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

Form 10-K

#### ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) $\checkmark$ **OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

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)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3078125 (I.R.S. Employer Identification No.)

3155 PORTER DRIVE, PALO ALTO, CA 94304 (Address of principal offices) (zip code)

Registrant's telephone number, including area code: (650) 475 3100

Securities registered pursuant to Section 12(b) of the Act: NONE

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

# **COMMON STOCK, \$.01 PAR VALUE** JUNIOR PREFERRED STOCK PURCHASE RIGHTS

Title of class

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

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 an accelerated filer as defined in Exchange Act Rule 126(2). Yes 🗹 No o

Aggregate market value of Common Stock held by non-affiliates at June 30, 2004: \$81,006,548. 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 8, 2005: 62,417,451 shares.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the registrant's 2005 Annual Meeting of Stockholders to be filed with the Commission pursuant to Regulation 14A are incorporated by reference in Part III of this report.

## FORWARD LOOKING STATEMENTS

THIS REPORT CONTAINS FORWARD-LOOKING STATEMENTS AS DEFINED UNDER THE FEDERAL SECURITIES LAWS, ACTUAL RESULTS COULD VARY MATERIALLY. FACTORS THAT COULD CAUSE ACTUAL RESULTS TO VARY MATERIALLY ARE DESCRIBED HEREIN AND IN OTHER DOCUMENTS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. READERS SHOULD PAY PARTICULAR ATTENTION TO THE CONSIDERATIONS DESCRIBED IN THE SECTION OF THIS REPORT ENTITLED "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" AS WELL AS EXHIBIT 99 TO THIS REPORT, ENTITLED "CAUTIONARY FACTORS RELEVANT TO FORWARD-LOOKING INFORMATION." READERS SHOULD ALSO CAREFULLY REVIEW ANY RISK FACTORS DESCRIBED IN OTHER DOCUMENTS WE FILE FROM TIME TO TIME WITH THE SECURITIES AND EXCHANGE COMMISSION.

Item 1 Item 2 Item 3. Item 4 **Table of Contents** 

<u>Item 5.</u>	Market for Registrant's Common Equity, Related Stockholders Matters and Issuer Purchases of Equity	25
	Securities	
<u>Item 6.</u>	Selected Financial Data	27
<u>Item 7.</u>	Management's Discussion and Analysis of Financial Condition and Results of Operations	28
<u>Item 7A.</u>	Quantitative and Qualitative Disclosures about Market Risk	48
<u>Item 8.</u>	Financial Statements and/supplementary Data	49
<u>Item 9.</u>	Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	77
<u>Item 9A.</u>	Controls and Procedures	77
<u>Item 10.</u>	Directors and Executive Officers of the Registrant	78
<u>Item 11.</u>	Executive Compensation	78
<u>Item 12.</u>	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	78
<u>Item 13.</u>	Certain Relationships and Related Transactions	78
<u>Item 14.</u>	Principal Accountant Fees and Services	79
<u>Item 15.</u>	Exhibits and Financial Statement Schedules	79
EXHIBIT 23.1		
EXHIBIT 23.2		
<u>EXHIBIT 31.1</u>		
EXHIBIT 31.2		
EXHIBIT 32.1		
EXHIBIT 32.2		
EXHIBIT 99		

## ITEM 1. BUSINESS

## Overview

We are engaged in research aimed at the development of therapies that would use stem and progenitor cells to treat, and possibly cure, human diseases and injuries such as neurodegenerative diseases (for instance, Batten's, Parkinson's, and Alzheimer's diseases, and other metabolic genetic disorders), demyelinating disorders (for instance, Multiple Sclerosis), spinal cord injuries, stroke, hepatitis, chronic liver failure, and diabetes. We believe that our stem cell technologies, if successfully developed, may provide the basis for effective therapies for these and other conditions. Our aim is to return patients to productive lives and significantly reduce the substantial health care costs often associated with these diseases and disorders. The body uses certain key cells known as stem cells to produce all the functional mature cell types found in normal organs of healthy individuals. Progenitor cells are cells that have already developed from the stem cells, but can still produce one or more types of mature cells within an organ. We use cells derived from fetal or adult tissue sources, and are not developing embryonic stem cells for therapeutic use. Neither are we involved in any activity directed toward human cloning; our programs are all directed toward the use of tissue-derived cells for treating or curing diseases and injuries.

Many diseases, such as Alzheimer's, Parkinson's, lysosomal storage diseases and other degenerative diseases of the brain or nervous system, involve the failure of organs that cannot be transplanted. Other diseases, such as hepatitis and diabetes, involve organs such as the liver or pancreas that can be transplanted, but there is a very limited supply of those organs available for transplant. We estimate that these neural, liver and pancreatic conditions affect more than 50 million people in the United States and account for more than \$300 billion annually in health care costs.(1)

Our stem cell discovery engine relies upon our state of the art cell sorting capabilities and our library of proprietary monoclonal antibodies to human proteins. Using this library of monoclonal antibodies, we have successfully identified, purified, and characterized the human central nervous system stem cell. We have also used our proprietary monoclonal antibodies to make significant advances in our search for stem or progenitor cells of the liver and the pancreas. We have established an intellectual property position in all three areas of our stem cell research — the nervous system, the liver and the pancreas — by patenting our discoveries and entering into exclusive in-licensing arrangements. We believe that, if successfully developed, our platform of stem cell technologies may create the basis for therapies that would address a number of conditions with significant unmet medical needs. We are concentrating our efforts on the preclinical and clinical development of our neural stem cell program and research endeavors in characterizing the candidate stem/progenitor cells for the liver and pancreas programs.

In late December 2004, we submitted our first Investigational New Drug application (IND), for a clinical trial in Batten Disease. That IND is currently on clinical hold, and discussions with the U.S. Food and Drug Administration (FDA) are continuing as the Company formulates plans to respond to the FDA's questions and concerns.

## **Cell Therapy Background**

## Role of Cells in Human Health and Traditional Therapies

Cells maintain normal physiological function in healthy individuals by secreting or metabolizing substances, such as sugars, amino acids, neurotransmitters and hormones, which are essential to life. When

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

cells are damaged or destroyed, they no longer produce, metabolize or accurately regulate those substances. Impaired cellular function is associated with the progressive decline common to many degenerative diseases of the nervous system, such as Parkinson's disease and Alzheimer's disease. Recent advances in medical science have identified cell loss or impaired cellular function as leading causes of degenerative diseases. Biotechnology advances have led to the identification of some of the specific substances or proteins that are deficient in some diseases, such as dopamine which is deficient in the brains of individuals with Parkinson's disease as a result of the loss of dopamine producing neurons. While administering these substances or proteins as medication does overcome some of the limitations of traditional pharmaceuticals such as lack of specificity, there is no existing technology that can deliver them to the precise sites of action and in the appropriate physiological regulation and quantities or for the duration required to cure the degenerative condition. Cells, however, can do this naturally. As a result, investigators have considered supplementing the failing cells that are no longer producing the needed substances or proteins by implanting stem or progenitor cells. Where there has been irreversible tissue damage or organ failure, transplantation of these stem or progenitor cells offers the possibility of generating new and healthy mature cells, thus potentially restoring the organ function and the patient's health.

## The Potential of our Tissue-Derived Stem Cell-Based Therapy

We believe that, if successfully developed, stem cell-based therapy — the use of stem or progenitor cells to treat diseases — has the potential to provide a broad therapeutic approach comparable in importance to traditional pharmaceuticals and genetically engineered biologics.

Stem cells are rare and only available in limited supply, whether from the patients themselves or from donors. Cells obtained from the same person who will receive them may be abnormal if the patient is ill or the tissue is contaminated with disease-causing cells. Also, such cells can often be obtained only through significant surgical procedures. The challenge, therefore, has been three-fold:

1) to identify the stem or progenitor cells of a particular organ;

2) to create techniques and processes that can be used to expand these rare cells in sufficient quantities to transplant into multiple patients; and

3) to establish a bank of normal human stem or progenitor cells that can be used for transplantation into individuals whose own cells are not suitable because of disease or other reasons.

We have developed techniques for discovering novel monoclonal antibodies that can be used to label markers on the cell surface to identify and isolate specific cell types, and particularly stem and progenitor cells. This methodology allows us to purify the stem cell population and eliminate other unwanted cell types. For example, we have discovered and patented the use of monoclonal antibodies to identify human central nervous system, or CNS, stem cells, as well as a candidate human liver stem-like cell and a candidate pancreatic stem/progenitor cell.

We have also developed a process, based on a proprietary *in vitro* culture system in chemically defined media, that reproducibly grows normal human CNS, stem and progenitor cells. We believe this is the first reproducible process for growing normal human CNS stem cells. Together, these discoveries enable us to select normal human CNS stem cells and to expand them in culture to produce a large number of pure stem cells. This process facilitates the banking of large quantities of individual vials of these cells, which could then be used for distribution to transplant centers worldwide for administration to patients.

Because these cells have not been genetically modified, they may be especially suitable for transplantation and may provide a safer and more effective alternative to therapies that are based on cells derived from cancer cells, from cells modified by a cancer gene to make them grow, from an unpurified mixture of many different cell types, or from animal derived cells. We believe our proprietary stem cell technologies may be used to restore function by replacing specific cells that have been damaged or destroyed. In our research, we have shown that when human stem cells of the central nervous system are transplanted into animals, they are accepted, migrate, and successfully specialize to produce mature neurons and glial cells.

More generally, because the tissue-derived stem cell is the pivotal cell that produces all the functional mature cell types of the organ from which it originates, we believe these cells, if successfully identified, expanded and stored as frozen cell banks, may serve as platforms for five major areas of regenerative medicine and biotechnology:

- tissue repair and replacement,
- correction of genetic disorders,
- drug discovery and screening,
- gene discovery and use, and
- diagnostics.

We intend to research, develop, and commercialize the therapeutic uses of our stem and progenitor cells alone or in partnership with third parties. We also intend to monetize non-core uses of our stem cell technology, such as diagnostics, gene discovery and use, drug discovery and drug screening, by engaging in a number of non-exclusive agreements

#### Stem Cell Technology

Stem cells have two defining characteristics:

- some of the cells developed from stem cells produce all the kinds of mature cells making up the particular organ; and
- they self renew that is, other cells developed from stem cells are themselves new stem cells, thus permitting the process to continue again and again.

Stem cells are known to exist for a number of systems of the human body, including the blood and immune system, the central and peripheral nervous systems (including the brain), the skin, bone, and even the hair. They are thought to exist for many others, including the liver and pancreas endocrine systems, gut, muscle, and heart. Stem cells are responsible for organ regeneration during normal cell replacement and, to greater or lesser extent, after injury. We believe that further research and development will allow stem cells to be cultivated and administered in ways that enhance their natural function, so as to form the basis of therapies that will replace specific subsets of cells that have been damaged or lost through disease, injury or genetic defect.

We also believe that the person or entity that first identifies and isolates a stem cell and defines methods to culture any of the finite number of different types of human stem cells will be able to obtain patent protection for the methods and the composition, making the commercial development of stem cell treatment and possible cure of currently intractable diseases financially feasible.

Our strategy is to be the first to identify, isolate and patent multiple types of human stem and progenitor cells, derived from human tissue, with commercial importance. We have also obtained rights to certain inventions relating to stem cells and progenitor cells from academic institutions. We expect to continue to expand our search for, and to seek to acquire rights from third parties relating to, new stem and progenitor cells, and to further develop our intellectual property positions with respect to them in-house and through research at scholarly institutions. Our portfolio of issued patents includes a method of culturing normal human central nervous system stem and progenitor cells in our proprietary chemically defined media, and our published studies show that these cultured and expanded cells give rise to all three major cell types of the central nervous system. In rodents, we have shown that these cells exhibit the unique properties of stem cells: They migrate and colonize throughout the organ from which they were derived and mature into the specialized cells, such as neurons and glial cells, that are normally found in that region of the organ. We also have patent applications pending in connection with our search for liver and pancreas stem and progenitor cells.



Neurological disorders such as Parkinson's disease, Alzheimer's disease, the side effects of stroke, and the neural degeneration that accompanies genetic disorders such as Gaucher's Disease, Tay-Sachs Disease, and Batten Disease affect a significant portion of the U.S. population and there currently are no effective long-term therapies for them. We believe that therapies based on our process for identifying, isolating and culturing neural stem and progenitor cells may be useful in treating such diseases. We are continuing our research into, and have initiated the development of, human central nervous system stem and progenitor cell-based therapies for some of these diseases.

## Our Neural Stem Cell Program

We have published the results of a study showing that human central nervous system stem cells can be successfully isolated by markers present on the surface of freshly obtained brain cells. We believe this is the first reproducible process for isolating highly purified populations of well-characterized normal human central nervous system stem cells. We own or have exclusive licenses to U.S. patents on this process, as well as issued patents and pending patent applications for compositions of matter. Because the cells are highly purified and have not been genetically modified, they may be especially suitable for transplantation and may provide a safer and more effective alternative than therapies that are based on cells derived from cancer cells, or from cells modified by a cancer gene to make them grow, or from an unpurified mixture of many different cell types or cells derived from animals. We are the exclusive licensee of a U.S. patent issued in December, 2002, covering the transplantation of central nervous system stem cells (U.S. Patent No. 6,497,872, "Neural transplantation using proliferated multipotent neural stem cells and their progeny"). We have also filed patent applications covering the growth and expansion of these purified normal human central nervous system cells.

In 2001, we also announced the results of a new study (published in 2002) in which we used novel human specific monoclonal antibodies to demonstrate the extent of engraftment, migration and site-specific formation of the human neural stem cells into mature neurons. These neuronal cells integrate in a 3-dimensional array within the normal architecture of the mouse brain. Astrocytes and oligodendrocytes, the other two principle types of central nervous system cells, are also generated from the human neural stem cells.

In 2003, we announced results of three preclinical studies showing proof of principle of the human CNS-SC for a neurodegenerative disease using the mouse model for Infantile Batten Disease (a rare lysosomal storage disease), for spinal cord injury using a spinal cord crush mouse model and for myelination in the shiverer mouse model. We also demonstrated in a mouse model for the Batten disease mouse model that the Company's human CNS-SC engraft, migrate throughout the brain and produce the enzyme that is missing in this transgenic mouse. The transplanted human cells are able to neuroprotect specific neurons, in the transgenic mouse, from death and quantitatively reduce the insoluble storage material in the brain, a characteristic hallmark of this disease. We discussed these results with the FDA, and began preparations toward the filing of an Investigational New Drug application (IND).

At the October, 2004 Society for Neuroscience meeting in San Diego, the Company presented an update to the preclinical data demonstrating the secretion from the human neural stem cells of the enzyme that is missing in Batten disease. The secreted enzyme can be taken up by cells in culture derived from Batten's patients, which provides additional evidence for the Company's hypothesis that these purified and expanded human neural stem cells may provide a source of enzyme to deficient cells. The Company also presented data in the transgenic mouse model for Batten disease showing the steady rise in enzyme levels in the brains of these mice over time.

In late December 2004, the Company filed an IND for a Phase I clinical trial of StemCells' proprietary neural cell therapy product (HuCNS SC)-in Batten disease. The FDA has informed the Company that it has suggestions and questions related to the proposed trial that require additional information from the Company and has placed the proposed trial on clinical hold. StemCells expects to be in active dialogue with the FDA to address the outstanding issues. We note that none of the FDA's suggestions or questions are related to contaminated embryonic stem cells that have been the matter of media attention. StemCells, Inc. does not use embryonic stem cells, and does not use mouse feeder cells in any way in preparing its stem cells. All cells

prepared by StemCells, Inc. are grown in serum-free media and do not come into contact with cells from animals.

The Company's proprietary human neural stem cells have also shown promising results in preclinical results in spinal cord injury. Drs. Aileen Anderson and Brian Cummings of the Reeve-Irvine Center at the University of California presented the data from their study in mice at theTenth Annual Conference of the American Society for Neural Transplantation and Repair on May 2, 2003, showing that the Company's stem cell technology has the potential to protect and regenerate damaged nerves and nerve fibers in patients with spinal cord injuries. In quantitative tests designed to measure functional recovery from complete hind limb paralysis to normal walking, the Company's researchers reported that injured mice transplanted with the Company's human neural stem cells (hCNS-SC) showed improved motor function compared to control animals. Inspection of the spinal cords from these mice showed significant levels of human neural cells derived from the transplanted stem cells. Previously, injured rats have been given stem cells from other rats or mice, but not stem cells from humans. The performance of the human cells in this rodent injury model suggests the possibility that similar results may be obtainable in humans. We believe that the significance of this study is that there is now hope in treating two aspects of spinal cord injury: nerve damage and loss of motor function.

In November 2003, the Company presented data at the 33rd Annual Society for Neuroscience Meeting showing production of myelin, the insulator for nerve cells. In the mutant shiverer mouse, which is deficient in myelin production, transplantation of hCNS-SC into the brain resulted in widespread engraftment of human cells that matured into oligodendrocytes, the myelin producing cells. Analysis of the brain tissue of these mice shows the human cells juxtaposed to the mouse nerves where the myelin produced by the human cells now ensheath the mouse nerve, providing the proper layers of insulation. Further studies are in progress to demonstrate proper function of the newly produced myelin. Loss of myelin characterizes conditions such as spinal cord injury, multiple sclerosis, cerebral palsy and certain genetic disorders (for example, Krabbe's disease, metachormatic leukodystrophy, Tay Sachs disease).

#### Our Other Stem Cell Programs

We continue to advance our research programs on the candidate liver and pancreas stem and/or progenitor cells. Liver stem cells may be useful in the treatment of diseases such as hepatitis, liver failure, blood-clotting disorder, cirrhosis of the liver and liver cancer. Islet cells are the pancreas cells that produce insulin, so pancreatic stem cells may be useful in the treatment of Type 1 diabetes and those cases of Type 2 diabetes where insulin secretion is defective. These programs are discussed below.

## Note on State and Federal Grants

In November 2004, California State Proposition 71 (Prop. 71), the California Stem Cell Research and Cures Initiative, was adopted by the electorate. It is intended to encourage stem cell research in the State of California, and to finance such research with State funds of approximately \$295 million annually for 10 years beginning with 2005. It is our understanding that the California Institute for Regenerative Medicine to be created under the Initiative will provide grants, primarily but not exclusively to academic institutions, to advance both embryonic stem cell research and adult stem cell research; the latter is the current and exclusive focus at StemCells. StemCells, Inc. is eligible to receive Prop. 71 generated funds and we do intend to apply for such funding. We also remain eligible for federal government support from the National Institute of Health (NIH) due to our focus on adult stem cells. NIH grants to the Company or to its academic collaborators assist research in the use of our cells for various diseases and conditions such as Alzheimer's disease and spinal cord injuries. Prop. 71 funds will not go to any project that receives NIH funding. The Company considers government grants to be important confirmation of the quality of its science and intellectual property, but does not rely on them as a significant source of financial support.

## **Expected Advantages of Our Stem Cell Technology**

## 1. No Other Treatment

To our knowledge, no one has developed an FDA-approved method for replacing lost or damaged tissues from the human nervous system. Replacement of tissues in other areas of the human body is mainly limited to those few sites, such as bone marrow or peripheral blood cell transplants, where transplantation of the patient's own cells is now feasible. In a few additional areas, including the liver, transplantation of donor organs is now used, but is limited by the scarcity of organs available through donation. We believe that our stem cell technologies have the potential to reestablish function in at least some of the patients who have suffered the losses referred to above.

## 2. Replaced Cells May Provide Normal Function for the Life of the Patient

Because stem cells can duplicate themselves, or self-renew, and specialize into the multiple kinds of cells that are commonly lost in various diseases, transplanted stem cells may be able to migrate limited distances to the proper location within the body, to expand and specialize and to replace damaged or defective cells, facilitating the return to proper function. We believe that such replacement of damaged or defective cells by functional cells is unlikely to be achieved with any other treatment.

## 3. Stem Cell Therapy Targets the Root Cause of the Disease

Most approved therapies for the diseases being targeted by the Company are palliative in nature, primarily treating the symptoms of the disease. Stem cell therapy, by contrast, has the potential to arrest or slow down the progression of the disease or even cure the patient.

## **Research and Development Programs**

## **Overview of Strategy**

We have devoted substantial resources to our research programs to isolate and develop a series of stem and progenitor cells that we believe can serve as a basis for replacing diseased or injured cells. Our efforts to date have been directed at methods to identify, isolate and culture large varieties of stem and progenitor cells of the human nervous system, liver and pancreas and to develop therapies utilizing these stem and progenitor cells.

The following Table lists the potential therapeutic indications for, and current status of, our primary research and product development programs and projects. The table is qualified in its entirety by reference to the more detailed descriptions of such programs and projects appearing elsewhere in this report. We continually evaluate our research and product development efforts and reallocate resources among existing programs or to new programs in light of experimental results, commercial potential, availability of third party funding, likelihood of near-term efficacy, collaboration success or significant technology enhancement, as well as other factors. Our research and product development programs are at relatively early stages of development and will require substantial resources to commercialize.

#### **Research and Product Development Programs Program Description and Objective** Stage/Status(1) Human Neural Stem Cell Preclinical/IND filing Repair or replace damaged central nervous system tissue (including spinal • Demonstrated the ability to reproducibly identify and purify human cord, stroke-damaged tissue, and tissue affected by certain genetic neural stem cells (hCNS-SC). disorders) • Demonstrated the ability to create human neural stem cell banks. • Demonstrated in vitro the ability to initiate and expand stem cellcontaining human neural cultures and specialization into three types of central nervous system cells. • Demonstrated in rodent studies that transplanted human brain-derived stem cells are accepted and properly specialized into the three major cell types of the central nervous system with no tumor formation. • Commenced preclinical testing of human neural stem cells in wellcharacterized small animal models of human diseases. • Batten Disease Indication (Preclinical): • Demonstrated in vivo proof of principle showing in a mouse model that hCNS-SC can continuously produce the enzyme that is deficient in Infantile Batten disease. • An Investigational New Drug (IND) application was filed at the end of 2004; the IND is currently on holdpending response to FDA questions and concerns. • Spinal Cord Injury: Demonstrated in vivo proof of principle in a mouse model that transplanted cells show preferential migration towards injured sites • Stroke Indication: Demonstrated in vivo proof of principle shows functional integration of myelin onto the mouse nerve axons. 9

Program Description and Objective Liver Stem Cell	<u>Stage/Status(1)</u> Research						
Repair or replace liver tissue damaged or destroyed by cirrhosis and certain metabolic genetic diseases	<ul> <li>Identified a candidate human liver stem cell-like population referred to as a human liver engrafting cell (hLEC).</li> <li>Identified <i>in vitro</i> culture assay for growth of human liver progenitor cells that express markers for both bile duct cells and hepatocytes</li> <li>Shown that the <i>in vitro</i> culture of human liver progenitor cells also can grow human hepatitis virus; this is a potential assay system to screen for novel anti-viral compounds.</li> <li>Demonstrated the engraftment and survival of the candidate hLEC in an <i>in vivo</i> mouse model.</li> <li>Detected human albumin in mouse serum in animals transplanted with hLECs.</li> </ul>						
Pancreas Islet Stem Cell	Research						
Repair or replace damaged pancreas islet tissue	<ul> <li>Identified markers on the surface of a rare human stem-cell-like pancreatic cell, which is a candidate pancreatic stem/progenitor cell.</li> <li>Commenced testing of a candidate human pancreatic stem/progenitor of <i>in vitro</i> and <i>in vivo</i> in small animal model.</li> </ul>						

(1) "Research" refers to early stage research and product development activities *in vitro*, including the selection and characterization of product candidates for preclinical testing. "Preclinical" refers to further testing of a defined product candidate *in vitro* and in animals prior to clinical studies.

Our portfolio of stem cell technology results from our exclusive licensing of central nervous system, stem and progenitor cell technology, animal models for the identification and/or testing of stem and progenitor cells and our own research and development efforts to date. We believe that therapies using stem cells represent a fundamentally new approach to the treatment of diseases caused by lost or damaged tissue. We have assembled an experienced team of scientists and scientific advisors to consult with and advise our scientists on their continuing research and development of stem and progenitor cells. This team includes founding scientists Irving L. Weissman, M.D., of Stanford University, Fred H. Gage, Ph.D., of The Salk Institute, and David Anderson, Ph.D., of the California Institute of Technology, as well as other occasional consultants including William C. Mobley, M.D., Ph.D., Maria Millan, M.D., Ben Barres, Ph.D., and Seung Kim, M.D., Ph.D., all of Stanford University, and Stephen Back, M.D., of the Oregon Health Science University.

## **Neural Program**

We began our work with central nervous system stem and progenitor cell cultures in collaboration with NeuroSpheres, Ltd., in 1992. We believe that NeuroSpheres was the first to invent these cultures. We are the exclusive, worldwide licensee from NeuroSpheres to such inventions and associated patents and patent applications for all uses, including transplantation in the human body, as embodied in these patents. See "NeuroSpheres Ltd." under "License Agreements" below.

In 2000, using our proprietary markers on the surface of the cell, our researchers succeeded in identifying, isolating and purifying human CNS stem cells from brain tissue. We believe that this study, published in Proceedings of the National Academy of Science in December 2000, was the first to show a reproducible

process for isolating highly purified populations of well-characterized normal human CNS stem cells. Because the cells are normal human CNS stem cells and have not been genetically modified, they may be especially suitable for transplantation and may provide a safer and more effective alternative to therapies that are based on cells derived from cancer cells or from an unpurified mix of many different cell types, or from animal derived cells. Even more importantly, in our view, our researchers have been able to take these purified and expanded stem cells and transplant them into the normal brains of immunodeficient mouse hosts, where they take hold and grow into neurons and glial cells.

We have found, during the course of long-term studies using a number of our cell lines, that the transplanted human CNS stem cells survived for as long as one year and migrated to specific functional domains of the host brain, with *no sign* of tumor formation or adverse effects on the animal recipients; moreover, the cells were still dividing. These findings show that when CNS stem cells isolated and cultured with our proprietary processes are transplanted, they adopt the characteristics of the host brain and act like normal stem cells. In other words, the study suggests the possibility of a continual replenishment of normal human brain cells.

The company has established a number of research collaborations in the neural field to assess the effects of transplanting the human CNS stem cells into preclinical animal models, including the spinal cord injury collaboration with Drs. Aileen Anderson and Brian Cummings of the Reeve-Irvine Center at the University of California and a collaboration with the laboratory of Dr. Gary Steinberg, Chairman of the Department of Neurosurgery of Stanford University School of Medicine and Co-director of the Stanford Stroke Center, pertaining to the evaluation of our human neural stem cells in animal models of stroke. Pilot studies have been initiated with Stephen A. Back, M.D., Ph.D., of the Oregon Health Sciences University and with Jeffery D. Kocsis, Ph.D., of the Yale University School of Medicine for understanding myelin production and repair, as well as with Jay Pasricha, M.D., of The University of Texas Medical Branch and with Martin Marsala, M.D., of the University of California, San Diego, regarding the formation of specific populations of neurons; (UCSD). In addition, we have an NIH-funded collaboration with Dr. George A. Carlson of the McLaughlin Research Institute, to understand the role of Alzheimer's plaques in neuronal cell death in Alzheimer's disease.

As noted above, human CNS stem and progenitor cells harvested, purified and expanded using our proprietary processes may be useful for creating therapies for the treatment of degenerative brain diseases like Parkinson's and Alzheimer's diseases and genetic disorders affecting the brain such as Batten Disease. These conditions affect about 5 million people in the United States and there are no effective long-term therapies currently available. We believe our ability to purify human brain stem cells directly from tissue and to expand them into cell banks is important because:

- it provides an enriched source of normal stem cells;
- it opens the way to a better understanding of the properties of these cells and how they might be manipulated to treat specific diseases. For example, in certain genetic diseases such as Tay Sachs and Batten's, a key metabolic enzyme required for normal development and function of the brain is absent. Brain-derived stem cells might produce enough enzyme after transplantation to delay disease progression, or, if not enough enzyme is made naturally, the cells might be genetically modified to produce those proteins. The native or modified brain stem cells could be transplanted into patients with these genetic diseases;
- the efficient acceptance of these non-transformed normal human stem cells into host brains means that the cell product can be tested in animal models for its ability to correct deficiencies caused by various human neurological diseases. This technology could also provide a unique animal model for the testing of drugs that act on human brain cells either for effectiveness of the drug against the disease or its toxicity to human nerve cells.

StemCells Inc holds a substantial portfolio of issued and allowed patents in the neural field. See "Patents, Proprietary Rights and Licenses."



