

STEMCELLS INC
Form S-3/A
November 03, 2005

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As filed with the Securities and Exchange Commission on November 3, 2005

Registration No. 333-128797

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

**AMENDMENT NO. 1
TO
Form S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

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 Number)*

**3155 Porter Drive
Palo Alto, CA 94304
(650) 475-3100**

(Address, including zip code, and telephone number, including area code of principal executive offices)

**Iris Brest, Esq.
General Counsel
StemCells, Inc.
3155 Porter Drive
Palo Alto, CA 94304
(650) 475-3100**

*(Name, address, including zip code, and telephone
number, including area code, of agent for service)*

Please send copies of all communications to:

**Geoffrey Davis, Esq.
Ropes & Gray LLP
One International Place
Boston, Massachusetts 02110
(617) 951-7000**

Approximate date of commencement of proposed sale to the public: From time to time after the effectiveness of the Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement under the earlier effective registration

statement for the same offering. o

If this form is a post effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box: o

CALCULATION OF REGISTRATION FEE

| <i>Title of each class securities to be registered</i> | <i>Amount to be Registered (1)(2)</i> | <i>Proposed Maximum Offering Price (1)</i> | <i>Proposed Maximum Aggregate Offering Price(1)</i> | <i>Amount of Registration Fee (2)</i> |
|--|---|--|---|---|
| Common Stock (3) | \$100,000,000 | | \$100,000,000 | \$11,770 (4) |

(1) There are being registered under this Registration Statement such indeterminate number of shares of Common Stock of the Registrant as shall have an aggregate offering price not to exceed \$100,000,000. The proposed maximum offering price per share will be determined, from time to time, by the Registrant in connection with the issuance of the securities registered under this Registration Statement.

(2) Calculated pursuant to Rule 457(o) under the Securities Act.

(3) Including such indeterminate number of shares of Common Stock as may from time to time be issued at indeterminate prices.

(4) Previously paid.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Security and Exchange Commission, acting pursuant to said section 8(a), may determine.

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Information contained in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

SUBJECT TO COMPLETION

November 3, 2005

\$100,000,000
STEMCELLS, INC.
COMMON STOCK

We may sell from time to time up to \$100,000,000 of our common stock in one or more transactions. We will provide specific terms of these securities and offerings in supplements to this prospectus. You should read this prospectus and any supplement carefully before you invest.

The securities offered in this prospectus involve a high degree of risk. You should carefully consider the Risk Factors set forth herein beginning on page 1 and in our future filings made with the Securities and Exchange Commission, which are incorporated by reference in this prospectus, in determining whether to purchase our securities.

Our common stock is currently listed on the Nasdaq National Market with the ticker symbol: STEM. On October 31, 2005, the closing price of one share of our common stock on the Nasdaq National Market was \$4.57. **Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this Prospectus is .

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. This prospectus may only be used where it is legal to sell these securities. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

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SUMMARY

The following summary is qualified in its entirety by the more detailed information and financial statements appearing elsewhere or incorporated by reference in this prospectus. Without limiting the generality of the foregoing, prospective investors should carefully consider factors set forth under the caption Risk Factors below.

OUR COMPANY

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, 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.

Our stem cell discovery engine relies upon our state-of-the-art cell sorting capabilities and our library of known and 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) to the U.S. Food and Drug Administration (FDA) for a clinical trial using our proprietary human neural stem cells to treat Batten disease. On October 19, 2005, the Company received clearance from the FDA to begin a Phase I safety and preliminary efficacy trial. The Company plans to seek Institutional Review Board (IRB) approval from a number of leading medical institutions. Such approval is needed before the clinical trial may begin.

Our principal executive offices are located at StemCells, Inc., 3155 Porter Drive, Palo Alto, CA 94304 and our phone number is (650) 475-3100.

RISK FACTORS

Investing in our common stock is risky. In addition to the other information in this prospectus, the following risk factors should be considered carefully in evaluating us and our business. If any of the following risks were to occur, our business, financial condition or results of operations would likely suffer. In that event, the trading price of our common stock could decline, and you could lose all or a part of your investment.

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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. 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.

Institutional Review Boards (IRBs) at the clinical sites to which we apply may fail to approve the clinical protocol for our Phase I clinical trial of our proprietary neural cell therapy product in Batten disease.

We filed our first Investigational New Drug application, or IND, with 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 to treat Batten disease. The FDA recently informed us that it has approved our IND. We plan to seek Institutional Review Board (IRB) approval from a number of leading medical institutions. Such approval is needed before the clinical trial may begin. There can be no guarantee that we will obtain IRB approval.

