STEMCELLS INC
Form 10-K
March 21, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2012

or

¨ **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	**94-3078125**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

7707 GATEWAY BLVD

NEWARK, CA **94560**
(Address of principal offices) **(zip code)**

Registrant s telephone number, including area code:

(510) 456-4000

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.01 par value	NASDAQ Capital Market

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

None

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

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 x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 ¨ (Do not check if a smaller reporting company) Smaller reporting company x

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

Aggregate market value of common stock held by non-affiliates at June 30, 2012: $20,259,263. 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 4, 2013: 38,877,586 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement relating to the registrant s 2013 Annual Meeting of Stockholders to be filed with the Commission pursuant to Regulation 14A are incorporated by reference in Part III of this report.

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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. FORWARD-LOOKING STATEMENTS SPEAK ONLY AS OF THE DATE OF THIS REPORT. WE DO NOT UNDERTAKE ANY OBLIGATION TO PUBLICLY UPDATE ANY FORWARD-LOOKING STATEMENTS.

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NOTE REGARDING REFERENCES TO OUR COMMON STOCK

Throughout this Form 10-K, the words we, us, our, and StemCells refer to StemCells, Inc., including our directly and indirectly wholly-owned subsidiaries. Common stock refers to the common stock of StemCells, Inc., $0.01 par value.

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PART I

Item 1. ***BUSINESS***

Overview

StemCells, Inc. is engaged in the research, development, and commercialization of stem cell therapeutics and related tools and technologies for academia and industry. We believe that understanding cells and cell biology, and in particular stem cells, will play an increasingly important role in the understanding of human diseases and in the discovery of new medical therapies. Consequently, we are focused on developing and commercializing (i) stem and progenitor cells as the basis for novel therapeutics and therapies, and (ii) cells and related tools and technologies to enable stem cell-based research and drug discovery and development.

Our primary research and development efforts are focused on identifying and developing stem and progenitor cells as potential therapeutic agents. Our lead product development program is our CNS Program, in which we are developing applications for HuCNS-SC® cells, our proprietary human neural stem cell product candidate. We estimate that degenerative conditions of the central nervous system (CNS) currently affect more than 30 million people in the United States.[1]

We are currently in clinical development with our HuCNS-SC cells for a range of diseases and disorders of the central nervous system. The CNS includes the brain, spinal cord and eye, and we are currently the only stem cell company in clinical development for indications in all three organs comprising the CNS, specifically:

(i) with respect to the brain,

in October 2012, we published in *Science Translational Medicine,* a peer-reviewed journal, the data from our Phase I clinical trial in Pelizeaus-Merzbacher Disease (PMD), a fatal myelination disorder in the brain. The data showed preliminary evidence of progressive and durable donor cell-derived myelination in all four patients transplanted with HuCNS-SC cells. Three of the four patients showed modest gains in neurological function; the fourth patient remained stable;

we have completed a Phase I clinical trial in infantile and late infantile neuronal ceroid lipofuscinosis (NCL, also known as Batten disease), which is a neurodegenerative disorder of the brain. The data from that trial showed that our HuCNS-SC cells were well tolerated, non-tumorigenic, and there was evidence of engraftment and long-term survival of the transplanted HuCNS-SC cells; and

we are also conducting preclinical studies of our HuCNS-SC cells in Alzheimer s disease,

(ii) with respect to the spinal cord, we are conducting a Phase I/II clinical trial of our HuCNS-SC cells in Switzerland for the treatment of chronic spinal cord injury. In February 2013, we announced that the first patient cohort had completed the trial, and that the data from this first cohort showed multi-segment gains in sensory function in two of the three patients; the third patient remained stable; and

(iii) with respect to the eye, in June 2012, we initiated a Phase I/II clinical trial for dry age-related macular degeneration (AMD), the most common form of AMD, with the first patient enrolled and dosed in October 2012.

In our tools and technologies programs, we are engaged in developing and commercializing applications of our technologies to enable stem cell-based research. We currently market a range of proprietary cell culture products, research grade human cells, and antibody reagents under the SC Proven® brand. Our cell culture products include iSTEM®, GS1-R®, GS2-M®, RHB-A®, RHB-Basal®, NDiff227 , NDiff® N2, and NDiff

[1] 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, and the Cincinnati Children s Hospital Medical Center.

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N27 supplements. Our cell lines available for research use include human neural stem cells and hFB101 , ultra primary human fibroblasts for genetic reprogramming. Our antibody reagents include STEM24 , STEM101®, STEM121®, and STEM123®, which can be used for cell detection, isolation and characterization. Academic and industrial laboratories conducting stem cell research need specialized cell culture products and reagents for the derivation, growth, maintenance, and manipulation of stem cells, as well as their detection, isolation and characterization in both *in vitro* and *in vivo* models. As this type of research continues to grow, the market for such cell culture products and reagents should also continue to expand. We are seeking to leverage our proprietary technologies, including technologies relating to embryonic stem cells, induced pluripotent stem (iPS) cells, and tissue-derived (adult) stem cells, for use in stem cell-based research. Several of the cell technologies and intellectual property related to our enabling cell technologies programs were acquired in April 2009 through our acquisition of substantially all of the operating assets and liabilities of Stem Cell Sciences Plc (SCS).

The Potential of Our Tissue-Derived Cell-Based Therapeutics

Stem cells are building block cells as they produce all the mature functional cell types found in normal organs. Stem cells have two defining characteristics: (i) they produce all of the mature cell types of the particular organ, and (ii) they self renew that is, some of the cells developed from stem cells are themselves new stem cells. Progenitor cells are cells that have already developed from stem cells, but can still produce one or more mature cell types within an organ. Stem cells are rare; to date only four human stem cells have been identified and characterized *in vivo*: (i) the hemotopoietic stem cell, (ii) the mesenchymal stem cell, (iii) the neural stem cell, and (iv) the embryonic stem cell. Because of this self-renewal property, we believe that stem cell-based therapies may have the potential to return an impaired organ to proper function for the life of the patient.

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 the many substances essential to life. 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 of this naturally. Transplantation of stem or progenitor cells may therefore prevent the loss of, or even generate new, functional cells and thereby potentially maintain or restore organ function and the patient s health.

We are focused on identifying and purifying tissue-derived stem and progenitor cells for use in homologous therapy. Homologous therapy means the use of cells derived from a particular organ to treat a disease of that same organ (for example, use of brain-derived neural stem cells for treatment of CNS disorders). 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 is the most direct way to provide for engraftment and differentiation into functional cells, and should minimize the risk of transplantation or growth of unwanted cell types.

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. We are currently developing embryonic stem cells and iPS cells as potential research tools. We are not currently developing embryonic or induced pluripotent stem cells for therapeutic use, although we may in the future explore their applicability as cell-based therapeutic products.

Business Strategy

Our aim is to create a sustainable business based on our belief that understanding cells and cell biology will play an increasingly important role in life science research and in the discovery, development and implementation of new medical therapies. Our primary strategy is to identify multiple types of human stem and progenitor cells with therapeutic and commercial importance, to develop techniques and processes to purify these

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cells for direct transplant and to expand and bank these cells, to advance these cells into clinical development and ultimately, to commercialize them as cell-based therapeutic products.

The fundamental competencies required to execute this strategy are knowledge and expertise in cell biology, particularly stem cell biology, and a commitment to rigorous and robust research and development. We believe that these competencies are critical to identifying, characterizing and understanding cells with therapeutic potential and importance.

Consequently, we have made significant investments in our research and development, clinical and regulatory, and cell processing and process development capabilities. Our management and staff have many years of experience in the stem cell field and in developing potential cell therapies. Two of the four human stem cells identified and characterized to date (the hematopoietic and neural stem cells) were discovered by scientists who are currently on our staff, and we believe we were the first company to receive authorization from the FDA to conduct a clinical trial of a purified neural stem cell product candidate, as well as the first to complete such a clinical trial. We are committed to proving that groundbreaking science, especially in the field of stem cell biology, has the potential to create truly breakthrough medicine.

Many of our core competencies in cell biology have applicability beyond the development of therapeutic products. Therefore, another element of our business strategy is to leverage these core competencies to develop non-therapeutic applications for our cell technologies, which we believe represent nearer-term commercial opportunities. As scientific and medical research increasingly focuses on stem cells and cell biology, our technologies are expected to have utility as tools to help enable this research. We currently market specialized cell culture products and antibody reagents through our SC Proven product line and are seeking to develop and commercialize applications of our technologies for use in stem cell-based research.

Further, a key element of our business strategy is to obtain patent protection for the compositions, processes and uses of multiple types of cells, as well as for those technologies that appear applicable and useful to enable cell-based research. 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 therapeutics and enabling applications financially feasible. In addition to discovering and developing technologies in-house, we have obtained from various academic and commercial institutions rights to certain inventions relating to stem and progenitor cells, cell culture media, and technologies to reprogram, isolate and manipulate cells. 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 and cell technologies. We have created an extensive patent estate, see Patents, Proprietary Rights and Licenses, below.

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Therapeutic Product Development Programs

Overview

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

CNS Program	**Cell-based therapeutics to restore or preserve function to central nervous system tissue by protecting, repairing or replacing dysfunctional or damaged cells.**
Diseases and Disorders of the Brain	Pelizeaus-Merzbacher Disease: Four-patient Phase I clinical trial completed February 2012. Data from the Phase I trial was published in *Science Translational Medicine,* a peer-reviewed scientific journal, in October 2012 and showed preliminary evidence of new myelin in all four patients, and three of the four patients showed modest gains in neurological function; the fourth patient remained stable. The data also showed that the HuCNS-SC cells, the transplantation procedure, and the immunosuppression were all well tolerated. Demonstrated *in vivo* proof of principle by showing in the myelin deficient shiverer mouse that transplanted HuCNS-SC cells can: generate and integrate myelin producing oligodendrocytes into the mouse brain; and tightly wrap the mouse nerve axons to form myelin sheath. *Neuronal Ceroid Lipofuscinosis (also known as Batten disease):* Six-patient Phase I clinical trial completed in January 2009. Trial results showed that the HuCNS-SC cells, the transplantation procedure, and the immunosuppression were well tolerated and the cells were not tumorigenic, and that there was evidence of engraftment and survival of the transplanted cells.

Demonstrated *in vivo* proof of principle by showing in a mouse model for infantile NCL that transplanted HuCNS-SC cells can:

- continuously produce the enzyme that is deficient in infantile NCL;
- protect host neurons from death; and
- delay the loss of motor function in HuCNS-SC transplanted mice.

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	Alzheimer s Disease:
	In July 2012, reported data that showed our HuCNS-SC cells can restore memory in two mouse models relevant to Alzheimer s disease.
	Demonstrated that our HuCNS-SC cells are capable of engrafting and surviving in the hostile environment reflective of an Alzheimer s brain, which characteristically features abnormal accumulations of brain lesions called plaques and tangles.
Diseases and Disorders of the Spinal Cord	*Spinal Cord Injury:*
	Conducting 12-patient Phase I/II clinical trial in Switzerland for chronic spinal cord injury, including both complete and incomplete injuries.
	In February 2013, reported that the first patient cohort had completed the Phase I/II trial, and that two of the three patients in the first cohort showed multi-segment gains in sensory function; the third patient remained stable. The data also showed that the cells, the transplantation procedure, and the immunosuppression were all well tolerated.
	Demonstrated *in vivo* proof of principle by showing in a mouse model for spinal cord injury that transplanted HuCNS-SC cells can:
	restore motor function in injured animals;
	directly contribute to functional recovery (and that when human cells are ablated restored function is lost); and
	become specialized oligodendrocytes and neurons.
Diseases and Disorders of the Eye	*Age-Related Macular Degeneration:*
	16-patient Phase I/II clinical trial in dry AMD initiated in June 2012, with first patient enrolled and dosed in October 2012.
	Demonstrated *in vivo* proof of principle by showing in the Royal College of Surgeons rat, a widely accepted model for retinal degeneration, that HuCNS-SC cells can:

protect photoreceptor cells from death; and

prevent or slow loss of vision.