#### Liver Program

We initiated our discovery work for the liver stem and progenitor cell through a sponsored research agreement with Markus Grompe, Ph.D., of Oregon Health Sciences University. Dr. Grompe's work focuses on the discovery and development of a suitable method for identifying and assessing liver stem and progenitor cells for use in transplantation. We have also obtained rights to a novel mouse model of liver failure for evaluating cell transplantation developed by Dr. Grompe: The "FAH transgenic mouse." This mouse lacks a key enzyme (FAH, or fumaryl-acetoacetate hydrolase), which results in build-up of a toxic substance which causes liver damage. In addition, we obtained an exclusive license to U.S. Patent No. 6,132,708, claiming a method of regenerating a functional liver by transplantation of pancreas cells in mammals, including humans.

Approximately 1 in 10 Americans suffers from diseases and disorders of the liver for many of which there are currently no effective, long-term treatments. Our researchers continue to advance methods for establishing enriched cell populations suitable for transplantation in preclinical animal models. We are focused on discovering and utilizing proprietary methods to identify and isolate liver stem and progenitor cells and to evaluate these cells in culture and in preclinical animal models.

The Company focuses on discovering and utilizing proprietary methods to identify and isolate liver stem and progenitor cells and to evaluate these cells in culture and in preclinical animal models. The Company intends to use these advanced methods, as they become available, to establish enriched cell populations suitable for transplantation.

StemCells has devised a culture assay that it uses in its efforts to identify liver stem and progenitor cells. In addition, the culture assay can support the growth of an early human liver bipotent progenitor cell — a cell that can develop into two kinds of mature liver cells: bile duct cells and hepatocytes. Further, since cells in this culture can be infected with human hepatitis virus, it provides a valuable system for study of the virus. This technology also could provide a unique *in vitro* model for the testing of drugs that act on, or are metabolized by, human liver cells.

The Company's scientists have identified proprietary monoclonal antibodies that permit us to purify a population of human liver-engrafting cells, including a candidate human liver stem cell (hLEC). When tested in the Company's in vitro culture assay, these antibody-enriched cells produce human serum albumin, a measure of hepatocyte generation. Studies to date show that these hLECs can produce human serum albumin in mouse serum following transplantation into immunodeficient mice, suggesting that the human liver-engrafting cell, once transplanted, becomes a functional cell. The program will focus on demonstrating the robust engraftment and function of these hLECs in a preclinical animal model of liver degeneration for proof of principle of a therapeutic cell for liver disease. A source of defined human cells capable of engraftment and substantial liver regeneration could provide a cell-based therapeutic product available to a wider patient base than liver transplants. An in vitro culture system that can reproducibly grow human liver progenitor cells might also provide cells for genetic modification to correct inborn errors of metabolism.

## Pancreas Program

The Company's scientists have again used StemCells' monoclonal antibody-based search engine to identify a rare subset of human pancreatic cells that may be candidate pancreatic stem/progenitor cells. The Company has filed a patent application on the monoclonal antibodies used. In 2002, the Company established a collaboration with Dr. Seung Kim of Stanford University to pursue other avenues to identify an insulin-producing cell. Dr. Kim's laboratory is studying the developmental biology and controlling events of generating insulin-producing cells. We believe that these approaches may lead to the development of cell-based treatments for Type 1 diabetes and that portion of Type 2 diabetes characterized by defective secretion of insulin. The Company has developed what we believe to be an appropriate animal model to test the biological activity of the purified candidate pancreatic stem cells.

## Subsidiary

#### StemCells California, Inc.

On September 26, 1997, we acquired by merger StemCells California, Inc., a California corporation, in exchange for 1,320,691 shares of our common stock and options and warrants for the purchase of 259,296 common shares. StemCells California remains our wholly-owned subsidiary, and the owner or licensee of most of our intellectual property. The members of its Board of Directors are Irving L. Weissman, M.D., David J. Anderson, Ph.D., and Fred H. Gage, Ph.D., who were the founders of StemCells California, as well as John J. Schwartz, Ph.D. and Martin McGlynn. Drs. Weissman and Schwartz and Mr. McGlynn are also members of the Board of the parent company; Mr. McGlynn is President of StemCells California as well as President and CEO of StemCells, Inc. References in this annual report to "the Company," "we," "us," and similar words include this subsidiary.

#### **License Agreements**

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

In the case of Scripps, we must pay \$50,000 upon the initiation of the Phase II trial for our first product using Scripps licensed technology, and upon completion of that Phase II trial we must pay Scripps an additional \$125,000. Upon approval of the first product for sale in the market, we must pay Scripps \$250,000.

Pursuant to the terms of our license agreement with Cal Tech and our acquisition of our wholly owned subsidiary, StemCells California, we issued 14,513 shares of our common stock to Cal Tech. We issued an additional 12,800 shares of common stock to Cal Tech with a market value of approximately \$40,000 in May 2000, upon execution of an amendment adding four families of patent applications to the license agreement. We must pay an additional \$10,000 upon the issuance of the patent licensed to us under the relevant agreement and \$5,000 on the first anniversary of the issuance of the patent licensed to us under the relevant agreement and \$5,000 on the first anniversary of the issuance of the patent licensed to us under the relevant agreement. These amounts are creditable against royalties we must pay under the license agreements. The maximum royalties that we will have to pay to the California Institute of Technology will be \$2 million per year, with an overall maximum of \$15 million. Once we pay the \$15 million maximum royalty, the licenses will become fully paid and irrevocable. In August 2002 we acquired an additional license from Cal Tech to different technology, pursuant to which we issued 27,535 shares of our common stock with a market value of approximately \$35,000; we have also issued 9,535 shares of our common stock with a market value of approximately \$15,000 to Cal Tech on the issuance of two patents covered under this additional license.

Pursuant to the terms of the license agreement with OHSU and our acquisition of StemCells California, we issued 4,838 shares of our common stock and an option to purchase up to 62,888 additional shares to OHSU with an exercise price of \$.01 per share. The option has vested as to 9,675 shares for which shares were issued on March 31, 2002; the remaining option was terminated and we issued 4,000 shares of our common stock, with a market value of approximately \$3,900, to OHSU in January 2003, pursuant to an amendment to the license agreement.



In 2002, we issued a license to BioWhittaker, Inc., for the exclusive right to make, sell and distribute one of our proprietary cells for the research market only. In 2003 and 2004 respectively, we issued non-exclusive licenses to StemCell Technologies, Inc. to make, use and sell certain proprietary mouse and rat neural stem cells and culture media for all mammalian neural stem cells, and to R&D Systems to make, use and sell certain stem cell expansion kits, also for the research market. These licenses are not expected to generate material revenues.

## Signal Pharmaceuticals, Inc.

In December 1997, we entered into two sublicense agreements with Signal Pharmaceuticals (Signal), Inc. under which each party sublicensed to the other certain patent rights and biological materials for use in defined fields. Signal has now been acquired by Celgene, which in 2004 relinquished its license to the University of California, which then terminated the sublicense to StemCells for lack of diligence. The remaining sublicense with Signal will terminate no later than at the expiration of all patents licensed under it, but StemCells can terminate it earlier if Celgene breaches its obligations under the agreement or declares bankruptcy; Celgene can terminate the agreement at any time upon notice to StemCells.

#### NeuroSpheres, Ltd.

In March 1994, we entered into a Contract Research and License Agreement with NeuroSpheres, Ltd., which was clarified in a License Agreement dated as of April 1, 1997. Under the agreement as clarified, we obtained an exclusive patent license from NeuroSpheres in the field of transplantation, subject to a limited right of NeuroSpheres to purchase a nonexclusive license from us, which right was not exercised and has expired. We have developed additional intellectual property relating to the subject matter of the license. We entered into an additional license agreement with NeuroSpheres as of October 30, 2000, under which we obtained an exclusive license in the field of non-transplant uses, such as drug discovery and drug testing. Together, our rights under the licenses are exclusive for all uses of the technology. We made up-front payments to NeuroSpheres of 65,000 shares of our common stock in October 2000 and \$50,000 in January 2001, and we will make additional cash payments when milestones are achieved in the non-transplant field, or in any products employing NeuroSpheres patents for generating cells of the blood and immune system from neural stem cells. 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. The first milestone for a potential product is \$50,000, became due in 2004 when the product candidate for Batten disease entered pre-clinical development in a non-rodent model. The next milestone for that product candidate will be \$75,000, due upon acceptance of our Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) and the commencement of clinical trials in human patients. In addition, we made our first annual payment of \$50,000 in 2004; the annual payments are due by the last day of the year and are fully creditable against royalties due to NeuroSpheres. Our agreements wi

## Manufacturing

We believe that our facility in Palo Alto has the capacity to be used for cell processing under FDA-determined Good Manufacturing Practices-like conditions in quantities sufficient for clinical trials, and we have developed a robust and replicable process for producing and processing the cells.

#### Marketing

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

#### **Patents, Proprietary Rights And Licenses**

We believe that proprietary protection of our inventions will be critical to our future business. We vigorously seek out intellectual property that we believe might be useful in connection with our products, and have an aggressive program of protecting our intellectual property. We believe that our know-how will also provide a significant competitive advantage, and we intend to continue to develop and protect our proprietary know-how. We may also from time to time seek to acquire licenses to important externally developed technologies.

We have exclusive or non-exclusive rights to a portfolio of patents and patent applications related to various stem and progenitor cells and methods of deriving and using them. These patents and patent applications relate to compositions of matter, methods of obtaining such cells, and methods for preparing, transplanting and utilizing such cells. Currently, our U.S. patent portfolio includes forty-three issued U.S. patents, three of which issued in 2004. More than thirty additional patent applications are pending, two of which have been allowed. In addition, we have foreign counterparts to many of the U.S. applications and patents; counterparts to fourteen of our U.S. patents or applications have issued in various countries, making a total of about 130 individual non-U.S. patents from those fourteen cases. In 2003, one party filed an opposition to two of our issued European patent cases. While we are confident that we will overcome the opposition, there is no guarantee that we will prevail. If we are unsuccessful in our defense of the opposed patents, all claimed rights in the opposed patents will be lost in Europe. U.S. counterparts to these patents are part of our issued patent portfolio; they are not subject to opposition, since that procedure does not exist under U.S. patent law, although other types of proceedings may be available to third parties to contest our U.S. patents.

In December 1998, the U.S. Patent and Trademark Office granted Patent No. 5,851,832, covering our methods for the human CNS cell cultures containing central nervous system stem cells, for compositions of human CNS cells expanded by these methods, and for use of these cultures in human transplantation. These human CNS stem and progenitor cells expanded in culture may be useful for repairing or replacing damaged central nervous system tissue, including the brain and the spinal cord. U.S. Patent No. 5,968,829, entitled "Human CNS Neural Stem Cells," which covers our composition of matter for human CNS stem cells, was granted in 1999, and U.S. Patent No. 6,103,530, covering our media for culturing human CNS stem cells, was granted in 2000.

In 2002, the U.S. Patent Office issued a key strategic patent to us: U.S. Patent Number 6,468,794, entitled "Enriched central nervous system stem cell and progenitor cell populations, and methods for identifying, isolating and enriching for such populations." The patent issued on October 22, 2002 and covers the identification and purification of the human CNS stem cell. In 2001, we were granted U.S. Patent No. 6,238,922 ("Use of collagenase in the preparation of neural stem cell cultures") which described methods to advance the *in vivo* culture and passage of human CNS stem cells that result in a 100-fold increase in CNS stem and progenitor cell production after 6 passages. We believe the methodologies of these two patents together will augment our leadership position in the stem cell field by providing a reproducible proprietary method for obtaining and expanding stem cells for therapeutic uses.

Another significant patent in the neural field, of which we are the exclusive licensees, was also issued in 2002, and, we believe, may prove even more important: We believe that U.S. Patent Number 6,497,872, entitled "Neural transplantation using proliferated multipotent neural stem cells and their progeny," 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. The patent gives us the right to exclude others from practicing the claimed invention.

In 2003, two neurogenin-related patents were issued (U.S. Patents Numbers 6,555,337 and 6,566,496) as well as U.S. Patent Number 6,638,501, covering the use of multipotent neural stem cell progeny to augment non-neural tissues and U.S. Patent Number 6,541,251, covering a novel pancreatic progenitor gene and its uses.

In 2004, U.S. Patent Number 6,777,233, covering a cell culture composition of multipotent human neural stem cells regardless of the source of tissue from which the cells are derived, was issued to the Company. In

## **Table of Contents**

addition, U.S. Patent Number 6,824,774, covering antibodies that specifically bind to a neuron-restrictive silencer factor protein, and U.S. Patent Number 6,753,153, covering markers for identification and isolation of certain pancreatic islet progenitors, were issued; these patents are exclusively licensed to the Company.

These new patents, together with U.S. Patent Number 6,294,346 ("Use of multipotent neural stem cells and their progeny for the screening of drugs and other biological agents"), which issued September 25, 2001, have strengthened our already extensive patent portfolio and, we believe, give StemCells the dominant intellectual property position in the field, covering methods for identification, isolation, expansion, and transplantation of neural stem cells as well as drug discovery and testing.

The following table lists our issued U.S. patents and published international patent applications:

U.S. Patent Number	Subject
Owned by StemCells	
5,968,829	Human CNS neural stem cells
6,103,530	Human CNS neural stem cells — culture media
6,238,922	Use of collagenase in the preparation of neural stem cell cultures
6,468,794	Enriched neural stem cell populations, and methods for identifying, isolating and
	enriching for neural stem cells
6,498,018	Human CNS neural stem cells
6,777,233	Cultures of human CNS neural stem cells.
Licensed from NeuroSpheres	
5,750,376	In vitro genetic modification
5,851,832	In vitro proliferation
5,980,885	Methods for inducing in vivo proliferation of precursor cells
5,981,165	In vitro production of dopaminergic cells from mammalian central nervous system
	multipotent stem cell compositions
6,071,889	Methods for in vivo transfer of a nucleic acid sequence to proliferating neural cells
6,093,531	Generation of hematopoietic cells from multipotent neural stem cells
6,165,783	Methods of inducing differentiation of multipotent neural stem cells
6,294,346	Methods for screening biological agents
6,368,854	Hypoxia-mediated neurogenesis
6,399,369	cDNA libraries derived from populations of non-primary neural cells
6,497,872	Neural transplantation using proliferated multipotent neural stem cells and their progeny
6,638,501	Use of multipotent neural stem cell progeny to augment non-neural tissues
Licensed from University of California, San Diego	
5,766,948	Method of production of neuroblasts
6,013,521	Method of production of neuroblasts
6,020,197	Method of production of neuroblasts
6,045,807	Method of production of neuroblasts
6,265,175	Method of production of neuroblasts
6599695	Method for assaying for early gene expression in neuroblasts

U.S. Patent Number	Subject
Licensed from the California Institute of Technology	
5,589,376	Mammalian neural crest stem cells
5,629,159	Immortalization and disimmortalization of cells
5,654,183	Genetically engineered mammalian neural crest stem cells
5,672,499	Methods for immortalizing multipotent neural crest stem cells
5,693,482	In vitro neural crest stem cell assay
5,824,489	Methods for isolating mammalian multipotent neural crest stem cells
5,849,553	Immortalizing and disimmortalizing multipotent neural crest stem cells
5,928,947	Mammalian multipotent neural crest stem cells
5,935,811	Neuron restrictive silencer factor proteins
6,001,654	Methods for differentiating neural stem cells to neurons or smooth muscle cells (TGFb)
6,033,906	Differentiating mammalian neural stem cells to glial cells using neuregulins
6,270,990	Neuron restrictive silencer factor proteins
6,555,337	Neurogenin
6,566,496	Neurogenin
6,824,774	Antibodies that bind neuron-restrictive silencer factor proteins
Licensed from the Scripps Research Institute	
6,242,666	An animal model for identifying a common stem/ progenitor to liver cells and pancreatic cells
6,541,251	Pancreatic progenitor 1 gene and its uses
6,753,153	Markers for identification and isolation of pancreatic islet alpha and beta progenitors
Licensed from Oregon Health Sciences University	
6,132,708	Liver regeneration using pancreas cells

## **Table of Contents**

Published International Patent Applications	Subject
Owned by StemCells	
WO 99/11758	Cultures of human CNS neural stem cells
WO 00/47762	Enriched neural stem cell populations and methods of identifying, isolating, and
	enriching neural stem cells
WO 00/50572	Use of collagenase in the preparation of neural stem cell cultures
WO 04/020597	Enriched central nervous system stem cell and progenitor cell populations, and methods
	for identifying, isolating, and enriching for such populations
Licensed from NeuroSpheres	
WO 93/01275	Mammalian central nervous system multipotent stem cell compositions
WO 94/09119	Remyelination using mammalian central nervous system multipotent stem cell compositions
WO 94/10292	Biological factors useful in differentiating mammalian central nervous system multipotent stem cell compositions
WO 94/16718	Genetically engineered mammalian central nervous system multipotent stem cell compositions
WO 95/13364	In situ modification and manipulation of stem cells of the CNS
WO 96/15224	In vitro production of dopaminergic cells from mammalian central nervous system
	multipotent stem cell composition
WO 99/16863	Generation of hematopoietic cells
WO 99/21966	Erythropoietin-mediated neurogenesis
Licensed from University of California, San Diego	
WO 94/16059	Method of production of neuroblasts
Licensed from the California Institute of Technology	
WO 94/02593	Mammalian neural crest stem cells
WO 00/52143	Isolation and enrichment of neural stem cells from uncultured tissue based on cell-
	surface marker expression
WO 96/27665	Neuron restrictive silencer factor proteins
WO 96/40877	Immortalization and disimmortalization of cells
WO 98/48001	Methods for differentiating neural stem cells to neurons or smooth muscle cells using TGF-# super family growth factors
Licensed from The Scripps Research Institute	
WO 00/36091	An animal model for identifying a common stem/progenitor to liver cells and pancreatic cells

We also rely upon trade-secret protection for our confidential and proprietary information and take active measures to control access to that information.

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

We have obtained rights from universities and research institutions to technologies, processes and compounds that we believe may be important to the development of our products. These agreements typically require us to pay license fees, meet certain diligence obligations and, upon commercial introduction of certain products, pay royalties. These include exclusive license agreements with NeuroSpheres, The Scripps Institute, the California Institute of Technology and the Oregon Health Sciences University, to certain patents and know-how regarding present and certain future developments in CNS, liver and pancreas stem cells. Our licenses may be canceled or converted to non-exclusive licenses if we fail to use the relevant technology or if we breach our agreements. Loss of such licenses could expose us to the risks of third party patents and/or technology. There can be no assurance that any of these licenses will provide effective protection against our competitors.

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

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

One party has opposed two of our issued European patents. While we are confident that we will overcome the opposition, there is no guarantee that we will prevail. If we are unsuccessful in our defense of the opposed patents, all claimed rights in the opposed patents will be lost in Europe. U.S. counterparts to these patents are part of our issued patent portfolio; they are not subject to opposition, since that procedure does not exist under U.S. patent law, although other types of proceedings may be available to third parties to contest our U.S. patents.

A number of pharmaceutical, biotechnology and other companies, universities and research institutions have filed patent applications or have been issued patents relating to cell therapy, stem cells and other technologies potentially relevant to or required by our expected products. We cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware that a number of companies have filed applications relating to stem cells. We are also aware of a number of patent applications and patents claiming use of genetically modified cells to treat disease, disorder or injury. We are aware of two patents issued to a competitor claiming certain methods for treating defective, diseased or damaged cells in the mammalian CNS by grafting genetically modified donor cells from the same mammalian species.

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

## Competition

The targeted disease states for our initial products in some instances currently have no effective long-term therapies. However, we do expect that our initial products will have to compete with a variety of therapeutic products and procedures. Major pharmaceutical companies currently offer a number of pharmaceutical products to treat lysosomal storage disorders, neurodegenerative and liver diseases, diabetes 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. We expect competition to increase. We believe that our most significant competitors will be fully integrated pharmaceutical companies and more established biotechnology companies. Many of these competitors have significant products approved or in development that could be competitive with our potential products.

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, and gene therapy. We believe that some of our competitors are also trying to develop stem and progenitor cell-based technologies. We expect that all of these products will compete with our potential stem and progenitor cell products based on efficacy, safety, cost and intellectual property positions.

We may also face competition from companies that have filed patent applications relating to the use of genetically modified cells to treat disease, disorder or injury. In the event our therapies should require the use of such genetically modified cells, we may be required to seek licenses from these competitors in order to commercialize certain of our proposed products, and such licenses may not be granted.

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.

While we believe that the primary competitive factors will be product efficacy, safety, and the timing and scope of regulatory approvals, other factors include, in certain instances, obtaining marketing exclusivity under the Orphan Drug Act, availability of supply, marketing and sales capability, reimbursement coverage, price, and patent and technology position.

#### **Government Regulation**

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

In the United States, pharmaceuticals, biologicals and medical devices are subject to rigorous Food and Drug Administration, or FDA, regulation. The Federal Food, Drug and Cosmetic Act, as amended, and the Public Health Service Act, as amended, the regulations promulgated thereunder, and other Federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, 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, the federal, state, and other jurisdictions have restrictions on the use of fetal tissue.

## FDA Approval

The steps required before our potential 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. <i>In vivo</i> studies are performed in normal animals and specific disease models to assess the potential safety and efficacy of the cell therapy product.					
2. Submission to the FDA of an Investigational New Drug application (IND), which must become effective before U.S. human clinical trials may commence	The IND is submitted to the FDA with the preclinical data, a proposed development plan and a proposed protocol for a study in humans. The IND becomes effective 30 days following receipt by the FDA, provided there are no questions, requests for delay or objections from the FDA. If the FDA has questions or concerns, it notifies the sponsor, and the IND will then be on clinical hold until the sponsor responds satisfactorily.					
3. Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product	Clinical trials involve the evaluation of a potential product under the supervision of a qualified physician, in accordance with a protocol that details the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. The protocol for each clinical study must be approved by an independent Institutional Review Board (IRB) of the institution at which the study is conducted and the informed consent of all participants must be obtained. The IRB reviews the existing information on the product, considers ethical factors, the safety of human subjects, the potential benefits of the therapy and the possible liability of the institution. The IRB is responsible for ongoing safety assessment of the subjects during the Clinical Investigation. Clinical development is traditionally conducted in three sequential phases, Phase 1, 2 and 3. Phase 1 studies for a cell therapy product are designed to evaluate safety in a small number subjects in a selected patient population by assessing adverse effects, and may include multiple dose levels. This study may also gather preliminary evidence of a beneficial effect on the disease. Phase 2 may involve studies in a limited patient population to determine biological and clinical effects of the product and to identify possible adverse effects and safety risks of the product in the selected patient population. Phase 3 trials would be undertaken to conclusively demonstrate clinical benefit or effect and to test further for safety within a broader patient population, generally at multiple study sites.					

Steps	Considerations						
	The FDA continually reviews the clinical trial plans and results and may						
	suggest changes or may require discontinuance of the trials at any time if						
	significant safety issues arise.						
4. Submission to the FDA of marketing authorization applications	The results of the preclinical studies and clinical studies are submitted to						
	the FDA in the form of marketing approval authorization applications.						
5. FDA approval of the application(s) prior to any commercial sale or	The testing and approval process will require substantial time, effort and						
shipment of the drug. Biologic product manufacturing establishments	expense. The time for approval is affected by a number of factors,						
located in certain states also may be subject to separate regulatory and	including relative risks and benefits demonstrated in clinical trials, the						
licensing requirement	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.						

After FDA approval for the product, the manufacturing and the initial indications, further clinical trials may be required to gain approval for the use of the product for additional indications. The FDA may also require unusual or restrictive post-marketing testing and surveillance to monitor for adverse effects, which could involve significant expense, or may elect to grant only conditional approvals.

#### 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 (cGMP) requirements. Even after product licensure approval, the manufacturer must comply with cGMP on a continuing basis, and what constitutes cGMP may change as the state of the art of manufacturing changes. Domestic manufacturing facilities are subject to regular FDA inspections for cGMP 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 with reciprocal inspection agreements with the FDA. 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 types of 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 products and has published current Good Tissue Practice (cGTP) regulations. As part of this approach, the FDA has published final rules for registration of establishments that engage in the recovery, screening, testing, processing, storage or distribution of human cells, tissues, and cellular and tissue-based products, and for the



listing of such products. In addition, the FDA has published rules for making suitability and eligibility determinations for donors of cells and tissue and for current good tissue practice for manufacturers using them, which come into effect in May 2005. We cannot now determine the full effects of this regulatory initiative, including precisely how it may affect the clarity of regulatory obligations and the extent of regulatory burdens associated with multipotent stem cell research (for stem cells that give rise to various tissue types, including blood), and the manufacture and marketing of stem cell products.

## **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.

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, or EU, is revising its regulatory approach to high tech 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.

#### **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 revenues and profitability of some health care-related companies have been affected by the continuing efforts of governmental and third party payers to contain or reduce the cost of health care through various means. Payers are increasingly attempting to limit both coverage and the level 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. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, there have been a number of Federal and state proposals to implement government control over health care costs.

#### Employees

As of December 31, 2004, we had thirty-six full-time employees, of whom nine have Ph.D. degrees. Twenty-eight full-time employees work in research and development and laboratory support services. No employees are covered by collective bargaining agreements.

#### **Risk Factors**

We are subject to a number of risks, which you should be aware of before you decide to buy our common stock. These risks are discussed more fully in the "Cautionary Factors Relevant to Forward-Looking Information" attached to this Annual Report on Form 10-K as Exhibit 99. Our approach to drug discovery is unproven and all of our current product candidates are in preclinical development. While we have submitted an IND to the U.S. Food and Drug Administration, that IND is currently on clinical hold. We have not received regulatory approval for, or generated revenues from, any of our product candidates. If we do not successfully commercialize any of our product candidates, we will be unable to generate product revenue or achieve profitability. As of December 31, 2004, we had an accumulated deficit of \$174,205,214. We expect to continue to incur significant and increasing losses over the next several years and we may never be profitable.



## **Scientific Advisory Board**

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

- Irving L. Weissman, M.D., is the Karel and Avice Beekhuis Professor of Cancer Biology, Professor of Pathology and Professor of Developmental Biology at Stanford University, Stanford California, and Director of the Stanford University Institute for Cancer/ Stem Cell Biology and Medicine. Dr. Weissman's lab was responsible for the discovery of the first ever mammalian 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. He is a member of the Board of Directors and Chairman of the Scientific Advisory Boards of StemCells and Cellerant. Dr. Weissman co-discovered the mammalian and human hematopoietic stem cells and the human neural stem cell. Past achievements of Dr. Weissman's laboratory include identification of the states of development between stem cells and mature blood cells and identification of the states of thymic lymphocyte development. More recently, 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. Dr. Weissman has been elected to the National Academy of Science. He has received the Kaiser Award for Excellence in Preclinical Teaching, the Pasarow Foundation Award, and the Outstanding Investigator Award from the National Institutes of Health.
- David J. Anderson, Ph.D., is 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 nerval 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 a glial cell rather than a neuron. Dr. Anderson is a co-founder of StemCells and a member of its SAB. Dr. Anderson also serves on the SAB 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, and the 1999 W. Alden Spencer Award in Neurobiology from Columbia University.
- 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 the mammalian central nervous system stem cell. His research focus is on the development of strategies to induce recovery of function following central nervous system (CNS) damage. Dr. Gage is a co-founder of StemCells and a member of its SAB. Dr. Gage also serves on the Scientific Advisory Board of Ceregene, Inc. 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. In 2003, Professor Gage was elected to the National Academy of Science.

Consultants to our SAB include William C. Mobley, M.D., Ph.D., Maria Millan, M.D., Ben Barres, Ph.D., and Seung Kim, M.D., Ph.D., all of Stanford University and Stephen Back, M.D., of the Oregon Health Science University.

## AVAILABLE INFORMATION

Our principal executive offices are located at 3155 Porter Drive, Palo Alto, CA 94304, and our main telephone number is (650) 475-3100. Investors can obtain access to this annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and all amendments to these reports, free of charge, on our website at http://www.stemcellsinc.com as soon as reasonably practicable after such filings are electronically filed with the SEC. The public may read and copy any material we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington D.C., 20549. The public may obtain information on the operations of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site, http://www.sec.gov, which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

## ITEM 2. **PROPERTIES**

We entered into a 5-year lease, as of February 1, 2001, for a 40,000 square foot facility, located in the Stanford Research Park in Palo Alto, California. This facility includes space for animals as well as laboratories, offices, and a suite designed to be used to manufacture materials for clinical trials. The facility will better enable us to achieve our goal of utilizing genetically unmodified human stem cells for the treatment of disorders of the nervous system, liver, and pancreas. We have space-sharing agreements for part of the animal facility not needed for our own use, including one with Stanford University.