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 the FDA has approved our IND with respect to our human neural (brain) stem cells, as described above we need to obtain IRB approval before we can proceed with our clinical trial.

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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.

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 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 September 30, 2005, the reserve was \$5,520,000. The Company incurred \$845,000 in operating expenses for the nine month period ending September 30, 2005, which was recorded against the reserve. 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.

Table of Contents***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. 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

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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 large 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, Shire Pharmaceuticals, BioMarin, Celgene, Biogen Idec, and Titan Pharmaceuticals/Schering AG. Finally, we also expect to compete with smaller biotechnology companies, such as NeuralStem, Geron, NeuroNova, ReNeuron, and ES Cell International, some of which are privately owned.

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 received approval for our first IND to treat the Infantile and Late Infantile forms of Batten disease, which are among the LSDs that affect the CNS. However, we will need to obtain IRB approval prior to initiating our clinical trial, and we have no assurance as to when IRB approval will be obtained. There are, so far as we know, no approved therapies for Batten Disease or any of the other CNS-specific LSDs, but other companies, including Genzyme, BioMarin, and Shire, 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, ViaCell, and Serono. Consequently, should we successfully develop a cell-based therapy for diabetes, we would expect to face severe competition from these and similar companies.

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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 FDA 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 our internal controls over financial reporting. Such deficiencies collectively constituted

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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 would not be prevented or detected. In the opinion of Grant Thornton LLP, our independent auditors, management's assessment that we 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, we have 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 already taken remedial steps, and will continue our on-going evaluation of internal controls and attempts to improve our internal controls over financial reporting as necessary to assure their effectiveness, but there can be no assurance that we 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 FDA 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.

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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:

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

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 October 31, 2005, our common stock was listed on the Nasdaq Capital Market (previously known as the Nasdaq SmallCap Market) until September 30, 2005, when it began listing on the Nasdaq National Market. During such two-year period, the closing price of our common stock as reported on the Nasdaq Capital Market and the Nasdaq National Market ranged from a high of \$6.26 to a low of \$1.24. 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.

As of October 31, 2005, our common stock is listed on the Nasdaq National Market. To keep our listing on this market, we must meet Nasdaq's listing maintenance standards. If we are unable to continue to meet Nasdaq's listing maintenance standards, our common stock could be delisted from the Nasdaq National Market. If our common stock were delisted, we likely would seek to list the common stock on the Nasdaq Capital Market, the American Stock Exchange or a regional stock exchange. Listing on such other market or exchange could reduce the liquidity for our common stock. If we were unable to list our common stock on such other market or exchange, trading of our common stock likely would be conducted in the over-the-counter market on an electronic bulletin board established for unlisted securities or directly through market makers in our common stock. If our common stock were to trade in the over-the-counter market, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, the common stock.

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

As of September 30, 2005, there were outstanding and exercisable warrants to purchase 3,341,212 shares of our common stock, at a weighted average exercise price of \$2.10 per share. As of September 30, 2005, there were also outstanding options to purchase 6,641,401 shares of our common stock, at a weighted average exercise price of \$3.00 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.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated in this prospectus by reference may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These statements may be identified by the use of forward-looking words or phrases such as anticipate, believe, could, expect, intend, look forward, may, planned, potential, should, will, and would. These forward-looking statements reflect our current expectations and are based upon currently available data. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in the forward-looking statements. 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

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timing of, additional capital and capital expenditures, partnering prospects, costs of manufacture of products, the protection of and the need for additional intellectual property rights, effects of regulations, the need for additional facilities and potential market opportunities. Our actual results may vary materially from those contained in such forward-looking statements because of the risks to which we are subject, including those listed above.

USE OF PROCEEDS

Unless otherwise indicated in the applicable prospectus supplement, we anticipate that the net proceeds from the sale of the securities offered under this prospectus will be used for working capital and general corporate purposes, as well as in connection with selected acquisitions that may be considered in the future or for other strategic purposes. Pending the application of the net proceeds, we expect to invest the proceeds in investment-grade, interest-bearing instruments or other securities.

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PLAN OF DISTRIBUTION

General. We may sell the securities offered hereby to or through underwriters, through agents or dealers, directly to one or more purchasers, or through a combination of such methods. A prospectus supplement or supplements will describe the terms of the offering of these securities, including:

the name or names of any underwriters, agents or dealers, if any;

the number of securities involved;

the purchase price of the securities and the proceeds we will receive from the sale;

any over-allotment options under which underwriters may purchase additional securities from us;

any agency fees or underwriting discounts and other items constituting underwriters', agents' or dealers' compensation;

any public offering price;

any discounts or concessions allowed or reallocated or paid to dealers; and

other information material to the transaction.

