government grants and funding from collaborative arrangements, to fund our operations. If we exhaust our cash reserves and are unable to obtain adequate financing, we may be unable to meet our operating obligations and we may be required to initiate bankruptcy proceedings. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

***Principles of Consolidation***

The consolidated financial statements include the accounts of StemCells, Inc., and our wholly owned subsidiary, StemCells California, Inc. Material intercompany accounts and transactions have been eliminated.

***Use of Estimates***

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make judgments, assumptions and estimates that affect the amounts reported in our consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Significant estimates include the following:

Accrued wind-down expenses (See Note 8).

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The fair value of share-based awards recognized as compensation expense in accordance with the provisions of Statement of Financial Accounting Standards No. 123 (Revised 2004) Share Based Payment (SFAS 123R). (See Note 7).

Valuation allowance against net deferred tax assets (See Note 14).

The fair value of warrants recorded as a liability in accordance with Emerging Issues Task Force Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock* EITF 00-19. The warrants were issued as part of our November 2008 financing (See Note 10).

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**StemCells, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

***Financial Instruments***

***Cash Equivalents and Marketable Securities***

All money market and highly liquid investments with a maturity of 90 days or less at the date of purchase are classified as cash equivalents. Highly liquid investments with maturities of 365 days or less not previously classified as cash equivalents are classified as marketable securities, current. Investments with maturities greater than 365 days are classified as marketable securities, non-current. Our marketable debt and equity securities have been classified and accounted for as available-for-sale. Management determines the appropriate classification of its investments in marketable debt and equity securities at the time of purchase and reevaluates the available-for-sale designations as of each balance sheet date. These securities are carried at fair value (see Note 2, Financial Instruments, below), with the unrealized gains and losses reported as a component of stockholders' equity. The cost of securities sold is based upon the specific identification method.

If the estimated fair value of a security is below its carrying value, we evaluate whether we have the intent and ability to retain our investment for a period of time sufficient to allow for any anticipated recovery to the cost of the investment, and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. Other-than-temporary declines in estimated fair value of all marketable securities are charged to other income (expense), net. After considering various criteria, including the duration of the impairment and our intent to liquidate all or part of our investment within a reasonably short period of time, we determined that the impairment of our investment in ordinary shares of ReNeuron (marketable equity securities) (see Note 2, Financial Instruments, below), was other than temporary. For the year ended December 31, 2008, we recorded on our Consolidated Statements of Operations under Other Income (expense) a loss of \$2,082,894, which is the difference between the investment's carrying value and its quoted market price at that date. No other than temporary impairment was recognized during the years ended December 31, 2007 and 2006.

***Other Receivables***

Our non-trade receivables generally consist of interest income on our financial instruments, revenue from licensing agreements and rent from our sub-lease tenants.

***Estimated Fair Value of Financial Instruments***

The estimated fair value of cash and cash equivalents, other receivables, accounts payable and the current portion of the bonds payable approximates their carrying values due to the short maturities of these instruments. The estimated fair value of our marketable debt securities approximates its carrying value based on current rates available to us for similar debt securities.

***Property, Plant and Equipment***

Property, plant, and equipment, including those held under capital lease, are stated at cost. Depreciation is computed by use of the straight-line method over the estimated useful lives of the assets, or the lease term if shorter, as follows:

Building and improvements	3 - 20 years
Machinery and equipment	3 - 10 years
Furniture and fixtures	3 - 10 years

Repairs and maintenance costs are expensed as incurred.

***Intangible Assets (Patent and License Costs)***

Prior to fiscal year 2001, we capitalized certain patent costs, which are being amortized over the estimated life of the patent and would be expensed at the time such patents are deemed to have no continuing value. Since 2001, all

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**StemCells, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

patent costs are expensed as incurred. License costs are capitalized and amortized over the estimated life of the license agreement.

***Impairment of Long-Lived Assets***

We review property, plant, and equipment and certain identifiable intangibles for impairment in accordance with Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of these assets is measured by comparing the carrying amount to future undiscounted cash flows the assets are expected to generate. If property, plant, and equipment and patents are considered to be impaired, the impairment to be recognized equals the amount by which the carrying value of the assets exceeds its estimated fair market value. No such impairment was recognized during the years ended December 31, 2008, 2007 and 2006.

***Warrant Liability***

We account for our warrants in accordance with EITF 00-19, which defines how freestanding contracts that are indexed to and potentially settled in a company's own stock should be measured and classified. The general concept under EITF 00-19 is that contracts that could require net-cash settlement should be classified as assets or liabilities and contracts that only provide for settlement in shares should be classified as equity. In order for a contract to be classified as equity, each of the specific conditions enumerated in EITF 00-19 must be met; these conditions are intended to identify situations in which net cash settlement could be forced upon the issuer. As part of our November 2008 financing, we issued warrants with a five year term to purchase 10,344,828 shares of our common stock at \$2.30 per share. In accordance with EITF 00-19, we are required to classify the fair value of the warrants issued as a liability, with subsequent changes in fair value to be recorded as income (loss) on change in fair value of warrant liability. The fair value of the warrants is determined using the Black-Scholes-Merton (Black-Scholes) option pricing model and is affected by changes in inputs to that model including our stock price, expected stock price volatility and contractual term. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability.

***Revenue Recognition***

We currently recognize revenue resulting from the licensing and use of our technology and intellectual property. Such licensing agreements may contain multiple elements, such as up-front fees, payments related to the achievement of particular milestones and royalties. Revenue from up-front fees for licensing agreements that contain multiple elements are generally deferred and recognized on a straight-line basis over the term of the agreement. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement, and royalties received are recognized as earned. Revenue from collaborative agreements and grants are recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the relevant collaborative agreement or grant.

***Research and Development Costs***



Our research and development expenses consist primarily of salaries and related personnel expenses, costs associated with clinical trials and regulatory submissions; costs associated with preclinical activities such as toxicology studies; certain patent-related costs such as licensing; facilities-related costs such as depreciation; lab equipment and supplies. Clinical trial expenses include payments to vendors such as clinical research organizations,

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**StemCells, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

contract manufacturers, clinical trial sites, laboratories for testing clinical samples and consultants. All research and development costs are expensed as incurred.

***Stock-Based Compensation***

On January 1, 2006, we adopted SFAS No. 123 (revised 2004) (SFAS 123R), *Share-Based Payment*, SFAS 123R requires us to expense the fair value of our stock-based compensation awards to employees. We apply SFAS 123R to new awards, as well as to awards that vest, are modified, repurchased, or cancelled after the date of adoption. The compensation cost we record for these awards are based on their grant-date fair value as calculated and amortized over their vesting period. See Note 7, *Stock-Based Compensation* for further information.

We account for stock options granted to non-employees in accordance with SFAS 123 and Emerging Issues Task Force (EITF) 96-18 *Accounting For Equity Instruments That Are Issued To Other Than Employees For Acquiring, Or In Conjunction With Selling, Goods Or Services*, and accordingly, expense the estimated fair value of such options as calculated using the Black-Scholes model over the service period. The estimated fair value is re-measured at each reporting date and is amortized over the remaining service period.

***Income Taxes***

We account for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes* (SFAS 109) and FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*, as amended by FASB Staff Position No. 48-1 (FIN 48). This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Income tax receivables and liabilities and deferred tax assets and liabilities are recognized based on the amounts that more likely than not will be sustained upon ultimate settlement with taxing authorities.

Developing our provision for income taxes and analyzing our uncertain tax positions requires significant judgment and knowledge of federal and state income tax laws, regulations and strategies, including the determination of deferred tax assets and liabilities and, any valuation allowances that may be required for deferred tax assets.

We assess the realization of our deferred tax assets to determine whether an income tax valuation allowance is required. Based on such evidence that can be objectively verified, we determine whether it is more likely than not that all or a portion of the deferred tax assets will be realized. The main factors that we consider include:

Cumulative losses in recent years;

Income/losses expected in future years;

The applicable statute of limitations.

Tax benefits associated with uncertain tax positions are recognized in the period in which one of the following conditions is satisfied: (1) the more likely than not recognition threshold is satisfied; (2) the position is ultimately settled through negotiation or litigation; or (3) the statute of limitations for the taxing authority to examine and challenge the position has expired. Tax benefits associated with an uncertain tax position are derecognized in the

period in which the more likely than not recognition threshold is no longer satisfied.

We concluded that the realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)*****Net Loss per Share***

Basic net loss per share is computed based on the weighted-average number of shares of our common stock outstanding during the period. Diluted net loss per share is computed based on the weighted-average number of shares of our common stock and other dilutive securities.