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

## ITEM 3. LEGAL PROCEEDINGS

Geron Corporation has opposed two of our European patents that relate to neural stem cells and their uses. The oppositions were filed with the European Patent Office on December 11, 2003 (Patent No. EP-B-0594669) and February 13, 2004 (Patent No. EP-B-0669973). We filed responses to both oppositions on September 23, 2004. Geron alleges that each patent should be revoked on multiple grounds.

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

None.

#### PART II

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

The common stock of StemCells is traded on the SmallCap Market System of NASDAQ under the Symbol STEM. Prior to December 23, 2002 our common stock was traded on the NASDAQ National

## **Table of Contents**

Market. The quarterly ranges of high and low bid prices for the last two fiscal years as reported by NASDAQ are shown below:

	High	Low
2004		
First Quarter	\$ 2.69	\$ 1.56
Second Quarter	\$ 2.19	\$ 1.30
Third Quarter	\$ 1.82	\$ 1.25
Fourth Quarter	\$ 4.85	\$ 1.52
2003		
First Quarter	\$ 1.45	\$ 0.85
Second Quarter	\$ 2.82	\$ 0.65
Third Quarter	\$ 2.59	\$ 1.17
Fourth Quarter	\$ 3.10	\$ 1.70

No cash dividends have been declared on the Company common stock since the Company's inception.

As of March 9, 2005, there were approximately 538 holders of record of the common stock, and as of the same date the closing price per share of the common stock on the NASDAQ SmallCap Market was \$4.55.

The Company issued the following unregistered securities in 2004:

- In August 2004, StemCells issued 9,535 shares of common stock to the California Institute of Technology (Cal Tech) as payment for fees of \$10,000 and \$5,000 that were due on the issuance of two patents to which StemCells holds a license from Cal Tech that were payable in cash or stock at the Company's option. The shares were issued in a transaction not involving any public offering pursuant to Section 4(2) of the Securities Act of 1933, as amended.
- In December 2004, StemCells issued 1,816 shares of common stock to inventors of a technology as part payment for approximately \$2,800 of the total option fee of \$25,000 to acquire an exclusive license to the technology from the Board of Trustees of The Leland Stanford Junior University. The shares were issued in a transaction not involving any public offering pursuant to Section 4(2) of the Securities Act of 1933, as amended.

Equity Compensation Plan Information

The following table provides certain information with respect to all of the Company's equity compensation plans in effect as of the end of December 31, 2004.

	E	quity Compensation Plan Informati	011
	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants	Weighted- Average Exercise Price of Outstanding Options, Warrants and	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected
Plan Category	and Rights (a)	Rights (b)	in Column (a)) (c)
Equity compensation plans approved by security			
holders	6,682,201(1)	\$2.67	\$2,057,440
Equity compensation arrangements not approved by			
security holders	346,199(2)	\$2.14	N/a
Totals	7,028,400	\$2.64	\$2,057,440

(1) Consists of Incentive Stock Options issued to employees and options issued as compensation to consultants for consultation services. These options were issued under the Company's 1992 Equity

Incentive Plan, its Directors' Stock Option Plan, its StemCells, Inc. Stock Option Plan, or its 2001 and 2004 Equity Incentive Plans.

- (2) Consists of warrants outstanding that are fully vested to purchase:
  - 146,199 shares of our common stock that was issued in December 2001 for external services fully vested with an exercise price of \$3.42 per share and exercisable, in whole or in part, for four years from the date of issuance.
  - 200,000 shares of our common stock that was issued in January 2003 for external services fully vested with an exercise price of \$1.20 per share and exercisable, in whole or in part, for five years from the date of issuance.
  - These warrants, which constitute the equity compensation arrangements not approved by security holders, were all issued in exchange for advisory services by non-employees.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected historical information has been derived from the audited financial statements of the Company. The financial information as of December 2004 and 2003 and for each of the three years in the period ended December 31, 2004 are derived from audited financial statements included elsewhere in this Form 10-K.

	Year Ended December 31,								
		2004		2003		2002		2001	
			(In thousands, except per share amounts)						
Consolidated Statement of Operations									
Revenue from collaborative and licensing agreements	\$	22	\$	18	\$	40	\$	_	
Revenue from grants		119		255		375		505	
Revenue from assignment of rights to technology				_				300	
Total revenue		141		273		415		805	
Research and development expenses		8,760		6,144		7,382		8,603	
General and administrative expenses		3,954		3,391		3,359		3,788	
Encapsulated Cell Technology (ECT) wind-down and corporate									
relocation(1)		2,827		2,885		1,164		575	
Loss before deemed dividends and cumulative effect of change in									
accounting principle		(15,330)		(12,291)		(11,644)		(4,021)	
Net loss applicable to common stockholders		(15,330)		(14,425)		(13,276)		(5,567)	
Basic and diluted loss per share applicable to common stockholders	\$	(0.31)	\$	(0.45)	\$	(0.53)	\$	(0.25)	
Shares used in computing basic and diluted loss per share amounts		49,606		32,080		25,096		22,242	

		December 31,							
	2004	2003	2002	2001					
		(In thous	sands)						
Consolidated Balance Sheet									
Cash and cash equivalents	\$ 41,060	\$ 13,082	\$ 4,236	\$ 13,697					
Restricted investments	—	—	—						
Total assets	47,627	19,786	11,329	20,803					
Accrued wind-down expenses and deferred rent(1)	5,528	3,823	1,931	575					
Long-term debt, including capital leases	1,646	1,850	2,087	2,316					
Redeemable preferred stock(2)	—	—	2,660	2,663					
Stockholders' equity	36,950	10,964	1,933	12,633					

- (1) Relates to wind-down expenses in respect of the Company's Rhode Island facility. See footnote 7 in the consolidated financial statements
- (2) See footnote 9 in the consolidated financial statements

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the accompanying financial statements and the related footnotes thereto.

This report contains forward looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act that involve substantial risks and uncertainties. Such statements include, without limitation, all statements as to expectation or belief and statements as to our future results of operations, the progress of our research, product development and clinical programs, the need for, and timing of, additional capital and capital expenditures, partnering prospects, costs of manufacture of products, the protection of and the need for additional intellectual property rights, effects of regulations, the need for additional facilities and potential market opportunities. Our actual results may vary materially from those contained in such forwardlooking statements because of risks to which we are subject, including uncertainty as to whether the U.S. Food and Drug Administration will remove the clinical hold on our proposed initial clinical trial and permit us to proceed to clinical testing despite the novel and unproven nature of the Company's technology; the risk that, even if approved, our initial clinical trial could be substantially delayed beyond its expected dates or cause us to incur substantial unanticipated costs; uncertainties regarding the 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; failure to obtain a corporate partner or partners to support the development of our stem cell programs, the uncertainty regarding the outcome of the Phase I clinical trial and any other trials the Company may conduct in the future; the uncertainty regarding the validity and enforceability of issued patents; the uncertainty whether any products that may be generated in the Company's stem cell programs will prove clinically effective and not cause tumors or other side effects; the uncertainty whether the Company will achieve revenues from product sales or become profitable; uncertainties regarding the Company's obligations in regard to its former encapsulated cell therapy facilities in Rhode Island; obsolescence of our technology; competition from third parties; intellectual property rights of third parties; litigation and other risks to which we are subject. See "Cautionary Factors Relevant to Forward-Looking-Information" filed herewith as Exhibit 99 and incorporated herein by reference.

#### Overview

Since our inception in 1988, we have been primarily engaged in research and development of human therapeutic products. Since the second half of 1999, our sole focus has been on our stem cell technology. In the last quarter of 2004 we filed the first in a planned series of INDs for CNS diseases or conditions with the FDA. This IND, which is for a Phase I clinical trial of our human neural stem cells in Batten disease, is currently on clinical hold until questions and issues raised by the FDA have been resolved.

We have not derived any revenues from the sale of any products apart from license revenue for the research use of our human neural stem cells and other patented cells and media, and we do not expect to receive revenues from product sales for at least several years. We have not commercialized any product and in order to do so we must, among other things, substantially increase our research and development expenditures as research and product development efforts accelerate and clinical trials are initiated. We had expenditures for toxicology and other studies in preparation for submitting the Batten disease IND to the FDA, and will incur more such expenditures for any future INDs. We have incurred annual operating losses since inception and expect to incur substantial operating losses in the future. As a result, we are dependent upon external financing from equity and debt offerings and revenues from collaborative research arrangements with corporate sponsors to finance our operations. There are no such collaborative research arrangements at this

time and there can be no assurance that such financing or partnering revenues will be available when needed or on terms acceptable to us.

In June 2004, the Company entered into an agreement with institutional and other accredited investors with respect to the private placement of approximately 13,160,000 shares of its common stock at a purchase price of \$1.52 per share, for gross proceeds of approximately \$20,000,000. Investors also received warrants exercisable for five years to purchase approximately 3.3 million shares of common stock at an exercise price of \$1.90 per share. C.E. Unterberg, Towbin LLC (Unterberg) served as placement agent for the transaction. For acting as the Company's placement agent, Unterberg received fees totaling \$1,200,000, expense reimbursement of approximately \$25,000 and a five year warrant to purchase 526,400 shares of the Company's common stock at an exercise price of \$1.89 per share. (See "Liquidity and Capital Resources" below for further detail on these transactions.)

In October 2004, the Company entered into agreements with institutional investors with respect to the direct placement of 7,500,000 shares of its registered common stock at a purchase price of \$3.00 per share, for gross proceeds of \$22,500,000. Unterberg and Shoreline Pacific, LLC (Shoreline) served as placement agents for the transaction. For acting as the Company's placement agent, Unterberg and Shoreline received fees totaling \$1,350,000 and expense reimbursement of approximately \$40,000. (See "Liquidity and Capital Resources" below for further detail on these transactions.)

In September 2004, the National Institutes of Health (NIH) awarded the Company a Small Business Technology Transfer grant of \$464,000 for studies in Alzheimer's disease, consisting of \$308,000 for the first year and \$156,000 for the remainder of the grant term, September 30, 2004 through March 31, 2006. The studies will be conducted by Dr. George A. Carlson of the McLaughlin Research Institute (MRI) in Great Falls, Montana, which will receive approximately \$222,000 of the total award. A multi-year grant was awarded by the NIH to the Reeve-Irvine Center at the University of California-Irvine to fund new studies by Drs. Aileen J. Anderson and Brian J. Cummings of the human central nervous system stem cell (hCNS-SC) grafts in the treatment of spinal cord injuries. The Company will not receive any funds from this grant, but will collaborate with Drs. Anderson and Cummings by providing its proprietary cells for the studies. In October 2004, the Company also entered a long-term license agreement with R&D Systems, authorizing it to manufacture, use and sell certain kits for the expansion of neural stem cells, for educational and research purposes worldwide.

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 facilities in Rhode Island and the increasing costs associated with our facility in California. To expand and provide high quality systems and support to our Research and Development programs, as well as to enhance our internal controls over financial reporting, we will need to hire more personnel, which will lead to higher operating expenses. We hired a Vice President of Development and contracted with an Acting Chief Medical Officer in 2003, and have hired a Chief Financial Officer in 2004.

Our program in neural stem and progenitor cells ranges from the preclinical stage, as we focus increasingly on testing human neural stem cells in small animal models of human diseases, both in-house and through external academic collaborators, through the development phase with respect to the planned clinical trial in Batten disease mentioned above. In our liver stem cell program, we are engaged in evaluating our proprietary liver engrafting cell in various *in vivo* assays. Our pancreas program research will focus on the candidate human pancreatic stem/progenitor cell. Our key focus will be to demonstrate the in vivo engraftment and biological activity of the cells in an appropriate animal model after expansion in culture.

#### **Critical Accounting Policies**

The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements:

#### Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements. Actual results could differ from these estimates. The significant estimates are the accrued wind-down expenses (Note 7) and valuation allowance against net deferred tax assets (Note 11).

## **Stock-Based Compensation**

As permitted by the provisions of Statement of Financial Accounting Standards (SFAS) No. 148, "Accounting for Stock-Based Compensation — *Transition and Disclosure*," and SFAS No. 123, "Accounting for Stock-Based Compensation," the Company's employee stock option plan is accounted for under Accounting Principles Board Opinion No. 25 (APB 25), "Accounting for Stock Issued to Employees." The Company grants qualified stock options for a fixed number of shares to employees with an exercise price equal to the fair market value of the shares at the date of grant. In these circumstances and in accordance with APB 25, the Company recognizes no compensation expense for qualified stock option grants. The Company also issues non-qualified stock options for a fixed number of shares to employees with an exercise price less than the fair market value of the shares at the date of grant. When such options vest, the Company recognizes the difference between the exercise price and fair market value at date of grant as compensation expense in accordance with APB 25.

The Company accounts for certain stock options granted to non-employees, in accordance with FAS No. 123 and Emerging Issues Task Force (EITF) 96-18, "Accounting for equity instruments that are issued to other than employees for acquiring, or in conjunction with selling, goods or services", and accordingly, recognizes as expense the estimated fair value of such options as calculated using the Black-Scholes valuation model. The calculated value is remeasured during the service period. Fair value is determined using methodologies allowable by FAS No. 123. The cost is amortized over the vesting period of each option or the recipient's contractual arrangement, if shorter.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123R (revised 2004), "*Share-Based Payment*." This statement revises SFAS No. 123, Accounting for Stock-Based Compensation, and requires companies to expense the value of employee stock options and similar awards. The effective date of this standard is interim and annual periods beginning after June 15, 2005. Upon the adoption of SFAS No. 123R the Company will be required to expense stock options in its Statement of Operations. Note 9 of the Notes to the Consolidated Financial Statements describes our equity compensation plans, and Note 1 of the Notes to the Consolidated Financial Statements contains a summary of the pro forma effects to reported net (loss) and (loss) per share for 2004, 2003, and 2002 as if we had elected to recognize compensation cost based on the fair value of the options granted at grant date, as prescribed by FAS No. 123R.

#### Long-Lived Assets

The Company adopted FAS No. 144, "Accounting for the Impairment or Disposal of Long-lived Assets," at the beginning of 2002. As permitted by the transition rules of FAS No. 144, long-lived assets classified as held for sale as a result of activities that were initiated prior to this Statement's initial application shall continue to be accounted for in accordance with FAS No. 121. If however, the criteria for classifying long-lived assets held for sale under FAS No. 144 are not met by the end of the fiscal year in which this Statement is initially applied, the related long-lived assets shall be reclassified as held and used. At December 31, 2002, the criteria under FAS No. 144 for classifying the Company's long-lived assets held for sale were not met and accordingly, such assets were reclassified as held and used on the balance sheet.

The Company routinely evaluates the carrying value of its long-lived assets. The Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that assets may be impaired and the undiscounted cash flows estimated to be generated by the assets are less than the carrying amount of those assets. If an impairment exists, the charge to operations is measured as the excess of the carrying amount over the fair value of the assets.

## **Research and Development Costs**

The Company expenses all research and development costs as incurred. Research and Development costs include costs of personnel, external services, supplies, facilities and miscellaneous other costs.

## Wind-down and Exit Costs

In connection with the Company's wind-down of its Encapsulated Cell Therapy (ECT) operations, its research and manufacturing operations in Lincoln, Rhode Island, and the relocation of its remaining research and development activities and corporate headquarters, to California, in October 1999, the Company has provided its estimate of the exit cost obligation in accordance with EITF 94-3, "Other Cost to Exit an Activity." On an ongoing basis the Company will re-evaluate such estimate.

## **RESULTS OF OPERATIONS**

#### Years Ended December 31, 2004, 2003 and 2002

#### Revenues

Revenues totaled \$141,000, \$273,000, and \$415,000 for the years ending December 31, 2004, 2003 and 2002, respectively.

**2004 versus 2003.** Revenues for 2004 include \$93,000 that is part of a one-year Small Business Innovation Research grant of \$342,000 from the National Institute of Neurological Disease and Stroke (NINDS) received at the end of 2003, and \$26,000 which is part of a Small Business Technology Transfer (STTR) grant received in 2004 for approximately \$464,000 over one and one half years for studies in Alzheimer's disease. The STTR grant will support joint work with the McLaughlin Research Institute (MRI) in Great Falls, Montana. We will retain \$243,000 and the remaining \$221,000 will be disbursed to MRI. Revenues for 2004 also include \$22,000 in licensing revenue.

Revenues for 2003 include \$143,000, which was part of the \$342,000 NINDS grant and \$112,000 from the grant awarded by the National Institute of Diabetes & Digestive & Kidney Disorders (NIDDKD) of the National Institutes of Health. In addition, revenues for 2003 include \$18,000 in licensing revenue. The decrease from 2003 to 2004 was primarily attributable to the NIDDKD grant, for which, in 2003 the draw down was \$112,000 but we did not, and shall not, draw further funds from the grant since we are no longer pursuing the particular research that the grant covered. The decrease was also attributable to the completed draw down of the \$342,000 NINDS grant. The draw down was \$143,000 in 2003 and \$93,000 in 2004. The remaining \$106,000 was paid to a subcontractor.

**2003 versus 2002.** Revenues for 2002 include \$150,000 that was part of a 2001 SBIR grant from the National Institute of Allergy and Infectious Diseases (NIAID), \$225,000 from the NIDDKD grant, and \$40,000 in licensing revenue. The decrease in revenue from 2002 to 2003 was primarily due to the completion of the NIAID grant in 2002, and to a partial draw down in 2003 from the \$225,000 NIDDKD grant.

## Research & development expenses

Research and development expenses totaled \$8,760,000 in 2004, as compared to \$6,144,000 in 2003 and \$7,382,000 in 2002.

**2004 versus 2003.** The increase of \$2,616,000 or 43% from 2003 to 2004 was primarily due to the expenditures required for pre-clinical pharmacology and toxicology studies, supplies, personnel and other external services in preparation for submitting our first IND to the FDA. The increase was also attributable to

a higher valuation in 2004 of stock options granted as compensation to non-employees as compared to the valuation in 2003. The valuation — computed by the Black Scholes Method — is dependant on variable factors at the time of such valuation such as stock price, stock price volatility, interest rate and remaining life of the option. Our stock price at December 31, 2004 was \$4.23 as compared to \$1.98 at December 31, 2003. In addition, the increase reflects higher patent fees and costs than incurred in the same period in 2003. At December 31, 2004, we had twenty-eight full-time employees working in research and development and laboratory support services as compared to twenty-one at December 31, 2003.

**2003 versus 2002.** The decrease of \$1,238,000 or 17% from 2002 to 2003, was primarily attributable to the cost reduction program initiated in the last quarter of 2002 which resulted in a reduction in personnel and related expenses, reduction in expenditure on supplies and outside services, and a reduction in rent expense as a result of an amendment to the lease on our current facilities in California. This decrease in expenses in 2003 relative to 2002 was offset by the effect of a lower valuation in 2002 of stock options granted as compensation to non-employees as compared to the valuation in 2003. At December 31, 2003, we had twenty-one full-time employees working in research and development and laboratory support services as compared to twenty-eight at December 31, 2002.

#### General & administrative expenses

General and administrative expenses were \$3,954,000 in 2004, compared with \$3,391,000 in 2003 and \$3,359,000 in 2002.

**2004 versus 2003.** The increase of \$563,000 or 17% from 2003 to 2004 was primarily attributable to, the cost of external services incurred in the evaluation and testing of our internal financial control systems so as to meet the requirements of and be in compliance with the new Securities and Exchange Commission rules issued under section 404 of the Sarbanes-Oxley Act. The increase in general and administrative expenses was also attributable to the separate printing of our proxy statement and our Form 10-K and the effect of a greater number of shareholders in 2004 when compared to 2003 on these costs. In addition, we incurred an increase in the external auditor fees in the first quarter of 2004 as a result of the restatement of our prior year financials.

**2003 versus 2002.** The increase of \$32,000 or 1%, from 2002 to 2003 was primarily attributable to the depreciation expense of our Rhode Island facility (Pilot plant building related to our former ECT research). No depreciation expense was recorded in 2002, as the assets were classified as held for sale. At December 31, 2002, the criteria under FAS No. 144 for classifying the Company's long-lived assets held for sale were not met and accordingly, such assets with a fair value of \$3,203,491 at December 31, 2002 were reclassified as held and used on the balance sheet for all periods presented and are included in building and improvements. We resumed depreciating these assets effective January 2003. This increase in expense relative to 2002 was offset by a decrease in other expenses such as external services, facilities, information technology related expenses, all of which resulted from a cost reduction program initiated in the last quarter of 2002.

## Wind-down expenses

In 1999 we created a reserve for the estimated lease payments and operating costs of the Rhode Island facilities through June 30, 2000, when we expected to full sublease, assign or sell our remaining interests in the property. We did not fully sublet the Rhode Island facilities in 2000 and therefore made a change in estimate to accrue additional expenses of \$3,327,000 to cover operating lease payments, utilities, taxes, insurance, maintenance, interest and other non-employee expenses through 2001. In the year 2001 we paid \$1,780,000 of lease payments and operating expenses net of subtenant income which were recorded against the reserve. At December 31, 2001 we revised our estimate and recorded an additional reserve of \$575,000 as operating expenses net of subtenant income for our former corporate headquarters in Rhode Island. This reserve was based on information provided by our broker/realtor that estimated, based on assumptions relevant to the real estate market conditions as of the end of 2001, the time it would be likely to take until the facility would be fully sub-leased. In 2002, we incurred \$964,000 in lease payments and operating expenses, net of subtenant income for this facility, of which \$575,000 was booked against the reserve created at the end of 2001 and the remainder recorded as wind-down expenses. At the end of December 2002, based on an analysis of the real



estate market conditions at that time, we revised the reserve to \$775,000. In 2003 we incurred \$984,000 in lease payments and operating expenses, net of subtenant income for this facility of which \$775,000 was recorded against the reserve and the remainder recorded as wind-down expenses. At the end of 2003, after considering various factors such as the Company's lease payments through to the end of the lease, operating expenses, the current real estate market in Rhode Island, and estimated subtenant income based on occupancy both actual and projected, we revised the reserve at December 31, 2003 to \$2,676,000. In 2004, we recorded \$1,152,000 in operating expenses against this reserve. In 2004, after evaluating the afore-mention factors, at the end of each quarter — March 31, 2004, June 30, 2004 and September 30, 2004 and December 31, 2004 — we re-evaluated our estimate and adjusted the reserve to \$2,510,000, \$2,680,000, \$3,743,000 and \$4,350,000 respectively, by recording an additional \$130,000 at March 31, 2004, \$468,000 at June 30, 2004, \$1,345,000 at September 30, 2004 and Seetember 31, 2004 as wind-down expenses. Even though it is the intent of the Company to sublease, assign or sell our interests in the facility at the earliest possible time, we cannot determine with certainty a fixed date by which such events will occur. In light of this uncertainty, based on estimates, we will periodically re-evaluate and adjust the reserve, as necessary.

## Other income (expense)

Interest income for the years ended December 31, 2004, 2003 and 2002 totaled \$322,000, \$39,000 and \$109,000, respectively. The increase in interest income from 2003 to 2004 was primarily attributable to a higher average bank balance as a result of our financing transactions in 2004 (See "Liquidity and Capital Resources" below for further detail on these transactions.). Our decrease in interest income from 2002 to 2003 was attributable to the lower interest rate on overnight and money market funds and a lower average bank balance.

In 2004, interest expense was \$191,000, compared to \$207,000 in 2003 and \$227,000 in 2002. The decrease from 2002 to 2004 was attributable to lower outstanding debt and capital lease balances.

Other expenses for 2004 include a loss of \$56,000 resulting from a write-off of obsolete lab equipment and \$6,000 in state franchise taxes. For 2003, other income net of other expenses was \$24,000, consisting of income received from the leasing of equipment to subtenants and state franchise taxes paid. For 2002 other expenses includes \$34,000 paid in state franchise taxes and a \$3,000 loss in disposal of equipment.

#### Deemed Dividends Related to Convertible Preferred Stock

We recorded deemed dividends of \$2,066,000 and \$1,280,000 for 2003 and 2002 respectively. The dividends are related to the 3% Cumulative Convertible Preferred Stock (see note 9 to the consolidated financial statements) which includes the accretion of common stock warrants, the accretion of the beneficial conversion feature and the accretion of related issuance costs. The aggregate accretion value associated with the warrants, beneficial conversion feature and issuance costs were included in the calculation of net loss applicable to common stockholders.

There is no longer any preferred stock outstanding, as all of the Company's previously outstanding 3% and 6% cumulative convertible preferred stock was converted to the Company's common stock prior to the end of 2003.

#### 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, revenues from collaborative agreements, research grants and interest income.

We had cash and cash equivalents totaling \$41,060,000 at December 31, 2004. Cash equivalents are invested in U.S. Treasuries with maturities of less than 90 days. We used \$11,274,000, \$8,543,000, and \$10,087,000 of cash, in 2004, 2003 and 2002 respectively, in our operating activities. The increase in cash used in 2004 in comparison to 2003 was primarily attributable to the expenses incurred in preparing to submit our first IND to the FDA, for a clinical trial of our human neural stem cells as a treatment for Batten disease. The

decrease in cash used in operating activities from 2002 to 2003 was primarily due to a cost reduction program initiated in the last quarter of 2002 which included a reduction in head count and other operating expenses. In addition, we negotiated an amendment in our rent obligations under the lease on our current facilities in California which reduced our average annual rent over the remaining term of the lease from approximately \$3.7 million to \$2.0 million.

On June 16, 2004, we entered into an agreement with institutional and other accredited investors with respect to the private placement of approximately 13,160,000 shares of our common stock at a purchase price of \$1.52 per share, for gross proceeds of approximately \$20,000,000. Investors also received warrants exercisable for five years to purchase approximately 3,290,000 shares of common stock at an exercise price of \$1.90 per share. During the period October 2004 to December 2004, 306,525 of these warrants were exercised to purchase an aggregate of 306,525 shares of the Company's common stock at \$1.90 per share. The Company received proceeds of \$582,000 on issuance of the shares. C.E. Unterberg, Towbin LLC (Unterberg) served as placement agent for the private placement. For acting as our placement agent, Unterberg received fees of approximately \$1,200,000, expense reimbursement of approximately \$25,000 and a five year warrant to purchase 526,400 shares of our common stock at an exercise price of \$1.89 per share.

On October 26, 2004, the Company entered into an agreement with institutional investors with respect to the registered direct placement of 7,500,000 shares of its common stock at a purchase price of \$3.00 per share, for gross proceeds of \$22,500,000. Unterberg and Shoreline Pacific, LLC (Shoreline) served as placement agents for the transaction. The Company sold these shares under a shelf registration statement previously filed with and declared effective by the U.S. Securities and Exchange Commission. For acting as our placement agent Unterberg and Shoreline received fees of approximately \$1,350,000 and expense reimbursement of approximately \$40,000. No warrants were issued as part of this financing transaction.

On December 10, 2003 the Company completed a \$9.5 million financing transaction with Riverview Group L.L.C. (Riverview), through the sale of 5 million shares of common stock at a price of \$1.90 per share. The closing price of the Company's common stock on that date was \$2.00 per share.

On May 7, 2003, the Company entered into a stock purchase agreement with Riverview under which Riverview agreed to purchase 4 million shares of the Company's common stock for \$6.5 million, or \$1.625 per share. On the date of the agreement, the sale price was above the trading price of the Company's common stock, which closed at \$1.43 per share on that date. The Company also agreed to issue a 2-year warrant to Riverview to purchase 1,898,000 shares of common stock at \$1.50 per share. The exercise price is subject to adjustment for stock splits, dividends, distributions, reclassifications and similar events. In the event that certain conditions are met, including the closing sale price of the Common Stock remaining at or above \$2.50 per share for 10 consecutive trading days, the Company may require Riverview to exercise the warrant for any remaining shares or to relinquish any unexercised portion. On November 11, 2003, Riverview exercised part of the warrant acquiring 1,098,000 shares at \$1.50 per share. The proceeds to the Company from this warrant exercise totaled \$1,647,000. The warrant is exercisable for the remaining 800,000 shares until April 8, 2005, subject to our right to require exercise or forfeiture as described above.

On August 23, 2002, we entered into an agreement with Triton West Group, Inc. (Triton) pursuant to which we sold 1,028,038 shares of common stock to Triton for aggregate proceeds of \$1,100,000, or approximately \$1.07 per share.