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 in which transplanting HuCNS-SC cells would protect or restore organ function of the patient before such function is irreversibly damaged or lost due to disease progression. Our initial target indications are

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(i) Pelizeaus-Merzbacher Disease, and more generally, diseases in which deficient myelination plays a central role, such as cerebral palsy or multiple sclerosis; (ii) spinal cord injury; and (iii) disorders in which retinal degeneration plays 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 and expanded composition of normal human neural stem cells. Alternative therapies based on cells derived from cancer cells, embryonic stem cells, iPS cells, animal-derived cells, or unpurified mixes of cell types have a significantly higher safety hurdle to overcome and while they may provide an effective therapy, technologies to remove potentially harmful cells are still being developed and tested. Furthermore, our HuCNS-SC cells can be directly transplanted, unlike embryonic stem cells or iPS cells, which require one or more prerequisite differentiation steps prior to administration in order to preclude teratoma formation (tumors of multiple differentiated cell types). It is still unclear whether cellular transplants derived from embryonic stem cells or iPS cells can avoid forming teratomas or other abnormal cellular structures due to contaminating cell types in the transplant product.

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 neural stem cells, suggesting the possibility of a continual replenishment of normal human neural cells in transplant recipients. In the longer term, then, we believe stem cells have the potential to restore or replace lost cells and cellular function.

We hold a substantial portfolio of issued and allowed patents in the neural stem cell field, which cover the isolation, expansion and use of neural stem and progenitor cells, as well as the compositions of the cells themselves. See Patents, Proprietary Rights and Licenses, below.

Diseases and Disorders of the Brain

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 that surrounds 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. PMD is most frequently diagnosed in early childhood and is associated with abnormal eye movements, abnormal muscle function, and in some cases, seizures. The course of the disease is marked by progressive neurological deterioration resulting in premature death.

In February 2012, we completed a Phase I clinical trial in PMD. A total of four patients were transplanted with HuCNS-SC cells and were evaluated periodically over a 12-month period. The study was designed to help detect evidence of new myelin, including by magnetic resonance imaging (MRI) of the brain, changes in neuropsychological tests of development and cognitive function, and clinical changes in neurological function. The trial was conducted at the University of California, San Francisco. In October 2012, we published the results of the trial in *Science Translational Medicine,* a peer-reviewed journal. The clinical data from this study showed evidence of new myelin in all four patients who were transplanted with HuCNS-SC cells. In addition, three of the four patients showed modest gains in neurological function; the fourth patient remained stable. The data also showed that the cells, the transplantation procedure and the immunosuppression regimen were all well tolerated.

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.

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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). Loss of myelin can also play a role in certain spinal cord indications. Based on our preclinical data, we believe our HuCNS-SC product candidate may have applicability to a range of myelin disorders.

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

Neuronal ceroid lipofuscinosis, which is often referred to as Batten disease, is a neurodegenerative disease that affects infants and young children. Infantile and late infantile NCL are brought on by inherited genetic mutations which result in either a defective or missing enzyme, leading to the accumulation of cellular waste product in various neuronal 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.

We completed a six-patient Phase I clinical trial of our HuCNS-SC cells in infantile and late infantile NCL in January 2009. We believe that this clinical trial was the first FDA-authorized trial to evaluate purified human neural stem cells as a potential therapeutic agent. The trial data demonstrated that the HuCNS-SC cells, the transplantation procedure and the immunosuppression regimen were well tolerated by all six patients, and the patients medical, neurological and neuropsychological conditions, following transplantation, appeared consistent with the normal course of the disease. In addition to this favorable safety profile, there was evidence of engraftment and long-term survival of the HuCNS-SC cells. This Phase I trial was conducted at OHSU Doernbecher Children s Hospital.

Our preclinical data demonstrate that HuCNS-SC cells, when transplanted in a mouse model of infantile NCL, engraft, migrate throughout the brain, produce the relevant missing enzyme, measurably reduce the toxic storage material in the brain, protect host neurons so that more of them survive, and delay the loss of motor function compared to a control group of non-transplanted mice. A summary of this data was published in September 2009 in the peer-reviewed journal *Cell Stem Cell.* We have also demonstrated *in vitro* that HuCNS-SC cells produce the enzyme that is deficient in late infantile NCL.

Alzheimer s Disease.

Alzheimer s disease is a progressive, fatal neurodegenerative disorder that results in loss of memory and cognitive function. Today, there is no cure or effective treatment option. According to the Alzheimer s Association, approximately 5.4 million Americans have Alzheimer s disease, including nearly half of people aged 85 and older. The prevalence of Alzheimer s disease is expected to increase rapidly as a result of our aging population.

In July 2012, we reported data that showed that our HuCNS-SC cells restored memory and enhanced synaptic function in two animal models relevant to Alzheimer s disease. This research was a result of a collaboration we entered into with a world renowned leader in Alzheimer s disease research at the University of California, Irvine (UCI) to study the therapeutic potential of our HuCNS-SC cells in Alzheimer s disease. Our collaborator s published research had shown that mouse neural stem cells enhance memory in a mouse model of Alzheimer s disease, and the goal of the collaboration was to replicate these results using our human neural stem cells.

Previously, we conducted studies of our HuCNS-SC cells in another model of Alzheimer s disease as part of a collaboration with researchers at the McLaughlin Research Institute. This research, which was funded by a National Institutes of Health (NIH) grant, demonstrated that our HuCNS-SC cells are capable of engrafting and surviving in the hostile environment reflective of an Alzheimer s brain, which characteristically features abnormal accumulations of brain lesions called plaques and tangles.

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In September 2012 the governing board of the California Institute of Regenerative Medicine (CIRM) approved our application for a Disease Team Therapy Development Research Award for the study of HuCNS-SC cells as a potential treatment for Alzheimer s disease. Under this disease team program, CIRM would provide up to $20 million in the form of a forgivable loan. Negotiation of the terms and conditions for this loan is on-going.

Previously, in September 2011, CIRM awarded us and our collaborators a Disease Team Therapy Development Planning Award which totaled approximately $100,000.

Diseases and Disorders of the Spinal Cord

According to a recent study initiated by the Christopher and Dana Reeve Foundation, nearly 1.3 million people in the United States are estimated to be living with chronic spinal cord injury. There are no therapies today that can address the paralysis or loss of function caused by a spinal cord injury, but neural stem cells may have the potential to provide a novel therapeutic approach.

We are conducting a Phase I/II clinical trial in Switzerland to evaluate our HuCNS-SC cells as a treatment for chronic spinal cord injury. The trial is being conducted at University Hospital Balgrist in Zurich and was authorized by Swissmedic, the regulatory agency for therapeutic products in Switzerland. A total of twelve patients are expected to enroll in the study, all of whom will be three to twelve months post-injury. The study will follow a progressive study design, beginning with patients with complete injuries and then enrolling patients with incomplete injuries, all as classified by the American Spinal Injury Association Impairment Scale (AIS). In addition to assessing safety, the trial will evaluate preliminary efficacy using defined clinical endpoints, such as changes in sensation, motor function, and bowel/bladder function. In February 2013, we reported that the first patient cohort, all of whom had complete injuries classified as AIS A, had completed the trial, and that data from this first cohort showed that two of the three patients showed multi-segment gains in sensory function compared to pre-transplant baseline. The gains in sensory function were first observed at the six month assessment and persisted to the 12 month assessment. The third patient remained stable. The trial is continuing to enroll patients (in the second cohort) and the first patient with an incomplete injury (classified as AIS B) was enrolled and dosed in September 2012.

The results of numerous preclinical studies demonstrate the therapeutic potential of our human neural stem cells for the treatment of spinal cord injury. Using a mouse model of spinal cord injury, our collaborators at the Reeve-Irvine Research Center at the University of California, Irvine have shown that our HuCNS-SC cells have the potential to protect and regenerate damaged nerves and nerve fibers, and that injured mice transplanted with our HuCNS-SC 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. The researchers 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. Moreover, our preclinical studies show that our human neural stem cells enable a significant and persistent recovery of motor function when transplanted in spinal cord-injured mice at both sub-acute and chronic injury time points.

In July 2012, the governing board of CIRM approved our application for a Disease Team Therapy Development Research Award for the study of HuCNS-SC cells as a potential treatment for cervical spinal cord injury. Under this disease team program, CIRM would have provided up to $20 million in the form of a forgivable loan. However, in March 2013, we elected not to borrow these funds from CIRM.

Diseases and Disorders of the Eye

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. A loss of function in retinal cells leads to impairment or loss of vision. The

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most common forms of retinal degeneration are age-related macular degeneration (AMD) and retinitis pigmentosa. AMD is the leading cause of vision loss and blindness in people over the age of 55 and afflicts some 30 million people worldwide.

In June 2012, we initiated a Phase I/II clinical trial in dry age-related macular degeneration, the more common form of AMD, and in October 2012, the first patient was enrolled and dosed with HuCNS-SC cells. The trial, which was authorized by the FDA in January 2012, is expected to enroll a total of 16 patients and will evaluate the safety and preliminary efficacy of our HuCNS-SC cells as a treatment for dry AMD. Patients vision will be evaluated using conventional methods of ophthalmological assessment at predetermined intervals over a one-year period.

Our preclinical data have shown that our HuCNS-SC cells, when transplanted in a well-established animal model of retinal degeneration, engraft long-term, can protect photoreceptors (the key cells involved in vision) from progressive degeneration, and can slow or prevent loss of visual function. In this model, called the Royal College of Surgeons (RCS) rat, a genetic mutation causes dysfunction of the retinal pigmented cells, which leads to progressive loss of the photoreceptors and ultimately, loss of visual function in the rat. Our preclinical data shows that our human neural stem cells protect both rod and cone photoreceptors in the eye from progressive degeneration and preserve visual function long term. The cone photoreceptors are light sensing cells that are highly concentrated within the macula of the human eye, and the ability to protect these cells suggests a promising approach to treating AMD. A summary of our preclinical data was featured as the cover article in February 2012 edition of the international peer-reviewed *European Journal of Neuroscience*.

Other CNS Collaborations.

We have collaborated on a number of research programs to assess both the *in vitro* potential of the HuCNS-SC cells and the effects of transplanting HuCNS-SC cells into preclinical animal models. One such collaboration was with researchers at the Stanford University School of Medicine that evaluated our human neural stem cells in animal models of stroke. The results of these studies demonstrated 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.

Tools and Technologies Programs

Overview

Cells, and stem cells in particular, are an important resource for researchers seeking to understand human diseases, advance medical research and develop more effective therapies. Stem cells provide potentially unlimited sources of different cell types owing to their ability to be expanded and subsequently differentiated into particular cell types. Embryonic stem cells, for example, have the ability to become any one of the more than 200 specialized cell types found in the human body (they are said to be *pluripotent*); induced pluripotent stem (iPS) cells also possess this ability. Because of this versatility, these cells are valuable tools for examining and researching the fundamental biology of cells and the pathways involved in early development and tissue formation. In recent years, the pharmaceutical industry has become increasingly interested in using stem cell-based assays in its drug discovery and development efforts.

Specialty Cell Culture Products and Antibody Reagents

Stem cell research is a growing and highly specialized field. Because of their nature, stem and progenitor cells are rare and they require specific conditions to survive and thrive. For this reason, researchers require specialized cell culture products that enable the derivation, growth, maintenance, and manipulation of such cells. One of the greatest challenges facing researchers is the limited quality and quantity of stem and progenitor cells available. The challenge is in maintaining the pluripotency or multipotency of stem or progenitor cells in culture,

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i.e., keeping these cells from differentiating into other cell types, which is their natural tendency. Our cell biology expertise has enabled us to develop and commercialize proprietary cell culture products to optimize the derivation, growth, maintenance, and differentiation of stem cells. In contrast to common industry practice, we have developed media formulations that are free of animal serum and feeder cells (helper cells added to promote cell growth), which are known sources of undesirable agents affecting stem cell performance and safety.