Underwriters. If underwriters are used in the sale of the securities, we will execute an underwriting agreement relating to the securities that we will offer. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. Unless otherwise set forth in the applicable prospectus supplement, the underwriting agreement will provide that the obligations of the underwriters will be subject to certain conditions precedent and that the underwriters with respect to a sale of the securities will be obligated to purchase all the securities if any are purchased.

The securities subject to the underwriting agreement will be acquired by the underwriters for their own account and may be resold by them from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Underwriters may be deemed to have received compensation from us in the form of underwriting discounts or commissions and may also receive commissions from the purchasers of these securities for whom they may act as agent. Underwriters may sell these securities to or through dealers. These dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agent. Any initial public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

We also may sell the securities in connection with a remarketing upon their purchase, in connection with a redemption or repayment, by a remarketing firm acting as principal for its own account or as our agent. Remarketing firms may be deemed to be underwriters in connection with the securities that they remarket.

During and after an offering through underwriters, the underwriters may purchase and sell the securities in the open market. These transactions may include over-allotment and stabilizing transactions and purchases to convey syndicate short positions created in connection with the offering. The underwriters may also impose a penalty bid, which means that selling concessions allowed to syndicate members or other broker-dealers for the offered securities sold for their account may be reclaimed by the syndicate if the offered securities are repurchased by the syndicate in stabilizing or covering transactions. These activities may stabilize, maintain or otherwise affect

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the market price of the offered securities, which may be higher than the price that might otherwise prevail in the open market. If commenced, the underwriters may discontinue these activities at any time.

Agents. We may also sell any of the securities through agents designated by us from time to time. We will name any agent involved in the offer or sale of these securities and will list commissions payable by us to these agents in the prospectus supplement. These agents will be acting on a best efforts basis to solicit purchases for the period of their appointment, unless we state otherwise in the applicable prospectus supplement.

Direct Sales. We may sell any of the securities directly to purchasers. In this case, we will not engage underwriters or agents in the offer and sale of these securities.

Indemnification. We may indemnify underwriters, dealers or agents who participate in the distribution of the securities against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and agree to contribute to payments which these underwriters, dealers or agents may be required to make.

Listing. Our common stock is currently listed on the Nasdaq National Market under the symbol STEM. No underwriters will be obligated to make a market in our securities. We cannot predict the activity or liquidity of any trading in our securities.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings are available over the Internet at the SEC's web site at <http://www.sec.gov>. You may also read and copy any document we file with the SEC at its public reference facility:

Public Reference Room
100 F Street, N.E.
Washington, D.C. 20549

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC, 100 F Street, N.E., Washington, DC 20549. Please call 1-800-SEC-0330 for further information on the operations of the public reference facility and copying charges.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and the information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference in this prospectus the following documents filed by us with the SEC:

Our Annual Report on Form 10-K for the year ended December 31, 2004, including any amendment filed for the purpose of updating such Annual Report;

Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005 including any amendment filed for the purpose of updating such Quarterly Reports;

A Proxy Statement for Annual Meeting of Stockholders on Schedule 14A filed with the SEC on March 23, 2005;

The description of our common stock contained in our registration statements on Form 8-A (File No. 1-19871) filed under the Exchange Act, including any amendment or report filed for the purpose of updating such description; and

Our Current Reports on Form 8-K filed with the SEC on November 1, 2005, October 20, 2005, September 27, 2005, September 8, 2005, September 1, 2005, August 3, 2005, July 6, 2005, April 27, 2005, March 15, 2005, March 4, 2005, February 1, 2005 and January 11, 2005.

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Any statement made in a document incorporated by reference or deemed incorporated herein by reference is deemed to be modified or superseded for purposes of this prospectus if a statement contained in this prospectus or in any other subsequently filed document which is also incorporated or deemed incorporated by reference herein modifies or supersedes that statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. We also incorporate by reference all documents filed pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the termination of this offering; provided, however, that we are not incorporating any information furnished under any of Item 2.02 or Item 7.01 of any current report on Form 8-K.

Statements made in this prospectus or in any document incorporated by reference in this prospectus as to the contents of any contract or other document referred to herein or therein are not necessarily complete, and in each instance reference is made to the copy of such contract or other document filed as an exhibit to the documents incorporated by reference, each such statement being qualified in all material respects by such reference.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address:

StemCells, Inc.
3155 Porter Drive
Palo Alto, Ca 94304
Attention: Investor Relations
Phone: (650) 475-3100
email: irpr@stemcellsinc.com

Copies of these filings are also available, without charge, on our Internet website at www.stemcellsinc.com as soon as reasonably practicable after they are filed electronically with the SEC.