On December 4, 2001, we issued 5,000 shares of 3% cumulative convertible preferred stock to Riverview. We received total proceeds of \$4,728,000 net of the fee to Cantor Fitzgerald and other associated costs. This preferred stock is convertible into shares of our common stock at a current conversion price of \$2.00 per share of common stock. There was a mandatory redemption provision in the preferred stock under which any preferred stock remaining on December 4, 2003, was to be redeemed on that date. In connection with the preferred stock agreement, we issued to Riverview Group a warrant to purchase 350,877 shares of our common stock at a price of \$3.42 per share. We paid Cantor Fitzgerald & Co., our financial advisor in connection with the transaction, a fee of \$200,000 and issued them a warrant for 146,199 shares exercisable at \$3.42 per share. Both warrants expire on December 4, 2005. On December 7, 2001, Riverview converted 1,000 shares of its 3% cumulative convertible preferred stock for 500,125 shares of the Company's common

stock. On April 9, 2003, the Company agreed with Riverview to reduce the conversion price to \$0.80 per share for a period of 20 trading days. The inducement resulted in a deemed dividend of approximately \$1,000,000. Riverview immediately agreed to convert 2,000 shares with a face value of \$2 million, at the reduced price. Riverview received 2,521,041 shares of common stock upon conversion, which includes 21,041 shares valued at \$16,833 as accrued dividends. On November 11, 2003, Riverview converted the remaining 2,000 shares of its 3% cumulative convertible preferred stock for 1,010,833 shares of the Company's common stock, which includes 10,833 shares valued at \$21,666 as accrued dividends. As a result of the above transactions all of the 3% cumulative convertible preferred stock were fully converted into our common stock before the mandatory redemption date of December 4, 2003.

On May 10, 2001, we entered into a common stock purchase agreement with Sativum Investments Limited for the potential future issuance and sale of up to \$30,000,000 of our common stock, subject to restrictions and other obligations. The agreement expired in January 2004. We had the right to draw down on this facility, sometimes termed an equity line, from time to time, and Sativum was obligated to purchase shares of our common stock at a 6% discount to a volume weighted average market price over the 20 trading days following the draw-down notice. We were limited with respect to how often we could exercise a draw down and the amount of each draw down. The Company did draw down \$4,000,000 by issuance of 707,947 shares in July of 2001, \$118,000 by issuance of 107,812 shares in December of 2002, \$66,000 by issuance of 58,516 shares in January of 2003, and \$375,000 by issuance of 245,472 shares in May of 2003, before applicable fees. In connection with our execution of the common stock purchase agreement with Sativum, we issued three-year warrants to purchase an aggregate of 350,000 shares of our common stock at \$2.38 per share to Sativum (250,000 shares) and our placement agents (Pacific Crest Securities Inc., 75,000 shares and Granite Financial Group, Inc., 25,000 shares). Our placement agents exercised their warrants in full in July 2001, and we received payment of \$238,050 for the shares issued to them.

We continue to have outstanding obligations in regard to our former facilities in Lincoln, Rhode Island. In 1997, we had entered into a fifteen-year lease for a scientific and administrative facility (the SAF) in a sale and leaseback arrangement. The lease includes escalating rent payments. For the year 2005, we expect to pay \$938,000 as an operating lease payment and in addition, based on our 2004 expenses, approximately \$500,000 as operating expenses. In 1992 and 1994 we had undertaken direct financing transactions with the State of Rhode Island and received proceeds from the issuance of industrial revenue bonds totaling \$5,000,000 to finance the construction of a pilot manufacturing facility and a related cell processing facility. The related leases are structured such that lease payments will fully fund all semiannual interest payments and annual principal payments through maturity in August 2014. For these related facilities we expect to pay approximately \$460,000 in principal, interest and related expenses in 2005. In addition based on 2004 expenses we expect to incur approximately \$40,000 in expenses common to both facilities such as property management and legal fees. We have subleased the pilot manufacturing facility and the cell processing facility, as well as a portion (approximately one-fourth) of the SAF. We expect to receive, in aggregate, approximately \$708,000 in sub-tenant rent for all of the Rhode Island facilities. As a result of the above transactions, our estimated costs net of sub-tenant rent for the Rhode Island facilities. Failure to do so within a reasonable period of time will have a material adverse effect on our liquidity and capital resources.

The following table summarizes our future contractual cash obligations (including both Rhode Island and California leases, but excluding interest income and sub-lease income with respect to the Rhode Island properties):

	0			Payable in Payable in 2005 2006				Payable in 2007	:	Payable in 2008	1	Payable in 2009		Payable in 2010 and Beyond
Capital lease payments	\$	2,839,805	\$	472,680	\$	445,486	\$	332,545	\$	244,531	\$	244,572	\$	1,099,991
Operating lease payments		11,652,113		3,007,630		1,115,186		937,500		1,171,875		1,171,875	_	4,248,047
Total contractual cash														
obligations	\$	14,491,918	\$	3,480,310	\$	1,560,672	\$	1,270,045	\$	1,416,406	\$	1,416,447	\$	5,348,038

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 revenues to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for general and administrative expenses and other working capital requirements. We rely on cash balances and proceeds from equity and debt offerings, 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. If we exhaust our cash balances and are unable to realize adequate financing, we may be unable to meet operating obligations and be required to initiate bankruptcy proceedings.

We intend to pursue opportunities to obtain additional financing in the future through equity and debt financings, grants and collaborative research arrangements. 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 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.

With the exception of operating leases for facilities, we have not entered into any off balance sheet financial arrangements and have not established any special purpose entities. We have not guaranteed any debts or commitments of other entities or entered into any options on non-financial assets. During 2001, we were party to a space-sharing agreement entered into between us and Celtrans, LLC. (now Cellerant, Inc.). Dr. Irving Weissman, a member of our Board of Directors and Chairman of our Scientific Advisory Board, is the founder and Chairman of Cellerant, a privately-owned biotechnology company that is a subtenant in the building in which the Company is located. Under the agreement, which was effective as of September 1, 2001, Cellerant or, with our approval, a subtenant of Cellerant, may use certain animal space in our facility, which we do not currently require for our own use. That agreement was partially in abeyance until February 2005, since the animal space was used by a third party by agreement with us and with Cellerant. We also provide certain services to Cellerant with respect to animal care for mice housed in Cellerant's own space. In addition, Dr. Weissman remains a consultant to us under an agreement entered in 1997.

## **Recent Accounting Pronouncements**

#### Accounting for Stock-Based Compensation

In December 2004, FASB issued SFAS No. 123R (revised 2004), Share-Based Payment. This Statement is a revision of SFAS No. 123, Accounting for Stock-Based Compensation and amends SFAS No. 95, Statement of Cash Flows This Statement supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and its related implementation guidance. Upon the adoption of SFAS No. 123R the Company will be required to expense stock options in its Statement of Operations. Among other items, the new standard would require the expensing of stock options issued by the Company in the financial statements using a fair-value-based method. The provisions of SFAS 123R are effective for the first interim or annual reporting period that begins after June 15, 2005; the Company will therefore adopt the new requirements no later than the beginning of its third quarter of fiscal 2005. Adoption of the expensing requirements will reduce the Company's reported earnings. See 'Stock-based Compensation' in Note 1 for dis closures regarding the effect on net earnings and earnings per share if we had applied the fair value recognition provisions of SFAS No. 123R.

# Accounting for Costs Associated with Exit or Disposal Activities

In June 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 provides guidance related to accounting for costs associated with disposal activities

covered by SFAS No. 144 and with one-time termination benefits and other exit or restructuring activities previously covered by Emerging Issues Task Force (EITF) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 supersedes EITF Issue No. 94-3 in its entirety. Under SFAS No. 146, the following conditions must be met for an action to qualify as an exit or disposal plan: management having the authority to approve the action commits to a plan of termination; the plan identifies the number of employees to be terminated, their job classifications or functions and their locations, and the expected completion date; the plan establishes the terms of the benefit arrangement including the benefits that employees will receive upon termination (including but not limited to cash payments) in sufficient detail to enable employees to determine the type and amount of benefits they will receive if they are involuntarily terminated; and actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn. SFAS No. 146 was effective in 2003 and will be applied prospectively to qualifying exit or disposal activities initiated after December 31, 2002.

## CAUTIONARY FACTORS RELEVANT TO FORWARD-LOOKING INFORMATION

YOU SHOULD CAREFULLY CONSIDER THE RISKS DESCRIBED BELOW BEFORE MAKING AN INVESTMENT DECISION REGARDING STEMCELLS, INC. Any of the following risks could materially adversely affect our business, financial conditions or results of operation. Additional risks and uncertainties not known to us or that we currently deem immaterial may also impair our business operations.

Our business, financial condition or results of operations could be materially adversely affected by any of these risks. Consequentially, the trading price of our common stock could decline, resulting in the loss of all or part of your investment.

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

# Our financial situation is precarious and, based on currently estimated operating expenses, our existing capital resources may not be sufficient to fund our operations beyond 2006

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 revenues to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts and for acquisition of technologies and intellectual property rights, preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, general and administrative expenses and other working capital requirements. We rely on cash reserves 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. If we exhaust our cash reserves and are unable to realize adequate financing, we may be unable to meet operating obligations and be required to initiate bankruptcy proceedings. Our existing capital resources may not be sufficient to fund our operations beyond 2006. These conditions raise doubt about our ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

We intend to pursue opportunities to obtain additional financing in the future through equity and debt financings, grants and collaborative research arrangements. 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 to delay, scale back or eliminate some or all of our research and product development programs and/or our capital expenditures or to license our potential products or technologies to third parties.

# The FDA may fail to approve our Investigational New Drug Application for our proposed Phase I clinical trial of our proprietary neural cell therapy product in Batten disease, and the Institutional Review Board (IRB) at the clinical site may fail to approve the clinical protocol for the trial.

We filed our first Investigational New Drug, or IND, application to the U.S. Food and Drug Administration (FDA) in late December, 2004, for our proposed Phase I clinical trial of our proprietary neural cell therapy product — HuCNS SC — in Batten disease. The FDA has informed us that it has suggestions and questions related to the proposed trial that require additional information and has placed our proposed trial on hold. We cannot be certain whether the FDA will remove the clinical hold on the Company's proposed initial clinical trial and permit the Company to proceed to clinical testing despite the novel and unproven nature of our technology. We may not be able to satisfy the FDA's concerns without conducting extensive and time consuming additional preclinical studies, if at all. Even if approved, our clinical trial could be substantially delayed beyond its expected dates. In addition to requiring FDA approval, the trial cannot go forward until the IRB of the trial site has approved the proposed clinical protocol. The IRB for Stanford

University, theproposed site of the trial, has not yet acted on the protocol. Should it fail to approve the trial, or require modifications to the protocol that are not acceptable to the Company, the Company would need to find another trial site.

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

We have yet to develop any products. Our stem cell technology is still at the discovery phase for the liver and pancreas stem cells and, while we have filed an IND with respect to our human neural (brain) stem cells, the U.S. Food and Drug Administration (FDA) has placed a clinical hold on our proposed clinical trial pending the Company's response to its concerns. We may fail to discover the stem cells we are seeking, to develop any products, to obtain regulatory approvals, to enter clinical trials, or to commercialize any products. Any product using stem cell technology may fail to:

- survive and persist in the desired location;
- provide the intended therapeutic benefits;
- properly integrate into existing tissue in the desired manner; or
- achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing.

In addition, our products may cause undesirable side effects. Results of early pre-clinical research may not be indicative of the results that will be obtained in later stages of pre-clinical or clinical research. If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would have limited ability to commercialize our products, and our business and results of operations would be harmed. Furthermore, because stem cells are a new form of therapy, the marketplace may not accept any products we may develop. If we do succeed in developing products, we will face many potential obstacles such as the need to obtain regulatory approvals and to develop or obtain manufacturing, marketing and distribution capabilities. In addition, we will face substantial additional risks such as product liability claims.

Moreover, because our cell therapy treatments will be derived from tissue of individuals other than the patient (that is, they will be 'non-self' or 'allogeneic' transplant products), patients will require the use of immunosuppressive drugs such as cyclosporine, FK506, or others to prevent rejection of the cells. While immunosuppression is now standard in connection with allogeneic transplants of various kinds, long-term maintenance on immunosuppressive drugs can produce complications that include infection, cancer, cardiovascular disease, renal dysfunction and other side effects depending upon which immunosuppressive regimen is employed. Immunosuppression has not been tested with our therapies since we have not yet conducted any clinical trials.

As noted above, we filed an IND with the FDA earlier this year which is currently on clinical hold. Before we are permitted to move forward, as part of the IND process, the FDA will need to be satisfied that the cell bank to be used in these trials qualifies as a suitable source of the cells for the proposed clinical trial, and that the pre-clinical safety testing (i.e., pharmacology and toxicology studies) we conducted in various animal models is adequate. We must also obtain the approval of the internal review board at the medical institution where the clinical trial would be conducted. We may not be able to satisfy all of the requirements to move the Batten disease program into clinical trials, which could have a material adverse effect on our product development timeline.

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

Prior to our reorganization in 1999 and the consolidation of our business in California, we carried out our former encapsulated cell therapy programs in Lincoln, Rhode Island, where we also had our administrative offices. Although we have vacated the Rhode Island facilities, we remain obligated to make on average, lease payments and payments for operating costs of approximately \$1,450,000 per year before sub-tenant rent income for our former science and administrative facility, which we have leased through June 30, 2013, and



debt service payments and payments for operating costs of approximately \$500,000 per year for our former encapsulated cell therapy pilot manufacturing facility, which we own. We have currently subleased a portion of the science and administrative facility, and are seeking to sublease the remaining portion, but we cannot be sure that we will be able to keep any part of the facility subleased for the duration of our obligation. We have currently subleased the entire pilot manufacturing facility to a privately-held biotechnology company, but may not be able to sublease or sell the facility in the future once the current sublease agreements expire. These continuing costs significantly reduce our cash resources and adversely affect our ability to fund further development of our stem cell technology. 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 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 gound either fully sublease, assign or sell our remaining interests in the could either fully sublease, assign or sell our remaining interests in the our former facility sublease, assign or sell our remaining interests in the could either fully sublease, assign or sell our remaining interests in the property. At December 31, 2004, the reserve was \$5,528,000. In 2004, we incurred \$1,152,000 in operating expenses net of subtenant 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. Even though it is our intern to sublease, assign, sell or otherwise

## We may need but fail to obtain partners to support our stem cell development efforts and to commercialize our technology.

Equity and debt financings alone may not be sufficient to fund the cost of developing our stem cell technologies, and we may need to rely on our ability to reach partnering arrangements to provide financial support for our stem cell discovery and development efforts. In addition, in order to successfully develop and commercialize our technology, we may need to enter into a wide variety of arrangements with corporate sponsors, pharmaceutical companies, universities, research groups and others. While we have engaged, and expect to continue to engage, in discussions regarding such arrangements, we have not reached any agreement, and we may fail to obtain any such agreement on terms acceptable to us. Even if we enter into these arrangements may require us to grant certain rights to third parties, including exclusive marketing rights to one or more products, may require us to issue securities to our collaborators or may contain other terms that are burdensome to us. If any of our collaborators terminates its relationship with us or fails to perform its obligations in a timely manner, the development or commercialization of our technology and potential products may be adversely affected.

#### We have a history of operating losses, and we may fail to obtain revenues or become profitable.

We expect to continue to incur substantial operating losses in the future in order to conduct our research and development activities, and, if those activities are successful, to fund clinical trials and other expenses. These expenses include the cost of acquiring technology, product testing, acquiring regulatory approvals, establishing production, marketing, sales and distribution programs and administrative expenses. We have not earned any revenues from sales of any product. All of our past revenues have been derived from, and any revenues we may obtain for the foreseeable future are expected to be derived from, cooperative agreements, research grants, investments and interest on invested capital. We currently have no cooperative agreements, we have only one current research grant for our stem cell technology, and we may not obtain any such agreements or additional grants in the future or receive any revenues from them.

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

We own or license a number of patents and pending patent applications related to various stem and progenitor cells and methods of deriving and using them, including human neural stem cell cultures. Patent protection for products such as those we propose to develop is highly uncertain and involves complex and continually evolving factual and legal questions. The governmental authorities that consider patent applications can deny or significantly reduce the patent coverage requested in an application before or after issuing the patent. Consequently, we do not know whether any of our pending applications will result in the issuance of patents, if any existing or future patents will provide sufficient protection or significant commercial advantage or if others will circumvent these patents. We cannot be certain that we were the first to discover the inventions covered by each of our pending patent applications or that we were the first to file patent applications for such inventions because patent applications are secret until they are published, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Patents may not issue from our pending or future patent applications or, if issued, may not be of commercial benefit to us. In addition, our patents may not afford us adequate protection from competing products. Third parties may challenge our patents or governmental authorities may declare them invalid. In the event that a third party has also filed a patent application relating to inventions claimed in our patent applications, we may have to participate in proceedings to determine priority of invention. This could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us, and the outcome might not be favorable to us. Even if a patent issues, a court could decide that the patent was issued invalidly. Further, patents issue for a limited term, and our patents may expire before we utilize them profitably. Under the procedures of the European Patent Office, third parties may oppose our issued European patents during the relevant opposition period. Such oppositions could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us, and the outcome might not be favorable to us. One party has opposed two of our granted European patents. While we are confident in our position, there is no guarantee that we will prevail. If we are unsuccessful in our defense of the opposed patents, all claimed rights in the opposed patents will be lost in Europe.

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 others are first to discover and patent the stem cells we are seeking to discover, we could be blocked from further work on those stem cells.

Because the first person or entity to discover and obtain a valid patent to a particular stem or progenitor cell may effectively block all others, it will be important for us or our collaborators to be the first to discover any stem cell that we are seeking to discover. Failure to be the first could prevent us from commercializing all of our research and development affected by that patent.

# 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 cells and other technologies potentially relevant to or necessary for our expected products. We cannot predict which, if any, of the applications will issue as patents. If third party patents or patent applications contain valid claims that our technology infringes upon their technology, we may be unable to obtain licenses to these patents at a reasonable cost, if at all, and may also be unable to develop or obtain alternative technology. If we are unable

to obtain such licenses at a reasonable cost, our business could be significantly harmed. We have obtained rights from 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 risks of third-party patents and/or technology. 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. Many of the world's pharmaceutical companies, including Merck, Pfizer, Abbott, Bristol-Myers Squibb, Novartis and GlaxoSmithKline, have made significant commitments to the CNS field. Any cell-based therapy to treat diseases of, or injuries to, the CNS is likely to face intense competition from the small molecule sector. In addition, a number of biotechnology companies with resources far greater than ours may also emerge as competitors. These include Genzyme, Amgen, Cephalon, Transkaryotic Therapies, BioMarin, Celgene, Biogen, and Titan Pharmaceuticals. Finally, we also expect to compete with smaller biotechnology companies, some of which are privately owned, such as Neuralstem, Geron, NeuroNova, ReNeuron, ES Cell International, and CellFactors/ Diacrin.

We believe that our human neural stem cells may have application to many or most of the Lysosomal Storage Diseases ("LSDs") with CNS involvement. We have submitted our first IND for Batten Disease, which is one of the LSDs that affect the CNS; that IND is currently on clinical hold, and we have no assurance as to when or whether the FDA will release the hold and permit the clinical trial to begin. There are, so far as we know, no approved therapies for Batten's or any of the other CNS-specific LSDs, but other companies, including Genzyme, BioMarin, and Transkaryotic Therapies, have products approved to treat peripheral aspects of some of the other LSDs, and other products are in clinical trials.

In the field of diabetes, a number of major companies currently market products for the treatment of diabetes and are also engaged in the research and development of new therapies. Such companies include Eli Lilly, Novo Nordisk, J&J, Amylin, Serono. Consequently, should we successfully develop a cell-based therapy for diabetes, we would expect to face severe competition from these and similar companies.

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

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

Our research and development efforts, as well as any future clinical trials, and the manufacturing and marketing of any products we may develop, will be subject to and restricted by extensive regulation by governmental authorities in the United States and other countries. The process of obtaining U.S. Food and Drug Administration and other necessary regulatory approvals is lengthy, expensive and uncertain. 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 fetal tissue. The federal and state governments and other jurisdictions impose restrictions on the use of fetal tissue. 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 guidelines for cell procurement. Further, we may not be able to obtain such cells in



the quantity or quality sufficient to satisfy the commercial requirements of our potential products. As a result, we may be unable to develop or produce our products in a profitable manner.

Although we do not use embryonic stem cells, government regulation and threatened regulation of embryonic tissue may lead top researchers to leave the field of stem cell research, or the country, in order to assure that their careers will not be impeded by restrictions on their work. Similarly, these factors may induce the best graduate students to choose other fields less vulnerable to changes in regulatory oversight, thus exacerbating the risk, discussed below, 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. In addition, we cannot assure you that constraints on the use of embryonic stem cells will not be extended to use of fetal stem cells. Moreover, it is possible that concerns regarding research using embryonic stem cells will impact our ability to attract collaborators and investors and our stock price.

We may apply for status under the Orphan Drug Act for some of our therapies to gain a seven-year period of marketing exclusivity for those therapies. The U.S. Congress in the past has considered, and in the future again may consider, legislation that would restrict the extent and duration of the market exclusivity of an orphan drug. If enacted, such legislation could prevent us from obtaining some or all of the benefits of the existing statute even if we were to apply for and be granted orphan drug status with respect to a potential product.

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

We are highly dependent on the principal members of our management and scientific staff and some of our outside consultants, including the members of our scientific advisory board, our chief executive officer, our vice presidents and the directors of our neural stem cell and liver stem cell programs. 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.

## We need to improve our financial control procedures.

Management's Annual Report on Internal Controls Over Financial Reporting found deficiencies in the operating effectiveness of its internal controls over financial reporting that collectively constitute significant deficiencies and a material weakness under standards established by the American Institute of Certified Public Accountants, resulting in more than a remote likelihood that a material misstatement of the annual or interim financial statements of the Company will not be prevented or detected. In the opinion of Grant Thornton LLP, the Company's independent auditors, Management's assessment that that StemCells Inc. did not maintain effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects. It is also the opinion of Grant Thornton that because of the effect of the material weakness identified by management (i.e., instances where both the preparation and review of general journal entries were performed by the same individual) on the achievement of the objectives of the control criteria, StemCells Inc. has not maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company has already taken remedial steps, and will continue its on-going evaluation of internal controls and attempts to improve its internal controls over financial reporting as necessary to assure their effectiveness, but there can be no assurance that it will succeed or that other deficiencies will not be identified.

# Since 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 reduced.

In both domestic and foreign markets, sales of potential products are likely to depend in part upon the availability and amounts of reimbursement from third party health care payor organizations, including government agencies, private health care insurers and other health care payors, such as health maintenance organizations and self-insured employee plans. There is considerable pressure to reduce the cost of therapeutic products, and 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 U.S. Food and Drug Administration has not granted marketing approval. Significant uncertainty exists as to the reimbursement status of newly approved health care products or novel therapies such as ours. 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 stem cell technology. 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 at health care reform 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 payers for health care goods and services may take in response to health care reform proposals or legislation. We cannot predict the effect government control and other health

# We have limited liquidity and capital resources and may not obtain the significant capital resources we will need to sustain our research and development efforts.

We have limited liquidity and capital resources and must obtain substantial additional capital to support our research and development programs, for acquisition of technology and intellectual property rights and, to the extent we decide to undertake these activities ourselves, for pre-clinical and clinical testing of our anticipated products, pursuit of regulatory approvals, establishment of production capabilities, establishment of marketing and sales capabilities and distribution channels, and general administrative expenses. If we do not obtain the necessary capital resources, we may have to delay, reduce or eliminate some or all of our research and development programs or license our technology or any potential products to third parties rather than commercialize them ourselves. We intend to pursue our needed capital resources through equity and debt financings, corporate alliances, grants and collaborative research arrangements. We may fail to obtain the necessary capital resources when needed or on terms acceptable to us. Our ability to complete successfully any such arrangements will depend upon market conditions and, more specifically, on continued progress in our research and development efforts.

# **Risks Related to the Securities Market**

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

The market price of our stock has been and is likely to continue to be highly volatile due to the risks and uncertainties described in this section of the prospectus, as well as other factors, including:

- our ability to develop and test our technology;
- our ability to patent or obtain licenses to necessary technology;
- 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;

• 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, 2004, the closing price of our common stock as reported on the Nasdaq SmallCap Market ranged from a high of \$4.48 to a low of \$.66. As a result of this volatility, your investment in our stock is subject to substantial risk. Furthermore, the volatility of our stock price could negatively impact our ability to raise capital in the future.

## We are contractually obligated to issue shares in the future, diluting your interest in us.

As of December 31, 2004, there were outstanding and exercisable warrants to purchase 5,490,285 shares of our common stock, at a weighted average exercise price of \$2.08 per share. As of December 31, 2004, there were also outstanding and exercisable options to purchase 6,682,201 shares of our common stock, at a weighted average exercise price of \$2.67 per share. Moreover, we expect to issue additional options to purchase shares of our common stock to compensate employees, consultants and directors, and may issue additional shares to raise capital, to acquire other companies or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of further diluting the interest of the purchasers of the securities being sold in this offering.

#### Management's Annual Report on Internal Controls Over Financial Reporting

StemCells, Inc., is responsible for establishing and maintaining adequate internal control over financial reporting. StemCells' internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements.

StemCells' management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making its assessment of internal control over financial reporting, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework.

Management's assessment identified the following material weakness in the Company's internal control over financial reporting: significant deficiencies were identified in the Company's general ledger process as a result of the fact that some journal entries and reports were both prepared and reviewed by the same individual and not reviewed by another individual; management has determined that these significant deficiencies, in the aggregate, constituted a material weakness in the design and operation of the Company's internal controls in effect prior to December 31, 2004. Although the Company hired a separate chief financial officer in November 2004, the new controls this addition allowed had not been in operation for a sufficient period of time to enable management to obtain sufficient evidence about their operating effectiveness.

Because of the material weakness described in the preceding paragraph, management believes that, as of December 31, 2004, the company's internal control over financial reporting was not effective based on the COSO criteria.

StemCells' independent auditors have issued an audit report on our assessment of the Company's internal control over financial reporting. This report appears below.

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

Board of Directors and Stockholders StemCells, Inc.

We have audited management's assessment, included in the accompanying StemCells Inc. Management's Report on Internal Control Over Financial Reporting, that StemCells Inc. did not maintain effective internal control over financial reporting as of December 31, 2004, because of the effect of the material weakness identified in management's assessment, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). StemCells Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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

A material weakness is a control deficiency, or combination of control deficiencies, that results in a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The following material weakness has been identified and included in management's assessment. The company identified instances where both the preparation and review of general journal entries were performed by the same individual. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2004 consolidated financial statements, and this report does not affect our report dated March 4, 2005, on those consolidated financial statements.

In our opinion, management's assessment that StemCells Inc. did not maintain effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, StemCells Inc. has not maintained effective internal control over financial reporting as of December 31, 2004, based on criteria

established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of StemCells Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, changes in redeemable preferred stock and stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2004 and our report dated March 4, 2005 expressed an unqualified opinion on those financial statements.

/s/ Grant Thornton LLP

San Jose, California March 4, 2005

# ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company has no financial instruments that are sensitive to market risk.

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

# STEMCELLS, INC.

# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Grant Thornton LLP, Independent Registered Public Accounting Firm	50
Report of Ernst & Young LLP, Independent Registered Public Accounting Firm	51
Consolidated Balance Sheets	52
Consolidated Statements of Operations	53
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity	54
Consolidated Statements of Cash Flows	57
Notes to Consolidated Financial Statements	59

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders StemCells Inc.

We have audited the consolidated balance sheets of StemCells Inc. and subsidiary as of December 31, 2004 and 2003, and the related consolidated statements of operations, changes in redeemable preferred stock and stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2004. These financial statements are the responsibility of management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of StemCells Inc. as of December 31, 2004 and 2003, and the consolidated results of their operations and their consolidated cash flows for each of the two years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with standards of the Public Company Accounting Oversight Board (United States), the effectiveness of StemCells Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 4, 2005, expressed an unqualified opinion on management's assessment, and an adverse opinion on the operating effectiveness, of such internal control over financial reporting.

/s/ Grant Thornton LLP

San Jose, California March 4, 2005

# **REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Stockholders and Board of Directors StemCells, Inc.

We have audited the consolidated balance sheet (not presented herein) of StemCells, Inc. as of December 31, 2002, and the related consolidated statements of operations, changes in redeemable preferred stock and stockholders' equity, and cash flows for the year the ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of StemCells, Inc. at December 31, 2002, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that StemCells, Inc. will continue as a going concern. As more fully described in Note 1, the Company has incurred significant operating losses and negative cash flows since inception and expects to continue to incur significant operating losses for the foreseeable future. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Palo Alto, California March 4, 2003, except for Note 1, as to which the date is March 25, 2004.