The following are the basic and dilutive net loss per share computations for the last three fiscal years:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Net loss	\$ (29,086,777)	\$ (25,022,802)	\$ (18,948,380)
Weighted average shares outstanding used to compute basic and diluted net loss per share	82,716,455	79,772,351	74,611,196
Basic and diluted net loss per share	\$ (0.35)	\$ (0.31)	\$ (0.25)

Outstanding options, restricted stock units and warrants to purchase shares of our common stock were excluded from the computation of diluted net loss per share because the effect would have been anti-dilutive for all periods presented below:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Outstanding options	8,340,530	9,028,810	8,501,503
Restricted stock units	1,650,000		
Outstanding warrants	11,599,828	1,355,000	1,930,658
Total	21,590,358	10,383,810	10,432,161

***Comprehensive Income (Loss)***

Comprehensive income (loss) is comprised of net losses and other comprehensive income (or OCI). OCI includes certain changes in stockholders' equity that are excluded from net losses. Specifically, we include in OCI changes in unrealized gains and losses on our marketable securities. Comprehensive loss for the years ended December 31, 2008, 2007 and 2006 has been reflected in the Consolidated Statements of Stockholders' Equity.

The activity in OCI is as follows:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
(Decrease) increase in unrealized gains(losses) on marketable securities	\$ (1,806,768) 2,082,894	\$ (2,756,268)	\$ 3,442,125

Recognition in net loss, other than temporary impairment of  
marketable securities

Reclassification adjustment for gains on marketable securities  
included in net income

(715,584)

Other comprehensive income (loss)	\$ 276,126	\$ (3,471,852)	\$ 3,442,125
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### ***Recent Accounting Pronouncements***

In February 2008, the FASB issued FASB Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-2 delays the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except for certain items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). We are currently evaluating the impact of SFAS 157 on our consolidated financial statements for items within the scope of FSP 157-2, which will become effective beginning with our first quarter of 2009.

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**StemCells, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* (FSP 157-3). FSP 157-3 clarifies the application of SFAS 157, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP shall be effective upon issuance, including prior periods for which financial statements have not been issued. Revisions resulting from a change in the valuation technique or its application shall be accounted for as a change in accounting estimate. Adoption of FSP 157-3 did not have a material impact on our consolidated financial statements.

In April 2008, the FASB issued FSP No. 142-3, *Determination of the Useful Life of Intangible Assets* (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). FSP 142-3 amends paragraph 11(d) of SFAS 142 to require an entity to use its own assumptions about renewal or extension of an arrangement, adjusted for the entity-specific factors in paragraph 11 of SFAS 142, even when there is likely to be substantial cost or material modifications. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, with early adoption prohibited. We do not expect that the adoption of FSP 142-3 on January 1, 2009, to have a material effect on our consolidated financial condition and results of operations.

In December 2007, FASB issued SFAS No. 141R, *Business Combinations* (SFAS 141R). SFAS 141R provides companies with principles and requirements on how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, liabilities assumed, and any non controlling interest in the acquiree as well as the recognition and measurement of goodwill acquired in a business combination. SFAS 141R also requires certain disclosures to enable users of the financial statements to evaluate the nature and financial effects of the business combination. Acquisition costs associated with the business combination will generally be expensed as incurred. SFAS 141R is effective for business combinations occurring in fiscal years beginning after December 15, 2008. Early adoption of SFAS 141R is not permitted. We will be required to apply the guidance in SFAS 141R to any future business combinations effective January 1, 2009.

In June 2008, the FASB issued EITF Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*. EITF Issue No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. EITF Issue No. 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. We do not expect the adoption of EITF Issue No. 07-05 to have a material impact on our consolidated financial statements.

Table of Contents**StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)****Note 2. Financial Instruments*****Cash, cash equivalents and marketable securities***

The following table summarizes the fair value of our cash, cash equivalents and available-for-sale securities held in our investment portfolio:

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
<b>December 31, 2008</b>				
Cash	\$ 243,883	\$	\$	\$ 243,883
Cash equivalents (money market accounts)	29,799,103			29,799,103
Marketable debt securities, current (maturity within 1 year)	4,002,537		(7,748)	3,994,789
Marketable equity securities, current	186,803			186,803
Total cash, cash equivalents, and marketable securities	\$ 34,232,326	\$	\$ (7,748)	\$ 34,224,578
<b>December 31, 2007</b>				
Cash	\$ 549,544	\$	\$	\$ 549,544
Money market accounts	5,079,564			5,079,564
Marketable debt securities (maturity within 90 days)	4,130,404		(343)	4,130,061
Total cash equivalents	9,209,968		(343)	9,209,625
Marketable debt securities (maturity within 1 year)	26,680,824	19,137	(3,548)	26,696,413
Total marketable securities, current	26,680,824	19,137	(3,548)	26,696,413
Marketable debt securities	1,180,394	9,109		1,189,503
Marketable equity securities	2,269,697		(308,229)	1,961,468
Total marketable securities, non-current	3,450,091	9,109	(308,229)	3,150,971
Total cash, cash equivalents, and marketable securities	\$ 39,890,427	\$ 28,246	\$ (312,120)	\$ 39,606,553

At December 31, 2008, our investment in marketable debt securities were in money market accounts composed primarily of US Treasury securities and repurchase agreements that are backed by US Treasury securities.

Our investment in marketable equity securities consists of ordinary shares of ReNeuron Group plc, a publicly listed UK corporation. In July 2005, we entered into an agreement with ReNeuron. As part of the agreement, we granted ReNeuron a license that allows ReNeuron to exploit their c-mycER conditionally immortalized adult human neural stem cell technology for therapy and other purposes. We received shares of ReNeuron common stock, as well as a cross-license to the exclusive use of ReNeuron's technology for certain diseases and conditions, including lysosomal storage diseases, spinal cord injury, cerebral palsy, and multiple sclerosis. The agreement also provides for full settlement of any potential claims that either we or ReNeuron might have had against the other in connection with any putative infringement of certain of each party's patent rights prior to the effective date of the agreement. In July and August 2005 we received approximately 8,836,000 ordinary shares of ReNeuron common stock (net of approximately 104,000 shares that were transferred to NeuroSpheres), and subsequently, as a result of



Table of Contents**StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)**

certain anti-dilution provisions in the agreement, we received approximately 1,261,000 more shares, net of approximately 18,000 shares that were transferred to NeuroSpheres. In February 2007, we sold 5,275,000 shares for net proceeds of approximately \$3,075,000. We recognized approximately \$716,000 as realized gain from this transaction. We owned approximately 4,822,000 ordinary shares of ReNeuron at December 31, 2008 and 2007.

If the fair value of a security is below its carrying value, we evaluate whether we have the intent and ability to retain our investment for a period of time sufficient to allow for any anticipated recovery to the cost of the investment, and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. Other-than-temporary declines in estimated fair value of all marketable securities are charged to other income (expense), net. After considering various criteria, including the duration of the impairment and our intent to liquidate all or part of our investment within a reasonably short period of time, we determined that the impairment of our investment in ordinary shares of ReNeuron (marketable equity securities) (see Note 2, Financial Instruments, below), was other than temporary. For the year ended December 31, 2008, we recorded on our Consolidated Statements of Operations under Other Income (expense) a loss of \$2,082,894, which is the difference between the investment's carrying value and its quoted market price at that date. No other than temporary impairment was recognized during the years ended December 31, 2007 and 2006.

Changes in fair value as a result of changes in market price per share or the exchange rate between the US dollar and the British pound are accounted for under other comprehensive income (loss) if deemed temporary and are not recorded as other income or loss until the shares are disposed of and a gain or loss realized or an impairment is considered other than temporary. After considering various criteria, including the duration of the impairment and our intent to sell within a reasonably short period of time, we determined that the impairment of our investment in shares of ReNeuron (marketable equity securities) was other than temporary. For the year ended December 31, 2008, we recorded, on our Consolidated Statements of Operations under Other Income (expense), a loss of \$2,082,894, which is the difference between the investment's carrying value and its quoted market price at that date. No other than temporary impairment was recognized during the years ended December 31, 2007 and 2006.

