Neuralstem, Inc. Form 424B3 April 07, 2009

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**PROSPECTUS** 

#### NEURALSTEM, INC.

#### 1,984,672 Shares of Common Stock

This prospectus relates to the resale of up to 1,984,672 shares of our common stock being offered by the selling shareholders listed on page 13. We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders.

Our shares of common stock are quoted on The American Stock Exchange under the symbol "CUR" The average of the high and low price of our common stock on January 27, 2009, was \$1.58.

Our principal executive offices are located at 9700 Great Senecca Highway, Rockville, MD, telephone number 301-366-4841.

Investing in our common stock involves a high degree of risk. You are urged to read the section entitled "Risk Factors" beginning on page 3; of this prospectus, which describes specific risks and other information that should be considered before you make an investment decision.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED THESE SECURITIES, OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The Date of this Prospectus is April 7, 2009

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#### PROSPECTUS SUMMARY

The summary below highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding to invest in our securities. We urge you to read this entire prospectus carefully, including the" Risk Factors" section and the consolidated financial statements and related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, filed with the Securities and Exchange Commission ("SEC") on March 27, 2008 as well as all subsequent Quarterly Reports on Form 10-Q. As used in this prospectus, unless context otherwise requires, the words "we," "us," "our," "the Company" and "Neuralstem" refer to Neuralstem, Inc. Also, any reference to "common shares," "Common Stock," "common shares" or "Common Shares" refers to our \$.01 par value common stock.

#### Overview

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

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts in the area of neural stem cell research. We own or exclusively license four (4) issued patents and thirteen (13) patent pending applications in the field of regenerative medicine and related technologies. We believe our technology base, in combination with our know-how, and collaborative projects with major research institutions provides a competitive advantage and will facilitate the successful development and commercialization of products for use in the treatment of a wide array of neurodegenerative conditions and in regenerative repair of acute disease.

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

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

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

#### Technology

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

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

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

#### Research

We have devoted substantial resources to our research programs in order to isolate and develop a series of neural stem cell banks that we believe can serve as a basis for therapeutic products. Our efforts to date have been directed at methods to identify, isolate and culture large varieties of stem cells of the human nervous system, and to develop therapies utilizing these stem cells. This research is conducted both internally and through the use of third party laboratory consulting companies under our direct supervision.

### **Employees and Location**

As of January 23, 2009, we had 7 full-time employees. Of these employees, three work on research and development and four in administration. We also use the services of numerous outside consultants in business and scientific matters. We believe that we have good relations with our employees and consultants.

Our principal executive offices are located at 9700 Great Senecca Highway, Rockville, MD, telephone number 301-366-4841.

#### THE OFFERING

Common stock being offered by Selling

Shareholders

Up to 1,984,672 shares

American Stock Exchange Symbol

Risk Factors The securities offered by this prospectus are speculative

**CUR** 

and involve a high degree of risk and investors purchasing securities should not purchase the securities unless they can afford the loss of their entire investment.

See "Risk Factors" beginning on page 3.

Use of Proceeds We will not receive any proceeds from the sale of the

common shares by the Selling Shareholders. In the event the warrants held by the Selling Shareholders are exercised for cash, we will receive approximately \$2,519,840. The proceeds, if any, will be used for

general working capital.

#### FORWARD LOOKING STATEMENTS

This prospectus, and the documents incorporated into it by reference, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), which are intended to convey our expectations or predictions regarding the occurrence of possible future events or the existence of trends and factors that may impact our future plans and operating results. These forward-looking statements are derived, in part, from various assumptions and analyses we have made in the context of our current business plan and information currently available to us and in light of our experience and perceptions of historical trends, current conditions and expected future developments and other factors we believe are appropriate in the circumstances. You can generally identify forward looking statements through words and phrases such as "believe", "expect", "seek", "estimate", "anticipate", "intend", "plan", "budget", "project", "may likely result", "may be", "may cont similar expressions.

When reading any forward-looking statement you should remain mindful that actual results or developments may vary substantially from those expected as expressed in or implied by such statement for a number of reasons or factors, including but not limited to:

- the success of our research and development activities, the development of a viable commercial product, and the speed with which regulatory authorizations and product launches may be achieved;
- whether or not a market for our product develops and, if a market develops, the rate at which it develops;
- · our ability to successfully sell our products if a market develops;
- · our ability to attract and retain qualified personnel to implement our growth strategies;
- · our ability to develop sales, marketing, and distribution capabilities;
- our ability to obtain reimbursement from third party payers for our proposed products if and when they are developed;
- the accuracy of our estimates and projections;
- · our ability to fund our short-term and long-term financing needs;
- · changes in our business plan and corporate strategies; and
- · other risks and uncertainties discussed in greater detail in the section captioned "Risk Factors"

Each forward-looking statement should be read in context with and in understanding of the various other disclosures concerning our company and our business made elsewhere in this Prospectus as well as our public filings with the SEC. You should not place undue reliance on any forward-looking statement as a prediction of actual results or developments. We are not obligated to update or revise any forward-looking statements contained in this Prospectus or any other filing to reflect new events or circumstances unless and to the extent required by applicable law.