# **Consolidated Balance Sheets**

		December 31,				
		2004 2003		2003		
	ASSETS					
Current assets:						
Cash and cash equivalents		\$	41,059,532	\$	13,081,703	
Other receivable			180,963		145,463	
Other current assets			209,074		180,048	
Total current assets			41,449,569		13,407,214	
Property, plant and equipment, net			3,424,294		3,611,402	
Other assets, net			2,753,419		2,767,798	
Total assets		\$	47,627,282	\$	19,786,414	

# LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY

AND STOCKHOLDERS	LQUIII	
Current liabilities:		
Accounts payable	\$ 524,917	\$ 454,434
Accrued expenses and other	1,547,370	1,041,150
Accrued wind-down expenses	1,013,460	789,000
Capital lease obligations, current portion	52,843	—
Bonds payable, current portion	244,167	 237,084
Total current liabilities	3,382,757	 2,521,668
Capital lease obligations, less current maturities	41,065	—
Bonds payable, less current maturities	1,605,417	1,849,583
Deposits and other long-term liabilities	610,126	521,420
Accrued wind-down expenses non current	4,514,569	3,033,984
Deferred rent	523,801	 896,201
Total liabilities	10,677,735	8,822,856
Commitments (Note 5)		
Preferred stock \$0.01 par value; 1,000,000 shares authorized issuable, none		
outstanding (Note 9)	—	—
Stockholders' equity:		
Common stock, \$.01 par value; 125,000,000 and 75,000,000 shares authorized;		
62,129,407 and 40,998,858 shares issued and outstanding at December 31, 2004 and		
2003, respectively	621,293	409,988
Additional paid-in capital	211,419,300	170,406,393
Accumulated deficit	(174,205,214)	(158,874,915)
Deferred compensation	(885,832)	 (977,908)
Total stockholders' equity	36,949,547	 10,963,558
Total liabilities, redeemable convertible preferred stock, and stockholders' equity	\$ 47,627,282	\$ 19,786,414

See accompanying notes to consolidated financial statements.

# **Consolidated Statements of Operations**

		Year E	nded December 31,	
	 2004		2003	 2002
Revenue from collaborative and licensing agreements	\$ 22,206	\$	18,307	\$ 40,010
Revenue from grants	 118,828		255,123	 375,367
Total Revenues	141,034		273,430	415,377
Operating Expenses				
Research and development	8,760,431		6,143,676	7,382,272
General and administrative	3,953,564		3,390,652	3,358,581
Encapsulated Cell Therapy wind-down and corporate relocation	 2,826,879		2,885,329	 1,163,804
	 15,540,874		12,419,657	11,904,657
Loss from operations	 (15,399,840)		(12,146,227)	 (11,489,280)
Other Income (expense):				
Interest income	322,227		38,826	108,702
Interest expense	(191,006)		(207,112)	(226,723)
Loss on disposal of property, plant and equipment	(55,609)			(2,736)
Other income (expense)	(6,071)		23,761	(34,218)
	69,541		(144,525)	(154,975)
Loss before deemed dividend	 (15,330,299)		(12,290,752)	 (11,644,255)
Dividends to preferred stockholders	_		(68,497)	(351,727)
Deemed dividend to preferred stockholders			(2,065,911)	(1,280,004)
Net loss applicable to common stockholders	 (15,330,299)		(14,425,160)	 (13,275,986)
Basic and diluted net loss per share applicable to common				 :
stockholders	\$ (0.31)	\$	(0.45)	\$ (0.53)
Weighted average shares used in basic and diluted loss per share				
calculations	 49,606,277		32,080,233	 25,096,252

See accompanying notes to consolidated financial statements.

# STEMCELLS, INC.

# CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

		ble Convertible erred Stock	Common	Stock	Additional	Accumulated	Accumulated Other Comprehensive	Deferred	Total Stockholders'
	Shares	Amount	Shares	Amount	Paid-In Capital	Deficit	Income (Loss)	Compensation	Equity
Balances, December 31, 2001	5,500	\$ 2,662,932	24,220,021	\$ 242,200	\$ 149,180,388	\$ (134,519,684)	\$ —	\$ (2,270,097)	\$ 12,632,807
Issuance of common stock related to equity financing net of issuance cost \$89,706	_	_	1,135,850	11,359	1,117,285	_	_	_	1,128,644
Dividends paid to 3% convertible preferred holders in stock	_	_	97,969	980	128,290	(129,270)	_	_	_
Conversion of redeemable convertible preferred shares					-,				
to common stock	(1,500)	(1,283,250)	1,252,244	12,522	1,493,185	(222,457)	—	—	1,283,250
Accretion of redeemable preferred stock	_	1,280,004	_	_	(1,280,004)	_	_	_	(1,280,004)
Common stock issued for external services			61,419	614	90,913	_	_	_	91,527
Common stock issued pursuant to employee benefit plan	_	_	44,988	450	56,015	_	_	_	56,465
Exercise of employee and consultant stock									
options	_	—	47,587	476	8,859	_	_	—	9,335
Compensation expense from grant of options	_	_	_	_	124,689	_	_	_	124,689
Deferred					<i>(</i>				
compensation Amortization of deferred		_	_	_	(1,681,413)	_		1,681,413	_
compensation	_	_	_	_	_	_	_	(469,089)	(469,089)
Net loss	_	_	_	_	_	(11,644,255)	—		(11,644,255)
Balances, December 31,									
2002	4,000	2,659,686	26,860,078	268,601	\$ 149,238,207	\$ (146,515,666)	\$ —	\$ (1,057,773)	\$ 1,933,369
					54				

# STEMCELLS, INC.

# CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY — (Continued)

		mable Cor referred St		Common	Stock			Accumulated Other Comprehensive		Total
	Shares		Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Income (Loss)	Deferred Compensation	Stockholders' Equity
Balances,								<u> </u>		
December 31, 2002	4 000	¢	2 650 696	26 960 079	¢ 369 601	¢ 140 229 207		¢	¢ (1 057 772)	¢ 1,022,260
Issuance of	4,000	\$	2,659,686	26,860,078	\$ 268,601	\$ 149,238,207	\$ (146,515,666)	\$ —	\$ (1,057,773)	\$ 1,933,369
common stock related to equity financing net of issuance cost										
\$310,403	—		_	9,303,988	93,040	16,037,307	_		_	16,130,347
Dividends paid to 3% convertible preferred holders in stock	_			49,809	497	68,000	(68,497)	_	_	_
Accretion of				49,009	437	00,000	(00,497)		_	_
redeemable convertible preferred stock and beneficial conversion			2.005.011			(2.005.011)				(2.055.011)
feature Conversion of			2,065,911	_		(2,065,911)	_	_	_	(2,065,911)
redeemable convertible preferred shares to common stock	(4000)		(4,725,597)	3,500,000	35,000	4,690,597	_	_	_	4,725,597
Common stock	(4000)		(4,723,337)	3,300,000	55,000	4,030,337				4,723,337
issued for										
external services	—			98,180	982	296,821	_		_	297,803
Common stock issued pursuant to employee benefit plan	_		_	49,425	494	61,769	_		_	62,263
Exercise of				_,		. ,				
warrants	—		_	1,098,000	10,980	1,636,020	—	—	_	1,647,000
Exercise of employee and consultant stock				20.250	20.4	20.000				20.000
options	—		—	39,378	394	29,692	—	—	—	30,086
Compensation expense from grant of options	_					242,548	_	_	_	242,548
Deferred						171 242			(171 242)	
compensation Amortization of deferred	_		_	—	_	171,343	—	_	(171,343)	_
compensation	_		_	_	_	_	_	_	251,208	251,208
Net loss	—		—	—	—	—	(12,290,752)	—	—	(12,290,752)
Balances, December 31, 2003	_		_	40,998,858	\$ 409,988	\$ 170,406,393	\$ (158,874,915)	\$ —	\$ (977,908)	\$ 10,963,558
						55				

# STEMCELLS, INC.

# CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY — (Continued)

		mable Convertible referred Stock Common Stock Additional Accumulated						Accumulated Other Comprehensive				
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Income (Loss)	Deferred Compensation	Stockholders' Equity			
Balances,												
December 31,												
2003	—	—	40,998,858	\$ 409,988	\$ 170,406,393	\$ (158,874,915)	\$ —	\$ (977,908)	\$ 10,963,558			
Issuance of common stock related to equity financing net of issuance cost \$2,863,021		_	20,660,000	206,600	39,433,578	_	_	_	39,640,178			
Common stock												
issued for licensing agreements	_	_	11,351	114	17,719	_	_	_	17,833			
Common stock			11,001		1,,, 10				1,000			
issued for external services	_	_	41,050	410	72,640	_		_	73,050			
Common stock issued pursuant to employee benefit												
plan	_	_	48,707	487	93,526	_	_	_	94,013			
Exercise of employee and consultant stock options	_	_	62,916	629	44,750	_	_	_	45,379			
Exercise of					,							
warrants	_	_	306,525	3,065	579,333	_	_	_	582,398			
Compensation expense from grant of options					33,868				33,868			
Deferred					55,000				55,000			
compensation	_				737,493			(737,493)	_			
Amortization of deferred					737,435							
compensation	—						—	829,569	829,569			
Net loss	—	—	—	_	—	(15,330,299)	—	—	(15,330,299)			
Balances, December 31, 2004	_	_	62,129,407	\$ 621,293	\$ 211,419,300	\$ (174,205,214)	\$ —	\$ (885,832)	\$ 36,949,547			
			6	· · · · · · ·								

See accompanying notes to consolidated financial statements.

# **Consolidated Statements of Cash Flows**

	Year Ended December 31,								
		2004		2003		2002			
Cash flows from operating activities:									
Loss before deemed dividend	\$	(15,330,299)	\$	(12,290,752)	\$	(11,644,255)			
Adjustments to reconcile net loss to net cash used in operating									
activities:									
Depreciation and amortization		1,037,719		1,013,133		402,190			
Amortization of deferred compensation		829,569		251,208		(469,089)			
Issue of shares and options in exchange for services		200,931		602,613		237,680			
Loss on disposal of fixed assets		54,644		—		_			
Changes in operating assets and liabilities:									
Accrued interest receivable		(61,660)		(4,831)		1,687			
Other receivable		26,160		(75,740)		(12,351)			
Other current assets		(29,026)		(77,219)		258,807			
Other assets, net		—		(277,863)		(379,572)			
Accounts payable and accrued expenses		665,409		725,673		(147,523)			
Accrued wind-down expenses		1,705,045		1,891,620		437,833			
Deferred rent		(372,400)		(429,218)		1,123,943			
Deposits		_		128,180		103,345			
Net cash used in operating activities		(11,273,908)		(8,543,196)		(10,087,305)			
Cash flows from investing activities:									
Purchases of property, plant and equipment		(676,138)		(189,733)		(222,335)			
Acquisition of other assets		(72,167)		—		—			
Net cash used in investing activities		(748,305)		(189,733)		(222,335)			
Cash flows from financing activities:									
Proceeds from issuance of common stock, net		39,640,178		16,130,347		1,128,644			
Proceeds from the exercise of stock options		45,379		30,085		9,335			
Proceeds from the exercise of warrants		582,398		1,647,000		_			
Repayments of capital lease obligations		(30,830)		_		_			
Repayments of debt obligations		(237,083)		(229,167)		(289,167)			
Net cash provided by financing activities		40,000,042		17,578,265		848,812			
Increase (decrease) in cash and cash equivalents		27,977,829		8,845,336		(9,460,828)			
Cash and cash equivalents at beginning of year		13,081,703		4,236,367		13,697,195			
Cash and cash equivalents at end of the year	\$	41,059,532	\$	13,081,703	\$	4,236,367			
Supplemental disclosure of cash flow information:									
Interest paid	\$	191,006	\$	207,112	\$	226,723			
		57							

#### Consolidated Statements of Cash Flows — (Continued)

		Year	Ended December 31,	
	 2004		2003	 2002
Supplemental schedule of non-cash investing and financing				
activities:				
Stock issued for licensing agreements	\$ 17,833(1)	\$	3,920(2)	\$ 35,000(3)
Conversion of 6% cumulative preferred stock				\$ 1,505,707(4)
Conversion of 3% cumulative preferred stock	—	\$	4,725,597(5)	—
Dividends paid to 3% convertible preferred stock holders in				
stock	_	\$	68,497(6)	\$ 129,270(6)
Accretion of redeemable preferred stock		\$	1,067,579(7)	\$ 1,280,004(7)

[1] Under the terms of a license agreement with the California Institute of Technology (Cal Tech), fees of \$10,000 and \$5,000 were due on the issuance of two patents to which StemCells holds a license from Cal Tech, payable in cash or stock at the Company's choice. Company elected to pay the fees in stock and issued 9,535 unregistered shares to Cal Tech. Part payment in stock (1,816 shares) of \$2,833 as part of an option agreement with the Board of Trustees of the Leland Stanford Junior University to acquire an exclusive license to an invention.

[2] Under the terms of an amended license agreement with the Oregon Health Sciences University (OHSU), 4,000 shares of stock were due to OHSU on execution of the amended agreement.

[3] In August 2002 we acquired a license from Cal Tech, pursuant to which we issued 27,535 shares of our common stock with a market value of approximately \$35,000

[4] 1,500 shares of 6% cumulative convertible preferred stock including accumulated dividends was converted for 1,252,444 shares of common stock with a market value of \$1,505,707. The total of the accumulated dividends was \$222,457.

[5] 4,000 shares of the 3% cumulative convertible preferred stock was converted for 3,500,000 shares of the Company's common stock with a market value of \$4,725,597.

[6] Accumulated dividends to 3% convertible preferred stock holders was paid in stock with a total market value of \$129,270 (97,969 shares) and \$68,497(49,809 shares) in 2002 and 2003 respectively.

[7] See note 9 under "3% Cumulative Redeemable Convertible Preferred Stock"

See accompanying notes to consolidated financial statements.

# Notes to Consolidated Financial Statements December 31, 2004

## 1. Summary of Significant Accounting Policies

## Nature of Business

StemCells, Inc., a Delaware corporation, (the Company) is a biopharmaceutical company that operates in one segment, engaged in the development of novel stem cell therapies designed to treat human diseases and disorders.

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern. Since inception, the Company has incurred annual losses and negative cash flows from operations and has an accumulated deficit of approximately \$174.2 million at December 31, 2004. The Company has not derived revenues from the sale of products, and does not expect to receive revenues from product sales for at least several years. It may not be able to realize sufficient revenues to achieve or sustain profitability in the future.

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

In connection with the filing of the Annual Report on Form 10-K for the year ended December 31, 2003, the Company restated its financial statements for the year ended December 31, 2002 related to the accounting for wind-down expenses for the Company's former corporate headquarters in Rhode Island and lease incentives related to its current facilities in California.

# Principles of Consolidation

The consolidated financial statements include accounts of the Company and StemCells California, Inc., a wholly owned subsidiary. Significant intercompany balances and transactions have been eliminated on consolidation.

#### Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements. Actual results could differ from these estimates. The significant estimates include the accrued wind-down expenses (Note 7) and valuation allowance against deferred tax assets (Note 11).

#### Cash and Cash Equivalents

The Company considers cash equivalents to be only those investments that are highly liquid, readily convertible to cash and which mature within three months from the date of purchase.

#### Notes to Consolidated Financial Statements — (Continued)

#### **Comprehensive Income (Loss)**

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). The Company has no items of other comprehensive income therefore comprehensive income (loss) equals net income (loss).

## Property, Plant and Equipment

Property, plant and equipment, including that held under capital lease obligations, is stated at cost and depreciated using the straight-line method over the estimated life of the respective asset, or the lease term if shorter, as follows:

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

Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms.

The Company adopted FAS No. 144, "Accounting for the Impairment or Disposal of Long-lived Assets," at the beginning of 2002. As permitted by the transition rules of FAS No. 144, long-lived assets classified as held for sale as a result of activities that were initiated prior to this Statement's initial application shall continue to be accounted for in accordance with FAS No. 121. If however, the criteria for classifying long-lived assets held for sale under FAS No. 144 are not met by the end of the fiscal year in which this Statement is initially applied, the related long-lived assets shall be reclassified as held and used. At December 31, 2002, the criteria under FAS No. 144 for classifying the Company's long-lived assets held for sale were not met and accordingly, such assets with a fair value of \$3,203,491 at December 31, 2001 were reclassified as held and used on the balance sheet for all periods presented and are included in Property, Plant and Equipment, net. Depreciation of these assets resumed January 1, 2003.

#### Patent and License Costs

Prior to fiscal year 2001, the Company capitalized certain patent costs related to patent applications. Accumulated costs were amortized over the estimated economic life of the patents, not to exceed 17 years, using the straight-line method, commencing at the time the patent is issued. Costs related to patent applications are charged to expense at the time such patents are deemed to have no continuing value. Since 2001 the Company expenses all patent costs as incurred. At December 31, 2004 and 2003, total costs capitalized amounted to \$980,000 and the related accumulated amortization was \$292,000 and \$236,000, respectively. Patent related expenses totaled \$753,000, \$665,000, and \$650,000 in 2004, 2003 and 2002 respectively. License costs are capitalized and amortized over the period of the license agreement.

#### Stock-Based Compensation

The Company's employee stock option plan is accounted for under Accounting Principles Board Opinion No. 25 (APB 25), "Accounting for Stock Issued to Employees." The Company grants qualified stock options for a fixed number of shares to employees with an exercise price equal to the fair market value of the shares at the date of grant. In these circumstances and in accordance with APB 25, the Company recognizes no compensation expense for qualified stock option grants. The Company also issues non-qualified stock options for a fixed number of shares to employees with an exercise price less than the fair market value of the shares at the date of grant. When such options vest, the Company recognizes the difference between the exercise price and fair market value at date of grant as compensation expense in accordance with APB 25.

#### Notes to Consolidated Financial Statements — (Continued)

For purposes of disclosures pursuant to Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," (FAS 123) as amended by Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure," (FAS 148), the estimated fair value of options is amortized to expense over the options' vesting period. The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of FAS 123 to stock-based employee compensation:

,275,986) 143,002
1/13 002
1/13 002
140,002
(619,631)
,752,615)
(0.53)
(0.55)
,096,252
,

The effects on pro forma net loss and net loss per share of expensing the estimated fair value of stock options are not necessarily representative of the effects on reporting the results of operations for future years. As required by FAS 123, the Company has used the Black-Scholes model for option valuation, which method may not accurately value the options described.

The Company accounts for stock options granted to non-employees in accordance with FAS No. 123 and Emerging Issues Task Force (EITF) 96-18 — "Accounting For Equity Instruments That Are Issued To Other Than Employees For Acquiring, Or In Conjunction With Selling, Goods Or Services", and accordingly, recognizes as expense the estimated fair value of such options as calculated using the Black-Scholes valuation model. The fair value is remeasured during the service period and is amortized over the vesting period of each option or the recipient's contractual arrangement, if shorter. The expense recorded for the issuance of options to non-employees for the years ended December 31, 2004, 2003 and 2002 was \$829,569, \$251,206, and \$(469,088), respectively.

In December 2004, FASB issued SFAS No. 123R (revised 2004), *Share-Based Payment*. This Statement is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* and amends SFAS No. 95, *Statement of Cash Flows* This Statement supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. Upon the adoption of SFAS No. 123R the Company will be required to expense stock options in its Statement of Operations. Among other items, the new standard requires the expensing of stock options issued by the Company in the financial statements using a fair-value-based method. The provisions of SFAS 123R are effective for the first interim or annual reporting period that begins after June 15, 2005; the Company will therefore adopt the new requirements no later than the beginning of its third quarter of fiscal 2005. Adoption of the expensing requirements will reduce the Company's reported earnings.

#### Notes to Consolidated Financial Statements — (Continued)

#### Long Lived Assets

The Company routinely evaluates the carrying value of its long-lived assets. The Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that assets may be impaired and the undiscounted cash flows estimated to be generated by the assets are less than the carrying amount of those assets. If an impairment exists, the charge to operations is measured as the excess of the carrying amount over the fair value of the assets.

## **Income Taxes**

The liability method is used to account for income taxes. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax bases of assets and liabilities as well as net operating loss carry forwards and tax credits carryforwards and are measured using the enacted tax rates and laws that are expected to be in effect when the differences reverse. Deferred tax assets may be reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization.

#### **Revenue Recognition**

Revenues from collaborative agreements and grants are recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the collaborative agreement. Payments received in advance of research performed are designated as deferred revenue. The Company recognizes non-refundable upfront license fees and certain other related fees on a straight-line basis over the development period. Fees associated with substantive at risk, performance based milestones are recognized as revenue upon their completion, as defined in the respective agreements. Incidental assignment of technology rights are recognized as revenue at time of receipt.

## **Recent Accounting Pronouncements**

In June 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 provides guidance related to accounting for costs associated with disposal activities covered by SFAS No. 144 and with one-time termination benefits and other exit or restructuring activities previously covered by Emerging Issues Task Force (EITF) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 supersedes EITF Issue No. 94-3 in its entirety. Under SFAS No. 146, the following conditions must be met for an action to qualify as an exit or disposal plan: management having the authority to approve the action commits to a plan of termination; the plan identifies the number of employees to be terminated, their job classifications or functions and their locations, and the expected completion date; the plan establishes the terms of the benefit arrangement including the benefits that employees will receive upon termination (including but not limited to cash payments) in sufficient detail to enable employees to determine the type and amount of benefits they will receive if they are involuntarily terminated; and actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn. SFAS No. 146 was effective in 2003 and will be applied prospectively to qualifying exit or disposal activities initiated after December 31, 2002.

In January 2003, the FASB issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51(FIN 46)." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. The Company does not believe it has

#### Notes to Consolidated Financial Statements — (Continued)

any investments in variable interest entities and does not anticipate any impact with the adoption of this interpretation.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity, (SFAS 150). SFAS 150 establishes standards for classifying and measuring as liabilities certain financial instruments that embody obligations of the issuer and have characteristics of both liabilities and equity. SFAS 150 must be applied immediately to instruments entered into or modified after May 31, 2003. The adoption of SFAS 150 did not have a material effect on the Company's results of operations or financial position.

In December 2004, FASB issued SFAS No. 123R (revised 2004), *Share-Based Payment*. This Statement is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* and amends SFAS No. 95, *Statement of Cash Flows* This Statement supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. Upon the adoption of SFAS No. 123R the Company will be required to expense stock options in its Statement of Operations. Among other items, the new standard would require the expensing of stock options issued by the Company in the financial statements using a fair-value-based method. The new standard is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. FASB is encouraging companies to begin applying the new expensing requirements as of the beginning of 2005 The Company is considering expensing stock options as of the beginning of 2005. See "Stock-based Compensation" in this Note 1 for disclosures regarding the effect on net earnings and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123R

#### **Research and Development Costs**

The Company expenses all research and development costs as incurred. Research and Development costs include costs of personnel, external services, supplies, facilities and miscellaneous other costs.

# Net Loss per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. Basic earnings per share excludes any dilutive effects of options, shares subject to repurchase, warrants and convertible securities. Diluted earnings per share includes the impact of potentially dilutive securities if dilutive.

	Years Ended December 31,						
		2004		2003		2002	
Net loss applicable to common stockholders	\$	(15,330,299)	\$	(14,425,160)	\$	(13,275,986)	
Weighted average shares used in computing basic and diluted							
net loss per share amounts		49,606,277		32,080,233		25,096,252	
Basic and diluted net loss per share applicable to common							
stockholders	\$	(0.31)	\$	(0.45)	\$	(0.53)	

The Company has excluded outstanding stock options and warrants from the calculation of diluted loss per common share because all such securities are anti-dilutive for all applicable periods presented. These outstanding securities consist of the following potential common shares:

Years Ended December 31,			
2003	2002		
—	2,000,000		
5,025,374	4,294,050		
2,101,074	1,074,593		
	2,101,074		



#### Notes to Consolidated Financial Statements — (Continued)

# 2. Property, Plant and Equipment

Property, plant and equipment consists of the following:

	 December 31,			
	2004			
Building and improvements	\$ 3,308,098	\$	3,918,889	
Machinery and equipment	2,737,971		2,231,189	
Furniture and fixtures	339,458 339,		339,458	
	6,385,527		6,489,536	
Less accumulated depreciation and amortization	(2,961,233)		(2,878,134)	
	\$ 3,424,294	\$	3,611,402	

Depreciation and amortization expense was \$933,000, \$916,000, and \$307,000 for the years ended December 31, 2004, 2003 and 2002, respectively. In 2004 leasehold improvements related to a previous facility with a net book value of \$0 (carrying cost of \$705,000 and accumulated depreciation of \$705,000) were written off. In addition obsolete or unusable miscellaneous lab equipment with a net book value of \$55,000 was disposed and written off.

The Company adopted FAS No. 144, "Accounting for the Impairment or Disposal of Long-lived Assets," at the beginning of 2002. As permitted by the transition rules of FAS No. 144, long-lived assets classified as held for sale as a result of activities that were initiated prior to this Statement's initial application shall continue to be accounted for in accordance with FAS No. 121. If however, the criteria for classifying long-lived assets held for sale under FAS No. 144 are not met by the end of the fiscal year in which this Statement is initially applied, the related long-lived assets shall be reclassified as held and used. At December 31, 2002, the criteria under FAS No. 144 for classifying the Company's long-lived assets held for sale were not met and accordingly, such assets with a fair value of \$3,203,491 at December 31, 2001 were reclassified as held and used on the balance sheet for all periods presented and are included in building and improvements. Depreciation of these assets resumed in 2003.

#### 3. Other Assets, Net

Other assets are as follows:

	 December 31,			
	2004		2003	
Patents, net	\$ 687,567	\$	743,370	
License agreements, net	376,274		334,850	
Security deposit — building lease	752,500		752,500	
Restricted Cash-(Letter of Credit)	937,078		937,078	
	\$ 2,753,419	\$	2,767,798	

At December 31, 2004 and 2003, accumulated amortization was \$1,590,000 and \$1,485,000, respectively, for patents and license agreements.

#### Notes to Consolidated Financial Statements — (Continued)

# 4. Accrued Expenses

Accrued expenses are as follows:

		December 31,				
	2004			2003		
External services	\$	639,989	\$	268,545		
Employee compensation		834,039		620,340		
Other		73,342		152,265		
	\$	1,547,370	\$	1,041,150		

#### 5. Leases

The Company has undertaken direct financing transactions with the State of Rhode Island and received proceeds from the issuance of industrial revenue bonds totaling \$5,000,000 to finance the construction of its pilot manufacturing facility. The related leases are structured such that lease payments will fully fund all semiannual interest payments and annual principal payments through maturity in August 2014. Interest rates vary with the respective bonds' maturities, ranging from 8.1% to 9.5%. The bonds contain certain restrictive covenants which limit, among other things, the payment of cash dividends and the sale of the related assets. The Company entered into a fifteen-year lease for a laboratory facility in connection with a sale and leaseback arrangement in 1997. The lease has escalating rent payments and accordingly, the Company is recognizing rent expense on a straight-line basis. At December 31, 2004, the Company had \$1,177,000 in deferred rent expense for this facility which is presented as part of the wind-down accrual.

As of February 1, 2001, the Company entered into a 5-year lease for a 40,000 square foot facility located in the Stanford Research Park in Palo Alto, California. The facility includes space for animals, laboratories, offices, and a suite designed for manufacture of cells for use in clinical trials. On December 19, 2002 the Company negotiated an amendment to the lease, which resulted in reducing the average annual rent over the remaining term of the lease from approximately \$3.7 million to \$2.0 million. As part of the amendment the Company issued a letter of credit on January 2, 2003 for \$503,000, which was in addition to the letter of credit amounting to \$275,000 issued at commencement of the lease to serve as a deposit for the duration of the lease. The lease has a rent escalation clause and accordingly, the Company is recognizing rent expense on a straight-line basis. At December 31, 2004 the Company had \$524,000 in deferred rent expense for this facility included in accrued expenses.

#### Notes to Consolidated Financial Statements — (Continued)

As of December 31, 2004, future minimum lease payments and sublease income under operating and capital leases are as follows:

	Capital Leases(1)		Operating Leases		 Sublease Income
2005	\$	472,680	\$	3,007,630	\$ 1,421,012
2006		445,486		1,115,186	791,454
2007		332,545		937,500	73,068
2008		244,531		1,171,875	—
2009		244,572		1,171,875	—
Thereafter		1,099,991		4,248,047	—
Total minimum lease payments		2,839,805	\$	11,652,113	\$ 2,285,534
Less amounts representing interest		896,313			 
Present value of minimum lease payments		1,943,492			
Less current maturities		297,010			
Capitalized lease obligations, less current maturities	\$	1,646,482			

#### (1) Includes Bonds payable

Rent expense for the years ended December 31, 2004, 2003 and 2002, was \$1,109,000, \$1,040,000 and \$2,565,000 respectively.