In accordance with FASB Staff Position FAS 115-1 and FAS 124-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, the following table shows the gross unrealized losses and fair value for those investments that were in an unrealized loss position as of December 31, 2008, aggregated by investment category and the length of time that individual securities have been in a continuous loss position:

	<b>Less than 12 Months</b>		<b>12 Months of Greater</b>		<b>Total</b>	
	<b>Fair Value</b>	<b>Unrealized Loss</b>	<b>Fair Value</b>	<b>Unrealized Loss</b>	<b>Fair Value</b>	<b>Unrealized Loss</b>
<b>December 31, 2008</b>						
Marketable debt securities	\$ 3,994,789	\$ (7,748)	\$	\$	\$ 3,994,789	\$ (7,748)
Marketable equity securities	186,803				186,803	
<b>Total</b>	<b>\$ 4,181,592</b>	<b>\$ (7,748)</b>	<b>\$</b>	<b>\$</b>	<b>\$ 4,181,592</b>	<b>\$ (7,748)</b>

Unrealized losses in our marketable debt securities portfolio are due to four U.S. corporate debt securities primarily consisting of commercial paper. For these securities, the unrealized losses are primarily due to a change in interest rates. Because we have the ability and intent to hold these investments until a forecasted recovery of carrying value, which may be maturity or call date, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2008. See Note 1, Summary of Significant Accounting Policies Cash Equivalents and Marketable Securities, for further discussion of the criteria used to determine impairment of our marketable securities.

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**StemCells, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

***Note Receivable***

In December 2007, we committed to make a secured loan of up to \$3.8 million to Progenitor Cell Therapy, LLC (PCT) in return for a period of exclusivity to allow for due diligence and negotiation of a possible acquisition transaction. Of this amount, \$1.0 million was lent and outstanding at December 31, 2007 with the maturity date within twelve months from the effective date of the loan. In March 2008, we terminated discussions to acquire PCT. In April 2008 we were repaid the loan in accordance with its terms.

In December 2008, we made a secured loan of £200,000 (approximately \$298,000) to Stem Cell Sciences Plc in connection with a potential acquisition transaction. The loan accrues interest at 8% per annum and is repayable on June 23, 2009 if the acquisition of SCS does not occur before then.

**Note 3. Fair Value Measurement**

Effective January 1, 2008, we adopted SFAS 157, except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FSP SFAS 157-2. SFAS 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, SFAS 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

*Level 1* Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

*Level 2* Directly or indirectly observable inputs other than in Level 1, that include quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active.

*Level 3* Unobservable inputs which are supported by little or no market activity that reflects the reporting entity's own assumptions about the assumptions that market participants would use in pricing the asset or liability

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

In accordance with SFAS 157, we measure our financial assets and liabilities at fair value. Our cash equivalents and marketable securities are classified within Level 1 or Level 2. This is because our cash equivalents and marketable securities are valued primarily using quoted market prices or alternative pricing sources and models utilizing market observable inputs. We currently do not have any Level 3 financial assets or liabilities.

**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)**

The following table presents assets and liabilities measured at fair value:

	<b>Fair Value Measurement at Reporting Date Using Quoted Prices in Active Markets for</b>		<b>Significant Other Observable Inputs</b>	<b>As of</b>
	<b>Identical Assets (Level 1)</b>		<b>(Level 2)</b>	<b>December 31, 2008</b>
Assets				
Cash Equivalents:				
Money market funds	\$ 356,000	\$		\$ 356,000
U.S. Treasury obligations	29,443,103			29,443,103
Marketable Securities:				
Equity securities	186,803			186,803
Corporate bonds			2,798,580	2,798,580
Asset-backed securities			1,196,209	1,196,209
Total assets	\$ 29,985,906	\$	3,994,789	\$ 33,980,695
Liabilities				
Bond obligation	\$	\$	1,009,166	\$ 1,009,166

**Note 4. Property, Plant and Equipment**

Property, plant and equipment balances at December 31 are summarized below:

	<b>2008</b>	<b>2007</b>
Building and improvements	\$ 3,404,969	\$ 3,397,639
Machinery and equipment	6,308,603	6,002,945
Furniture and fixtures	369,068	369,068
	10,082,640	9,769,652
Less accumulated depreciation and amortization	(6,909,172)	(5,864,248)
Property, plant and equipment, net	\$ 3,173,468	\$ 3,905,404

Depreciation expense was approximately \$1,045,000 in 2008, \$1,012,000 in 2007, and \$944,000 in 2006.



**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)****Note 5. Intangible and Other Assets**

The components of our intangible assets at December 31 are summarized below:

<b>Intangible Asset Class</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
<b>2008</b>			
Patents	\$ 979,612	\$ (515,255)	\$ 464,357
License agreements	1,785,998	(1,604,817)	181,181
Total intangible assets	\$ 2,765,610	\$ (2,120,072)	\$ 645,538
<b>2007</b>			
Patents	\$ 979,612	\$ (459,452)	\$ 520,160
License agreements	1,761,623	(1,519,116)	242,507
Total intangible assets	\$ 2,741,235	\$ (1,978,568)	\$ 762,667

Amortization expense was approximately \$142,000 in 2008, \$163,000 in 2007, and \$101,000 in 2006.

The expected future annual amortization expense based on current balances of our intangible assets is as follows:

**For the year ending December 31:**

2009	\$ 119,687
2010	\$ 107,499
2011	\$ 69,718
2012	\$ 68,545
2013	\$ 66,212

Other assets at December 31 are summarized below:

	<b>2008</b>	<b>2007</b>
Prepaid royalties	\$ 551,199	\$ 180,250
Security deposit (building lease)	750,000	752,500
Restricted cash (letter of credit)	778,079	778,079
Total other non-current assets	\$ 2,079,278	\$ 1,710,829

**Note 6. Accrued Expenses and Other**

Accrued expenses at December 31 are summarized below:

	2008	2007
External services	\$ 466,360	\$ 360,340
Employee compensation	1,526,115	1,885,249
Other	268,770	216,663
Total accrued expenses and other liabilities	\$ 2,261,245	\$ 2,462,252

**Note 7. Stock-Based Compensation**

We currently grant options under three equity incentive plans and as of December 31, 2008, we had 15,227,243 shares authorized under these three plans. At our annual stockholders meeting held on June 12,

**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)**

2007, our stockholders approved an amendment to our 2006 Equity Incentive Plan to provide for an annual increase in the number of shares of common stock available for issuance under the plan each January 1 (beginning January 1, 2008) equal to 4% of the outstanding common shares as of that date. The amendment further provided an aggregate limit of 30,000,000 shares issuable pursuant to stock based awards under the plan. Under these three plans we may grant incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units and performance-based shares to our employees, directors and consultants, at prices determined by our Board of Directors. Incentive stock options may only be granted to employees under these plans with a grant price not less than the fair market value on the date of grant.

Generally, stock options and restricted stock units granted to employees have a maximum term of ten years, and vest over a four year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three-year service period. We may grant options with different vesting terms from time to time. Upon employee termination of service, any unexercised vested option will be forfeited three months following termination or the expiration of the option, whichever is earlier.

Our compensation expense for stock options and restricted stock units issued from our equity incentive plans for the last three fiscal years was as follows:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Research and development expense	\$ 1,845,523	\$ 1,347,239	\$ 1,048,697
General and administrative expense	1,909,348	1,558,056	1,236,334
Total stock-based compensation expense and effect on net loss	\$ 3,754,871	\$ 2,905,295	\$ 2,285,031

As of December 31, 2008, we have approximately \$5,207,000 of total unrecognized compensation expense related to unvested awards granted under our various share-based plans that we expect to recognize over a weighted-average period of 2.1 years.

The fair value of options granted is estimated as of the date of grant using the Black-Scholes option pricing model and expensed on a pro-rata straight-line basis over the period in which the stock options vest. The Black-Scholes option pricing model requires certain assumptions as of the date of grant. The weighted-average assumptions used for the last three fiscal years are as follows:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Expected life (years)(1)	7.24	6.25	6.25
Risk-free interest rate(2)	3.23%	4.36%	4.72%
Expected volatility(3)	94.0%	95.2%	109.0%
Expected dividend yield(4)	0%	0%	0%



- (1) The expected term represents the period during which our stock-based awards are expected to be outstanding. In 2008 we estimated this amount based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations. The expected term in 2007 and 2006 is equal to the average of the contractual life of the stock option and its vesting period as of the date of grant.
- (2) The risk-free interest rate is based on U.S. Treasury debt securities with maturities close to the expected term of the option as of the date of grant.
- (3) Expected volatility is based on historical volatility over the most recent historical period equal to the length of the expected term of the option as of the date of grant.
- (4) We have neither declared nor paid dividends on any share of common stock and we do not expect to do so in the foreseeable future.

Table of Contents**StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)**

At the end of each reporting period we estimate forfeiture rates based on our historical experience within separate groups of employees and adjust the stock-based compensation expense accordingly.