LEGAL OPINION

For the purpose of this offering, Ropes & Gray LLP, Boston, Massachusetts, is giving its opinion on the validity of the securities offered hereby.

EXPERTS

The financial statements incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K for each of the two years ended December 31, 2003 and 2004 have been audited by Grant Thornton LLP, independent registered public accounting firm, as stated in their reports, each of which is incorporated herein by reference and has been so incorporated in reliance upon such reports given upon their authority as experts in accounting and auditing.

The financial statements of StemCells, Inc. for the year ended December 31, 2002 appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2004, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

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PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF DISTRIBUTION

| | |
|-------------------------------|----------------|
| SEC registration fee | \$ 11,770 |
| Blue sky fees and expenses* | \$ 1,000 |
| Legal fees and expenses* | \$ 50,000 |
| Printing expenses* | \$ 10,000 |
| Accounting fees and expenses* | \$ 25,000 |
| Miscellaneous* | \$ 5,000 |
| Total expenses* | \$ 102,770 |

* Estimated

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Section 145 of the Delaware General Corporation Law (DGCL) provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal or investigative (other than an action by or in the right of the corporation) by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorney s fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

Section 145 further provides that a corporation similarly may indemnify any such person serving in any such capacity who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor, against expenses actually and reasonably incurred in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or such other court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Section 102(b)(7) of the DGCL permits a corporation to include in its certificate of incorporation a provision eliminating or limiting the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director s duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL (relating to unlawful payment of dividends and unlawful stock purchase and redemption) or (iv) for any transaction from which the director derived an improper personal benefit.

The Registrant s Certificate provides that the Company s Directors shall not be liable to the Registrant or its stockholders for monetary damages for breach of fiduciary duty as a director except to the extent that exculpation from liabilities is not permitted under the DGCL as in effect at the time such liability is determined. The Registrant s Certificate further provides that the Registrant shall indemnify its directors and officers to the fullest extent permitted by the DGCL.

The Company has a liability insurance policy in effect which covers certain claims against any officer or director of the Company by reason of certain breaches of duty, neglect, errors or omissions committed by such person in his or her capacity as an officer or director.

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ITEM 16. EXHIBITS

- 5.1 Opinion of Ropes & Gray LLP (1)

- 23.1 Consent of Ernst & Young LLP, independent registered public accounting firm (2)

- 23.2 Consent of Grant Thornton LLP, independent registered public accounting firm (2)

- 23.3 Consent of Ropes & Gray LLP (included in the opinion filed as Exhibit 5.1)

(1) Previously filed.

ITEM 17. UNDERTAKINGS

a. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions set forth in Item 15 above, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

b. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

c. The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

a. To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

b. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement;

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c. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; PROVIDED, HOWEVER, that paragraphs (c)(1)(a) and (c)(1)(b) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Palo Alto, State of California, on the 3rd day of November, 2005.

StemCells, Inc.

By: /s/ Martin M. McGlynn
 Name: Martin M. McGlynn
 Title: President and Chief Executive
 Officer
 * * * *

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

| Signature | Title | Date |
|--|---|------------------|
| /s/ Martin M. McGlynn Martin M. McGlynn | President, Chief Executive Officer and Director (principal executive officer) | November 3, 2005 |
| /s/ Rodney K.B. Young Rodney K.B. Young | Chief Financial Officer (principal financial officer) | November 3, 2005 |
| /s/ George Koshy George Koshy | Controller (principal accounting officer) | November 3, 2005 |
| /s/ John J. Schwartz, Ph.D.* John J. Schwartz, Ph.D | Chairman | November 3, 2005 |
| /s/ Eric H. Bjerkholt* Eric H. Bjerkholt | Director | November 3, 2005 |
| /s/ Ricardo B. Levy, Ph.D.* Ricardo b. Levy, Ph.D | Director | November 3, 2005 |
| /s/ Roger M. Perlmutter, M.D., Ph.D.* Roger M. Perlmutter M.D., Ph.D. | Director | November 3, 2005 |
| /s/ Irving L. Weissman, M.D.* Irving L. Weissman, M.D. | Director | November 3, 2005 |

*By: /s/ Martin M. McGlynn

Martin M. McGlynn
 Attorney-in-fact

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EXHIBIT INDEX

Exhibit

| No. | Title of Exhibit |
|------|--|
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| 23.2 | Consent of Grant Thornton LLP, independent registered public accounting firm (2) |
| 23.3 | Consent of Ropes & Gray LLP (included in the opinion filed as Exhibit 5.1) |

(1) Previously filed.

(2) Filed herewith.