## 6. Grants

In February 2001, the Company was awarded a two-year, \$300,000 per year grant from the National Institutes of Health's Small Business Innovation Research (SBIR) office. The grant, which will support joint work with virologist Dr. Jeffrey Glenn at Stanford University, is aimed at characterizing the human cells that can be infected by human hepatitis viruses and to develop a small animal model using the cells that are most infectable by these viruses to develop screening assays and identify novel drugs for the disease. For each of 2001 and 2002, the Company received \$300,000, of which \$150,367 represents the Company's share of the joint effort and has been recognized as revenue. The remainder, \$149,633, was paid to Stanford University as its share of the joint effort each year of the grant.

On September 30, 2001, the Company was awarded a four-year, \$225,000 per year grant from the National Institute of Diabetes & Digestive & Kidney Disorders of the National Institutes of Health for the Company's liver stem cell program which focuses on identifying liver stem and progenitor cells for the treatment of liver diseases. The grant is subject to the availability of funds and satisfactory progress of the project. For this award, the Company has recognized \$56,000, \$225,000 and \$112,000 as grant revenue for 2001, 2002 and 2003 respectively. The Company did not draw further funds in 2004 from this grant as it will no longer pursues the particular research it covered.

In September 2003 the Company was awarded a one year, \$342,000 Small Business Innovation Research grant from the National Institute of Neurological Disease and Stroke (NINDS), to further its work in the treatment of spinal cord injuries. For this award, the Company has recognized \$143,000 and \$93,000 as grant revenue for 2003 and 2004, respectively. The remaining \$106,000 will go towards reimbursing a subcontractor

In September 2004 the Company was awarded a Small Business Technology Transfer (STTR) grant for approximately \$464,000 over one and one half years for studies in Alzheimer's disease. The grant will support joint work with Dr. George A. Carlson of the McLaughlin Research Institute (MRI) in Great Falls, Montana.

#### Notes to Consolidated Financial Statements — (Continued)

The Company will receive \$243,000 and the remainder of \$221,000 will be reimbursed to MRI. The Company has recognized \$26,000 as grant revenue for 2004.

## 7. Wind-down of Encapsulated Cell Technology Research and Development Program

Until mid-1999, the Company engaged in research and development in encapsulated cell therapy technology, including a pain control program funded by AstraZeneca Group plc. In June 1999 AstraZeneca terminated the collaboration, as allowed under the terms of the original collaborative agreement signed in 1995. As a result of termination, management determined in July 1999 to restructure its research operations to abandon all further encapsulated cell technology research and concentrate its resources on the research and development of its proprietary platform of stem cell technologies. The Company wound down its research and manufacturing operations in Lincoln, Rhode Island, and relocated its remaining research and development activities, and its corporate headquarters, to California, in October 1999.

In 1999 the Company established a reserve for the estimated lease payments and operating costs of the Rhode Island facilities through an expected disposal date of June 30, 2000. The Company did not fully sublet the Rhode Island facilities in 2000 and therefore made a change in estimate to accrue additional expenses of \$3,327,000 to cover operating lease payments, utilities, taxes, insurance, maintenance, interest and other non-employee expenses through 2001. In the year 2001 the Company paid \$1,780,000 of expenses, which were recorded against the reserve. At December 31, 2001 the Company revised its estimate and recorded an additional reserve of \$575,000 as operating expenses net of subtenant income for its former corporate headquarters in Rhode Island. This reserve was based on information provided by the Company's broker/realtor that estimated, based on assumptions relevant to the real estate market conditions as of the end of 2001, the time it would be likely to take until the facility would be fully sub-leased. In 2002, the Company incurred \$964,000 in operating expenses for this facility, of which \$575,000 was booked against the reserve created at the end of 2001 and the remainder recorded as wind-down expenses. At the end of December 2002 based on an analysis of the real estate market conditions at that time the Company revised the reserve to \$775,000. In 2003 the Company incurred \$984,000 in operating expenses for this facility of which \$775,000 was recorded against the reserve and the remainder was recorded as wind-down expenses. At the end of 2003, after considering various factors such as the Company's lease payments through to the end of the lease, operating expenses, the current real estate market in Rhode Island, and estimated subtenant income based on occupancy both actual and projected, the Company revised the reserve at December 31, 2003 to \$2,676,000. In 2004, the Company recorded \$1,152,000 in operating expenses against the reserve. After evaluating the aforementioned factors, at the end of each quarter — March 31, 2004, June 30, 2004 and September 30, 2004 and December 31, 2004 — the Company re-evaluated its estimate and adjusted the reserve to \$2,510,000, \$2,680,000, \$3,743,000 and \$4,350,000 respectively, by recording an additional \$130,000 at March 31, 2004, \$468,000 at June 30, 2004, \$1,345,000 at September 30, 2004 and \$883,000 at December 31, 2004 as wind-down expenses. Even though it is the intent of the Company to dispose the facility at the earliest possible time, it cannot determine with certainty a fixed date by which such disposal will occur. In light of this uncertainty, based on estimates, the Company will periodically re-evaluate and adjust the reserve.

## Notes to Consolidated Financial Statements — (Continued)

#### Wind-down reserve

	Period Covered								
		January to March 31, 2004	April to June 30, 2004			July to September 30, 2004	]	October to December 31, 2004	
Accrued wind-down reserve at beginning of	<i>.</i>		<i>.</i>		<i>•</i>				
period	\$	2,676,000	\$	2,510,000	\$	2,680,000		3,743,000	
Less actual expenses recorded against estimated									
reserve during the period		(296,000)		(298,000)		(282,000)		(276,000)	
Additional expense recorded to revise estimated									
reserve at period-end		130,000		468,000		1,345,000		883,000	
Revised reserve at period-end		2,510,000		2,680,000		3,743,000		4,350,000	
Add deferred rent at period end		1,155,000		1,162,000		1,170,000		1,178,000	
Total accrued wind-down expenses at period-end									
(current and non current portion)	\$	3,665,000	\$	3,842,000	\$	4,913,000	\$	5,528,000	
Accrued wind-down Expenses									
Current Portion	\$	729,000	\$	993,000	\$	1,039,000	\$	1,013,000	
Non current portion		2,936,000		2,849,000		3,874,000		4,515,000	
Total Accrued wind-down expenses	\$	3,665,000	\$	3,842,000	\$	4,913,000	\$	5,528,000	

## 8. Consulting Arrangements

In September 1997, the Company entered into consulting arrangements with the principal scientific founders of StemCells California, Dr. Irving Weissman, Dr. Fred H. Gage and Dr. David Anderson and with Dr. Richard M. Rose, then President and CEO of the StemCells California. To attract and retain Drs. Rose, Weissman, Gage and Anderson, and to expedite the progress of the Company's stem cell program, the Company awarded these individuals options to acquire a total of approximately 1.6 million shares of the Company's common stock, at an exercise price of \$5.25 per share, the quoted market price at the grant date. The Company also designated a pool of 400,000 options to be granted to persons in a position to make a significant contribution to the success of the stem cell program. Under the original grants, approximately 100,000 of these options were exercisable immediately on the date of grant, 1,031,000 of these options would vest and become exercisable only upon the achievement of specified milestones related to the Company's stem cell development program and the remaining 468,750 options would vest over eight years. In connection with the 468,750 options issued to a non-employee, Dr. Anderson, the Company recorded deferred compensation of \$1,750,000, the fair value of such options at the date of grant, which will be amortized over an eight-year period. For Dr. Anderson's options the Company recorded an expense of \$62,000, \$49,000 and \$50,000 for the years 2004, 2003 and 2002 respectively. The deferred compensation expense associated with the unvested portion of Dr. Anderson's grants as of December 31, 2004 was \$807,000. The fair value was determined using the Black-Scholes method.

Effective October 31, 2000, the Company agreed with Drs. Weissman and Gage to revise their 468,750 milestone-vesting stock options to time-based vesting, on the same schedule as Dr. Anderson's option. Under each of the revised options, 168,750 shares vested immediately, and the remaining 300,000 shares will vest at 50,000 per year on September 25, until September 25, 2005, when the final 100,000 shares will vest. The exercise price remains \$5.25 per share. The Company recorded an expense of \$305,000, \$164,000 and a recovery of \$419,000 for the years 2004, 2003 and 2002 respectively, as compensation expense for the fair market value of the vested portion of such options in an amount determined using the Black-Scholes method.

#### Notes to Consolidated Financial Statements — (Continued)

The deferred compensation expense associated with the unvested portion of the grants was determined to be approximately \$79,000 at December 31, 2004. As part of the revision of the options, Drs. Weissman and Gage relinquished all rights under an agreement by whose terms they had the right to license the non-brain stem cell technology in exchange for a payment to the Company equal to all prior funding for such research plus royalty payments. The Company plans to revalue the options using the Black-Scholes method on a quarterly basis and recognize additional or reduced compensation expense accordingly.

# 9. Stockholders' Equity

## Sale of Common Stock

On August 23, 2002, the Company entered into an agreement with Triton West Group, Inc. (Triton) pursuant to which the Company sold 1,028,038 shares of common stock to Triton for aggregate proceeds of \$1,100,000, or approximately \$1.07 per share.

On May 7, 2003, the Company entered into a stock purchase agreement with Riverview, under which Riverview agreed to purchase 4 million shares of the Company's common stock for \$6.5 million, or \$1.625 per share. On the date of the agreement, the sale price was above the trading price of the Company's common stock, which closed at \$1.43 per share on that date. The Company also agreed to issue a 2-year warrant to Riverview to purchase 1,898,000 shares of common stock at \$1.50 per share. The exercise price is subject to adjustment for stock splits, dividends, distributions, reclassifications and similar events. On May 15, 2003 the Company issued the purchased shares and the warrant, and registered the resale of the purchased shares and the shares underlying the warrant. The exercise price may be below the trading market price at the time of the exercise. In the event that certain conditions are met, including the closing sale price of the Common Stock remaining at or above \$2.50 per share for 10 consecutive trading days, the Company may require Riverview to exercise the warrant for any remaining shares or to relinquish any unexercised portion. On November 11, 2003, Riverview exercised part of the warrant acquiring 1,098,000 shares at \$1.50 per share. The proceeds to the Company from this warrant exercise totaled \$1,647,000. The warrant is exercisable for the remaining 800,000 shares until April 8, 2005, subject to the Company's right to require exercise or forfeiture as described above.

On December 10, 2003 the Company completed a \$9.5 million financing transaction with Riverview through the sale of 5 million shares of common stock at a price of \$1.90 per share.

In June 2004, the Company entered into an agreement with institutional and other accredited investors with respect to the private placement of approximately 13,160,000 shares of its common stock at a purchase price of \$1.52 per share, for gross proceeds of approximately \$20,000,000. Investors also received warrants exercisable for five years to purchase approximately 3.3 million shares of common stock at an exercise price of \$1.90 per share. During the period October 2004 to December 2004, 306,525 of these warrants were exercised to purchase an aggregate of 306,525 shares of the Company's common stock at \$1.90 per share. The Company issued 306,525 shares of its common stock and received proceeds of \$582,000. C.E. Unterberg, Towbin LLC (Unterberg) served as placement agent for the transaction. For acting as the Company's placement agent, Unterberg received fees totaling \$1,200,000, expense reimbursement of approximately \$25,000 and a five year warrant, with a fair value of \$810,656, to purchase 526,400 shares of the Company's common stock at an exercise price of \$1.89 per share.

In October 2004, the Company entered into agreements with institutional investors with respect to the registered direct placement of 7,500,000 shares of its common stock at a purchase price of \$3.00 per share, for gross proceeds of \$22,500,000. Unterberg and Shoreline Pacific, LLC (Shoreline) served as placement agents for the transaction. For acting as the Company's placement agent, Unterberg and Shoreline received fees totaling \$1,350,000 and expense reimbursement of approximately \$40,000.

#### Notes to Consolidated Financial Statements — (Continued)

#### **Equity Line**

On May 10, 2001, the Company entered into a common stock purchase agreement with Sativum Investments Limited for the potential future issuance and sale of up to \$30,000,000 of the Company's common stock, subject to restrictions and other obligations. Under the agreement, which expired in January 2004, the Company had the right to draw down on the facility, from time to time, and Sativum was obligated to purchase shares of the Company's common stock at a 6% discount to a volume weighted average market price over the 20 trading days following the draw-down notice. There was neither a requirement that the Company draw on the facility nor a penalty for not doing so. The Company was limited with respect to how often it could exercise a draw down and the amount of each draw down.

In connection with the Company's execution of the common stock purchase agreement with Sativum, the Company issued three three-year warrants to purchase an aggregate of 350,000 shares of the Company's common stock at \$2.38 per share to Sativum (250,000 shares), and to the placement agents: Pacific Crest Securities Inc. (75,000 shares) and Granite Financial Group, Inc. (25,000 shares). The placement agents have exercised their warrants in full, and the Company received payment of \$238,050 for the shares issued to them in July 2001. The Company has valued the warrants using the Black-Scholes method and recorded the fair value in stockholders' equity. These amounts are \$522,500, \$167,750 and \$55,250 respectively. The exercise price and number of shares are subject to adjustment for subdivisions, combinations, stock dividends and reorganizations.

The Company did draw down \$4,000,000 by issuance of 707,947 shares in July of 2001, \$118,000 by issuance of 107,812 shares in December of 2002, \$66,000 by issuance of 58,516 shares in January of 2003, and \$375,000 by issuance of 245,472 shares in May of 2003, before applicable fees.

## 3% Cumulative Redeemable Convertible Preferred Stock

On December 4, 2001, the Company issued 5,000 shares of 3% cumulative convertible preferred stock to Riverview Group, L.L.C., (Riverview Group), a wholly owned subsidiary of Millennium Partners, L.P. plus a 5-year warrant to purchase 350,877 shares of common stock at \$3.42 per share. The Company received net proceeds of \$4,727,515. This preferred stock was convertible into shares of the Company's common stock at a conversion price of \$2.00 per share at the option of Riverview Group mandatory redemption feature requiring the Company to redeem unconverted preferred stock on December 4, 2003. The conversion price of \$2 per share was subject to adjustment for stock splits, dividends, distributions, reclassifications and similar events. The final closing price of the Company's common stock on the NASDAQ National Market on the December 4, 2001 commitment date was \$2.90 per share. The Company valued the warrants and the beneficial conversion feature reflecting the December 4, 2001 commitment date and the most beneficial per share discount available to the preferred shareholders. As the preferred shares contained a stated redemption, such value of \$3,185,000, including issuance costs of \$272,485, was recorded as a discount to the preferred shares. The preferred shares were accreted to the mandatory redemption amount and the accretion resulted in a deemed dividend. The deemed dividend has been reflected as an adjustment to net loss applicable to common stockholders. The holders of the preferred stock had liquidation rights equal to their original investment plus accrued but unpaid dividends. Dividends due on the shares of the preferred stock outstanding on a Dividend Payment Date (June 30 and December 31) could be paid in the Company's common stock if the Company so elected by those dates. The Company did elect to pay the dividends in stock, and did so by issuing 38,313 shares of stock on July 3, 2002, 59,656 shares on December 23, 2002 and 17,935 shares June 30, 2003, valued at approximately \$60,000, \$69,000 and \$30,00

#### Notes to Consolidated Financial Statements — (Continued)

The Riverview Group converted all of its holdings of the Company's 3% cumulative convertible preferred stock as follows:

- On December 7, 2001, 1,000 shares of the 3% cumulative convertible preferred stock were converted into 500,125 shares of the Company's common stock.
- On April 9, 2003, the Company agreed with Riverview to reduce the conversion price to \$0.80 per share for a period of 20 trading days. Riverview immediately agreed to convert 2,000 shares with a face value of \$2 million, at the reduced price. Riverview received 2,521,041 shares of common stock upon conversion, which includes 21,041 shares valued at \$16,833 as accrued dividends. As a result of the change in the conversion price, the Company recorded a deemed dividend to preferred shareholders related to the beneficial conversion feature of approximately \$1,000,000 in the second quarter of 2003.
- On November 11, 2003, Riverview converted the remaining 2,000 shares of its 3% cumulative convertible preferred stock for 1,010,833 shares of the Company's common stock, which includes 10,833 shares valued at \$21,666 as accrued dividends.

The Company recorded deemed dividends related to the 3% cumulative convertible preferred stock of \$2,065,911 and \$1,280,004 in 2003 and 2002. As all of the 3% cumulative convertible preferred stock was converted prior to December 31, 2003, no deemed dividends were recorded in 2004.

## 6% Cumulative Convertible Preferred Stock

On April 13, 2000 the Company issued 1,500 shares of 6% cumulative convertible preferred stock plus a warrant for 75,000 shares of common stock to two members of its Board of Directors for \$1,500,000 on terms more favorable to the Company than it was then able to obtain from outside investors. The shares were initially convertible at the option of the holders into common stock at \$3.77 per share (based on the face value of the preferred shares). The conversion price was subject to adjustment upon certain equity transactions, as defined by the applicable agreement. The Company valued the beneficial conversion feature reflecting the April 13, 2000 commitment date and the most beneficial per share discount available to the preferred shareholders. Such value was \$481,000 and was treated as a deemed dividend as of the commitment date. The holders of the preferred stock had liquidation rights equal to their original investment plus accrued but unpaid dividends.

During the first and second quarters of 2001, the conversion price was reduced as a result of the issuance of adjustable warrants to Millennium LP, as described above. The Company revalued the beneficial conversion feature reflecting the reduced conversion prices and the most beneficial per share discount available to the preferred shareholders and recorded additional deemed dividends aggregating \$802,000 as of the applicable reset dates.

On June 7, 2002, one of the preferred stockholders converted 750 shares of 6% cumulative convertible preferred stock plus accumulated dividends, at an effective conversion price of \$1.94 per share for 439,442 shares of common stock. On October 4, 2002, the remaining 750 shares, which were held by the other preferred shareholder, together with accumulated dividends, converted automatically at the then-effective conversion price of \$1.07 to 812,802 shares of common stock. The accumulated dividends were paid in common stock with a value of \$222,457. No 6% cumulative convertible preferred stock outstanding as of December 31, 2004.

## Stock Issued For Technology Licenses

Under a 1997 License Agreement with NeuroSpheres, Ltd., the Company obtained an exclusive patent license in the field of transplantation. The Company entered into an additional license agreement with NeuroSpheres as of October 31, 2000, under which the Company obtained an exclusive license in the field of



#### Notes to Consolidated Financial Statements — (Continued)

non-transplant uses, such as drug discovery and drug testing, so that together the licenses are exclusive for all uses of the technology. The Company made upfront payments to NeuroSpheres of 65,000 shares of its common stock and \$50,000, and will make additional cash payments when milestones are achieved. Effective in 2004, the Company began making annual \$50,000 payments, creditable against royalties.

Pursuant to the terms of a license agreement with the California Institute of Technology (Cal Tech) and the Company's acquisition of its wholly owned subsidiary, StemCells California, StemCells issued 14,513 shares of common stock to Cal Tech. The Company issued an additional 12,800 shares of common stock to Cal Tech with a market value of approximately \$40,000 in May 2000, upon execution of an amendment adding four families of patent applications to the license agreement. The Company must pay an additional \$10,000 upon the issuance of each of the four patents licensed under the amended agreement. These amounts are creditable against royalties the Company must pay under the license agreements. The maximum royalties that the Company will have to pay to the California Institute of Technology will be \$2 million per year, with an overall maximum of \$15 million. Once the Company pays the \$15 million maximum royalty, the licenses will become fully paid and irrevocable. In August 2002 the Company acquired an additional license from Cal Tech to a different technology, pursuant to which the Company issued 27,535 shares of its common stock with a market value of approximately \$15,000 to Cal Tech on the issuance of two patents covered under this additional license.

In December 2004, the Company made part payment of \$2,833 in stock (1,816 shares) as part of an option agreement with the Board of Trustees of the Leland Stanford Junior University to acquire an exclusive license to an invention. The remainder of the option fee (\$7,167) was paid in cash.

Upon entering a license agreement with the Oregon Health Sciences University (OHSU) in March 1997, the Company issued it 4,838 shares of common stock and an option to purchase up to 62,888 additional shares to OHSU with an exercise price of \$.01 per share. The option has vested as to 9,675 shares for which shares were issued on March 31, 2002; the remaining option was terminated and the Company issued 4,000 shares of its common stock, with a market value of approximately \$3,900, to OHSU in January 2003, pursuant to an amendment to the license agreement.

## **Stock Option Plans**

The Company has adopted several stock plans that provide for the issuance of incentive and nonqualified stock options, various stock and performance awards and stock appreciation rights, at prices to be determined by the Board of Directors. In the case of incentive stock options, such price will not be less than the fair market value on the date of grant. Options granted to employees generally vest ratably over four years and are exercisable for ten years from the date of grant or within three months of termination. The Company has paid its directors and some of its consultants in below-market options or in stock awards from its stock plans.

### Notes to Consolidated Financial Statements — (Continued)

The following table presents the combined activity of the Company's stock option plans for the years ended December 31:

	2004				2003				2002		
	Options	Weighted Average Exercise Price		Options	Weighted Average tions <u>Exercise Price</u>		Options		nted Average rcise Price		
Outstanding at January											
1	5,025,374	\$	2.91	4,294,050	\$	3.14	3,652,560	\$	3.98		
Granted	1,932,772		1.92	1,125,161		1.25	1,041,478		0.98		
Exercised	(152,673)		0.30	(97,233)		0.31	(47,587)		0.20		
Canceled	(123,272)		3.49	(296,604)		2.34	(352,401)		4.51		
Outstanding at											
December 31	6,682,201		2.67	5,025,374		2.91	4,294,050		3.14		
Options exercisable at											
December 31	3,687,243	\$	2.98	3,048,940	\$	3.11	2,378,778	\$	3.45		

The following table presents weighted average price and life information about significant option groups outstanding at December 31, 2004:

	Options Outstanding			Options Exerc	Options Exercisable			
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Yrs.)	A Ez	eighted verage kercise Price	Number Exercisable	A Ez	eighted verage xercise Price	
Less than \$2.00	3,280,665	8.26	\$	1.21	1,377,152	\$	0.88	
\$2.00 - \$3.99	1,676,597	7.55	\$	2.89	964,529	\$	2.80	
\$4.00 - \$5.99	1,724,939	3.01	\$	5.22	1,345,562	\$	5.22	
	6,682,201				3,687,243			

The weighted average fair value per share of options granted during 2004, 2003 and 2002 was \$1.64, \$0.86 and \$1.15, respectively. The fair value of options at the date of grant were estimated using the Black-Scholes model with the following weighted average assumptions:

		Options		
	2004	2003	2002	
Expected life (years)	5	5	5	
Interest rate	3.60%	3.29%	3.03%	
Volatility	111.6%	121.1%	171.8%	

The Company has neither declared nor paid dividends on any share of its common stock and does not expect to do so in the foreseeable future.

#### Notes to Consolidated Financial Statements — (Continued)

#### Common Stock Reserved

The Company has the following shares of common stock reserved for the exercise of options, warrants and other contingent issuances of common stock, as of December 31, 2004:

Shares reserved for exercise of stock options	8,806,400
Shares reserved for warrants related to financing transactions	7,713,075
Shares reserved for compensation related to external services	200,000
Shares reserved for warrants related to previously converted 6% convertible preferred stock	158,242
Shares reserved for warrants related to previously converted 3% convertible preferred stock	861,345
Shelf reserve for possible future issuances of shares	1,471,962
Total	19,211,024

## 10. Research Agreements

The Company has entered various research agreements and collaborations with academic institutions. Under such arrangements, the Company is typically granted rights to the related intellectual property or an option to obtain such rights on terms to be agreed, in exchange for research funding and specified royalties on any resulting product revenue. In addition, StemCells occasionally makes grants to academic institutions to support research of interest to the Company without requesting any intellectual property interests in return.

In November 1997, the Company signed a Research Funding and Option Agreement with The Scripps Research Institute (Scripps) relating to certain stem cell research. Under the terms of the Agreement, StemCells agreed to fund research in the total amount of approximately \$931,000 at Scripps over a period of three years. StemCells paid Scripps approximately \$225,000 in 2000. In addition, the Company agreed to issue to Scripps 4,837 shares of the Company's common stock and a stock option to purchase 9,674 shares of the Company's Common Stock with an exercise price of \$.01 per share upon the achievement of specified milestones. Under the Agreement, StemCells has an option for an exclusive license to the inventions resulting from the sponsored research, subject to the payment of royalties and certain other amounts, and is obligated to make payments totaling \$425,000 for achievement of certain milestones. The Company also entered a Sponsored Research Agreement and a License Agreement with Oregon Health Sciences University (OHSU) in March 1997, relating to other certain research concerning liver repopulating cells. Under subsequent Sponsored Research Agreements with OHSU, StemCells paid OHSU approximately \$80,500 in 2000, \$105,000 in 2001 and \$110,000 in 2002. In addition, the Company issued 4,838 shares of common stock and an option to purchase up to 62,888 additional shares to OHSU with an exercise price of \$.01 per share. The option has vested as to 9,675 shares for which shares were issued on March 31, 2002; the remaining option was terminated and the Company issued 4,000 shares of its common stock, with a market value of approximately \$3,900, to OHSU in January 2003, pursuant to an amendment to the license agreement.

In 2001, the Company entered into a collaboration with Stanford University to pursue certain additional research funded by the National Institutes of Health under an SBIR grant discussed above. Pursuant to agreement, the Company paid Stanford approximately \$150,000 in each of 2001 and 2002. In 2002, the Company entered into a research agreement with the University of California, Irvine (Irvine), under which it paid Irvine approximately \$3,200 in 2002 and \$16,000 in 2003. The Company also entered a sponsored research agreement with the University of Texas Medical Branch (UTMB) under which it paid UTMB approximately \$21,000 in 2002 and accrued for payment approximately \$56,000 in 2003.

In 2004, the Company made research grants totaling \$61,000 to three academic institutions.

### Notes to Consolidated Financial Statements — (Continued)

## 11. Income Taxes

Deferred income taxes reflect net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows:

	 December 31,				
	 2004 2003				
Deferred tax assets:					
Capitalized research and development costs	\$ \$ 16,046,000 \$ 12,540,00				
Net operating losses	39,287,000		42,050,000		
Research and development credits	4,742,000		4,399,000		
Accrued wind down cost	1,740,000		1,070,000		
Other	 544,000		326,000		
	62,359,000		60,385,000		
Valuation allowance	 (62,359,000)		(60,385,000)		
Net deferred tax assets	\$ _	\$	_		

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$1,974,000, \$3,495,000, and \$4,880,000 during 2004, 2003, and 2002 respectively.

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

	2004	2003	2002
Statutory federal income tax (benefit) rate	(34)%	(34)%	(34)%
Increase (decrease) resulting from:			
Expenses not deductible for taxes	1.9	(2.1)	(1.2)
Other			
Expiration of State net operating losses	19.2	7.7	
Increase in valuation allowance	12.9	28.4	35.2
Effective tax (benefit) rate	0%	0%	0%

### 12. Employee Retirement Plan

The Company has a qualified defined contribution plan covering substantially all employees. Participants are allowed to contribute a fixed percentage of their total annual cash compensation to the plan (subject to the maximums defined by law) and the Company matches 50% of employee contributions, up to a maximum of 6% of the employee's compensation, with the Company's common stock. The related expense was \$78,000, \$60,000, and \$76,000 for the years ended December 31, 2004, 2003 and 2002, respectively

# Notes to Consolidated Financial Statements — (Continued)

#### 13. Quarterly Financial Information (unaudited)

			Quart	er		
	 First	5	Second		Third	 Fourth
		(In	thousands, excep	t per shar	re data)	
Year ended December 31, 2004:						
Total revenue	\$ 93	\$	6	\$	4	\$ 38
Operating expenses	2,862(1)		3,284(1)		4,325(1)	5,070(1)
Other income (expense)	(1)		(25)		(17)	113
Net loss	(2,770)		(3,303)		(4,338)	(4,919)
Net loss applicable to common stockholders	(2,770)		(3,303)		(4,338)	(4,919)
Basic and diluted (loss) per share applicable to common						
stockholders	\$ (0.07)	\$	(0.08)	\$	(0.08)	\$ (0.08)
Year ended December 31, 2003:						
Total revenue	\$ 59	\$	60	\$	33	\$ 121
Operating expenses	2,409		2,743		2,451	4,817(1)
Other income (expense)	(59)		(30)		(11)	(44)
Net loss (before deemed dividend)	(2,409)		(2,713)		(2,429)	(4,740)
Net loss applicable to common stockholders	(2,729)		(3,928)		(2,599)	(5,169)
Basic and diluted income (loss) per share applicable to						
common stockholders	\$ (0.10)	\$	(0.13)	\$	(0.08)	\$ (0.14)

(1) Includes adjustment of wind-down accrual — see note 7.