A summary of our stock option activity and related information for the last three fiscal years is as follows:

	<b>Number</b>	<b>Outstanding Options</b>	<b>Weighted-Average</b>	<b>Aggregate</b>
	<b>of Shares</b>	<b>Weighted-Average</b>	<b>Remaining</b>	<b>Intrinsic</b>
		<b>Exercise</b>	<b>Contractual</b>	<b>Value(1)</b>
		<b>Price</b>	<b>Term</b>	
<b>Balance at December 31, 2005</b>	6,608,109	\$ 3.02		
Granted	2,818,684	\$ 2.38		
Exercised	(369,214)	\$ 1.82		
Cancelled (forfeited and expired)	(556,076)	\$ 2.82		
<b>Balance at December 31, 2006</b>	8,501,503	\$ 2.88		
Granted	2,484,100	\$ 2.33		
Exercised	(175,186)	\$ 1.20		
Cancelled (forfeited and expired)	(1,781,607)	\$ 4.91		
<b>Balance at December 31, 2007</b>	9,028,810	\$ 2.36	7.26	\$ 826,558
Granted	353,000	\$ 1.24		
Exercised	(114,700)	\$ 1.11		
Cancelled (forfeited and expired)	(926,580)	\$ 2.44		
<b>Balance at December 31, 2008</b>	8,340,530	\$ 2.32	6.55	\$ 692,739
Exercisable at December 31, 2008	5,726,441	\$ 2.33	5.76	\$ 635,969
Vested and expected to vest(2)	7,927,918	\$ 2.32	6.46	\$ 685,157

(1) Aggregate intrinsic value represents the value of the closing price per share of our common stock on the last trading day of the fiscal period in excess of the exercise price multiplied by the number of options outstanding or exercisable.

(2) Shares include options vested and those expected to vest net of estimated forfeitures.

The estimated weighted average fair value per share of options granted was approximately \$1.00 in 2008, \$1.85 in 2007, and \$2.37 in 2006, based on the assumptions in the Black-Scholes model discussed above. Total intrinsic value of options exercised at time of exercise was approximately \$39,000 in 2008, \$397,000 in 2007, and \$453,000 in 2006.

The following is a summary of changes in unvested options:

<b>Unvested Options</b>	<b>Number of Options</b>		<b>Weighted Average Grant Date Fair Value</b>
Unvested options at December 31, 2007	4,428,209	\$	2.01
Granted	353,000		1.00
Vested	(1,792,976)		2.05
Cancelled	(374,144)		1.95
Unvested options at December 31, 2008	2,614,089	\$	1.85

The estimated fair value of options vested were approximately \$3,671,000 in 2008, \$3,173,000 in 2007 and \$2,292,000 in 2006.

**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)**

The following table presents weighted average exercise price and term information about significant option groups outstanding at December 31, 2008:

<b>Options Outstanding at December 31, 2008</b>				
<b>Range of</b>		<b>Weighted</b>	<b>Weighted</b>	<b>Aggregate Intrinsic</b>
<b>Exercise Prices</b>	<b>Number</b>	<b>Average</b>	<b>Average</b>	<b>Value at</b>
	<b>Outstanding</b>	<b>Remaining</b>	<b>Exercise</b>	<b>December 31,</b>
		<b>Term (Yrs.)</b>	<b>Price</b>	<b>2008</b>
Less than \$2.00	2,340,086	5.5	\$ 1.17	\$ 692,739
\$2.00 \$3.99	5,312,661	7.1	\$ 2.44	
\$4.00 \$5.99	687,783	6.1	\$ 5.27	
	8,340,530		\$ 2.32	\$ 692,739

<b>Vested Options Outstanding at December 31, 2008</b>		
<b>Range of Exercise Prices</b>	<b>Number Outstanding</b>	<b>Weighted Average Exercise Price</b>
Less than \$2.00	1,981,126	\$ 1.16
\$2.00 \$3.99	3,161,619	\$ 2.53
\$4.00 \$5.99	583,696	\$ 5.26
	5,726,441	\$ 2.33

***Restricted Stock Units***

In March 2008, we granted restricted stock units to certain employees that entitle the holders to receive shares of our common stock upon vesting. These restricted stock units vest over a three-year period from the date of grant: one-third of the award will vest on each grant date anniversary over the following three years. The fair value of restricted stock units granted are based upon the market price of the underlying common stock as if it were vested and issued on the date of grant.

A summary of our restricted stock unit activity for the year ended December 31, 2008 is as follows:

<b>Number of RSUs</b>	<b>Weighted-Average Grant Date Fair Value</b>
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Outstanding at January 1, 2008			
Granted	1,650,000	\$	1.26
Exercised			
Cancelled			
Outstanding at December 31, 2008	1,650,000	\$	1.26
Vested RSUs outstanding at December 31, 2008			

#### *Stock Appreciation Rights*

In July 2006, we granted cash-settled Stock Appreciation Rights (SARs) to certain employees under the 2006 Equity Incentive Plan. The SARs give the holder the right, upon exercise, to the difference between the price per share of our common stock at the time of exercise and the exercise price of the SAR. The exercise price of the SAR is equal to the market price of our common stock at the date of grant. The SARs vest 25% on the first anniversary of the grant date and 75% vest monthly over the remaining three-year service period. Compensation expense is based on the fair value of SARs which is calculated using the Black-Scholes option pricing model. The share-based compensation expenses and liability are re-measured at each reporting date through the date of settlement. The share-based compensation liability as re-measured at December 31, 2008 was \$500,720.

**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)**

The following is a summary of the changes in non-vested SARs for the last three fiscal years:

	<b>2008</b>		<b>2007</b>		<b>2006</b>	
	<b>Number</b>	<b>Weighted Average Exercise Price</b>	<b>Number</b>	<b>Weighted Average Exercise Price</b>	<b>Number</b>	<b>Weighted Average Exercise Price</b>
Outstanding at January 1,	1,478,219	\$ 2.00	1,564,599	\$ 2.00		
Granted					1,564,599	\$ 2.00
Exercised						
Forfeited	(47,390)		(86,380)	\$ 2.00		
Outstanding at December 31,	1,430,829	\$ 2.00	1,478,219	\$ 2.00	1,564,599	\$ 2.00
Exercisable at December 31,	864,467	\$ 2.00	506,754	\$ 2.00		

The total compensation expense related to SARs was approximately \$73,000 in 2008, \$135,000 in 2007 and \$294,000 in 2006. At December 31, 2008, approximately \$318,000 of unrecognized compensation expense related to SARs is expected to be recognized over a weighted average period of approximately 1 year. The resulting effect on net loss and net loss per share attributable to common stockholders is not likely to be representative of the effects in future periods, due to changes in the fair value calculation which is dependent on the stock price, volatility, interest and forfeiture rates, additional grants and subsequent periods of vesting.

**Note 8. Wind-down and exit costs**

In October 1999, we relocated to California from Rhode Island and established a wind-down reserve for the estimated lease payments and operating costs of the Rhode Island facilities through an expected disposal date of June 30, 2000. We did not fully sublet the Rhode Island facilities in 2000. Even though we intend to dispose of the facility at the earliest possible time, we cannot determine with certainty a fixed date by which such disposal will occur. In light of this uncertainty, we periodically re-evaluate and adjust the reserve. We consider various factors such as our lease payments through to the end of the lease, operating expenses, the current real estate market in Rhode Island, and estimated subtenant income based on actual and projected occupancy.

The components of our wind-down reserve at December 31 are as follows:

	<b>2008</b>	<b>2007</b>
Accrued wind-down reserve at beginning of period	\$ 4,875,000	\$ 5,512,000
Less actual expenses recorded against estimated reserve during the period	(1,293,000)	(1,420,000)

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Additional expense recorded to revise estimated reserve at period-end	866,000	783,000
Revised reserve at period-end	4,448,000	4,875,000
Add deferred rent at period end	1,065,000	1,268,000
Total accrued wind-down expenses at period-end (current and non current)	\$ 5,513,000	\$ 6,143,000
Accrued wind-down expenses, current portion	\$ 1,420,000	\$ 1,374,000
Non current portion	4,093,000	4,769,000
Total accrued wind-down expenses	\$ 5,513,000	\$ 6,143,000

**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)****Note 9. Commitments and Contingencies*****Leases******Bonds Payable***

We entered into direct financing transactions with the State of Rhode Island and received proceeds from the issuance of industrial revenue bonds totaling \$5,000,000 to finance the construction of Rhode Island's pilot manufacturing facility. The related lease agreements are structured such that lease payments fully fund all semiannual interest payments and annual principal payments through maturity in August 2014. Interest rates vary with the respective bonds' maturities, ranging from 8.2% to 9.5%. The outstanding principal and interest owed at December 31, 2008 was approximately \$1,345,000. The bonds contain certain restrictive covenants which limit, among other things, the payment of cash dividends and the sale of the related assets.