Our current range of cell culture products, which are sold under the SC Proven brand, includes iSTEM, GS1-R, GS2-M, RHB-A, RHB-Basal, NDiff N2, and NDiff 227. The following table describes each of these in more detail:

iSTEM	A serum-free, feeder-free medium that maintains mouse embryonic stem cells (ESCs) in their pluripotent ground state by using selective small molecule inhibitors to block the pathways which induce differentiation.
RHB-A	A defined, serum-free culture medium for the selective culture of human and mouse neural stem cells and their maintenance and expansion as adherent cell populations.
RHB-Basal	A defined, serum-free basal medium. When supplemented with specific growth factors, this media is specifically formulated for the propagation and differentiation of adherent neural stem cells. RHB-Basal can also be tailored to specific-cell type requirements by the addition of customer preferred supplements.
NDiff N2	A defined serum-free cell culture supplement for the derivation, maintenance, expansion and/or differentiation of human and mouse ESCs and tissue-derived neural stem cells supplement.
NDiff N2-AF	A serum-free and animal component-free version of NDiff N2.
NDiff 227	A defined, serum-free medium for the differentiation of mouse ESCs to neural cell types.
NDiff N27	Defined, serum-free cell culture supplement for the derivation, maintenance, expansion and/or differentiation of human and mouse ESCs induced pluripotent stem (iPS) cells and tissue-derived neural stem cells.
NDiff N27-AF	A serum-free and animal component-free version of NDiff N27.
GS1-R	The first defined, serum-free media formulation shown to enable the derivation and long-term maintenance of true, germline competent rat ESCs without the addition of cytokines or growth factors.
GS2-M	A defined, serum- and feeder-free medium for the derivation and long-term maintenance of true, germline competent mouse iPS cells.

We also currently market a number of antibody reagents for use in cell detection, isolation and characterization. These reagents are also under the SC Proven brand. The following table describes each of these in more detail:

STEM24	A human antibody that recognizes human CD24, also known as Heat Stable Antigen (HSA), a glycoprotein expressed on the surface of many human cell types, including immature human hematopoietic cells, peripheral blood lymphocytes, erythrocytes, and many human carcinomas. CD24 is also a marker of human neural differentiation.
STEM101	A human-specific mouse antibody that recognizes the Ku80 protein found in human nuclei.
STEM121	A human-specific mouse antibody that recognizes a cytoplasmic protein of human cells.
STEM123	A human-specific mouse antibody that recognizes human glial fibrillary acidic protein (GFAP).

We also market a number of human cell lines for use in research, including human neural stem cells derived from different areas of the CNS as well as hFB101, ultra primary human fibroblasts for use in genetic reprogramming and the creation of human IPS cells.

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Other products marketed under SC Proven include total cell genomic DNA (gDNA), RNA and protein lysate reagents purified from homogenous stem cell populations for intra-comparative studies, such as Epigenetic fingerprinting, Southern, Western and Northern blots, PCR, RT-PCR, and microarrays. This range of purified stem cell line lysates includes:

Mouse ESCs propagated in proprietary SC Proven 2i inhibitor-based GS2-M media; and

Mouse ES cell-derived and fetal tissue-derived neural stem cells propagated in proprietary SC Proven RHB-A® media.

Other Technologies

In addition to our cell therapeutics and research reagent programs, we hold a number of non-core technologies which we feel present important licensing opportunities. The most significant of these are likely to be certain proprietary technology within the Company for the generation of transgenic rats and for drug screening using stem and progenitor cells.

Transgenic Rat Program.

As part of our acquisition of assets from SCS in April 2009, we acquired exclusive rights to an intellectual property portfolio that broadly covers rat pluripotent stem cells, methods for using these cells to generate transgenic rats, and media for the culturing of these cells. This intellectual property was based upon research done at the University of Edinburgh, which showed for the first time the successful derivation and culture of true germline competent rat ES cells required for precise genetic engineering.

In August 2010, researchers demonstrated for the first time the creation of genetically modified rats using rat pluripotent cells that have been gene targeted via homologous recombination, a method which involves adding DNA sequences to the cells to delete (knock-out), add (knock-in) or otherwise modify genes of interest. This work resulted in the successful generation of knock-out rats missing the tumor suppressor gene p53 and served as a proof-of-principle for creating genetically engineered rats using rat ES cells. Prior to this breakthrough, these types of genetic manipulations were only possible in mice, and genetically engineered mice are widely used as disease models. While both mice and rats are used as animal models of human disease, aspects of the rat s physiology, behavior, and metabolism are closer to the human, making rats the preferred species for drug development and studying human disease. Moreover, the rat cells used to generate these genetically engineered rats were cultured using a proprietary 2i inhibitor-based media formulation marketed as part of our SC Proven line of specialty cell culture products under the product name GS1-R. GS1-R is the first and only commercially available medium shown to enable the derivation and long-term maintenance of the true rat pluripotent cells required for precise genetic manipulation.

We believe that over the past few years a number of researchers have used our rat pluripotent cell technology to derive different knock-out and knock-in rat models. And, over this time, the first of the patents in this portfolio issued (GB Patent No. 2451523), and the proprietary media patent application was allowed in Europe (EPO Patent No. 1999249). We are therefore exploring our rat pluripotent cell technology and our inhibitor-based media as important licensing and commercial opportunities.

Contract Services and Supply Agreements

Our team members have been at the forefront of the research, development, manufacture and clinical translation of various different stem cells and cell-based therapies for over 20 years. We have demonstrated expertise in the development and implementation of state-of-the-art cell separation devices, bioreactors, closed systems and robotic platforms for manufacture of cells at the required scales. Leveraging this expertise, we now offer contract services for process development, process scale-up/scale-out and production, including use of our automated TAP Biosystems CompacT® SelecT Robotic platform.

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In an extension of the process development and production services we have been contracted to scale-up and supply quantities of cell lines, reagents, cell line derivatives and assay protocols for use in client s drug development and other programs.

Our clients include the service division of a global biotechnology company developing new medicines, and a world-renowned scientific research institute.

Operations

Manufacturing

We have made considerable investments in our manufacturing operations. Our team includes world-recognized experts with proven track records in the development, manufacture and delivery of a range of different cell-based products. For clinical trials, our highly-qualified personnel manufacture cell products in clean room environments in compliance with current Good Manufacturing Practice (cGMP) and to quality standards that meet US as well as international regulatory requirements. By combining expertise and experience, we believe our expandable and bankable cell products can ultimately be manufactured and distributed at commercial scale as stem cells in a bottle, much like an off-the-shelf pharmaceutical product. We believe we also have sufficient ability to manufacture the cell culture media and reagent products that we are currently selling commercially, and that we have sufficient resources to add additional media and reagent manufacturing capacity should the business need arise.

Marketing

Because of the early stage of our stem and progenitor cell-based therapeutic product development programs, we have not yet addressed questions of channels of distribution or marketing of potential future products. We sell and ship our proprietary cell culture products directly from our facility in Cambridge, U.K. Customers can order these products through our dedicated website (www.scproven.com). In addition, we have a number of co-exclusive distribution agreements with Millipore Corporation for the marketing and sale of certain of our cell culture products, including HEScGRO and ESGRO Complete.

Employees

As of December 31, 2012, we had 49 full-time employees, 9 of whom have Ph.D., M.D. or D.V.M. degrees. 39 full-time employees work in research and development and laboratory support services. No employees are covered by collective bargaining agreements. We consider our employee relations in general to be good.

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 these cells. We also own or have exclusive rights to exploit a number of patents that claim tools and techniques important to cell-based research. A number of these patents were acquired from SCS in April 2009. Additional patents were acquired from NsGene A/S, a Danish company, in February 2013. These patents claim GFAP+ Nestin+ precursor cells capable of differentiating into neurons. Among our significant U.S. patents covering stem and progenitor cells 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;

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U.S. Patent No. 7,361,505, entitled Multipotent neural stem cell compositions, which covers mammalian 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 faster than 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 No. 5,851,832, entitled *In Vitro* growth and proliferation of multipotent neural stem cells and their progeny, which covers methods and compositions of proliferating and expanding human CNS cell cultures; and

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.

Among our significant U.S. patents covering cell-based research tools and technologies are:

U.S. Patent Nos. 7,005,299 and 6,150,169, both entitled Expression of heterologous genes according to a targeted expression profile, which cover the use of a gene sequence called IRES (internal ribosome entry site), a pivotal technology to target exogeneous gene expression in stem cells, thereby facilitating their identification and use; and

U.S. Patent Nos. 6,878,542 and 7,256,041, both entitled Isolation, selection and propagation of animal transgenic stem cells, and U.S. Patent No. 6,146,888, entitled Method of enriching for mammalian stem cells, which cover the isolation of stem cells using a nucleic acid construct including a selectable marker.

Of the thirteen patents identified above as being amongst our significant patents, four are owned by us and nine are exclusively licensed to us. The table below sets out the anticipated expiration dates of these patents absent the grant of any patent term extension, whether under the Hatch Waxman Act (Pub. L. 98-417) or otherwise:

Patents Owned	5,968,829 (2017); 7,153,686 (2019); 6,777,233 (2017); 6,468,794 (2019)
Patents Exclusively Licensed (licensor included):	7,361,505 (NeuroSpheres, 2015); 6,497,872 (NeuroSpheres, 2019); 5,851,832 (NeuroSpheres, 2015); 6,294,346 (NeuroSpheres, 2018); 7,005,299 (University of Edinburgh, 2014); 6,150,169 (University of Edinburgh, 2014); 6,878,542 (University of Edinburgh 2014); 7,256,041 (University of Edinburgh, 2014); 6,146,888 (University of Edinburgh, 2014)

We also rely upon trade secret protection for our proprietary information and 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.

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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 disclosed by us or developed 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 will be our exclusive property.

Licenses Agreements

Since inception, we have entered into a number of license agreements with academic organizations and commercial entities, including NeuroSpheres, Ltd. (Neurospheres), ReNeuron Ltd. (ReNeuron), Stem Cell Therapeutics Corp. (SCT), genOway SA (genOway), the University of Edinburgh, the California Institute of Technology (Cal Tech), Cambridge University, RIKEN Institute, and Oregon Health & Science University (OHSU), to either acquire or license out intellectual property rights. Under these license agreements, there are typically obligations of due diligence and the requirement to pay royalties on products that use patented technology licensed under these agreements. The license agreements with some of 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 licensed patents, unless governmental regulations require a shorter term. Typically, the licensee under each of these license agreements can terminate the agreement at any time upon notice. At this time, we do not believe the future success of our research and development efforts depend significantly on any particular license agreement or research collaboration. Nevertheless, we describe the more important license agreements below.

NeuroSpheres

In March 1994, we entered into a contract research and license agreement with NeuroSpheres, 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. All of the product-based royalty rates in the license agreement between the Company and NeuroSpheres are in the single digits. We made up-front payments to NeuroSpheres of 6,500 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.

In July 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.

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University of Edinburgh

In January 2006, we entered into an exclusive, world-wide license agreement with the University of Edinburgh covering approximately twelve separate patent families in the stem cell field. Since then, the parties added some additional patent families and dropped some patent families which were not considered core to our business activities. Today, the license agreement patent families, including several that cover culture media and research technologies, one that covers purified populations of neural stem cells, some that cover cell reprogramming technologies, and one that covers the manipulation and use of embryonic stem cells for the derivation of research animal models, such as knock-out rats, with one or more missing genes. Under the license agreement, we have the exclusive right to commercialize the technologies in all fields. We have been paying royalties to the University of Edinburgh on the commercial sale of certain SC Proven products, and will pay royalties on all net sales of products covered by any of the intellectual property licensed under this agreement. All of the product-based royalty rates in the license agreement between the Company and the University of Edinburgh are in the single digits and there are no provisions under the University of Edinburgh license agreement for the payment of potential milestones by the Company.

ReNeuron

In July 2005, we entered into an agreement with ReNeuron under which we granted ReNeuron a license that allows ReNeuron to exploit its 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. As part of the agreement, we received in aggregate, approximately 10,097,000 ordinary shares of ReNeuron common stock, net of approximately 122,000 shares that were transferred to NeuroSpheres. Between 2007 and 2011, we sold our entire holdings of shares of ReNeuron common stock for aggregate net proceeds of approximately $3,743,000. As of June 30, 2011, we no longer hold any shares of ReNeuron.

Stem Cell Therapeutics

In August 2006, we entered into an agreement with Stem Cell Therapeutics, 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.

genOway

In October 2008, we entered into a license agreement with genOway, a leading transgenics company located in France, in which we granted a non-exclusive sublicense to genOway for the use of Internal Ribosome Entry Site (IRES) technology. The IRES technology enables the dual expression of a protein of interest and a selectable marker, thereby enabling researchers to genetically modify any mammalian cell and monitor the activity of a particular gene of interest in living cells or tissues without blocking the normal function of the gene. The IRES technology is particularly important for evaluating the success of gene knock-outs or knock-ins in stem cells and for the successful creation of transgenic rodent disease models. The IRES technology has been used to develop hundreds of genetically modified models in the past decade, and the technology is now considered to be the reference technology for transgene expression in some key rodent animal models, such as humanized models, reporter model, and cell trafficking models. The IRES technology is covered by one of the patent families exclusively licensed to us by the University of Edinburgh, specifically U.S. Patents No. 7,005,299 and 6,150,169 and their foreign counterparts.