# 14. SUBSEQUENT EVENTS

In January 2005, a warrant issued as part of the June 16, 2004 financing arrangement, was exercised to purchase an aggregate of 50,250 shares of the Company's common stock at \$1.90 per share. The Company issued 50,250 shares of its common stock and received proceeds of \$95,475. Also in January 2005, 79,899 shares of unregistered stock were issued upon the cashless exercise by the holder of a warrant acquired as partial compensation for services to the Company.

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

None.

## ITEM 9A. CONTROLS AND PROCEDURES

# **Conclusion Regarding Effectiveness of Disclosure Controls and Procedures**

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

#### **Internal Controls Over Financial Reporting**

In connection with its audit of the Company's consolidated financial statements for the year ended December 31, 2003, Grant Thornton LLP, the Company's independent auditors, communicated to the Audit Committee and management regarding financial reporting matters that they considered to be significant deficiencies and which they considered, in the aggregate, to constitute a material weakness under standards established by the American Institute of Certified Public Accountants, primarily as a result of a lack of segregation of duties in the Company's finance and accounting duties were the responsibility of a limited number of individuals who were responsible for operational controls, as well as monitoring their performance.

During fiscal year 2004, the Company continued to evaluate its internal controls over financial reporting in order to allow management to report on, and our independent auditors to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the SEC and the Public Company Accounting Oversight Board there under. During the course of assessing the effectiveness of both the design and operation of our internal controls over financial reporting and in response to the deficiencies identified by Grant Thornton in connection with the fiscal 2003 audit, we made a number of significant changes in our internal control over financial reporting during fiscal year 2004 and the first quarter of 2005, as summarized below.

As a result of our efforts, we have concluded that the following internal control issues over our financial reporting constituted significant deficiencies during the fiscal year ended December 31, 2004:

a. Segregation of Duties — The lack of segregation of duties in the Company's accounting and finance department resulted in significant deficiencies in the Company's general ledger transactions in that some journal entries and reports were both prepared and reviewed by the same individual and not reviewed by another. As discussed above, management determined that these significant deficiencies, in the aggregate, constituted a material weakness in the design and operation of the Company's internal controls in effect prior to December 31, 2004.

b. Human Resources — During 2004, procedures relating to the hiring of new employees were not followed in all instances. Management determined that this significant deficiency did not constitute a material weakness in its internal controls.

c. Stock Administration — During 2004, procedures relating to administration of the Company's 2004 Equity Incentive Plan were not followed in all instances. Management determined that these deficiencies did not constitute a material weakness in its internal controls.

The underlying cause of a significant number of deficiencies noted during the testing of our internal control processes was the lack of sufficient resources within the Company's administrative staff, particularly its accounting and finance department. During fiscal year 2004, however, and particularly the fourth quarter of 2004, our management, under the supervision of the Company's Audit Committee, has added significant resources to remedy the material weakness identified by Grant Thornton in connection with the fiscal 2003 audit and the other significant deficiencies identified during our internal control review in 2004. Specifically, we have taken a number of steps that we believe will improve the effectiveness of our internal control over our financial reporting including the following:

a. Eric Bjerkholt, an individual meeting the SEC definition of audit committee financial expert, joined the Company's board of directors and became chairman of its Audit Committee in 2004.

b. We retained an independent third party during 2004 to assist the Company in its efforts to comply with Rule 404 of the Sarbanes-Oxley Act of 2002.

c. In November 2004, we appointed Judi Lum as our new Chief Financial Officer.

d. In February 2005 we hired an additional Senior Accountant.

e. In February 2005, we retained a Human Resource Coordinator.

f. In view of its expanded resources, we plan to move stock administration functions to our finance and accounting department during the first quarter of 2005.

We will continue with our on-going evaluation of internal controls and will improve our internal controls over financial reporting as necessary to assure their effectiveness.

The statements contained in Exhibit 31.1 and Exhibit 31.2 should be considered in light of, and read together with, the information set forth in this Item 9A.

## **Changes in Internal Controls**

During the quarter ended December 31, 2004, there have been changes in our internal controls over financial reporting that have materially affected, and are reasonably likely to materially affect, our internal control over financial reporting. These changes are discussed in detail above under "Management's Annual Report on Internal Controls Over Financial Reporting."

## PART III

# ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item is incorporated by reference from our Proxy Statement for the 2005 Annual Meeting of Shareholders.

## ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference from Item 5 of this Annual Report on Form 10-K and our Proxy Statement for the 2005 Annual Meeting of Shareholders.

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

The information required by this Item is incorporated by reference from our Proxy Statement for the 2005 Annual Meeting of Shareholders.

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item is incorporated by reference from our Proxy Statement for the 2005 Annual Meeting of Shareholders.

# PART IV

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference from our Proxy Statement for the 2005 Annual Meeting of Shareholders.

# ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) DOCUMENTS FILED AS PART OF THIS FORM 10-K.

(1) Financial Statements:

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

(2) Financial Statement Schedules:

Schedules are not included herein because they are not applicable or the required information appears in the Financial Statements or Notes thereto. (b) *Exhibits*.

Exhibit No.	Title or Description
3.1*	Restated Certificate of Incorporation of the Registrant
3.2++	Amended and Restated By-Laws of the Registrant.
3.3{*** }	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant.
3.4^	Certificate of Amendment of the Restated Certificate of Incorporation of the Registrant.
4.1^^	Specimen Common Stock Certificate.
4.2++++	Form of Warrant Certificate issued to a certain purchaser of the Registrant's Common Stock in April 1995.
4.3X	Warrant to Purchase Common Stock — Mark Angelo
4.4X	Warrant to Purchase Common Stock — Robert Farrell
4.5X	Warrant to Purchase Common Stock — Joseph Donahue
4.6X	Warrant to Purchase Common Stock — Hunter Singer
4.7X	Warrant to Purchase Common Stock — May Davis
4.8X	Common Stock Purchase Warrant
4.9X	Callable Warrant
4.10XXX	Registration Rights Agreement dated as of May 10, 2001 between the Registrant and Sativum Investments Limited.
4.11XXX	Warrant, dated May 10, 2001, to Purchase Common Stock issued to Sativum Investments Limited.
4.12XXX	Warrant, dated May 10, 2001, to Purchase Common Stock issued to Pacific Crest Securities, Inc.
4.13XXX	Warrant dated May 10, 2001 to Purchase Common Stock issued to Granite Financial Group, Inc.
4.14XXX	Callable Warrant, dated June 21, 2001, issued to Millennium Partners, L.P.
4.15XXX	Common Stock Purchase Warrant, Class A, dated June 21, 2001, issued to Millennium Partners, L.P.
4.16{** }	Certificate of Designations of the Powers, Preferences and Relative, Participating, Optional and other Special Rights of Preferred Stock and Qualifications, Limitations and Restrictions Thereof of 3% Cumulative Convertible Preferred Stock for StemCells, Inc.
4.17{** }	Warrant to Purchase Common Stock — Riverview Group, LLC
4.18XXXX	Warrant to Purchase Common Stock — Cantor Fitzgerald & Co.
4.19&&	Warrant to Purchase Common Stock — Riverview Group, LLC
	79

Exhibit No.	Title or Description
10.1*	Amendment to Registration Rights dated as of February 14, 1992 among the Registrant and certain of its stockholders.
10.2*	Form of at-will Employment Agreement between the Registrant and most of its employees.
10.3*	Form of Agreement for Consulting Services between the Registrant and members of its Scientific Advisory Board.
10.4*	Form of Nondisclosure Agreement between the Registrant and its Contractors.
10.5*	Master Lease and Warrant Agreement dated April 23, 1991 between the Registrant and PacifiCorp Credit, Inc.
10.6*	1988 Stock Option Plan.
10.7*	1992 Equity Incentive Plan.
10.8*	1992 Stock Option Plan for Non-Employee Directors.
10.9**!!!!	1992 Employee Stock Purchase Plan.
10.12++	Research Agreement dated as of March 16, 1994 between NeuroSpheres, Ltd. and Registrant.
10.13++	Term Loan Agreement dated as of September 30, 1994 between The First National Bank of Boston and Registrant.
10.14++	Lease Agreement between the Registrant and Rhode Island Industrial Facilities Corporation, dated as of August 1, 1992.
10.15++	First Amendment to Lease Agreement between Registrant and The Rhode Island Industrial Facilities Corporation dated as of September 15, 1994.
10.17**++++	Development, Marketing and License Agreement, dated as of March 30, 1995 between Registrant and Astra AB.
10.18++++	Form of Unit Purchase Agreement to be executed by the purchasers of the Common Stock and Warrants offered in April 1995.
10.19+++	Form of Common Stock Purchase Agreement to be executed among the Registrant and certain purchasers of the Registrant's Common Stock.
10.22###	Lease Agreement dated as of November 21, 1997 by and between Hub RI Properties Trust, as Landlord, and CytoTherapeutics, Inc., as Tenant.
10.24!!	CTI individual stockholders option agreement dated as of July 10, 1996 among the Company and the individuals listed therein.
10.25!!	CTI Valoria option agreement dated of July 10, 1996 between the Company and the Societe Financiere Valoria SA.
10.26!!!	Term Loan Agreement dated as of October 22, 1996 between The First National Bank of Boston and the Registrant.
10.27***	Agreement and Plan of Merger dated as of August 13, 1997 among StemCells, Inc., the Registrant and CTI Acquisition Corp.
10.28***	Consulting Agreement dated as of September 25, 1997 between Dr. Irving Weissman and the Registrant.
10.29###	Letter Agreement among each of Dr. Irving Weissman and Dr. Fred H. Gage and the Registrant.
10.32****	StemCells, Inc. 1996 Stock Option Plan.
10.33****	1997 StemCells Research Stock Option Plan (the "1997 Plan")
10.34****	Form of Performance-Based Incentive Option Agreement issued under the 1997 Plan.
10.35###	Employment Agreement dated as of September 25, 1997 between Dr. Richard M. Rose and the Registrant.
10.38{* }	Rights Agreement, dated as of July 27, 1998 between Bank Boston, N.A. as Rights Agent and the Registrant.

Table	of	Contents

Exhibit No.	Title or Description
10.40\$**	Consulting Services Agreement dated as of July 27, 1998, as amended December 19, 1998 between Dr. John J. Schwartz and the Registrant.
10.41\$**	Letter Agreement dated as of December 19, 1998 between John J. Schwartz and the Registrant.
10.42\$**	License Agreement dated as of October 27, 1998 between The Scripps Research Institute and the Registrant.
10.43\$**	License Agreement dated as of October 27, 1998 between The Scripps Research Institute and the Registrant.
10.44\$**	License Agreement dated as of November 20, 1998 between The Scripps Research Institute and the Registrant.
10.45\$\$**	Purchase Agreement and License Agreement dated as of December 29, 1999 between Neurotech S.A. and the Registrant.
10.46++++**	License Agreement dated as of June 1999 between The Scripps Research Institute and the Registrant.
10.47++++**	License Agreement dated as of June 1999 between The Scripps Research Institute and the Registrant.
10.48X	Form of Registration Rights Agreement dated as of July 31, 2000 between the Registrant and investors.
10.49X	Subscription Agreement dated as of July 31, 2000 between the Registrant and Millennium Partners, L.P.
10.50XXX	Common Stock Purchase Agreement, dated as of May 10, 2001, between the Registrant and Sativum Investments Limited.
10.51XXX	Escrow Agreement, dated as of May 10, 2001, among the Registrant, Sativum Investments Limited and Epstein, Becker & Green, P.C.
10.52XX	License Agreement, dated as of October 30, 2000, between the Registrant and NeuroSpheres Ltd.
10.53XX	Letter Agreement, dated January 2, 2001, between the Registrant and Martin McGlynn
10.54XX	Lease, dated February 1, 2001, between the Board of Trustees of Stanford University and the Registrant.
10.55XXX	Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.
10.56XXX	Subscription Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.
10.57\$\$\$	2001 Equity Incentive Plan
10.58{** }	Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.
10.59{** }	Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.
10.60{** }	Agreement dated as of December 4, 2001 between the Registrant and Millennium Partners, L.P.
10.61{** }	Agreement dated as of December 4, 2001 among the Registrant, Millennium Partners, L.P. and Riverview Group, L.L.C.
10.62\$\$\$ 10.63&	Common Stock Purchase Agreement, dated as of August 23, 2002, between the Registrant and Triton West Group, Inc. Agreement, dated as of April 9, 2003, between the Registrant and Riverview Group, L.L.C.
10.64&&	Form of Registration Rights Agreement between the Registrant and Riverview Group, L.L.C.
10.65&&&	Securities Purchase Agreement, dated as of May 7, 2003, between the Registrant and Riverview Group, L.L.C.
	81

	Exhibit No.	Title or Description
10.66%		Securities Purchase Agreement dated as of December 9, 2003, between the Registrant and Riverview Group, L.L.C.
10.67^^	٨	Form of Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and certain Purchasers parties thereto.
10.68^^	Λ.	Form of Warrant.
10.69^^	~^	Amended and Restated 2004 Equity Incentive Plan of the Registrant.
10.70^^	~~~	Letter Agreement dated as of October 7, 2004 between the Registrant and Judi Lum.
14.1%%		Code of Ethics
21X		Subsidiaries of the Registrant.
23.1		Consent of Grant Thornton, LLP, Independent Registered Public Accounting Firm.
23.2		Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1		Certification Pursuant to Securities Exchange Act Rule 13(a)-14(a), as Adopted Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002 (Martin McGlynn, Chief Executive Officer).
31.2		Certification Pursuant to Securities Exchange Act Rule 13(a)-14(a), as Adopted Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002 (Judi Lum, Chief Financial Officer).
32.1		Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Martin McGlynn, Chief Executive Officer)
32.2		Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Judi Lum, Chief Financial Officer)
99 99.1XX		Cautionary Factors Relevant to Forward-Looking Information Side Letter, dated March 17, 2001, between the Company and Oleh S. Hnatiuk regarding NeuroSpheres License Agreement, dated October 30, 2000.
++	Previously filed with th File No. 33-85494.	e Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1,
+++	Previously filed with th File No. 33-97272.	e Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-3,
++++		e Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1,
*		e Commission as Exhibits to, and incorporated herein by reference to, Registration Statement on Form S-1, File No. 33-
#	Previously filed with th	e Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for nber 31, 1992 and filed March 30, 1993.
**	Confidential treatment	requested as to certain portions. The term "confidential treatment" and the mark "**" as used throughout the indicated erial has been omitted and separately filed with the Commission.
##	Previously filed with th	The Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Quarterly Report on Form 10-Q for h 31, 1994 and filed on May 14, 1994.
	-	

- + Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993 and filed on March 30, 1994.
- ! Previously filed with the Commission as an Exhibit to and incorporated by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.
- !! Previously filed with the Commission as an Exhibit to and incorporated by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.

- In Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996 and filed on March 31, 1997.
- !!!! Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.
- \*\*\* Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997 and filed on November 14, 1997.
- \*\*\*\* Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-8, File No. 333-37313.
- ### Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's annual report on Form 10-K for the fiscal year ended December 31, 1997 and filed on March 30, 1998.
- {\*} Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on August 3, 1998.
- {\*\*} Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on December 7, 2001.
  - \$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's annual report on Form 10-K for the fiscal year ended December 31, 1998 and filed on March 31, 1999.
  - **\$\$** Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on January 14, 2000.
  - \$\$\$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's definitive proxy statement filed May 1, 2001.
  - X Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1, File No. 333-45496.
- XX Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 and filed on April 2, 2001.
- XXX Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Registration Statement filed on Form S-1 as amended to Form S-3, File No. 333-61726.
- XXXX Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Registration Statement filed on Form S-3, File No. 333-75806.
- {\*\*\*} Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Amendment No. 1 to Registration Statement filed on Form S-3, File No. 333-83992.
- \$\$\$\$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on August 28, 2002.
  - & Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on April 15, 2003.
- && Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on May 13, 2003.
- &&& Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on May 15, 2003.
  - % Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on December 10, 2003.
- %% Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

- ^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on October 25, 2004.
- ^^ Previously filed with the Commission as an Exhibit to, and incorporated by reference to, the Registrant's Registration Statement on Form S-3, File No. 333-117360.
- ^^^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on June 17, 2004.
- ^^^^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrants Registration Statement on Form S-8, File No. 333-118263.
- ^^^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on November 9, 2004.



# SIGNATURES

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

# STEMCELLS, INC.

By:

/s/ MARTIN MCGLYNN

# Martin McGlynn PRESIDENT AND CHIEF EXECUTIVE OFFICER

Dated: March 14, 2005

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

Signature	Capacity	Date
/s/ MARTIN McGLYNN	President and Chief Executive Officer and Director (principal executive officer)	March 14, 2005
Martin McGlynn	(principal executive officer)	
/s/ JUDI LUM	Chief Financial Officer	March 14, 2005
Judi Lum		
/s/ GEORGE KOSHY	Controller (principal accounting officer)	March 14, 2005
George Koshy		
/s/ ERIC BJERKHOLT	Director	March 14, 2005
Eric Bjerkholt		
/s/ RICARDO B. LEVY, PH.D.	Director	March 14, 2005
Ricardo B. Levy, Ph.D.		
/s/ ROGER PERLMUTTER, M.D.	Director	March 14, 2005
Roger Perlmutter, M.D.		
/s/ JOHN J. SCHWARTZ, PH.D.	Director, Chairman of the Board	March 14, 2005
John J. Schwartz, Ph.D.		
/s/ IRVING L. WEISSMAN, M.D.	Director	March 14, 2005
Irving L. Weissman, M.D.		
	85	

# EXHIBIT INDEX

Exhibit No. 3.1*	Title or Description
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10.8*	1992 Stock Option Plan for Non-Employee Directors.
10.9**!!!!	1992 Employee Stock Purchase Plan.
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	86

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10.40\$**	Consulting Services Agreement dated as of July 27, 1998, as amended December 19, 1998 between Dr. John J. Schwartz and the Registrant.
10.41\$**	Letter Agreement dated as of December 19, 1998 between John J. Schwartz and the Registrant.
10.42\$**	License Agreement dated as of October 27, 1998 between The Scripps Research Institute and the Registrant.
10.43\$**	License Agreement dated as of October 27, 1998 between The Scripps Research Institute and the Registrant.
10.44\$**	License Agreement dated as of November 20, 1998 between The Scripps Research Institute and the Registrant.
10.45\$\$**	Purchase Agreement and License Agreement dated as of December 29, 1999 between Neurotech S.A. and the Registrant.
10.46++++**	License Agreement dated as of June 1999 between The Scripps Research Institute and the Registrant.
10.47+++**	License Agreement dated as of June 1999 between The Scripps Research Institute and the Registrant.
	87

10.51XXX         Escrow Agreement, dated as of May 10, 2001, among the Registrant, Sativum Investments Limited and Epstein, Beck Green, P.C.           10.52XX         License Agreement, dated as of October 30, 2000, between the Registrant and NeuroSpheres Ltd.           10.53XX         Letter Agreement, dated January 2, 2001, between the Registrant and Martin McGlynn           10.54XX         Lease, dated February 1, 2001, between the Board of Trustees of Stanford University and the Registrant.           10.55XXX         Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.           10.55XXX         Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.I.C.           10.56XXX         Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.I.C.           10.59(**)         Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.I.C.           10.60(**)         Agreement dated as of December 4, 2001 between the Registrant and Riverview Group, L.I.C.           10.61(**)         Agreement, dated as of April 9, 2003, between the Registrant and Riverview Group, L.I.C.           10.63&         Agreement, dated as of April 9, 2003, between the Registrant and Riverview Group, L.I.C.           10.64&&         Form of Registration Rights Agreement dated as of December 9, 2003, between the Registrant and Riverview Group, L.I.C.           10.65&&&         Securities Purchase Agreeme	Exhibit No.	Title or Description
10.50XXX       Common Stock Purchase Agreement, dated as of May 10, 2001, between the Registrant and Sativum Investments Limited and Epstein, Beck Green, P.C.         10.51XXX       Excrow Agreement, dated as of May 10, 2001, among the Registrant, Sativum Investments Limited and Epstein, Beck Green, P.C.         10.52XX       License Agreement, dated as of October 30, 2000, between the Registrant and NeuroSpheres Ltd.         10.53XX       Letter Agreement, dated January 2, 2001, between the Registrant and Martin McGlyna         10.54XX       Lease, dated February 1, 2001, between the Board of Trustees of Stanford University and the Registrant.         10.55XXX       Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.         10.56XXX       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.58(**)       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.69(**)       Agreement dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.61(**)       Agreement dated as of Apreement, dated as of August 23, 2002, between the Registrant and Triton West Group, L.L.C.         10.63&       Agreement, dated as of More 7, 2003, between the Registrant and Riverview Group, L.L.C.         10.63&       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreem	0.48X	Form of Registration Rights Agreement dated as of July 31, 2000 between the Registrant and investors.
10.51XXX       Escrow Agreement, dated as of May 10, 2001, among the Registrant, Sativum Investments Limited and Epstein, Beck Green, P.C.         10.52XX       License Agreement, dated as of October 30, 2000, between the Registrant and NeuroSpheres Ltd.         10.52XX       Letter Agreement, dated January 2, 2001, between the Registrant and Martin McGlynn         10.54XX       Lesse, dated February 1, 2001, between the Board of Trustees of Stanford University and the Registrant.         10.55XXX       Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.         10.56XXX       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.56X*       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.56(**)       Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.66(**)       Agreement dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.63&       Common Stock Purchase Agreement, dated as of August 23, 2002, between the Registrant and Riverview Group, L.L.C.         10.63&       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.65&&&       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of Ju	0.49X	Subscription Agreement dated as of July 31, 2000 between the Registrant and Millennium Partners, L.P.
Green, P.C.           10.52XX         License Agreement, dated as of October 30, 2000, between the Registrant and NeuroSpheres Ltd.           10.53XX         Letter Agreement, dated January 2, 2001, between the Registrant and Martin McGlynn           10.54XX         Lease, dated February 1, 2001, between the Board of Trustees of Stanford University and the Registrant.           10.55XXX         Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.           10.56XXX         Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.           10.56X*         Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.           10.59(**)         Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.           10.60(**)         Agreement dated as of December 4, 2001 between the Registrant and Nillennium Partners, L.P.           10.61(**)         Agreement dated as of December 4, 2001 between the Registrant and Nillennium Partners, L.P.           10.632         Common Stock Purchase Agreement, dated as of August 23, 2002, between the Registrant and Thiton West Group, L.L.C.           10.638         Greemities Purchase Agreement dated as of December 9, 2003, between the Registrant and Riverview Group, L.L.C.           10.658&&         Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.           1	0.50XXX	Common Stock Purchase Agreement, dated as of May 10, 2001, between the Registrant and Sativum Investments Limited.
10.53XX       Letter Agreement, dated January 2, 2001, between the Registrant and Martin McGlynn         10.54XX       Lease, dated February 1, 2001, between the Board of Trustees of Stanford University and the Registrant.         10.55XXX       Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.         10.56XXX       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.58(**)       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.60(**)       Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.60(**)       Agreement dated as of December 4, 2001 between the Registrant and Triton West Group, L.L.C.         10.61(**)       Agreement dated as of April 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.63&       Agreement, dated as of April 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.64&&       Form of Registration Rights Agreement between the Registrant and Riverview Group, L.L.C.         10.65%&&&       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L	0.51XXX	Escrow Agreement, dated as of May 10, 2001, among the Registrant, Sativum Investments Limited and Epstein, Becker & Green, P.C.
10.54XX       Lease, dated February 1, 2001, between the Board of Trustees of Stanford University and the Registrant.         10.55XXX       Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.         10.55XXX       Subscription Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.         10.56XXX       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.58(**)       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.50(**)       Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.61(**)       Agreement dated as of December 4, 2001 among the Registrant, Millennium Partners, L.P. and Riverview Group, L.L.C.         10.63&       Common Stock Purchase Agreement, dated as of August 23, 2002, between the Registrant and Triton West Group, L.C.         10.64&&       Form of Registration Rights Agreement between the Registrant and Riverview Group, L.L.C.         10.65&&       Securities Purchase Agreement dated as of December 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Certain Purchasers parti         10.66%       Securiti	0.52XX	License Agreement, dated as of October 30, 2000, between the Registrant and NeuroSpheres Ltd.
10.55XXX       Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.         10.55XXX       Subscription Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.         10.57XS       2001 Equity Incentive Plan         0.58(**)       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.59(**)       Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.60(**)       Agreement dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.61(**)       Agreement dated as of December 4, 2001 among the Registrant, Millennium Partners, L.P. and Riverview Group, I.L.         10.63&       Common Stock Purchase Agreement, dated as of August 23, 2002, between the Registrant and Triton West Group, Inc         10.63&       Agreement, dated as of April 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.63&       Securities Purchase Agreement, dated as of May 7, 2003, between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of December 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Certain Purchasers parti         10.66%       Form of Securities Purchase Agreement dated as of June 16, 2004 between the Registrant.	0.53XX	Letter Agreement, dated January 2, 2001, between the Registrant and Martin McGlynn
10.56XXX       Subscription Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.         10.57\$\$       2001 Equity Incentive Plan         10.58{**}       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.59{**}       Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.60{**}       Agreement dated as of December 4, 2001 between the Registrant and Millennium Partners, L.P.         10.61{**}       Agreement dated as of December 4, 2001 among the Registrant, Millennium Partners, L.P. and Riverview Group, L.L.C.         10.63&       Agreement, dated as of April 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.64&&       Form of Registration Rights Agreement between the Registrant and Riverview Group, L.L.C.         10.65&       Securities Purchase Agreement, dated as of December 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.	0.54XX	Lease, dated February 1, 2001, between the Board of Trustees of Stanford University and the Registrant.
10.57\$\$       2001 Equity Incentive Plan         10.58[***]       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.59[***]       Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.60[***]       Agreement dated as of December 4, 2001 between the Registrant and Millennium Partners, L.P.         10.61[***]       Agreement dated as of December 4, 2001 among the Registrant, Millennium Partners, L.P. and Riverview Group, L.L.C.         10.62\$\$\$\$       Common Stock Purchase Agreement, dated as of August 23, 2002, between the Registrant and Triton West Group, Inc.         10.63&       Agreement, dated as of April 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.64&&       Form of Registration Rights Agreement between the Registrant and Riverview Group, L.L.C.         10.65&&&       Securities Purchase Agreement dated as of December 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and certain Purchasers parti         10.68       Form of Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and certain Purchasers parti         10.68       Form of Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and certain Purchasers parti <td>0.55XXX</td> <td>Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.</td>	0.55XXX	Registration Rights Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.
10.58 (**)       Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.59 (**)       Registration Rights Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.         10.60 (**)       Agreement dated as of December 4, 2001 among the Registrant and Millennium Partners, L.P.         10.61 (**)       Agreement dated as of December 4, 2001 among the Registrant, Millennium Partners, L.P. and Riverview Group, L.L.C.         10.62\$\$\$\$       Common Stock Purchase Agreement, dated as of August 23, 2002, between the Registrant and Triton West Group, I.C.         10.63&       Agreement, dated as of April 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.64&&       Form of Registration Rights Agreement between the Registrant and Riverview Group, L.L.C.         10.65&&&       Securities Purchase Agreement dated as of December 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of December 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.66%       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and certain Purchasers parti         10.68/^^       Form of Securities Purchase Agreement dated as of October 7, 2004 between the Registrant.         10.69/^^       Amended and Restated 2004 Equity Incentive Plan of the Registrant.         10.69/^       Letter Agreement dated as of October 7, 2004 between the Registrant.	0.56XXX	Subscription Agreement, dated as of June 21, 2001, by and between the Registrant and Millennium Partners, L.P.
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10.60{**}       Agreement dated as of December 4, 2001 between the Registrant and Millennium Partners, L.P.         10.60{**}       Agreement dated as of December 4, 2001 among the Registrant, Millennium Partners, L.P. and Riverview Group, L.L.         10.61{***}       Agreement dated as of December 4, 2001 among the Registrant, Millennium Partners, L.P. and Riverview Group, L.L.         10.63\$*       Common Stock Purchase Agreement, dated as of August 23, 2002, between the Registrant and Triton West Group, Int         10.63\$*       Agreement, dated as of April 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.64\$**       Form of Registration Rights Agreement between the Registrant and Riverview Group, L.L.C.         10.65\$*       Securities Purchase Agreement, dated as of December 9, 2003, between the Registrant and Riverview Group, L.L.C.         10.66\$*       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and certain Purchasers parti         10.66\$*       Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and certain Purchasers parti         10.66\$*       Form of Securities Purchase Agreement dated as of June 16, 2004 between the Registrant and certain Purchasers parti         10.66\$*       Form of Warrant.         10.69***       Amended and Restated 2004 Equity Incentive Plan of the Registrant.         10.70****       Letter Agreement dated as of October 7, 2004 between the Registrant and Judi Lum.         14.1%%       Code of Ethics	0.58{**}	Subscription Agreement, dated as of December 4, 2001 between the Registrant and Riverview Group, L.L.C.
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Act of 2002 (Judi Lum, Chief Financial Officer).	1.2	Certification Pursuant to Securities Exchange Act Rule 13(a)-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Judi Lum, Chief Financial Officer).