***Operating leases***

We entered into a fifteen-year lease agreement for a laboratory facility in Rhode Island in connection with a sale and leaseback arrangement in 1997. The lease term expires June 30, 2013. The lease contains escalating rent payments, which we recognize on a straight-line basis. At December 31, 2008, deferred rent expense was approximately \$1,065,000 for this facility and is included as part of the wind-down accrual on the accompanying Consolidated Balance Sheet.

We entered into and amended a lease agreement for an approximately 68,000 square foot facility located at the Stanford Research Park in Palo Alto, California. The facility includes space for animals, laboratories, offices, and a GMP (Good Manufacturing Practices) suite. GMP facilities can be used to manufacture materials for clinical trials. The lease term expires March 31, 2010. Under the term of the agreement we were required to provide a letter of credit for a total of approximately \$778,000, which serves as a security deposit for the duration of the lease term. The letter of credit issued by our financial institution is collateralized by a certificate of deposit for the same amount, which is reflected as restricted cash in other assets, non-current on our Consolidated Balance Sheets. The lease contains escalating rent payments, which we recognize on a straight-line basis. At December 31, 2008, deferred rent was approximately \$437,000 and is reflected as deferred rent on our Consolidated Balance Sheet. At December 31, 2008, we had a space-sharing agreement covering approximately 10,451 square feet of this facility. We receive base payments plus a proportionate share of the operating expenses based on square footage over the term of the agreement.

The table below summarizes the components of rent expense for the fiscal year ended December 31, as follows:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Rent expense	\$ 3,077,430	\$ 3,077,431	\$ 2,967,911
Sublease income	(809,065)	(606,398)	(616,600)
Rent expense, net	\$ 2,268,365	\$ 2,471,033	\$ 2,351,311





**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)**

Future minimum payments under all leases and bonds payable at December 31, 2008 are as follows:

	<b>Bonds Payable</b>	<b>Capital Leases</b>	<b>Operating Leases</b>	<b>Sublease Income</b>
2009	\$ 244,572	\$ 19,862	\$ 3,536,843	\$ 652,624
2010	242,559	6,623	1,767,304	97,508
2011	242,321		1,171,875	
2012	240,666		1,171,875	
2013	237,593		732,422	
Thereafter	136,852			
Total minimum lease payments	1,344,563	26,485	\$ 8,380,319	\$ 750,132
Less amounts representing interest	335,396	1,217		
Present value of bonds payable and capital lease payments	1,009,167	25,268		
Less current maturities	149,167	18,739		
Bonds payable, less current maturities	\$ 860,000	\$ 6,529		

***Contingencies***

In July 2006, we filed suit against Neuralstem, Inc. in the Federal District Court for the District of Maryland, alleging that Neuralstem's activities violate claims in four of the patents we exclusively licensed from NeuroSpheres. Neuralstem has filed a motion for dismissal or summary judgment in the alternative, citing Title 35, Section 271(e)(1) of the United States Code, which says that it is not an act of patent infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information to the FDA. Neuralstem argues that because it does not have any therapeutic products on the market yet, the activities complained of fall within the protection of Section 271(e)(1) — that is, basically, that the suit is premature. This issue will be decided after discovery is complete. Subsequent to filing its motion to dismiss, in December 2006, Neuralstem petitioned the U.S. Patent and Trademark Office (PTO) to reexamine two of the patents in our infringement action against Neuralstem, namely U.S. Patent No. 6,294,346 (claiming the use of human neural stem cells for drug screening) and U.S. Patent No. 7,101,709 (claiming the use of human neural stem cells for screening biological agents). In April 2007, Neuralstem petitioned the PTO to reexamine the remaining two patents in the suit, namely U.S. Patent No. 5,851,832 (claiming methods for proliferating human neural stem cells) and U.S. Patent No. 6,497,872 (claiming methods for transplanting human neural stem cells). These requests were granted by the PTO and, in June 2007, the parties voluntarily agreed to stay the pending litigation while the PTO considers these reexamination requests. In October 2007, Neuralstem petitioned the PTO to reexamine a fifth patent, namely U.S. Patent No. 6,103,530, which claims a culture medium for proliferating mammalian neural stem cells. In April 2008, the PTO upheld the 832 and 872 patents, as amended, and issued Notices of Intent to Issue an *Ex Parte* Reexamination Certificate for both. In August 2008, the PTO upheld the 530 patent, as amended, and issued a Notice

of Intent to Issue an *Ex Parte* Reexamination Certificate. The remaining two patents are still under review by the PTO.

In May 2008, we filed a second patent infringement suit against Neuralstem and its two founders, Karl Johe and Richard Garr. In this suit, which we filed in the Federal District Court for the Northern District of California, we allege that Neuralstem's activities infringe claims in two patents we exclusively license from NeuroSpheres, specifically U.S. Patent No. 7,361,505 (claiming composition of matter of human neural stem cells derived from any source material) and U.S. Patent No. 7,115,418 (claiming methods for proliferating human neural stem cells). In addition, we allege various state law causes of action against Neuralstem arising out of its repeated derogatory statements to the public about our patent portfolio. Also in May 2008, Neuralstem filed suit against us and

**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)**

NeuroSpheres in the Federal District Court for the District of Maryland seeking a declaratory judgment that the 505 and 418 patents are either invalid or are not infringed by Neuralstem and that Neuralstem has not violated California state law. In August 2008, the California court transferred our lawsuit against Neuralstem to Maryland for resolution on the merits. We anticipate that the Maryland District Court will consolidate these actions in some manner prior to trial.

**Note 10. Warrant Liability**

In November 2008, we sold 13,793,104 units to institutional investors at a price of \$1.45 per unit, for gross proceeds of \$20,000,000. The units, each of which consisted of one share of common stock and a warrant to purchase 0.75 shares of common stock at an exercise price of \$2.30 per share, were offered as a registered direct offering under an effective shelf registration statement previously filed with and declared effective by the Securities and Exchange Commission. We received total proceeds, net of offering expenses and placement agency fees, of approximately \$18,637,000. We recorded the fair value of the warrants to purchase 10,344,828 shares of our common stock as a liability. The fair value of the warrant liability will be revalued at the end of each reporting period, with the change in fair value of the warrant liability recorded as a gain or loss in our Consolidated Statement of Operations. We used the Black-Scholes option pricing model to estimate the fair value of these warrants. In using this model, we make certain assumptions about risk-free interest rates, dividend yields, volatility and expected term of the warrants. Risk-free interest rates are derived from the yield on U.S. Treasury securities. Dividend yields are based on our historical dividend payments, which have been zero to date. Volatility is derived from the historical volatility of our common stock as traded on Nasdaq. The expected term of the warrants is based on the time to expiration of the warrants from the date of measurement.

The assumptions used for the Black-Scholes option pricing model are as follows:

	<b>To Calculate Fair Value on Date of Issuance</b>	<b>To Calculate Fair Value at December 31, 2008</b>
Expected life (years)	5.5	5.4
Risk-free interest rate	2.42%	1.60%
Expected volatility	83.8%	84.5%
Expected dividend yield	0%	0%

  

	<b>At December 31, 2008</b>	<b>At November 17, 2008</b>	<b>Change in Fair Value of Warrant Liability at December 31, 2008</b>
Fair value of warrant liability	\$ 8,439,931	\$ 7,502,690	\$ 937,241

The fair value of the warrants will continue to be classified as a liability until such time as the warrants are exercised, expire or an amendment of the warrant agreement renders these warrants to be no longer classified as a liability.

**Note 11. Common Stock**

We have neither declared nor paid dividends on any share of common stock and do not expect to do so in the foreseeable future.

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**StemCells, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

***Sale of common stock***

Major transactions involving our common stock for the previous three years include the following:

In November 2008, we sold 13,793,104 units to institutional investors at a price of \$1.45 per unit, for gross proceeds of \$20,000,000. The units, each of which consisted of one share of common stock and a warrant to purchase 0.75 shares of common stock at an exercise price of \$2.30 per share, were offered as a registered direct offering under an effective shelf registration statement previously filed with and declared effective by the Securities and Exchange Commission. We received total proceeds net of offering expenses and placement agency fees of approximately \$18,637,000.

In April 2007, a warrant issued as part of our June 2004 financing was exercised to purchase an aggregate of 575,658 shares of our common stock at \$1.90 per share. We issued 575,658 shares of our common stock and received proceeds of approximately \$1,094,000.