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In March 2012, we agreed to amend the genOway license agreement to give genOway exclusive worldwide rights, including a right to grant sublicenses, under the IRES patent family in order to commercialize transgenic mice, and provide related services such as the genetic engineering of such mice. Under this exclusive license agreement, as amended, we received a six figure lump sum payment in lieu of annual maintenance fees, and will receive single digit royalties on licensed products and services.

Other Commercial Licenses

We have approximately fifteen other license agreements with commercial entities, which we entered into in the ordinary course of business to monetize certain of our patents. A number of these include sublicenses to certain patents exclusively licensed to us from either NeuroSpheres or the University of Edinburgh. Some of these are license agreements to commercialize cells. A number of these are license agreements to our research tools patents, such as the IRES and selectable marker technologies described above. We have an on-going licensing program at the Company with the goal of identifying likely infringers of our intellectual property rights in order to generate license revenues.

Scientific Advisory Board

Members of our Scientific Advisory Board provide us with strategic guidance primarily in regard to our therapeutic products research and 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 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.

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 Ludwig Center for Cancer Stem Cell Research and Medicine, 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 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

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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 hemopoieteic system, and many other awards. In 2010, Dr. Weissman was appointed as an Honorary Director of the Center for Biotech and BioMedicine and the Shenzhen Key Lab of Gene and Antibody Therapy at the Graduate School of Shenzhen at Tsinghua University. He was also appointed as an Honorary Professor at Peking Union Medical College and an Honorary Investigator at the State Key Laboratory of Experimental Hematology, Institute of Hematology and Blood Disease Hospital at the Chinese Academy of Medical Sciences and Peking Union Medical College. In 2011, Dr. Weissman was elected to the National Academy of Sciences Council.

David J. Anderson, Ph.D., is Seymour Benzer 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.

Government Regulation

Our research and development activities and the future manufacturing and marketing of our potential therapeutic 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.

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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.

FDA Marketing Approval

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

Steps	Considerations
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. *In vivo* 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.

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	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. 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. 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. 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.
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	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.
6. Post-marketing studies	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.

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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 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. 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.

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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.

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.

The U.S. Patient Protection and Affordance Care Act and the Health Care and Education Reconciliation Act were signed into law in March 2010. A number of provisions of those laws require further rulemaking action by governmental agencies to implement. The laws change access to health care products and services and create new fees for the pharmaceutical and medical device industries. Future rulemaking could increase rebates, reduce prices or the rate of price increases for health care products and services, or require additional reporting and disclosure. The laws also include new authorization to the FDA to approve companies to market biosimilar products within the United States, although biosimilar regulation and rulemaking has not yet been adopted. We cannot predict the timing or impact of any such future rulemaking on our business.

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 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.

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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.

The research markets served by our tools and technologies are highly competitive, complex and dynamic. Technological advances and scientific discoveries have accelerated the pace of change in biological research, and stem cell technologies have been evolving particularly fast. In these markets we face a wide array of competitors, ranging from specialized companies with strengths in niche segments of the life science markets to large manufacturers offering a broad portfolio of products, tools and services. Many of these competitors have significant financial, operational, sales, and marketing resources, and experience in research and development. In some cases, these and other competitors are also our customers, distributors and suppliers. In addition, many of our products can be home brewed by customers following publicly available procedures and methodologies.

Reliable independent information on sales and market share of products produced by our competitors is not generally available. We believe, however, based on our own estimates, that no one company is so dominant that it prevents other companies from competing effectively. We compete mainly by focusing on specialty products, which are custom designed for use in stem cell-based research, where we believe our expertise, intellectual property and reputation give us competitive advantage. We believe that, in this particular market niche, our products and technologies offer customers specific advantages over those offered by our competitors. We compete by offering innovative, quality-controlled products, consistently made and designed to produce reproducible results. We continue to make investments in research and development, quality management, quality improvement, and product innovation. We tend to avoid head to head competition against entrenched competitors with commoditized products.

Reverse Stock Split

We effected a 1-for-10 reverse stock split on July 6, 2011. As a result of the reverse stock split, the outstanding shares of common stock issued and outstanding were reduced from approximately 139 million to 13.9 million. Concurrent with the reverse stock split, we reduced the authorized number of common shares from 250 million to 75 million. The reverse stock split proportionately reduced all issued and outstanding shares of our common stock, as well as common stock underlying stock options, warrants and other common stock based equity grants outstanding immediately prior to the effectiveness of the reverse stock split. The exercise price on outstanding equity-based grants was proportionately increased, and the number of shares available under our equity-based plans was proportionately reduced. Share and per share data (except par value) for the periods presented reflect the effects of this reverse stock split. References to numbers of shares of common stock and per share data in the accompanying financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis.

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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:

- 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.

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, DC, 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 on 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 on 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 on Form 10-K. Forward-looking statements speak only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statements.*

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 cell technologies. Moreover, any material adverse occurrence in our first clinical trials could substantially impair our ability to initiate additional clinical trials to test our HuCNS-SC cells, whether in other potential indications or otherwise. This, in turn, could adversely impact our ability to raise additional capital and pursue our planned research and development efforts.

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 therapeutic 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

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expenses and other working capital requirements. In addition, we will require additional capital resources to continue to develop and grow our enabling cell technologies programs. 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, sales or dispositions of assets, 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, 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. 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. 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.

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 therapeutic 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 technologies are at early stages 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 therapeutic 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 therapeutic 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 Phase I NCL and Phase I PMD trials we completed, and our currently ongoing Phase I/II clinical trial in spinal cord injury and Phase I/II clinical trial in dry age-related macular degeneration, 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 regulatory agencies in the United States and Switzerland have approved the clinical study of our cells in a total of four indications, there can be no assurance that any of our clinical trials will be completed or result in a successful outcome.

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We may elect to delay or discontinue studies or clinical trials based on unfavorable results. Any product developed from, or based on, cell 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 therapeutic 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 all our clinical trials to date.

Our success will depend in large part on our ability to develop and commercialize products that treat diseases other than PMD, NCL or other rare diseases.

Although our initial clinical trials were 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 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.

Delays in the commencement or completion of clinical testing of our current and potential product candidates could result in increased costs to us and delay our ability to generate revenues.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- the preclinical studies necessary to demonstrate safety and efficacy in relevant animal models sufficient to obtain regulatory clearance to commence the planned clinical trials;
- the manufacturing activities needed to produce sufficient quantities of the product candidate that meets our quality standards for clinical testing;

regulatory approval needed to commence the planned clinical trials, including agreement with the FDA or other regulatory body on the clinical protocol and study design;

reaching agreement with our collaborators, including any contract research organizations (CROs) and the trial sites, on all aspects of the clinical trial; and

securing the institutional review board approval needed to conduct the clinical trials at the prospective sites.

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Even after commencement, the completion of clinical trials can be delayed or prevented for a number of reasons, such as:

- the FDA or similar foreign regulatory authorities may find that our product candidates are not sufficiently safe or effective or may find our cell culturing processes or facilities unsatisfactory;
- our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and/or clinical trials or to abandon one or more of our development programs;
- the FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations;
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects;
- we may experience difficulties in managing multiple clinical sites;
- we may be unable to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates for use in clinical trials; and
- our product candidates may be deemed unsafe or ineffective, or may be perceived as being unsafe or ineffective, by healthcare providers for a particular indication.

In addition, clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size and nature of the relevant patient populations, the nature of the protocols, the proximity of patients to clinical sites, the availability of effective treatments for the relevant diseases, clinical testing alternatives available to patients interested in enrolling in our studies, and the eligibility criteria for our clinical trials. Delays in clinical testing of our product candidate could prevent or delay us from obtaining the additional evidence of clinical efficacy we will need for the approval for our product candidate in any indication.

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 business. For example, in April 2009, we acquired substantially all of the operating assets and liabilities of Stem Cell Sciences Plc (SCS). 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 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. 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. 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. In December 2011, for example, we determined that the intangible in-process research and development (IPR&D) asset related to the assays technology was impaired. In part because of management s decision to focus on our therapeutic product development programs and not to allocate time and resources to the assays program, we determined that we could not predict the future cash flows from this asset and that the approximately $655,000 carrying value of the asset should be written-off in full.

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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 and enabling cell technologies programs.

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 $1,783,000 in 2012; 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 $356,000 per year for our former encapsulated cell therapy pilot manufacturing facility, which we own. We have currently subleased a small portion of the science and administrative facility, but we are no longer actively seeking additional subtenants due to the short time remaining on the lease period. We are currently seeking to sublease, assign or sell the pilot manufacturing facility, but may not be able to sublease, assign 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 cell 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, 2012, the reserve was $1,103,000. For the year 2012, we incurred $1,185,000 in operating expenses net of sub-tenant income for this facility. Expenses for this facility will fluctuate based on changes in tenant occupancy rates and other operating expenses related to the lease. We are no longer actively seeking additional subtenants due to the short time remaining on the lease period. 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 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 cell technologies, and we may need to rely on partnering or other arrangements to provide financial support for our product 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. With the exception of our distribution agreements with Millipore Corporation, we have no such agreements. While we have engaged, and expect to continue to engage, in discussions regarding such arrangements, 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. We also own or exclusively license a number of patents and patent applications related to certain mammalian pluripotent and multipotent stem cells, cellular reprogramming, genetic manipulation of stem cells,

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the creation of genetically engineered animals used for research, technologies that facilitate the identification and isolation of specific stem cell types, and media formulations for the culture of stem cells. 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, legal and occasionally ethical 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 and procedures exist in all relevant geographies for third parties to challenge even issued patents. 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 or invalidate 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. In 2006, for example, we filed suit against Neuralstem, Inc. for patent infringement. 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 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.

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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 small molecules, 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.

The life science and research markets are each highly competitive. Most of our competitors have greater financial resources than we do, making them better equipped to license technologies and intellectual property from third parties or to fund research and development, manufacturing and marketing efforts. Our competitors can be expected to continue to improve the design and performance of their products and to introduce new products with competitive price and performance characteristics. In order to compete successfully in these markets, we will likely need to continue to invest in research and development, sales and marketing and customer service and support. We cannot assure you that we will have sufficient resources to continue to make such investments.

The research market is heavily dependent on government funding, and changes in government funding can adversely affect revenues for our tools and technologies products.

Our customers include researchers at academic institutions, pharmaceutical and biotechnology companies and government laboratories, all of whom fund much of their stem cell research using government monies, such as grants. A number of these customers, for example, are dependent for their funding upon grants from U.S. government agencies, such as the U.S. National Institutes of Health (NIH) and agencies in other countries. The level of government funding of research and development is unpredictable. Research and development spending of our customers can fluctuate based on spending priorities and general economic conditions. There have been instances when NIH grants have been frozen or otherwise unavailable for extended periods. The availability of governmental research funding may also continue to be adversely affected by current economic instability. Any reduction or delay in governmental funding could cause our customers to delay or forego purchases or reallocate their budgets in a manner adverse to us, in which case our anticipated revenues could be materially lower.

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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 for human therapeutics 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 of both therapeutic products and certain of our enabling cell technologies. 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 product marketing 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, including our chief executive officer, our vice presidents, and the heads of key departments or functions, and on some of our outside consultants. 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.

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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 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 applicable state, federal and international law, 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.

Natural disasters and violent acts of public protest may cause damage or disruption to us and our employees, facilities, information systems, vendors, suppliers, and customers.

Our operations are concentrated in Northern California. The western United States has experienced a number of earthquakes, wildfires, flooding, landslides, and other natural disasters in recent years. These occurrences could damage or destroy our facilities which may result in interruptions to our business and losses that exceed our insurance coverage. In addition, we know that certain individuals are strenuously opposed to certain types of medical research, including animal testing and embryonic stem cell research engaged in by both us and many of our customers. Acts of both legal and illegal public protest, including picketing and bioterrorism, could affect the markets in which we operate and our business operations. Any of these events could cause a decrease in both our actual and anticipated revenue, earnings and cash flows.