I	Exhibit No.	Title or Description		
32.1		Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Martin McGlynn, Chief Executive Officer)		
32.2		Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Judi Lum, Chief Financial Officer)		
99 99.1XX		Cautionary Factors Relevant to Forward-Looking Information Side Letter, dated March 17, 2001, between the Company and Oleh S. Hnatiuk regarding NeuroSpheres License Agreement, dated October 30, 2000.		
++	Previously filed wi File No. 33-85494.	th the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1,		
+++	Previously filed wi File No. 33-97272.	th the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-3,		
++++	Previously filed wi File No. 33-91228.	th the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1,		
*	Previously filed wi 45739.	th the Commission as Exhibits to, and incorporated herein by reference to, Registration Statement on Form S-1, File No. 33-		
#		ly filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for ar ended December 31, 1992 and filed March 30, 1993.		
**		ent requested as to certain portions. The term "confidential treatment" and the mark "**" as used throughout the indicated material has been omitted and separately filed with the Commission.		
##		th the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Quarterly Report on Form 10-Q for <i>M</i> arch 31, 1994 and filed on May 14, 1994.		
+		th the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the becember 31, 1993 and filed on March 30, 1994.		
!	Previously filed wi quarter ended Mare	th the Commission as an Exhibit to and incorporated by reference to, the Registrant's Quarterly Report on Form 10-Q for the ch 31, 1996.		
!!	Previously filed wi quarter ended Sept	th the Commission as an Exhibit to and incorporated by reference to, the Registrant's Quarterly Report on Form 10-Q for the ember 30, 1996.		
!!!		th the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for ed December 31, 1996 and filed on March 31, 1997.		
!!!!		th the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for ed December 31, 1995.		
***		th the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Quarterly Report on Form 10-Q for september 30, 1997 and filed on November 14, 1997.		
****	Previously filed wi File No. 333-37313	th the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-8, 3.		
###		th the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's annual report on Form 10-K for the December 31, 1997 and filed on March 30, 1998.		
	Previously filed wit August 3, 1998.	h the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on		

- {\*\*} Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on December 7, 2001.
  - \$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's annual report on Form 10-K for the fiscal year ended December 31, 1998 and filed on March 31, 1999.
  - \$\$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on January 14, 2000.
  - \$\$\$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's definitive proxy statement filed May 1, 2001.
  - ++ Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1, File No. 33-85494.
- +++ Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-3, File No. 33-97272.
- +++ Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1, File No. 33-91228.
  - \* Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, Registration Statement on Form S-1, File No. 33-45739.
  - # Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for fiscal year ended December 31, 1992 and filed March 30, 1993.
  - \*\* Confidential treatment requested as to certain portions. The term "confidential treatment" and the mark "\*\*" as used throughout the indicated Exhibits mean that material has been omitted and separately filed with the Commission.
  - ## Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1994 and filed on May 14, 1994.
  - + Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993 and filed on March 30, 1994.
  - ! Previously filed with the Commission as an Exhibit to and incorporated by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.
  - !! Previously filed with the Commission as an Exhibit to and incorporated by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
  - !!! Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996 and filed on March 31, 1997.
  - !!!! Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.
- \*\*\* Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997 and filed on November 14, 1997.
- \*\*\*\* Previously filed with the Commission as Exhibits to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-8, File No. 333-37313.
- ### Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's annual report on Form 10-K for the fiscal year ended December 31, 1997 and filed on March 30, 1998.
  - {\*} Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on August 3, 1998.

- {\*\*} Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on December 7, 2001.
  - \$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's annual report on Form 10-K for the fiscal year ended December 31, 1998 and filed on March 31, 1999.
  - \$\$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on January 14, 2000.
  - \$\$\$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's definitive proxy statement filed May 1, 2001.
  - X Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Registration Statement on Form S-1, File No. 333-45496.
  - XX Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 and filed on April 2, 2001.
- XXX Previously filed with the Commission as an Exhibit to, and incorporate herein by reference to, the Registrant's Registration Statement filed on Form S-1 as amended to Form S-3, File No. 333-61726.
- XXXX Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Registration Statement filed on Form S-3, File No. 333-75806.
  - {\*\*\*} Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Amendment No. 1 to Registration Statement filed on Form S-3, File No. 333-83992.
  - \$\$\$ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on August 28, 2002.
    - & Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on April 15, 2003.
  - && Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on May 13, 2003.
  - &&& Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on May 15, 2003.
    - % Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K on December 10, 2003.
  - %% Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003.
    - ^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on October 25, 2004.
  - ^^ Previously filed with the Commission as an Exhibit to, and incorporated by reference to, the Registrant's Registration Statement on Form S-3, File No. 333-117360.
  - ^^^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on June 17, 2004.
  - Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrants Registration Statement on Form S-8, File No. 333-118263.
  - ^^^^ Previously filed with the Commission as an Exhibit to, and incorporated herein by reference to, the Registrant's current report on Form 8-K filed on November 9, 2004.

# CONSENT OF GRANT THORNTON LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated March 4, 2005, accompanying the consolidated financial statements and management's assessment of the effectiveness of internal control over financial reporting included in the Annual Report of Stemcells, Inc. on Form 10-K for the year ended December 31, 2004. We hereby consent to the incorporation by reference of said reports in the Registration Statements of Stemcells, Inc. on Forms S-3 (File No. 333-117360 effective July 14, 2004, File No. 333-105664, effective May 29, 2003, File No. 333-83992, effective March 8, 2002, File No. 333-75806, effective December 21, 2001, File No. 333-66692, effective August 3, 2001, and File No. 333-61726, effective June 29, 2001) and Forms S-8 (File No. 333-118263 effective August 16, 2004, File No. 333-66700, effective August 3, 2001, File No. 333-37313, effective October 7, 1997, File No. 333-29335, effective June 16, 1997, File No. 333-10773, effective August 23, 1996, and File No. 33-49524, effective July 10, 1992) and Registration Statements of CytoTherapeutics, Inc. on Forms S-3 (File No. 33-91228, effective April 14, 1995, and File No. 33-68900, effective September 15, 1993).

/s/ Grant Thornton LLP

San Jose, California March 14, 2005

# CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-66700) pertaining to the 2001 Equity Incentive Plan, in the Registration Statements (Form S-8 No. 333-49524 and 333-29335) pertaining to the 1998 Incentive Stock Plan, 1992 Equity Incentive Plan, 1992 Employee Stock Purchase Plan and 1992 Stock Option Plan for Non-Employee Directors, in the Registration Statement (Form S-8 No. 333-10773) pertaining to the 1992 Equity Incentive Plan, in the Registration Statement (Form S-8 No. 333-37313) pertaining to the 1996 StemCells, Inc. Stock Option Plan and the 1997 CytoTherapeutics, Inc. StemCells Research Stock Option Plan, in the Registration Statements (Form S-3 No. 333-75806, No. 333-66692, No. 333-61726 and No. 333-83992) of StemCells, Inc. and in the Registration Statements (Form S-3 No. 333-68900 and No. 333-91228) of CytoTherapeutics, Inc. and in the related Prospectuses of our report dated March 4, 2003, except for Note 1, as to which the date is March 25, 2004, with respect to the consolidated financial statements of StemCells, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP

Palo Alto, California March 14, 2005 CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

- I, Martin McGlynn, certify that:
  - (1) I have reviewed this annual report on Form 10-K of StemCells, Inc.;
  - (2) Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  - (3) Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  - (4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  - (5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
    - a. all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
    - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2005

Martin McGlynn President and Chief Executive Officer

#### CERTIFICATION OF ACTING CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

# I, Judi Lum, certify that:

- (1) I have reviewed this annual report on Form 10-K of StemCells, Inc.;
- (2) Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - a. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Judi Lum Chief Financial Officer

#### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the StemCells, Inc. (the "Company") Annual Report on Form 10-K for the year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Martin McGlynn, President and Chief Executive Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1). The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2). The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2005

/s/ Martin McGlynn

Martin McGlynn President and Chief Executive Officer

#### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the StemCells, Inc. (the "Company") Annual Report on Form 10-K for the year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Judi Lum, Chief Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1). The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2). The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2005

/s/ Judi Lum Judi Lum Chief Financial Officer

#### CAUTIONARY FACTORS RELEVANT TO FORWARD-LOOKING INFORMATION

YOU SHOULD CAREFULLY CONSIDER THE RISKS DESCRIBED BELOW BEFORE MAKING AN INVESTMENT DECISION REGARDING STEMCELLS, INC. Any of the following risks could materially adversely affect our business, financial conditions or results of operation. Additional risks and uncertainties not known to us or that we currently deem immaterial may also impair our business operations.

Our business, financial condition or results of operations could be materially adversely affected by any of these risks. Consequentially, the trading price of our common stock could decline, resulting in the loss of all or part of your investment.

### RISKS RELATED TO OUR BUSINESS

OUR FINANCIAL SITUATION IS PRECARIOUS AND, BASED ON CURRENTLY ESTIMATED OPERATING EXPENSES, OUR EXISTING CAPITAL RESOURCES MAY NOT BE SUFFICIENT TO FUND OUR OPERATIONS BEYOND 2006.

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 revenues to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts and for acquisition of technologies and intellectual property rights, preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, general and administrative expenses and other working capital requirements. We rely on cash reserves 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. If we exhaust our cash reserves and are unable to realize adequate financing, we may be unable to meet operating obligations and be required to initiate bankruptcy proceedings. Our existing capital resources may not be sufficient to fund our operations beyond 2006. These conditions raise doubt about our ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

We intend to pursue opportunities to obtain additional financing in the future through equity and debt financings, grants and collaborative research arrangements. 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 to delay, scale back or eliminate some or all of our research and product development programs and/or our capital expenditures or to license our potential products or technologies to third parties.

THE FDA MAY FAIL TO APPROVE OUR INVESTIGATIONAL NEW DRUG APPLICATION FOR OUR PROPOSED PHASE I CLINICAL TRIAL OF OUR PROPRIETARY NEURAL CELL THERAPY PRODUCT IN BATTEN DISEASE, AND THE INSTITUTIONAL REVIEW BOARD (IRB) AT THE CLINICAL SITE MAY FAIL TO APPROVE THE CLINICAL PROTOCOL FOR THE TRIAL.

We filed our first Investigational New Drug, or IND, application to the U.S. Food and Drug Administration (FDA) in late December, 2004, for our proposed Phase I clinical trial of our proprietary neural cell therapy product - HuCNS SC - - in Batten disease. The FDA has informed us that it has suggestions and questions related to the proposed trial that require additional information and has placed our proposed trial on hold. We cannot be certain whether the FDA will remove the clinical hold on the Company's proposed initial clinical trial and permit the Company to proceed to clinical testing despite the novel and unproven nature of our technology. We may not be able to satisfy the FDA's concerns without conducting extensive and time consuming additional preclinical studies, if at all. Even if approved, our clinical trial could be substantially delayed beyond its expected dates. In addition to requiring FDA approval, the trial cannot go forward until the IRB of the trial site has approved the proposed clinical protocol. The IRB for Stanford University, the proposed site of the trial, has not yet acted on the protocol. Should it fail to approve the trial, or require modifications to the protocol that are not acceptable to the Company, the Company would need to find another trial site.

OUR TECHNOLOGY IS AT AN EARLY STAGE OF DISCOVERY AND DEVELOPMENT, AND WE MAY FAIL TO DEVELOP ANY COMMERCIALLY ACCEPTABLE PRODUCTS.

We have yet to develop any products. Our stem cell technology is still at the discovery phase for the liver and pancreas stem cells and, while we have filed an IND with respect to our human neural (brain) stem cells, the U.S. Food and Drug Administration (FDA) has placed a clinical hold on our proposed clinical trial pending the Company's response to its concerns. We may fail to discover the stem cells we are seeking, to develop any products, to obtain regulatory approvals, to enter clinical trials, or to commercialize any products. Any product using stem cell technology may fail to:

- survive and persist in the desired location;
- provide the intended therapeutic benefits;
- properly integrate into existing tissue in the desired manner; or
- achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing.

In addition, our products may cause undesirable side effects. Results of early pre-clinical research may not be indicative of the results that will be obtained in later stages of pre-clinical or clinical research. If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would have limited ability to commercialize our products, and our business and results of operations would be harmed. Furthermore, because stem cells are a new form of therapy, the marketplace may not accept any products we may develop. If we do succeed in developing products, we will face many potential obstacles such as the need to obtain regulatory approvals and to develop or obtain manufacturing, marketing and distribution capabilities. In addition, we will face substantial additional risks such as product liability claims.

Moreover, because our cell therapy treatments will be derived from tissue of individuals other than the patient (that is, they will be "non-self" or "allogeneic" transplant products), patients will require the use of immunosuppressive drugs such as cyclosporine, FK506, or others to prevent rejection of the cells. While immunosuppression is now standard in connection with allogeneic transplants of various kinds, long-term maintenance on immunosuppressive drugs can produce complications that include infection, cancer, cardiovascular disease, renal dysfunction and other side effects depending upon which immunosuppressive regimen is employed. Immunosuppression has not been tested with our therapies since we have not yet conducted any clinical trials.

As noted above, we filed an IND with the FDA earlier this year which is currently on clinical hold. Before we are permitted to move forward, as part of the IND process, the FDA will need to be satisfied that the cell bank to be used in these trials qualifies as a suitable source of the cells for the proposed clinical trial, and that the pre-clinical safety testing (i.e., pharmacology and toxicology studies) we conducted in various animal models is adequate. We must also obtain the approval of the internal review board at the medical institution where the clinical trial would be conducted. We may not be able to satisfy all of the requirements to move the Batten disease program into clinical trials, which could have a material adverse effect on our product development timeline.

WE HAVE PAYMENT OBLIGATIONS RESULTING FROM REAL PROPERTY OWNED OR LEASED BY US IN RHODE ISLAND, WHICH DIVERTS FUNDING FROM OUR STEM CELL RESEARCH AND DEVELOPMENT.

Prior to our reorganization in 1999 and the consolidation of our business in California, we carried out our former encapsulated cell therapy programs in Lincoln, Rhode Island, where we also had our administrative offices. Although we have vacated the Rhode Island facilities, we remain obligated to make on average, lease payments and payments for operating costs of approximately \$1,450,000 per year before sub-tenant rent income for our former science and administrative facility, which we have leased through June 30, 2013, and debt service payments and payments for operating costs of approximately \$500,000 per year for our former encapsulated cell therapy pilot manufacturing facility, which we own. We have currently subleased a portion of the science and administrative facility, and are

seeking to sublease the remaining portion, but we cannot be sure that we will be able to keep any part of the facility subleased for the duration of our obligation. We have currently subleased the entire pilot manufacturing facility to a privately-held biotechnology company, but may not be able to sublease or sell the facility in the future once the current sublease agreements expire. These continuing costs significantly reduce our cash resources and adversely affect our ability to fund further development of our stem cell technology. 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 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. At December 31, 2004, the reserve was \$5,528,000. In 2004, we incurred \$1,152,000 in operating expenses net of sub-tenant income for this facility. In 2004 and 2003 respectively, we incurred \$1,152,000 and \$984,000 in lease payments and operating expenses net of subtenant 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. Even though it is our intent to sublease, assign, sell or otherwise divest ourselves of our interests in the facility at the earliest possible time, we cannot determine with certainty a fixed date by which such events will occur. In light of this uncertainty, based on estimates, we will periodically re-evaluate and adjust the reserve, as necessary.

WE MAY NEED BUT FAIL TO OBTAIN PARTNERS TO SUPPORT OUR STEM CELL DEVELOPMENT EFFORTS AND TO COMMERCIALIZE OUR TECHNOLOGY.

Equity and debt financings alone may not be sufficient to fund the cost of developing our stem cell technologies, and we may need to rely on our ability to reach partnering arrangements to provide financial support for our stem cell discovery and development efforts. In addition, in order to successfully develop and commercialize our technology, we may need to enter into a wide variety of arrangements with corporate sponsors, pharmaceutical companies, universities, research groups and others. While we have engaged, and expect to continue to engage, in discussions regarding such arrangements, we have not reached any agreement, and we may fail to obtain any such agreement on terms acceptable to us. Even if we enter into these 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 certain rights to third parties, including exclusive marketing rights to one or more products, may require us to issue securities to our collaborators or may contain other terms that are burdensome to us. If any of our collaborators terminates its relationship with us or fails to perform its obligations in a timely manner, the development or commercialization of our technology and potential products may be adversely affected.

WE HAVE A HISTORY OF OPERATING LOSSES, AND WE MAY FAIL TO OBTAIN REVENUES OR BECOME PROFITABLE.

We expect to continue to incur substantial operating losses in the future in order to conduct our research and development activities, and, if those activities are successful, to fund clinical trials and other expenses. These expenses include the cost of acquiring technology, product testing, acquiring regulatory approvals, establishing production, marketing, sales and distribution programs and administrative expenses. We have not earned any revenues from sales of any product. All of our past revenues have been derived from, and any revenues we may obtain for the foreseeable future are expected to be derived from, cooperative agreements, research grants, investments and interest on invested capital. We currently have no cooperative agreements, we have only one current research grant for our stem cell technology, and we may not obtain any such agreements or additional grants in the future or receive any revenues from them.

IF WE ARE UNABLE TO PROTECT OUR PATENTS AND PROPRIETARY RIGHTS, OUR BUSINESS, FINANCIAL CONDITION AND RESULTS OF OPERATIONS WILL BE HARMED.

We own or license a number of patents and pending patent applications related to various stem and progenitor cells and methods of deriving and using them, including human neural stem cell cultures. Patent protection for products such as those we propose to develop is highly uncertain and involves complex and continually evolving factual and legal questions. The governmental authorities that consider patent applications can deny or significantly reduce the patent coverage requested in an application before or after issuing the patent. Consequently, we do not know whether any of our pending applications will result in the issuance of patents, if any existing or future patents will provide sufficient protection or significant commercial advantage or if others will circumvent these patents. We cannot be certain that we were the first to discover the inventions covered by each of our pending patent applications or that we were the first to file patent applications for such inventions because patent applications are secret until they are published, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Patents may not issue from our pending or future patent applications or, if issued, may not be of commercial benefit to us. In addition, our patents may not afford us adequate protection from competing products. Third parties may challenge our patents or governmental authorities may declare them invalid. In the event that a third party has also filed a patent application relating to inventions claimed in our patent applications, we may have to participate in proceedings to determine priority of invention. This could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us, and the outcome might not be favorable to us. Even if a patent issues, a court could decide that the patent was issued invalidly. Further, patents issue for a limited term, and our patents may expire before we utilize them profitably. Under the procedures of the European Patent Office, third parties may oppose our issued European patents during the relevant opposition period. Such oppositions could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us, and the outcome might not be favorable to us. One party has opposed two of our granted European patents. While we are confident in our position, there is no guarantee that we will prevail. If we are unsuccessful in our defense of the opposed patents, all claimed rights in the opposed patents will be lost in Europe.

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 OTHERS ARE FIRST TO DISCOVER AND PATENT THE STEM CELLS WE ARE SEEKING TO DISCOVER, WE COULD BE BLOCKED FROM FURTHER WORK ON THOSE STEM CELLS.

Because the first person or entity to discover and obtain a valid patent to a particular stem or progenitor cell may effectively block all others, it will be important for us or our collaborators to be the first to discover any stem cell that we are seeking to discover. Failure to be the first could prevent us from commercializing all of our research and development affected by that patent.

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 cells and other technologies potentially relevant to or necessary for our expected products. We cannot predict which, if any, of the applications will issue as patents. If third party patents or patent applications contain valid claims that our technology infringes upon their technology, we may be unable to obtain licenses to these patents at a reasonable cost, if at all, and may also be unable to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, our business could be significantly harmed. We have obtained rights from 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 risks of third-party patents and/or technology. 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. Many of the world's pharmaceutical companies, including Merck, Pfizer, Abbott, Bristol-Myers Squibb, Novartis and GlaxoSmithKline, have made significant commitments to the CNS field. Any cell-based therapy to treat diseases of, or injuries to, the CNS is likely to face intense competition from the small molecule sector. In addition, a number

of biotechnology companies with resources far greater than ours may also

emerge as competitors. These include Genzyme, Amgen, Cephalon, Transkaryotic Therapies, BioMarin, Celgene, Biogen, and Titan Pharmaceuticals. Finally, we also expect to compete with smaller biotechnology companies, some of which are privately owned, such as Neuralstem, Geron, NeuroNova, ReNeuron, ES Cell International, and CellFactors/Diacrin.

We believe that our human neural stem cells may have application to many or most of the Lysosomal Storage Diseases ("LSDs") with CNS involvement. We have submitted our first IND for Batten Disease, which is one of the LSDs that affect the CNS; that IND is currently on clinical hold, and we have no assurance as to when or whether the FDA will release the hold and permit the clinical trial to begin. There are, so far as we know, no approved therapies for Batten's or any of the other CNS-specific LSDs, but other companies, including Genzyme, BioMarin, and Transkaryotic Therapies, have products approved to treat peripheral aspects of some of the other LSDs, and other products are in clinical trials.

In the field of diabetes, a number of major companies currently market products for the treatment of diabetes and are also engaged in the research and development of new therapies. Such companies include Eli Lilly, Novo Nordisk, J&J, Amylin, Serono. Consequently, should we successfully develop a cell-based therapy for diabetes, we would expect to face severe competition from these and similar companies.

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

DEVELOPMENT OF OUR TECHNOLOGY IS SUBJECT TO AND RESTRICTED BY EXTENSIVE GOVERNMENT REGULATION, WHICH COULD IMPEDE OUR BUSINESS.

Our research and development efforts, as well as any future clinical trials, and the manufacturing and marketing of any products we may develop, will be subject to and restricted by extensive regulation by governmental authorities in the United States and other countries. The process of obtaining U.S. Food and Drug Administration and other necessary regulatory approvals is lengthy, expensive and uncertain. 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 fetal tissue. The federal and state governments and other jurisdictions impose restrictions on the use of fetal tissue. 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 guidelines for cell procurement. Further, we may not be able to obtain such cells in the quantity or quality sufficient to satisfy the commercial requirements of our potential products. As a result, we may be unable to develop or produce our products in a profitable manner.

Although we do not use embryonic stem cells, government regulation and threatened regulation of embryonic tissue may lead top researchers to leave the field of stem cell research, or the country, in order to assure that their careers will not be impeded by restrictions on their work. Similarly, these factors may induce the best graduate students to choose other fields less vulnerable to changes in regulatory oversight, thus exacerbating the risk, discussed below, 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. In addition, we cannot assure you that constraints on the use of embryonic stem cells will not be extended to use of fetal stem cells. Moreover, it is possible that concerns regarding research using embryonic stem cells will impact our ability to attract collaborators and investors and our stock price.

We may apply for status under the Orphan Drug Act for some of our therapies to gain a seven-year period of marketing exclusivity for those therapies. The U.S. Congress in the past has considered, and in the future again may consider, legislation that would restrict the extent and duration of the market exclusivity of an orphan drug. If enacted, such legislation could prevent us from obtaining some or all of the benefits of the existing statute even if we were to apply for and be granted orphan drug status with respect to a potential product.

#### WE ARE DEPENDENT ON THE SERVICES OF KEY PERSONNEL.

We are highly dependent on the principal members of our management and scientific staff and some of our outside consultants, including the members of our scientific advisory board, our chief executive officer, our vice presidents and the directors of our neural stem cell and liver stem cell programs. 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.

WE NEED TO IMPROVE OUR FINANCIAL CONTROL PROCEDURES.

Management's Annual Report on Internal Controls Over Financial Reporting found deficiencies in the operating effectiveness of its internal controls over financial reporting that collectively constitute significant deficiencies and a material weakness under standards established by the American Institute of Certified Public Accountants, resulting in more than a remote likelihood that a material misstatement of the annual or interim financial statements of the Company will not be prevented or detected. In the opinion of Grant Thornton LLP, the Company's independent auditors, Management's assessment that that StemCells Inc. did not maintain effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects. It is also the opinion of Grant Thornton that because of the effect of the material weakness identified by management (i.e., instances where both the preparation and review of general journal entries were performed by the same individual) on the achievement of the objectives of the control criteria, StemCells Inc. has not maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control -- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company has already taken remedial steps, and will continue its on-going evaluation of internal controls and attempts to improve its internal controls over financial reporting as necessary to assure their effectiveness, but there can be no assurance that it will succeed or that other deficiencies will not be identified.

SINCE 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 REDUCED.

In both domestic and foreign markets, sales of potential products are likely to depend in part upon the availability and amounts of reimbursement from third party health care payor organizations, including government agencies, private health care insurers and other health care payors, such as health maintenance organizations and self-insured employee plans. There is considerable pressure to reduce the cost of therapeutic products, and 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 U.S. Food and Drug Administration has not granted marketing approval. Significant uncertainty exists as to the reimbursement status of newly approved health care products or novel therapies such as ours. 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 stem cell technology. 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 at health care reform 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 payers for health care goods and services may take in response to health care reform proposals or legislation. We cannot predict the effect government control and other health care reforms may have on our business.

WE HAVE LIMITED LIQUIDITY AND CAPITAL RESOURCES AND MAY NOT OBTAIN THE SIGNIFICANT CAPITAL RESOURCES WE WILL NEED TO SUSTAIN OUR RESEARCH AND DEVELOPMENT EFFORTS.

We have limited liquidity and capital resources and must obtain substantial additional capital to support our research and development programs, for acquisition of technology and intellectual property rights and, to the extent we decide to undertake these activities ourselves, for pre-clinical and clinical testing of our anticipated products, pursuit of regulatory approvals, establishment of production capabilities, establishment of marketing and sales capabilities and distribution channels, and general administrative expenses. If we do not obtain the necessary capital resources, we may have to delay, reduce or eliminate some or all of our research and development programs or license our technology or any potential products to third parties rather than commercialize them ourselves. We intend to pursue our needed capital resources through equity and debt financings, corporate alliances, grants and collaborative research arrangements. We may fail to obtain the necessary capital resources from any such sources when needed or on terms acceptable to us. Our ability to complete successfully any such arrangements will depend upon market conditions and, more specifically, on continued progress in our research and development efforts.

#### RISKS RELATED TO THE SECURITIES MARKET

OUR STOCK PRICE HAS BEEN, AND WILL LIKELY CONTINUE TO BE, HIGHLY VOLATILE, WHICH MAY NEGATIVELY AFFECT OUR ABILITY TO OBTAIN ADDITIONAL FINANCING IN THE FUTURE.

The market price of our stock has been and is likely to continue to be highly volatile due to the risks and uncertainties described in this section of the prospectus, as well as other factors, including:

- our ability to develop and test our technology;
- our ability to patent or obtain licenses to necessary technology;
- 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;
- 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, 2004, the closing price of our common stock as reported on the Nasdaq SmallCap Market ranged from a high of \$4.48 to a low of \$.66. As a result of this volatility, your investment in our stock is subject to substantial risk. Furthermore, the volatility of our stock price could negatively impact our ability to raise capital in the future.

WE ARE CONTRACTUALLY OBLIGATED TO ISSUE SHARES IN THE FUTURE, DILUTING YOUR INTEREST IN US.

As of December 31, 2004, there were outstanding and exercisable warrants to purchase 5,490,285 shares of our common stock, at a weighted average exercise price of \$2.08 per share. As of December 31, 2004, there were also outstanding and exercisable options to purchase 6,682,201 shares of our common stock, at a weighted average exercise price of \$2.67 per share. Moreover, we expect to issue additional options to purchase shares of our common stock to compensate employees, consultants and directors, and may issue additional shares to raise capital, to acquire other companies or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of further diluting the interest of the purchasers of the securities being sold in this offering.