In December 2006, we filed a Prospectus Supplement announcing the entry of a sales agreement with Cantor Fitzgerald & Co (Cantor) under which up to 10,000,000 shares may be sold from time to time under a shelf registration statement. In 2007 and 2008, we sold a total of 2,012,600 shares of our common stock under this agreement at an average price per share of \$2.68 for gross proceeds of approximately \$5,392,000. Cantor is paid compensation equal to 5.0% of the gross proceeds pursuant to the terms of the agreement.

In April 2006, we sold 11,750,820 shares of our common stock to institutional investors at a price of \$3.05 per share, for gross proceeds of approximately \$35,840,000. The shares were offered as a registered direct offering under an effective shelf registration statement previously filed with and declared effective by the Securities and Exchange Commission. We received total proceeds, net of offering expenses and placement agency fees, of approximately \$33,422,000. No warrants were issued as part of this financing transaction.

In March 2006, a warrant issued as part of our June 2004 financing was exercised to purchase an aggregate of 526,400 shares of our common stock at \$1.89 per share. We issued 526,400 shares of our common stock and received proceeds of approximately \$995,000.

***Stock Issued For Technology Licenses***

Under license agreements with NeuroSpheres, Ltd., we obtained an exclusive patent license covering all uses of certain neural stem cell technology. We made up-front payments to NeuroSpheres of 65,000 shares of our common stock and \$50,000, and will make additional cash payments as stated milestones are achieved. Effective in 2004, we began making annual \$50,000 payments, creditable against certain royalties.

Pursuant to the terms of a license agreement with the California Institute of Technology (Cal Tech) and our acquisition of its wholly owned subsidiary, StemCells California, we issued 14,513 shares of common stock to Cal Tech. We issued an additional 12,800 shares of common stock to Cal Tech with a market value of approximately \$40,000 in May 2000, upon execution of an amendment adding four families of patent applications to the license agreement. In August 2002, we acquired an additional license from Cal Tech for a different technology, pursuant to which we issued 27,535 shares of our common stock with a market value of approximately \$35,000. We also issued (with a market value of approximately \$10,000 each year), 6,924 shares in 2008, 3,865 shares in 2007, 3,848 shares in

2006, and 9,535 shares (market value of approximately \$15,000) in 2004 of our common stock to Cal Tech for the issuance and annual license fees of two patents covered under this additional license.

**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)*****Common Stock Reserved***

We reserved the following shares of common stock for the exercise of options, warrants and other contingent issuances of common stock, as of December 31, 2008:

Shares reserved for share based compensations	16,542,533
Shares reserved for warrants related to financing transactions	11,599,828
Shares reserved for license agreements	85,363
Shares reserved for possible future issuances under an effective shelf registration	62,678,858
Total	90,906,582

**Note 12. Grant Revenue**

In October 2008, we were awarded a \$305,000 grant from the National Institute of Diabetes and Digestive and Kidney Diseases to research and develop a potential cell-based therapeutic for liver disease arising from infection by the hepatitis C virus. The award is a Phase I grant under the Small Business Innovation Research (SBIR) Program of the National Institutes of Health. Should the objectives of the research funded by this grant be met, we anticipate applying for Phase II and additional funding under the SBIR Program. We recognized approximately \$26,000 as grant revenue in 2008 related to this grant.

In September 2004, we were awarded a Small Business Technology Transfer (STTR) grant for approximately \$464,000 for studies in Alzheimer's disease conducted over an 18 month period. The grant supported joint work with Dr. George A. Carlson of the McLaughlin Research Institute (MRI) in Great Falls, Montana. We received and recognized approximately \$26,000 in 2006, \$186,000 in 2005, and \$38,000 in 2004 as grant revenue, the remainder was reimbursed to MRI.

**Note 13. 401(k) Plan**

Our 401(k) Plan covers substantially all of our employees. Participants in the plan are permitted to contribute a fixed percentage of their total annual cash compensation to the plan (subject to the maximum employee contribution defined by law). We match 50% of employee contributions, up to a maximum of 6% of each employee's eligible compensation in the form of shares of common stock. We recorded an expense of \$181,000 in 2008, \$179,000 in 2007, and \$157,000 in 2006 for our contributions under our 401(k) Plan.

**Note 14. Income Taxes**

In July 2006, the FASB issued FIN 48 which clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. We adopted FIN 48 effective January 1, 2007. The adoption of FIN 48 did not impact our consolidated financial condition, results of operations or cash flows. At the adoption date of January 1, 2007 and as of December 31, 2008 and 2007, we have not recorded any unrecognized tax benefits. Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting





**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)**

purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities at December 31 are as follows:

	<b>2008</b>	<b>2007</b>
Deferred tax assets:		
Capitalized research and development costs	\$ 38,670,000	\$ 31,779,000
Net operating losses	42,247,000	42,716,000
Research and development credits	6,671,000	6,103,000
Accrued wind down cost	1,780,000	1,950,000
Stock-based compensation	465,000	245,000
Impaired asset	833,000	
Other	458,000	329,000
	91,124,000	83,122,000
Valuation allowance	(91,124,000)	(83,122,000)
Net deferred tax assets	\$	\$

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately \$8,002,000 in 2008, \$8,632,000 in 2007, and \$7,105,000 in 2006.

As of December 31, 2008, we had the following:

Net operating loss carry forwards for federal income tax purposes of approximately \$119,500,000 which expire in the years 2009 through 2028.

Federal research and development tax credits of approximately \$4,911,000 which expire in the years 2009 through 2028.

Net operating loss carry forwards for state income tax purposes of approximately \$26,964,000 which expire in the years 2009 through 2029.

State research and development tax credits of approximately \$2,666,000 (\$1,760,000 net of federal tax effect) which do not expire.

The effective tax rate as a percentage of income before income taxes differs from the statutory federal income tax rate (when applied to income before income taxes) for the years ended December 31 as follows:

<b>2008</b>	<b>2007</b>	<b>2006</b>
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Statutory federal income tax (benefit) rate	(34)%	(34)%	(34)%
State income tax (benefit) rate	(6)	(6)	(6)
Increase resulting from:			
Expenses not deductible for taxes	5.8	4.9	5.3
Increase in valuation allowance	34.2	35.1	34.7
Effective tax (benefit) rate	0%	0%	0%

Our policy is to recognize interest and penalties related to income tax matters in income tax expense. Because we have no tax liabilities, no tax-related interest and penalties have been expensed in our consolidated statements of operations during 2008 or accrued as a liability in our consolidated balance sheets at December 31, 2008. We do not anticipate any significant changes to total unrecognized tax benefits as a result of settlement of audits or the expiration of statute of limitations within the next twelve months.

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**StemCells, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

We file U.S. federal income tax returns, as well as tax returns with the State of California and the State of Rhode Island. Due to the carry forward of unutilized net operating losses and research and development credits, our federal tax returns from 1994 forward remain subject to examination by the Internal Revenue Service, and our State of California tax returns from 2000 forward and our State of Rhode Island tax returns from 2003 forward remain subject to examination by the respective state tax authorities.

**Note 15. Subsequent Events**

At December 31, 2008, we owned 4,821,924 shares of ReNeuron (marketable equity securities) trading on the Alternative Investment Market (a sub-market of the London Stock Exchange) with a carrying and fair market value of \$187,000. In the first quarter of 2009, we sold in aggregate, approximately 2,900,000 shares of ReNeuron and received proceeds of approximately \$512,000 for a realized gain of approximately \$400,000.

In February 2009, a warrant issued as part of a June 2004 financing arrangement, was exercised to purchase an aggregate of 164,474 shares of our common stock at \$1.90 per share. We issued 164,474 shares of our common stock and received proceeds of approximately \$312,500.

In the first quarter of 2009, we sold in aggregate, 3,325,000 shares of our common stock pursuant to the sales agreement we entered into with Cantor, at an average price per share of \$2.10 for gross proceeds of approximately \$6,999,000. Cantor is paid compensation equal to 5.0% of the gross proceeds pursuant to the terms of the agreement.