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 therapeutic 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 manufacture of cell-based and related products is complicated and difficult, 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

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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 and related 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 therapeutic 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, 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 considerable public debate, with many people voicing ethical, legal and social concerns. Although these concerns have mainly been directed to the use of embryonic stem cells, which we are not presently pursuing for therapeutic 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. In addition, we are continuing 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. The use of these cells could give rise to ethical and social commentary adverse to us, which could harm the market price of our common stock. Additional government-imposed restrictions on the use of embryos or human embryonic stem cells in research and development could also cause an adverse effect on us by harming our ability to establish important partnerships or collaborations, delaying or preventing the development of certain non-therapeutic products, and causing a decrease in the price of our stock or by otherwise making it more difficult for us to raise additional capital. For example, concerns regarding such possible regulation could impact our ability to attract

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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. Similarly, concerns and moral objections to embryonic and fetal-tissue derived technologies could delay or prevent us from patenting or enforcing our patents in certain geographies. Also, existing and potential 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 Our Stock

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;
- 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, 2012, the trading price of our common stock as reported on NASDAQ ranged from a high of $11.30 to a low of $0.59 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.

Our stock could be delisted from the NASDAQ Capital Market, which could affect our stock s market price and liquidity.

Our listing on the NASDAQ Capital Market is contingent upon meeting all the continued listing requirements of the NASDAQ Capital Market which include maintaining a minimum bid price of not less than $1.00 per share and a minimum of $2.5 million in stockholders equity. Our price per share and stockholders equity at December 31, 2012 was $1.63 and $14.0 million, respectively. If our common stock is delisted from the

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NASDAQ Capital Market, our ability to raise capital in the future may be limited. Delisting could also result in less liquidity for our stockholders and a lower stock price.

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

As of December 31, 2012, there were outstanding warrants to purchase 9,935,912 shares of our common stock, at a weighted average exercise price of $4.20 per share, outstanding options to purchase 447,359 shares of our common stock, at a weighted average exercise price of $19.59 per share, and outstanding restricted stock units for 1,534,200 shares of our common stock. We expect to issue additional options and restricted stock units 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***

In December 2010, we entered into a commercial lease agreement with BMR-Gateway Boulevard LLC (BMR), as landlord, for approximately 43,000 square feet of office and research space at BMR s Pacific Research Center in Newark, California. The initial term of the lease is approximately eleven and one-half years, and we relocated our corporate headquarters and core research activities from a facility located at the Stanford Research Park in Palo Alto, California, to this facility in July 2011. The lease for the Palo Alto facility expired on August 31, 2011. We will pay approximately $18,000,000 in aggregate as rent over the term of the lease to BMR. As part of the lease, BMR agreed to provide various financial allowances so that we can build initial and future laboratories, offices and other improvements, subject to customary terms and conditions relating to landlord-funded tenant improvements. We did not exercise an option under the lease agreement, to lease up to an additional 30,000 square feet in the building. The option expired on January 31, 2013.

In September 2010, we entered into a two-year sublease agreement with Caliper Life Sciences, Inc., for approximately 13,200 square feet in a facility located in Mountain View, California for part of our R&D operations. In June 2012, we extended the sublease term to September 30, 2013. We will pay approximately $1,081,000 in aggregate as rent over the term of the lease.

We continue to lease a facility 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. We have subleased small portions of this facility, amounting to approximately 11 percent of the total space as of December 31, 2012. We are no longer actively seeking additional subtenants due to the short time remaining on the lease period.

We own a 21,000 square-foot pilot manufacturing facility and a 3,000 square-foot cell processing facility in Rhode Island financed by bonds issued by the Rhode Island Industrial Facilities Corporation. We are actively seeking to sublease, assign or sell our remaining interests in these properties.

In January 2011, we amended the existing lease agreements of our wholly-owned subsidiary, Stem Cell Sciences (U.K.) Ltd, effectively reducing our leased space from approximately 5,000 square feet to approximately 1,900 square feet of office and lab space. We expect to pay approximately $61,000 as rental payments for 2013. StemCells, Inc. is the guarantor of Stem Cell Sciences (U.K.) Ltd s obligations under the existing lease.

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In March 2013, we entered into a commercial lease agreement with Prologis, L.P. (Prologis), as landlord, for approximately 18,700 square feet of office and research space in Sunnyvale, California. The initial term of the lease is ten years and we will pay approximately $3.5 million as rent over the term of the lease. As part of the lease, Prologis has agreed to provide us financial allowances to build initial tenant improvements, subject to customary terms and conditions relating to landlord-funded tenant improvements. The facility will house operations that support our clinical development activities.

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, specifically U.S. Patent No. 6,294,346 (claiming the use of human neural stem cells for drug screening), U.S. Patent No. 7,101,709 (claiming the use of human neural stem cells for screening biological agents), 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). 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. In July 2009, the Maryland District Court granted our motion to consolidate these two cases with the litigation we initiated against Neuralstem in 2006. Discovery is ongoing in these cases.

In addition to the actions described above, in April 2008, we filed an opposition to Neuralstem s European Patent No. 0 915 968 (methods of isolating, propagating and differentiating CNS stem cells), because the claimed invention is believed by us to be unpatentable over prior art, including the patents exclusively licensed by us from NeuroSpheres. In December 2010, the European Patent Office ruled that all composition claims in Neuralstem s 968 European patent were invalid and unpatentable over prior art including several of the NeuroSpheres patents licensed to us. Neuralstem has appealed this decision.

Effective 2008, as part of an indemnification agreement with NeuroSpheres, we are entitled to offset all litigation costs incurred in this patent infringement suit, against amounts that would otherwise be owed to NeuroSpheres under our exclusive license agreements with NeuroSpheres, such as annual maintenance fees, milestones and royalty payments. Under the terms of our license agreements, we are required to make annual payments of $50,000 to NeuroSpheres, and we expect to make these annual payments through the remaining life of the patent which, at December 31, 2012, was approximately 12 years. We have therefore capitalized $700,000 (14 years at $50,000 per year) to offset litigation costs. The amount capitalized is not dependent on the achievement of any milestones or related to any other contingent payments which may become due under the arrangement. We will reduce this asset by $50,000 per year in lieu of the cash payments due to NeuroSpheres. As the $50,000 annual payments are fully creditable against royalties due to NeuroSpheres, we have classified the capitalized amount as prepaid royalties under Other assets, non-current on our accompanying Consolidated Balance Sheets. We have concluded that the estimated balance of $600,000, as of December 31, 2012, is a fair estimate and realizable against future milestone and royalty payments to NeuroSpheres, and that litigation costs incurred above this amount will be expensed as incurred. Management will reevaluate this estimate on a quarterly basis based on actual costs and other relevant factors.

Item 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

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PART II

Item 5. ***MARKET FOR REGISTRANT S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***

Market price and dividend information

Our stock is traded on the NASDAQ Capital 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
2012		
First Quarter	$ 1.18	$ 0.65
Second Quarter	$ 1.10	$ 0.54
Third Quarter	$ 2.66	$ 0.77
Fourth Quarter	$ 2.49	$ 1.50
2011		
First Quarter	$ 11.20	$ 7.80
Second Quarter	$ 9.76	$ 5.05
Third Quarter	$ 6.58	$ 4.30
Fourth Quarter	$ 2.14	$ 0.70

Share prices have been adjusted for the 1-for-10 reverse stock split effected in July 2011. No cash dividends have been declared on our common stock since our inception.

PERFORMANCE GRAPH

We show below the cumulative total return to our stockholders during the period from December 31, 2007 through December 31, 2012[(1)] 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.

	December 31, 2007	December 31, 2008	December 31, 2009	December 31, 2010	December 31, 2011	December 31, 2012
StemCells, Inc.	$ 100.00	$ 90.67	$ 84.00	$ 72.00	$ 5.47	$ 10.87
S&P 500 Index	$ 100.00	$ 61.51	$ 75.94	$ 85.65	$ 85.65	$ 97.13
Amex Biotechnology Index	$ 100.00	$ 82.28	$ 119.79	$ 164.99	$ 138.77	$ 196.70

(1) Cumulative total returns assume a hypothetical investment of $100 on December 31, 2007.

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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 Company filing 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.

Approximate Number of Holders of Common Stock

As of March 1, 2013, there were approximately 247 holders of record of our common stock and the closing price of our common stock on the NASDAQ Capital Market was $1.70 per share.

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.

Recent Sales of Unregistered Securities (last three years ending December 31, 2012)

In September 2012, pursuant to Regulation S of the Securities Act of 1933, we issued 24,753 shares of restricted common stock under the terms of an agreement with a developer of biological materials in return for certain product rights including an exclusive right of first offer to commercialize the developer s products as may be developed on or before April 18, 2017.

We did not issue unregistered securities in 2010 and 2011.

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, 2012.

	Equity Compensation Plan Information		
Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Stock Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Stock Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a)) (c)
Equity compensation plans approved by security holders(1)	1,981,559	$ 4.42	593,199
Equity compensation plans not approved by security holders(2)	0		500,000

(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 2001, 2004 and 2006 Equity Incentive Plans.

(2) In 2012, we adopted by board action the 2012 Commencement Incentive Plan in accordance with NASDAQ Listing Rule 5635(c)(4) concerning inducement grants to new employees. As of December 31, 2012, no awards had been made under this plan.

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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,				
	2012	2011	2010	2009	2008
	(In thousands, except per share amounts)				
Consolidated Statements of Operations					
Revenue from licensing agreements and grants	$ 512	$ 558	$ 928	$ 608	$ 232
Revenue from product sales	856	663	499	385	
Research and development expenses	15,847	19,938	21,019	19,930	17,808
General and administrative expenses	7,447	8,202	9,377	9,530	8,296
Wind-down expenses(1)	356	287	222	650	866
Impairment of intangible asset(2)		655			
Gain (loss) on change in fair value of warrant liabilities(3)	(5,945)	6,612	3,005	1,899	(937)
Net loss	(28,491)	(21,329)	(25,244)	(27,026)	(29,087)
Basic and diluted loss per share	$ (0.99)	$ (1.50)	$ (2.05)	$ (2.55)	$ (3.52)
Shares used in computing basic and diluted loss per share amounts	28,824	14,188	12,330	10,605	8,272

	December 31,				
	2012	2011	2010	2009	2008
	(In thousands)				
Consolidated Balance Sheets					
Cash and cash equivalents	$ 8,471	$ 13,311	$ 19,708	$ 38,618	$ 30,043
Marketable securities	13,901	3,281	191	197	4,182
Total assets	30,170	25,205	30,602	51,190	41,230
Accrued wind-down expenses(1)	1,103	2,135	3,300	4,506	5,513
Fair value of warrant liabilities(3)	9,265	6,042	6,672	9,677	8,440
Long-term debt, including capital leases	138	331	540	785	867
Stockholders equity	13,985	10,725	15,481	30,495	21,809

(1) Relates to wind-down and exit expenses in respect of our Rhode Island facility and relocation of our operations in Australia. See Note 10 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.