In March 2009, we entered into an asset purchase agreement with Stem Cell Sciences Plc ( SCS ) to acquire substantially all of the operating assets and liabilities of SCS (the Acquisition ). The Acquisition is subject to customary closing conditions, including the approval of the stockholders of SCS, and is expected to close shortly after the SCS extraordinary general meeting scheduled for March 27, 2009. As consideration for the operating assets and liabilities to be acquired, we will issue to SCS, except as provided below, 2,650,000 shares of our common stock, plus waive certain commitments of SCS to repay approximately \$715,000 in cash made available by us to SCS for working capital purposes. The actual number of shares delivered to SCS at the closing will depend on the SCS operating subsidiaries having a specified minimum amount of working capital. In connection with the Acquisition, we also entered into a loan facility agreement with SCS pursuant to which we agreed to lend up to \$415,000 to SCS for working capital prior to the closing of the Acquisition. Upon closing of the Acquisition, we will waive SCS obligations to repay any amounts borrowed by SCS under this loan facility agreement as well as £200,000 (approximately \$298,000) previously borrowed by SCS from us in December 2008. The principal amounts owed on both of these loans accrue interest at 8% per annum and such principal amounts and accrued interest will become due and payable on June 23, 2009 if the Acquisition does not occur beforehand.

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**Table of Contents****StemCells, Inc.****Notes to Consolidated Financial Statements (Continued)****QUARTERLY FINANCIAL DATA (unaudited)**

	<b>2008 Quarter Ended</b>			
	<b>December 31</b>	<b>September 30</b>	<b>June 30</b>	<b>March 31</b>
	<b>(In thousands, except per share amounts)</b>			
Total revenue	\$ 172	\$ 12	\$ 30	\$ 17
Operating expenses(1)	7,270	5,857	6,929	6,914
Other income (expense), net(2)	(2,985)	101	183	352
Net loss	(10,082)	(5,744)	(6,716)	(6,545)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.07)	\$ (0.08)	\$ (0.09)

	<b>2007 Quarter Ended</b>			
	<b>December 31</b>	<b>September 30</b>	<b>June 30</b>	<b>March 31</b>
	<b>(In thousands, except per share amounts)</b>			
Total revenue	\$ 30	\$ 13	\$ 8	\$ 6
Operating expenses(1)	8,353	7,749	6,041	6,505
Other income, net	497	582	609	1,880
Net loss	(7,826)	(7,154)	(5,424)	(4,619)
Basic and diluted net loss per share	\$ (0.10)	\$ (0.09)	\$ (0.07)	\$ (0.06)

(1) Includes adjustment of wind-down accrual see Note 8.

(2) Other expense, net, for the quarter ended December 31, 2008, includes a loss of \$937,241 relating to the change in fair value of our warrant liability see Note 10, and a \$2,082,894 other than temporary impairment of marketable securities see Note 2.

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

None.

**Item 9A. *CONTROLS AND PROCEDURES***

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

The Company's management, with the participation of its chief executive officer and chief financial officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual report. Based on this evaluation, the Company's principal executive officer and principal financial officer concluded that these disclosure controls and procedures are effective to ensure that the information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the requisite time periods, and to provide reasonable assurance that information required to be disclosed by the Company in such reports is accumulated and communicated to the Company's management, including its chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

***Changes in Internal Controls***

There have been no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2008, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

***Management's Report on Internal Control Over Financial Reporting***

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's management, including its principal executive officer and principal financial officer, assessed the effectiveness of its internal control over financial reporting based on the framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The evaluation of the design and operating effectiveness of internal control over financial reporting include among others 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.

During the fiscal year 2008, the Company periodically tested the design and operating effectiveness of its internal control over financial reporting. Among other matters, 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. Nonetheless, it is important to acknowledge that due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's internal control over financial reporting as of December 31, 2008 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their report below.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM  
ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Board of Directors and Stockholders  
StemCells, Inc.

We have audited StemCells, Inc. (a Delaware corporation) and subsidiary s (collectively, the Company ) internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

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

In our opinion, StemCells, Inc. and subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008 based on criteria established in *Internal Control – Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of StemCells, Inc. and subsidiary as of December 31, 2008 and 2007, and the related consolidated statements of operations, changes in stockholders equity, and cash flows for each of the three years in the period ended December 31, 2008 and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ GRANT THORNTON LLP



San Francisco, California  
March 11, 2009

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**Item 9B. *Other Information***

None

**PART III**

**Item 10. *DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT***

**Executive Officers**

Below are the name, age and principal occupations for the last five years of each executive officer of StemCells, Inc., as of February 28, 2009. All such persons have been elected to serve until their successors are elected and qualified or until their earlier resignation or removal.

Martin M. McGlynn, President and Chief Executive Officer	62	Martin M. McGlynn joined the company on January 2001, when he was appointed President and Chief Executive Officer of the company and of its wholly-owned subsidiary, StemCells California, Inc. He was elected to the Board of Directors in February 2001.
Ann Tsukamoto, Ph.D. Executive Vice President, Research and Development	56	Ann Tsukamoto, Ph.D., joined the company in November 1997 as Senior Director of Scientific Operations; was appointed Vice President, Scientific Operations in June 1998; Vice President, Research and Development in February 2002; and Chief Operating Officer, with responsibility for the company's research and development efforts, in November 2006. In October 2008, Dr. Tsukamoto was appointed to the newly created position of Executive Vice President, Research and Development with responsibility for the Company's scientific and clinical development programs.
Rodney K.B. Young, Chief Financial Officer and Vice President, Finance and Administration	46	Rodney K.B. Young joined the company in September 2005 as Chief Financial Officer and Vice President, Finance. In November 2006 he became CFO and Vice President, Finance and Administration. He is responsible for functions that include Finance, Information Technology and Investor Relations. From 2003 to 2005, Mr. Young was Chief Financial Officer and a director of Extropy Pharmaceuticals, Inc., a private biopharmaceutical company focused on developing drugs for pediatric indications.
Stewart Craig, Ph.D. Senior Vice President, Development and Operations	47	Stewart Craig, Ph.D., joined the company in September 2008 with responsibilities for Development, Manufacturing, Regulatory, Quality Systems and Facilities. From 2005 to 2008, Dr. Craig was Chief Technology Officer and Vice President of Progenitor Cell Therapy, a contract services provider for research, development, manufacture and commercialization of cell-based therapies, prior to which he has held executive positions at Xcyte Therapies, Osiris Therapeutics and SyStemix.

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Kenneth Stratton, JD  
General Counsel

Kenneth Stratton, JD, joined the company in February 2007 as General Counsel, with responsibility for corporate compliance and legal affairs. In March 2008, he assumed responsibilities for the Human Resources function. Prior to StemCells, Mr. Stratton served as Deputy General Counsel for Threshold Pharmaceuticals and as Senior Legal Counsel for Medtronic's Vascular business unit.

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### **Directors**

Below are the name, age and principal occupations for the last five years of each Director of StemCells, Inc., as of February 29, 2008. Directors are elected to staggered three year terms.

Eric H. Bjerkholt	49	Eric H. Bjerkholt was elected to the Board of Directors in March 2004. Mr. Bjerkholt joined Sunesis Pharmaceuticals, Inc., in 2004 as Senior Vice President and Chief Financial Officer. Since February 2007, he has served as Senior Vice President, Corporate Development and Finance, and Chief Financial Officer. From 2002 to 2004, Mr. Bjerkholt was Senior Vice President and Chief Financial Officer at IntraBiotics Pharmaceuticals, Inc.
Ricardo B. Levy, Ph.D.	64	Ricardo B. Levy, Ph.D. was elected to the Board of Directors in September 2001. He currently serves on several boards of directors.
Martin M. McGlynn	62	Martin M. McGlynn was elected to the Board of Directors in February 2001. He is President and Chief Executive Officer of the Company, a position he has held since January 2001.
Roger Perlmutter, M.D., Ph.D.	56	Roger M. Perlmutter, M.D., Ph.D., was elected to the Board of Directors in December 2000. He is Executive Vice President, Research and Development, of Amgen, Inc., a position he has held since January 2001.
John J. Schwartz, Ph.D.	74	John J. Schwartz, Ph.D., was elected to the Board of Directors in December 1998 and was elected Chairman of the Board at the same time. He is currently President of Quantum Strategies Management Company.
Irving Weissman, M.D.	69	Irving L. Weissman, M.D., was elected to the Board of Directors in September 1997. He is the Virginia and Daniel K. Ludwig Professor of Cancer Research, Professor of Pathology and Professor of Developmental Biology at Stanford.

Certain other information required by this Item regarding our officers, Directors, and corporate governance is incorporated herein by reference to the information appearing under the headings Information About Our Directors and Information About Ownership of Our Common Stock in our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days of December 31, 2008 (the 2009 Proxy Statement ).

### **Item 11. EXECUTIVE COMPENSATION**

The information required by this Item is incorporated by reference from Item 5 of this Annual Report on Form 10-K and our Proxy Statement for the 2009 Annual Meeting of Stockholders.

### **Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this Item is incorporated by reference from Item 5 of this Annual Report on Form 10-K and from our Proxy Statement for the 2009 Annual Meeting of Stockholders.