(2) Relates to the impairment of our intangible asset. See Note 6 Goodwill and Other Intangible assets in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

(3) Relates to the fair value of warrants issued as part of our financings in November 2008, November 2009 and December 2011. See Note 12 Warrant Liability in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

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Item 7. ***MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

This report contains forward looking statements 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 the fact that additional trials will be required to confirm the safety and demonstrate the efficacy of our HuCNS-SC cells for the treatment of any disease or disorder; uncertainty as to whether the U.S. Food and Drug Administration (FDA), Swissmedic, 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 in the future; the uncertainty regarding the validity and enforceability of our issued patents; the risk that we may not be able to manufacture additional master and working cell banks when needed; 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 significant revenue from product sales or become profitable; uncertainties regarding our obligations with respect to our former 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. Forward-looking statements speak only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statements. 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

We are engaged in researching, developing, and commercializing cell-based therapeutics and enabling tools and technologies for stem cell-based research and drug discovery and development. Our research and development (R&D) programs are primarily focused on identifying and developing potential cell-based therapeutics which can either restore or support organ function. In particular, since we relocated our corporate headquarters to California in 1999, our R&D efforts have been directed at refining our methods for identifying, isolating, culturing, and purifying the human neural stem cell and developing this cell as potential cell-based therapeutics for the central nervous system (CNS). Our HuCNS-SC® product candidate (purified human neural stem cells) is currently in clinical development for several indications chronic spinal cord injury, dry age-related macular degeneration (AMD) and Pelizeaus-Merzbacher disease (PMD), which is a myelination disorder in the brain. In October 2012, we published in *Science Translational Medicine*, a peer-reviewed journal, the data from our four-patient Phase I clinical trial in PMD, which showed preliminary evidence of durable and progressive donor-derived myelination in all four patients. In addition, there were measurable gains in neurological function in three of the four patients, with the fourth patient clinically stable. We are conducting a Phase I/II clinical trial for the treatment of chronic spinal cord injury. This trial is being conducted in Switzerland under authorization from Swissmedic, and represents the first time that neural stem cells have been transplanted as a potential therapeutic agent for spinal cord injury. In February 2013, we announced that the first patient cohort, all of whom had complete spinal cord injuries, had completed the trial. In addition, data from this first cohort continued to demonstrate a favorable safety profile and showed that the considerable gains in sensory function observed at the six month assessment in two of the three patients compared to pre-transplant

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baselines had persisted at the 12 month assessment; the third patient remained stable. Also, in September 2012, the first patient with an incomplete spinal cord injury was enrolled and dosed with our HuCNS-SC cells. In June 2012, we initiated a Phase I/II clinical trial in dry AMD, and in October 2012, the first patient in this trial was enrolled and dosed. We previously completed a Phase I clinical trial in infantile and late infantile neuronal ceroid lipofuscinosis (NCL), and the data from that trial showed that our HuCNS-SC cells were well tolerated and non-tumorigenic, and that there was evidence of engraftment and long-term survival of the transplanted HuCNS-SC cells. In July 2012, the governing board of the California Institute for Regenerative Medicine (CIRM) approved our application for a disease team award for up to $20 million to fund preclinical development of our HuCNS-SC cells for cervical spinal cord injury; the funds would have been provided in the form of a forgivable loan. However, in March 2013, we elected not to borrow these funds from CIRM. In September 2012, the governing board of CIRM approved our application for a second, separate disease team award for up to $20 million to fund preclinical development of our HuCNS-SC cells for Alzheimer s disease; this award would also be in the form of a forgivable loan. Negotiation of the terms and conditions for this loan is ongoing. For a brief description of our significant therapeutic research and development programs see Overview Therapeutic Product Development Programs in the Business Section of Part I, Item 1 of this Form 10-K.

We are also engaged in developing and commercializing applications of our technologies to enable research, which we believe represent current and nearer-term commercial opportunities. Our portfolio of technologies includes cell technologies relating to embryonic stem cells, induced pluripotent stem (iPS) cells, and tissue-derived (adult) stem cells; expertise and infrastructure for providing cell-based assays for drug discovery; a cell culture products and antibody reagents business; and an intellectual property portfolio with claims relevant to cell processing, reprogramming and manipulation, as well as to gene targeting and insertion. Many of these enabling technologies were acquired in April 2009 as part of our acquisition of the operations of Stem Cell Sciences Plc (SCS).

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 technologies and sales of products for use in stem cell 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 dependent upon external financing, such as from equity and debt offerings, to finance our operations. 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) obtain 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 therapeutic 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.

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Given the early stage of development of our therapeutic 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 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, Swissmedic 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.

The research markets served by our tools and technologies products are highly competitive, complex and dynamic. Technological advances and scientific discoveries have accelerated the pace of change in biological research, and stem cell technologies have been evolving particularly fast. We compete mainly by focusing on specialty media and antibody reagent products and human cell lines where we believe our expertise, intellectual property and reputation give us competitive advantage. We believe that, in this particular market niche, our products and technologies offer customers specific advantages over those offered by our competitors. We compete by offering innovative, quality-controlled products, consistently made and designed to produce reproducible results. We continue to make investments in research and development, quality management, quality improvement, and product innovation. We cannot assure you that we will have sufficient resources to continue to make such investments. For the year ended December 31, 2012, we generated revenues from the sale of specialty cell culture products of approximately $856,000. We can give no assurances that we will be able to continue to generate such revenues in the future.

Significant Events

Therapeutic Product Development

In January 2012, we published preclinical data demonstrating that our proprietary HuCNS-SC cells protect host photoreceptors and preserve vision in a well-established animal model of retinal disease. Moreover, the number of cone photoreceptors, which are responsible for central vision, remained constant over an extended period. In humans, degeneration of the core photoreceptors accounts for the unique pattern of vision loss in dry AMD. The data was featured as the cover article in the peer-reviewed *European Journal of Neuroscience*.

Also in January 2012, the FDA authorized the initiation of a Phase I/II clinical trial of our proprietary HuCNS-SC cells in dry AMD, the most common form of AMD. AMD is the leading cause of vision loss and blindness in people over 55 years of age, and approximately 30 million people worldwide are afflicted with the disease. There are no approved treatments for dry AMD.

In February 2012, the fourth and final patient in our Phase I PMD trial completed the twelve-month follow up and evaluations required by the trial protocol, and the trial was completed.

In April 2012, we presented preliminary evidence of progressive and durable donor-cell derived myelination in all four patients who were transplanted with our proprietary HuCNS-SC cells in our Phase I clinical trial for PMD, a rare hypomyelination disorder in children. In addition, clinical assessment revealed small but measureable gains in motor and/or cognitive function in three of the four patients; the fourth patient remained clinically stable. The study was conducted by researchers at the University of California, San Francisco (UCSF). A summary of the trial results were presented at the 2012 European Leukodystrophy Association (ELA) *Families/Scientists Meeting* in Paris, France.

In May 2012, we presented data from the first interim safety review of our Phase I/II spinal cord injury clinical trial, which indicated that the surgery, immunosuppression and the HuCNS-SC cell transplants have been well tolerated. The trial, which was designed to evaluate the safety and preliminary efficacy of our proprietary

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HuCNS-SC cells, represents the first time that neural stem cells have been transplanted as a potential therapeutic agent for spinal cord injury. A summary of the data was presented at the *Interdependence 2012 Global SCI Conference* in Vancouver, Canada.

In June 2012, we initiated our Phase I/II clinical trial of our proprietary HuCNS-SC cells in dry AMD. The trial is being conducted at the Retina Foundation of the Southwest s (RFSW) in Dallas, Texas. We are currently exploring additional potential clinical trial sites for this study.

In July 2012, we presented preclinical data demonstrating that our proprietary human neural stem cells restored memory and enhanced synaptic function in two animal models relevant to Alzheimer s disease. Importantly, these results did not require reduction in beta amyloid or tau, substances that accumulate in the brains of patients with Alzheimer s disease and account for the pathological hallmarks of the disease. The data was presented at the *Alzheimer s Association International Conference 2012* in Vancouver, Canada.

In July 2012, the governing board of CIRM approved an award to us for up to a $20 million under the Disease Team Therapy Development Award program (RFA 10-05) to fund preclinical development of our HuCNS-SC cells in cervical spinal cord. Under RFA 10-05, funding would have been in the form of a forgivable loan. However, in March 2013, we elected not to borrow these funds from CIRM.

Also in July 2012, the Japan Patent Office granted us Patent Number 5007003 which broadly covers the prospective isolation and enrichment of neural stem and progenitor cells using antibody selection, as well as the use of these cells to treat disorders of the central nervous system. Some of the more noteworthy claims in this patent include methods for isolating human neural stem cells, as well as compositions of matter comprising enriched neural stem cells, such as our proprietary HuCNS-SC cells, and the use of enriched neural stem cells as a medicament for the treatment of neurodegenerative diseases, acute brain injury and dysfunction of the central nervous system. The term of this patent extends into 2020.

In September 2012, we presented interim six-month data from the first patient cohort in our Phase I/II clinical trial of our HuCNS-SC cells for chronic spinal cord injury. The first patient cohort all have no sensory or motor function below the level of injury and are considered to have complete spinal cord injuries. The interim data continues to demonstrate a favorable safety profile, and showed considerable gains in sensory function in two of the three patients compared to pre-transplant baselines; the third patient remained stable. The data was presented at the *51st Annual Scientific Meeting* of the International Spinal Cord Society in London, England.

Also in September 2012, the first patient with an incomplete spinal cord injury was enrolled and dosed in our Phase I/II clinical trial in chronic spinal cord injury. Patients who retain some sensory function below the level of trauma are considered to have an incomplete injury.

Also in September 2012, the governing board of CIRM approved a second disease team award to us for up to $20 million under RFA 10-05. This second award is to fund preclinical development of our HuCNS-SC cells in Alzheimer s disease. Funding for this award is also expected to be in the form of a forgivable loan. Negotiation of the terms and conditions of this loan is ongoing.

In October 2012, the first patient in our Phase I/II clinical trial in dry age-related macular degeneration (AMD) was enrolled and dosed. AMD afflicts approximately 30 million people worldwide and is the leading cause of vision loss and blindness in people over 55 years of age.

In October 2012, two papers reporting clinical and preclinical data demonstrating the therapeutic potential of our proprietary HuCNS-SC cells for a range of myelination disorders were published in *Science Translational Medicine*, the peer-reviewed journal of the American Association for the Advancement of Science. The first paper summarized the data from our Phase I trial in Pelizeus-Merzbacher disease (PMD), which showed preliminary evidence of progressive and durable donor cell-derived myelination in all four patients transplanted with HuCNS-SC cells. Three of the four patients showed modest gains in neurological function; the fourth

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patient remained stable. The second paper demonstrated that transplantation of our neural stem cells in an animal model of severe myelin deficiency results in new, functional myelin. Sophisticated analytical techniques were used to confirm that changes measured by magnetic resonance images were in fact derived from new human myelin generated by the transplanted HuCNS-SC cells and these results supported the use of similar techniques to detect and evaluate the degree of myelination in our Phase I PMD trial.

Also in October 2012, we were issued U.S. Patent Number 8,283,164 which broadly covers purified populations of human liver cells, including our human liver engrafting cells (hLEC). The hLEC cells were first isolated by our researchers in the late 1990s, and our scientists have repeatedly demonstrated the cells engraftment and robust bioactivity *in vivo* and that they are expandable. While our hLEC cells are purified from donated adult livers not suitable for transplant, the newly issued 164 patent claims cells independent of tissue source, and therefore, has potential relevance to those deriving liver cells from induced pluripotent or embryonic stem cell platforms. The term of the 164 patent extends into 2022.

In February 2013, we announced that the first patient cohort in our Phase I/II clinical trial of our proprietary HuCNS-SC cells for chronic spinal cord injury had completed the trial, and that data from this first cohort continued to demonstrate a favorable safety profile, and showed that the considerable gains in sensory function observed at the six month assessment in two of the three patients had persisted to the 12 month assessment. The third patient remains stable.

In March 2013, we acquired certain patents and patent applications from NsGene A/S, a Danish company. These patents and patent applications claim a purified population of GFAP+ Nestin+ precursor cells in which one or more of the cells are capable of differentiating into neurons.

Tools and Technologies Programs

In March 2012, we entered into a license agreement under which we granted genOway a worldwide, exclusive license to our Internal Ribosome Entry Site (IRES) technology for use in the development and commercialization of genetically engineered mice. We received an upfront license fee and could receive royalties on product sales.

In October 2012, we launched four new SC Proven human neural stem cell kits for use in neuroscience research. Each kit will contain high purity, multipotent neural stem cells derived from a different area of the human central nervous system, and will provide researchers with a reproducible and scalable serum-free platform with which to perform a broad range of assays. With these kits, researchers will now have the ability to compare and contrast the biological, functional and neural differentiation properties of human neural stem cells isolated from specific regions of the central nervous system, as well as to screen for the effects of different compounds on such cells.

Also in October 2012 we partnered with a UK-based biomedical company to develop and commercialize a range of cell lines and reagents to facilitate iPS cell-based research for regenerative medicine applications. The first product under the partnership, an ultra-primary human fibroblast cell line from which researchers can generate iPS cell lines, was launched under the SC Proven brand.

Financing and Other Business-related Activities

In 2012, we sold an aggregate of 9,647,471 shares of our common stock for gross proceeds of approximately $20,452,000. These sales were made under a sales agreement entered into in June 2009 and the sales agent was paid compensation equal to 3% of gross proceeds. The shares were offered under our shelf registration statement previously filed with, and declared effective by, the SEC.

In 2012, an aggregate of 2,700,000 Series B Warrants were exercised and we received gross proceeds of $3,375,000. The remaining 5,300,000 Series B Warrants expired unexercised by their terms on May 2, 2012. For the exercise of these warrants, we issued 2,700,000 shares of our common stock and 2,700,000 Series A Warrants.

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In 2012, an aggregate of 2,198,571 Series A Warrants were exercised. For the exercise of these warrants, we issued 2,198,571 shares of our common stock and received gross proceeds of approximately $3,078,000.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations is based on our Consolidated Financial Statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. 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 U.S. GAAP which defines how freestanding contracts that are indexed to and potentially settled in a company s own stock should be measured and classified. Authoritative accounting guidance prescribes that only warrants issued by us under contracts that cannot be net-cash settled, and are both indexed to and settled in our common stock, can be classified as equity. As part of both our November 2008 and November 2009 financings, we issued warrants with five year terms to purchase 1,034,483 and 400,000 shares of our common stock at $23.00 and $15.00 per share, respectively. As part of our December 2011 financing, we issued Series A Warrants with a five year term to purchase 8,000,000 shares at $1.40 per share and Series B Warrants with a ninety trading day term to purchase 8,000,000 units at $1.25 per unit. Each unit underlying the Series B Warrants consisted of one share of our common stock and one Series A Warrant. In the first and second quarter of 2012, an aggregate of 2,700,000 Series B Warrants were exercised. For the exercise of these warrants, we issued 2,700,000 shares of our common stock and 2,700,000 Series A Warrants. The remaining 5,300,000 Series B Warrants expired unexercised by their terms on May 2, 2012. As terms of the warrants issued in 2008 and 2009, as well as the Series A and Series B Warrants, do not meet the specific conditions for equity classification, we are required to classify the fair value of these warrants as a liability, with subsequent changes in fair value to be recorded as income (loss) due to change in fair value of warrant liability. The fair value of the warrants issued in the 2008 and 2009 financings is determined using the Black-Scholes-Merton (Black-Scholes) option pricing model and the fair value of the Series A and Series B Warrants is determined using a Monte Carlo simulation model (see Note 8, Warrant Liability). The fair value is affected by changes in inputs to these models including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. The use of a Monte Carlo simulation model requires input of additional assumptions including the progress of our R&D programs and its affect on potential future financings. 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, 2012, was approximately $9,265,000.

Stock-Based Compensation

U.S. GAAP requires us to recognize expense related to the fair value of our stock-based compensation awards, including employee stock options and restricted stock units. 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 2012, we estimated this amount based on historical

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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. We review our valuation assumptions at each grant date and, as a result, our assumptions in future periods may change. At the end of each reporting period we estimate forfeiture rates based on our historical experience within separate groups of employees and adjust stock-based compensation expense accordingly. For the year ended December 31, 2012, employee and external services stock-based compensation expense (stock options, restricted stock units and 401(k) Plan employer match in form of shares) was approximately $2,878,000. As of December 31, 2012, total compensation cost related to unvested stock options and restricted stock units not yet recognized was approximately $2,322,000, which is expected to be recognized as expense over a weighted-average period of 1.7 years.

Wind-down expenses

Rhode Island

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. 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. 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 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 ten years (2003 through 2012) was approximately 73%, varying from 62% to 89%. As of December 31, 2012, based on current information available to management, the vacancy rate is projected to be approximately 89% for the remainder of the lease beginning on January 1, 2013 and ending on June 30, 2013. These estimates are based on actual occupancy as of December 31, 2012, 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. Due to the short time remaining on the lease period, the reserve assumes no additional tenants. A 5% increase or decrease in the operating expenses for the facility for the remaining lease term in 2013 would have increased or decreased the reserve by approximately $23,000. 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, 2012, we recorded actual expenses against this reserve, net of subtenant income, of approximately $1,185,000. Based on management s evaluation of the factors mentioned above, and particularly the projected vacancy rates described above, we adjusted the reserve in 2012 by recording an additional $356,000 as wind-down expenses. At December 31, 2012, the reserve including deferred rent was approximately $1,103,000.

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Goodwill and Other Intangible Assets (Patent and License Costs)

Goodwill of approximately $1,983,000 at December 31, 2012, relates to the acquisition of SCS operations. Goodwill and intangible assets deemed to have indefinite lives are not amortized but are subject to annual impairment tests. If the assumptions and estimates used to allocate the purchase price are not correct, or if business conditions change, purchase price adjustments or future asset impairment charges could be required. We test goodwill for impairment on an annual basis or more frequently if we believe indicators of impairment exist. Impairment evaluations involve management estimates of asset useful lives and future cash flows. Significant management judgment is required in the forecasts of future operating results that are used in the evaluations, and it is possible, even likely, that the plans and estimates used may be incorrect. If our actual results, or the plans and estimates used in future impairment analysis are lower than the original estimates used to assess the recoverability of these assets, we could incur additional impairment charges in a future period. We completed our annual impairment testing during the fourth quarter of 2012, and determined that there was no impairment of goodwill.

Other intangible assets, net were approximately $1,823,000 at December 31, 2012. Intangible assets with finite useful lives are amortized generally on a straight-line basis over the periods benefited. Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. 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 patent costs are expensed as incurred. License costs are capitalized and amortized over the estimated life of the license agreement. In 2010, we wrote-off the unamortized amount of approximately $67,000 for certain license agreements that we terminated. In December 2011, in part because of management s decision to focus on our therapeutic product development programs and not to allocate time and resources to the assays technology, we determined that we could not predict the future cash flows from the intangible IPR&D asset related to the assays technology. Therefore, we determined that the intangible asset was impaired and wrote off the approximately $655,000 carrying value of the asset.

Impairment of Long-Lived Tangible Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. If property, plant, and equipment 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. In 2010 and 2012, we recorded a charge of approximately $63,000 and 28,000 respectively, to adjust the fair value of certain lab equipment we expect to dispose. No such impairment was recognized during the year 2011.

Income Taxes

When accounting for income taxes, we recognize 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 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.

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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.

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 increasing operating costs.

Revenue

Revenue totaled approximately $1,368,000 in 2012, $1,221,000 in 2011, and $1,427,000 in 2010.

	2012	2011	2010	Change in 2012 Versus 2011 $	Change in 2012 Versus 2011 %	Change in 2011 Versus 2010 $	Change in 2011 Versus 2010 %
Revenue							
Revenue from licensing agreements, grants and other	$ 511,558	$ 557,880	$ 927,772	$ (46,322)	(8)%	$ (369,892)	(40)%
Product sales	856,397	662,790	499,200	193,607	29%	163,590	33%
Total revenue	1,367,955	1,220,670	1,426,972	147,285	12%	(206,302)	(14)%
Cost of product sales	263,188	214,811	168,424	48,377	23%	46,387	27%
Gross profit	$ 1,104,767	$ 1,005,859	$ 1,258,548	$ 98,908	10%	$ (252,689)	(20)%

Total revenue in 2012 was approximately $1,368,000, which was 12% higher than total revenue in 2011. In 2012, revenue from product sales increased 29%, or approximately $194,000, compared to 2011. This increase was primarily attributable to increased unit volumes in our SC Proven line of media and reagents. In 2012, approximately 70% of our product sales were in Europe, 13% were in the United States, and 17% were in Asia. Aggregate licensing, grant and other revenue in 2012 were relatively flat in 2012 as compared to 2011. Grant revenue in 2012 was not significant and licensing fees in 2012 was primarily from a license agreement with genOway, under which we granted genOway a worldwide

exclusive license to our IRES technology for use in the development and commercialization of genetically engineered mice.

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Total revenue in 2011 was approximately $1,221,000, which was 14% lower than total revenue in 2010. In 2011, revenue from product sales increased 33%, or approximately $164,000, compared to 2010. This increase was primarily attributable to both increased unit volumes and new product launches in our SC Proven line of media and reagents. In 2011, approximately 70% of our product sales were in Europe, 13% were in the United States, and 17% were in Asia. Licensing, grant and other revenue declined approximately $370,000, or 40%, in 2011 compared to 2010. Grant revenue decreased from approximately $315,000 in 2010 to approximately $172,000 in 2011 as several projects funded by grants were completed or terminated in 2010. Licensing revenue decreased to approximately $414,000 in 2011 from approximately $613,000 in 2010. The higher licensing revenue in 2010 was primarily due to receipt of a milestone payment of approximately $438,000, net of royalty due to NeuroSpheres, Ltd. (NeuroSpheres), an Alberta corporation from which we have licensed some of our patent rights.

Operating Expenses

Operating expense totaled approximately $23,650,000 in 2012, $29,082,000 in 2011, and $30,618,000 in 2010.

				Change in 2012 Versus 2011		Change in 2011 Versus 2010	
	2012	2011	2010	$	%	$	$
Operating Expenses							
Research & development	$ 15,846,829	$ 19,937,764	$ 21,019,301	$ (4,090,935)	(21)%	$ (1,081,537)	(5)%
Selling, general & administrative	7,447,235	8,202,375	9,376,774	(755,140)	(9)%	(1,174,399)	(12)%
Wind-down expenses	356,379	287,122	221,991	69,257	24%	65,131	29%
Impairment of intangible asset		654,961		(654,961)	(100)%	654,961	*
Total operating expenses	$ 23,650,443	$ 29,082,222	$ 30,618,066	$ (5,431,779)	(19)%	$ (1,535,844)	(5)%

* Calculation is not meaningful.

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 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 2012) were approximately $168 million. Over this period, the majority of these cumulative costs were related to: (i) characterization of our proprietary HuCNS-SC cells, (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, (iv) costs associated with cell processing and process development, and (v) costs associated with our clinical studies.

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

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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 $15,847,000 in 2012, as compared to $19,938,000 in 2011 and $21,019,000 in 2010. At December 31, 2012, we had 39 full-time employees working in research and development and laboratory support services as compared to 40 at December 31, 2011 and 62 at December 31, 2010.

2012 versus 2011. R&D expenses decreased by approximately $4,091,000, or 21%, in 2012 compared to 2011. This decrease was primarily attributable to (i) a decrease of approximately $1,143,000 in personnel expenses primarily due to the reduction in force effected in May 2011, (ii) a decrease of approximately $310,000 in operating expenses at our U.K. operations as we consolidated our activities at the site, (iii) a decrease in facilities expense of approximately $1,050,000 attributable to the relocation of our corporate headquarters and core research activities in July 2011; the 2011 period includes facilities expense from the previous lease which expired on August 31, 2011, (iv) a decrease of approximately $784,000 in external services and clinical studies; the 2011 period includes higher external services expenses primarily related to the preclinical studies of our HuCNS-SC cells for retinal disorders, other potential indications and quality tests of our cell banks, (v) a decrease of approximately $295,000 in expenses related to the clinical development within our CNS program, and (vi) a decrease in supplies and other operating expenses of approximately $509,000.

2011 versus 2010. R&D expenses decreased by approximately $1,082,000, or 5%, in 2011 compared to 2010. This decrease was primarily attributable to (i) a decrease of approximately $1,949,000 in personnel expenses primarily due to the reduction in force effected in May 2011, (ii) a decrease of approximately $694,000 in operating expenses for our U.K. operations as cost reduction efforts initiated in 2010 took full effect, (iii) a decrease of approximately $1,134,000 in expenses related to cell manufacturing, and (iv) a decrease of approximately $518,000 in other operating expenses, primarily other external services and supplies. These decreases in expenses were offset by the following increases: (i) clinical study expenses increased approximately $1,006,000 as we conducted our Phase I/II clinical trial in chronic spinal cord injury, and our Phase I clinical trial in PMD, (ii) external services expenses increased approximately $1,319,000 primarily related to preclinical studies and IND-enabling activities related to retinal disorders, (iii) approximately $216,000 in severance payments related to the reduction in force effected in May 2011, and (iv) approximately $672,000 in facilities expense primarily due to recognizing operating lease expense on a straight-line basis (See Note 12 Commitment and Contingencies, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses are primarily comprised of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal, human resources, information technology, and other administrative personnel, facilities and overhead costs, and external legal, audit and other general and administrative services.

SG&A expenses totaled approximately $7,447,000 in 2012, compared with $8,202,000 in 2011 and $9,377,000 in 2010.

2012 versus 2011. SG&A expenses decreased by approximately $755,000, or 9%, in 2012 compared to 2011. This decrease was primarily attributable to (i) a decrease of approximately $500,000 in external services,

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primarily legal fees, (ii) a decrease in facilities expense of approximately $194,000 attributable to the relocation of our corporate headquarters in July 2011; the lease on our previous corporate headquarters expired on August 31, 2011, and (iii) a net decrease of approximately $61,000 in other operating expenses.