**Item 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS***

The information required by this Item is incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Stockholders.

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**Item 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES***

The information required by this Item is incorporated by reference from our Proxy Statement for the 2009 Annual Meeting of Stockholders.

**PART IV**

**Item 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES***

**(a) The following documents are included as part of this Annual Report on Form 10-K.**

(1) Financial Statements:

The financial statements filed as part of this Report are listed and indexed under Item 8 above.

(2) Financial Statement Schedules:

Schedules are not included herein because they are not applicable or the required information appears in the Financial Statements or Notes thereto.

(3) Exhibits.

The documents set forth below are filed herewith or incorporated by reference to the location indicated.

<b>Exhibit No.</b>	<b>Title or Description</b>
3.1-	Restated Certificate of Incorporation of the Registrant
3.2--	Amended and Restated By-Laws of the Registrant
4.1^^	Specimen common stock Certificate
4.2{*}	Warrant to Purchase common stock Riverview Group, LLC
4.3XXXX	Warrant to Purchase common stock Cantor Fitzgerald & Co.
4.4&2	Warrant to Purchase common stock Riverview Group, LLC
4.5&4	Form of Warrant Certificate issued to a certain purchasers of the Registrant's common stock in November 2008
10.1	Form of at-will Employment Agreement between the Registrant and most of its employees
10.2*	Form of Agreement for Consulting Services between the Registrant and members of its Scientific Advisory Board
10.3	Form of Nondisclosure Agreement between the Registrant and its Contractors
10.4*	1992 Equity Incentive Plan
10.5*	1992 Stock Option Plan for Non-Employee Directors
10.6+	Research Agreement, dated as of March 16, 1994, between NeuroSpheres, Ltd. and Registrant
10.7+	Lease Agreement between the Registrant and Rhode Island Industrial Facilities Corporation, dated as of August 1, 1992
10.8+	First Amendment to Lease Agreement between Registrant and The Rhode Island Industrial Facilities Corporation dated as of September 15, 1994
10.9#	Lease Agreement, dated as of November 21, 1997, by and between Hub RI Properties Trust, as Landlord, and CytoTherapeutics, Inc., as Tenant
10.10!	

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Consulting Agreement, dated as of September 25, 1997, between Dr. Irving Weissman and the Registrant

10.11!!! StemCells, Inc. 1996 Stock Option Plan

10.12!!! 1997 StemCells Research Stock Option Plan (the 1997 Plan )

10.13!!! Form of Performance-Based Incentive Option Agreement issued under the 1997 Plan

10.14XX License Agreement, dated as of October 30, 2000, between the Registrant and NeuroSpheres Ltd.

10.15XX Letter Agreement, dated January 2, 2001, between the Registrant and Martin McGlynn

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<b>Exhibit No.</b>	<b>Title or Description</b>
10.16XX	Lease, dated February 1, 2001, between the Board of Trustees of Stanford University and the Registrant
10.17\$\$	2001 Equity Incentive Plan
10.18^^	Form of Securities Purchase Agreement, dated as of June 16, 2004, between the Registrant and certain Purchasers parties thereto
10.19^^	Form of Warrant
10.20^^	Amended and Restated 2004 Equity Incentive Plan of the Registrant
10.21§	License Agreement, dated as of July 1, 2005, between the Registrant and ReNeuron Limited
10.22§§	Letter Agreement, effective as of September 6, 2005, between the Registrant and Rodney K.B. Young
10.23XX	Side Letter, dated March 17, 2001, between the Company and Oleh S. Hnatiuk regarding NeuroSpheres License Agreement, dated October 30, 2000
10.24@	License Agreement, dated April 1, 1997, by and among Registrant, NeuroSpheres Ltd. and NeuroSpheres Holdings Ltd.
10.25§§§	Indemnification Agreement, dated July 9, 2008, by and between registrant and NeuroSpheres Holdings, LTD.
10.26	Facility Agreement, dated December 23, 2008, by and among registrant and Stem Cell Sciences Plc
10.27	Second Facility Agreement, dated March 1, 2009, by and among registrant, Stem Cell Sciences Plc and Stem Cell Sciences Holdings Limited
10.28	Asset Purchase Agreement, dated March 1, 2009, by and between registrant and Stem Cell Sciences Plc
14.1	Code of Ethics
21X	Subsidiaries of the Registrant
23.1	Consent of Grant Thornton, LLP , Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Securities Exchange Act Rule 13(a)-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Martin McGlynn, Chief Executive Officer)
31.2	Certification Pursuant to Securities Exchange Act Rule 13(a)-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rodney K.B. Young, Chief Financial Officer)
32.1	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Martin McGlynn, Chief Executive Officer)
32.2	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Rodney K.B. Young, Chief Financial Officer)

! Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997 and filed on November 14, 1997.

!! Previously filed with the Commission as an Exhibit to and incorporated by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.

!!! Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-8, File No. 333-37313.

\$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's annual report on Form 10-K for the fiscal year ended December 31, 1998 and filed on March 31,



1999.

\$\$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's definitive proxy statement filed May 1, 2001.

% Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on December 10, 2003.

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- %% Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003
- &1 Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on April 15, 2003.
- &2 Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on May 13, 2003.
- &3 Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on May 15, 2003.
- &4 Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on November 12, 2008.
- \* Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, Registration Statement on Form S-1, File No. 33-45739.
- \*\* Confidential treatment requested as to certain portions. The term "confidential treatment" and the mark \*\* as used throughout the indicated Exhibits mean that material has been omitted and separately filed with the Commission.
- ^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on December 29, 2006.
- ^ Previously filed with the Commission as an Exhibit to, and incorporated by reference to, the Registrant's Registration Statement on Form S-3, File No. 333-151891.
- ^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on June 17, 2004.
- ^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-8, File No. 333-118263.
- {\*} Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on December 7, 2001.
- + Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1, File No. 33-85494.
- ++ Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1, File No. 33-91228.

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- Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and filed on March 15, 2007.
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- §§ Previously filed with the Commission as an Exhibit to and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on September 7, 2005.
- §§§ Previously filed with the Commission as an Exhibit to and incorporated herein by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008
- X Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1, File No. 333-45496.
- XX Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 and filed on April 2, 2001.
- XXX Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Registration Statement filed on Form S-1 as amended to Form S-3, File No. 333-61726.
- XXXX Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Registration Statement filed on Form S-3, File No. 333-75806.
- @ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2006 and filed on April 1, 1997.
- # Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's annual report on Form 10-K for the fiscal year ended December 31, 1997 and filed on March 30, 1998.

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**SIGNATURES**

Pursuant to the requirements of 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.

STEMCELLS, INC.

By: /s/ MARTIN MCGLYNN  
 Martin McGlynn  
 PRESIDENT AND CHIEF  
 EXECUTIVE OFFICER

Dated: March 13, 2009

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 capacities and on the dates indicated.

<b>Signature</b>	<b>Capacity</b>	<b>Date</b>
/s/ Martin McGlynn Martin McGlynn	President and Chief Executive Officer and Director (principal executive officer)	March 13, 2009
/s/ Rodney K.B. Young Rodney K.B. Young	Chief Financial Officer (principal financial officer)	March 13, 2009
/s/ George Koshy George Koshy	Chief Accounting Officer (principal accounting officer)	March 13, 2009
/s/ Eric Bjerkholt Eric Bjerkholt	Director	March 13, 2009
/s/ Ricardo B. Levy, Ph.D. Ricardo B. Levy, Ph.D.	Director	March 13, 2009
/s/ Roger M. Perlmutter, M.D. Roger M. Perlmutter, M.D.	Director	March 13, 2009
/s/ John J. Schwartz, Ph. D. John J. Schwartz, Ph.D.	Director, Chairman of the Board	March 13, 2009

/s/ Irving L. Weissman, M.D.

Director

March 13, 2009

Irving L. Weissman, M.D.

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10.25§§§	Indemnification Agreement, dated July 9, 2008, by and between registrant and NeuroSpheres Holdings, LTD.

10.26	Facility Agreement, dated December 23, 2008, by and among registrant and Stem Cell Sciences Plc
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<b>Exhibit No.</b>	<b>Title or Description</b>
10.27	Second Facility Agreement, dated March 1, 2009, by and among registrant, Stem Cell Sciences Plc and Stem Cell Sciences Holdings Limited
10.28	Asset Purchase Agreement, dated March 1, 2009, by and between registrant and Stem Cell Sciences Plc
14.1	Code of Ethics
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23.1	Consent of Grant Thornton, LLP , Independent Registered Public Accounting Firm
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