2011 versus 2010. SG&A expenses decreased by approximately $1,175,000, or 12%, in 2011 compared to 2010. This decrease was primarily attributable to (i) a decrease of approximately $649,000 in personnel expenses primarily due to the reduction in force effected in May 2011, (ii) a decrease of approximately $582,000 in operating expenses for our U.K. operations as cost reduction efforts initiated in 2010 took full effect, and (iii) a net decrease of approximately $68,000 in other operating expenses. These decreased expenses were partially offset by a net increase of approximately $124,000 in external services expenses, primarily attributable to legal and patent 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 inclusive of deferred rent was approximately $1,103,000 at December 31, 2012 and $2,135,000 at December 31, 2011. Payments net of subtenant income were recorded against this reserve of $1,185,000 in 2012, $1,248,000 in 2011, and $1,219,000 in 2010. We re-evaluated the estimate and adjusted the reserve by recording, in aggregate, additional wind-down expenses of $356,000 in 2012, $287,000 in 2011, and $291,000 in 2010. Expenses for this facility will fluctuate based on changes in tenant occupancy rates and other operating expenses related to the lease. In light of this uncertainty, based on estimates, we will periodically re-evaluate and adjust the reserve, as necessary. Due to the short time remaining on the lease period, the reserve assumes no additional tenants for the remainder of the lease beginning on January 1, 2013 and ending on June 30, 2013. See Note 10 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 $5,945,000 in 2012, compared with other income of approximately $6,748,000 in 2011 and other income of $4,116,000 in 2010.

	2012	2011	2010	Change in 2012 Versus 2011 $	Change in 2012 Versus 2011 %	Change in 2011 Versus 2010 $	Change in 2011 Versus 2010 %
Other income (expense)							
Realized gain on sale of marketable securities	$	$ 83,750	$	$ (83,750)	(100)%	$ 83,750	*
Change in fair value of warrant liability	(5,944,571)	6,612,092	3,005,040	(12,556,663)	(190)%	3,607,052	120%
Interest income	15,594	13,942	26,728	1,652	12%	(12,786)	(48)%
Interest expense	(50,193)	(71,363)	(93,382)	21,170	(30)%	22,019	(24)%
Qualifying Therapeutic Disc. Proj. Grant			977,917			(977,917)	(100)%
Other income (expense), net	33,693	109,404	199,664	(75,711)	(69)%	(90,260)	(45)%
Total other income (expense), net	$ (5,945,477)	$ 6,747,825	$ 4,115,967	$ 12,693,302	(188)%	$ 2,631,858	64%

* Calculation is not meaningful.

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Gain on Sale of Marketable Equity Securities

The gain on sale of marketable equity securities of approximately $84,000 in 2011 was primarily 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.

Change in Fair Value of Warrant Liability

We record changes in fair value of outstanding warrants as income or loss in our Consolidated Statements of Operations. We have warrants outstanding which were issued as part of several transactions since 2008 and have classified all these warrants as a liability. The fair value of the outstanding warrants is determined using various option pricing models, such as the Black-Scholes-Merton (Black-Scholes) option pricing model and the Monte Carlo simulation model, and is affected by changes in inputs to the various models, including our stock price, expected stock price volatility, the contractual term and the risk-free interest rate. The use of the Monte Carlo simulation model requires input of additional subjective assumptions including the progress of our R&D programs and its affect on potential future financings. 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 Statements of Operations. See Note 12 Warrant Liability, 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 $16,000 in 2012, $14,000 in 2011, and $27,000 in 2010. Interest income in 2012 was relatively flat as compared to 2011. The decrease in interest income from 2010 to 2011 was primarily attributable to lower average yields on cash, cash equivalents, and marketable securities and also due to lower average cash balances.

Interest Expense

Interest expense was approximately $50,000 in 2012, $71,000 in 2011, and $93,000 in 2010. The decrease in interest expense from 2010 to 2012 was primarily attributable to lower outstanding debt and capital lease balances.

Qualifying Therapeutic Discovery Project Grants

In October 2010, we were awarded four cash grants totaling approximately $978,000, in aggregate, for work related to our product development programs. These grants were certified under the federal government s Qualifying Therapeutic Discovery Projects program, which was created by Congress as part of the Patient Protection and Affordable Care Act of 2010. See Note 16 The Qualifying Therapeutic Discovery Project Grant, in the Notes to Consolidated Financial Statements of Part II, Item 8 of this Form 10-K for further information on these grants.

Other Income (Expense), net

Other income, net totaled approximately $34,000 in 2012, $109,000 in 2011, and $200,000 in 2010.

Other income, net in 2012 includes approximately $118,000 of R&D tax credits due to our wholly-owned subsidiary Stem Cell Sciences (U.K.) Ltd. The above income was offset by state franchise taxes of approximately $35,000 and a loss on disposal of fixed assets of approximately $49,000. Other income, net in 2011 includes the receipt of approximately $150,000 as a break-up fee paid to us upon the expiration of an exclusivity period granted to a potential licensee. Other income, net was partially offset in 2011 by other expenses, primarily state franchise taxes. Other income, net in 2010 includes approximately $227,000 from final settlement of various claims related to our acquisition of SCS in 2009. Other income, net also includes approximately $89,000 of R&D tax credits in 2010 due to our wholly-owned subsidiary Stem Cell Sciences (U.K.) Ltd. The above income was offset by other expenses, net of approximately $116,000, primarily related to write-down of assets and state franchise taxes.

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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 research grants, license fees, product sales and interest income.

	2012	2011	2010	Change in 2012 Versus 2011 $	%	Change in 2011 Versus 2010 $	%
At December 31:							
Cash and highly liquid investments(1)	$ 22,371,953	$ 16,591,852	$ 19,707,821	$ 5,780,101	35%	$ (3,115,969)	(16)%
Year ended December 31:							
Net cash used in operating activities	$ (19,869,344)	$ (22,058,283)	$ (24,519,913)	$ 2,188,939	(10)%	$ 2,461,630	(10)%
Net cash used in investing activities	$ (10,691,831)	$ (3,422,012)	$ (923,964)	$ (7,269,819)	212%	$ (2,498,048)	270%
Net cash provided by financing activities	$ 25,737,110	$ 19,129,484	$ 6,586,380	$ 6,607,626	35%	$ 12,543,104	190%

(1) Cash and highly liquid investments include unrestricted cash, cash equivalents, and short-term and long-term marketable debt securities. 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 $22,372,000 at December 31, 2012, compared with approximately $16,592,000 at December 31, 2011, and $19,708,000 at December 31, 2010.

Net Cash Used in Operating Activities

Cash used in operating activities consists of net loss for the year, adjusted for non-cash expenses such as depreciation and amortization and stock-based compensation and adjustments for changes in various components of working capital. Cash used in operating activities was approximately $19,869,000 in 2012, $22,058,000 in 2011, and $24,520,000 in 2010. The decrease in cash used in operating activities from 2010 to 2012 was primarily attributable to decreased operating expenses due to (i) the reduction in work force effected in May 2011, (ii) a decrease in facilities expense attributable to the relocation of our corporate headquarters in July 2011, and (iii) the consolidation of our activities at our UK operations.

Net Cash Used in Investing Activities

Net cash used in investing activities increased by approximately $7,270,000, or 212%, in 2012 compared to 2011. The increase was primarily attributable to an increase in net purchases of marketable debt securities in 2012 as compared to 2011. Net cash used in investing activities increased by $2,498,000, or 270%, in 2011 compared to 2010. The increase was primarily attributable to net purchases of marketable debt securities in 2011. No purchases of marketable debt securities were made in 2010. Our investment portfolio comprised primarily of U.S. Treasury debt securities, which are classified as cash equivalents and commercial paper and corporate debt securities, which are classified as short-term marketable securities, with no positions held in-long term marketable debt securities.

Net Cash Provided by Financing Activities

The increases in cash provided by financing activities from 2010 to 2012 were primarily attributable to higher net proceeds from sales of our common stock.

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Listed below are key financing transactions entered into by us in 2012, 2011 and 2010:

In 2012, we sold an aggregate of 9,647,471 shares of our common stock at an average price per share of $2.12 for gross proceeds of approximately $20,452,000. These sales were made under a sales agreement entered into in June 2009 (2009 sales agreement) and the sales agent was paid compensation equal to 3% of gross proceeds. The shares were offered under our shelf registration statement previously filed with, and declared effective by, the SEC.

In 2012, an aggregate of 2,700,000 Series B Warrants were exercised and we received gross proceeds of $3,375,000. The remaining 5,300,000 Series B Warrants expired unexercised by their terms on May 2, 2012. For the exercise of these warrants, we issued 2,700,000 shares of our common stock and 2,700,000 Series A Warrants.

In 2012, an aggregate of 2,198,571 Series A Warrants were exercised. For the exercise of these warrants, we issued 2,198,571 shares of our common stock and received gross proceeds of approximately $3,078,000.

In December 2011, we raised gross proceeds of $10 million through a public offering of 8,000,000 Units and 8,000,000 Series B Warrants. The combination of Units and Series B Warrants were sold at a public offering price of $1.25 per Unit. Each Series B Warrant gave the holder the right to purchase one Unit at an exercise price of $1.25 per Unit and was exercisable until May 2, 2012, the 90th trading day after the date of issuance. Each Unit consists of one share of our common stock and one Series A Warrant. Each Series A Warrant gives the holder the right to purchase one share of our common stock at an initial exercise price of $1.40 per share. The Series A warrants are immediately exercisable upon issuance and will expire in December 2016. The shares were offered under our effective shelf registration statement previously filed with, and declared effective by, the SEC.

In January 2011, we sold 1,000,000 shares of our common stock to selected institutional investors at a price of $10.00 per share. We received net proceeds, after deducting offering expenses and fees, of approximately $9,400,000. The investors were also granted an option to purchase an additional 6,000,000 shares at $10.00 per share. The option was not exercised and expired on February 18, 2011. The shares were offered under a shelf registration previously filed with, and declared effective by, the SEC.

In 2011, we sold a total of 525,116 shares of our common stock under the 2009 sales agreement at an average price per share of $2.47 for gross proceeds of approximately $1,297,000. The sales agent was paid compensation equal to 3.0% of gross proceeds pursuant to the terms of the agreement. The shares were offered under a shelf registration previously filed with, and declared effective by, the SEC.

In June 2010, we sold 700,000 shares of our common stock to an institutional investor, at a price of $8.65 per share. We received net proceeds, after deducting offering expenses and fees, of approximately $5,700,000. No warrants were issued in this transaction. The shares were sold under our effective shelf registration statement previously filed with the SEC. As part of the purchase agreement, the institutional investor agreed to purchase an additional 500,000 shares of common stock approximately 12 weeks after the initial sale, at our option and at a purchase price to be calculated using the then-current trading price. We decided not to sell these additional shares and on September 20, 2010, we terminated the purchase agreement.

In 2010, we sold a total of 147,520 shares of our common stock under the 2009 sales agreement at an average price per share of $11.60 for gross proceeds of approximately $1,705,000. The sales agent was paid compensation equal to 3.0% of the gross proceeds pursuant to the terms of the agreement. The shares were offered under a shelf registration previously filed with, and declared effective by, the SEC.

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

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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 selling, general and administrative expenses and other working capital requirements. We rely on cash balances and proceeds from equity and debt offerings, 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. In November 2010, we filed with the SEC, and the SEC declared effective, a universal shelf registration statement which permits us to issue up to $100 million worth of registered debt and equity securities. As of March 1, 2013, we had approximately $38 million under this universal shelf registration statement available for issuing debt or 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. In June 2009, we entered into the 2009 sales agreement pursuant to which we had the option to sell up to $30 million of our common stock, from time to time, in at-the-market offerings. Between June 2009 and November 2012, we sold common stock under the sales agreement worth approximately $26.7 million. In December 2012, we amended the 2009 sales agreement (2012 amended sales agreement) to, among other things, raise the dollar amount of shares available to sell under the agreement back to $30 million. The sales agreement, as amended, has been filed with the SEC.

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 11, 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.

Operating Leases California

In December 2010, we entered into a commercial lease agreement with BMR-Gateway Boulevard LLC (BMR), as landlord, for approximately 43,000 square feet of office and research space at BMR s Pacific Research Center in Newark, California. The initial term of the lease is approximately eleven and one-half years,

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and we relocated our corporate headquarters and core research activities from a facility located in Palo Alto, California, to this facility