# RISK FACTORS THAT MAY AFFECT OUR FUTURE RESULTS AND FINANCIAL CONDITION

We have described below a number of uncertainties and risks which, in addition to uncertainties and risks presented elsewhere in this Prospectus, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Prospectus should be considered carefully in evaluating our company and our business and the value of our securities.

Risks Relating to the Company's Stage of Development

Since the Company has a limited operating history and has significantly shifted its operations and strategies since inception, you cannot rely upon the Company's limited historical performance to make an investment decision.

Since inception in 1996 and through September 30, 2008, the Company has raised in aggregate, approximately \$58,646,554 of capital and recorded accumulated losses totaling \$54,066,078. On September 30, 2008, the Company had a working capital surplus of \$4,190,762 and stockholders' equity of \$4,580,476. Our net losses for the two most recent fiscal years have been \$7,063,272 and \$3,147,488 for 2007 and 2006 respectively. Our net loss for the nine month period ended September 30, 2008 was \$8,410,081. We had no revenues for the nine months ended September 30, 2008.

The Company's ability to generate revenues and achieve profitability depends upon its ability to complete the development of its stem cell products, obtain the required regulatory approvals, and manufacture, market and sell its products. In part because of the Company's past operating results, no assurances can be given that the Company will be able to accomplish all or any these goals.

Although the Company has generated some revenue to date, the Company has not generated any revenue from the commercial sale of its proposed stem cell products. Since inception, the Company has engaged in several related lines of business and has discontinued operations in certain areas. For example, in 2002, the Company lost a material contract with the Department of Defense and was forced to close its principal facility and lay off almost all of its employees in an attempt to focus the Company's strategy on its stem cell technology. This limited and changing history may not be adequate to enable you to fully assess the Company's current ability to develop and commercialize its technologies and proposed products, obtain approval from the U.S. Food and Drug Administration ("FDA"), achieve market acceptance of its proposed products and respond to competition. No assurances can be given as to exactly when, if at all, the Company will be able to fully develop, commercialize, market, sell and derive material revenues from its proposed products in development.

The Company will need to raise additional capital to continue operations, and failure to do so will impair the Company's ability to fund operations, develop its technologies and proposed products.

The Company has relied almost entirely on external financing to fund operations. Such financing has historically come primarily from the sale of common stock, and the exercise of investor warrants. As of December 31, 2008, the Company had cash and cash equivalents on hand of approximately \$5.0 million. Presently, the Company has a monthly cash burn rate of approximately \$700,000. The accelerated spending of the previous months reflects the effort to complete work on its Investigative New Drug Application ("IND"). Much of that work has been completed and so spending rates not related to clinical trials will fall. The Company will need to raise additional capital to fund anticipated operating expenses and future expansion. Among other things, external financing will be required to cover the further development of the Company's technologies and products and other operating costs. On December 18, 2008, the Company filed its first IND to commence clinical trials of one of its proposed products. In the event the IND is approved, the Company expects additional coast related to the trials to be phased in slowly over a year. Neuralstem has 2,416,000 warrants with strike price of \$1.25 which are callable by the company when the FDA approves clinical trials on humans. If all these warrants are exercise the Company would raise \$3 million. The Company cannot assure you that financing whether from external sources or related parties will be available if needed or on favorable terms. If additional financing is not available when required or is not available on acceptable terms, the Company may be unable to fund operations and planned growth, develop or enhance its technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on the Company's operations may make capital raising more difficult and may also resulting a lower price for the Company's securities.

The Company may have difficulty raising needed capital in the future as a result of, among other factors, the Company's limited operating history and business risks associated with the Company.

The Company's business currently generates limited amounts of cash which will not be sufficient to meet its future capital requirements. The Company's management does not know when this will change. The Company has expended and will continue to expend substantial funds in the research, development and clinical and pre-clinical testing of the Company's stem cell technologies and products with the goal of ultimately obtaining FDA approval. The Company will require additional funds to conduct research and development, establish and conduct clinical and pre-clinical trials and commercial-scale manufacturing arrangements and to provide for marketing and distribution. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable, the Company may have to delay, reduce the scope of or eliminate one or more of its research, development or commercialization programs, which may materially harm the Company's business, financial condition and results of operations.

The Company's long term capital requirements are expected to depend on many factors, including:

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

The Company may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. The Company may seek to raise any necessary additional funds through the exercising of warrants, options, equity or debt financings, collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on the Company's current or future business prospects. If adequate funds are not available, the Company may be required to significantly reduce or refocus its development and commercialization efforts.

The Company's additional financing requirements could result in dilution to existing stockholders.

At present, the Company is not able to finance it operations because it does not sell any products. Accordingly, the Company will be required to secure additional financing. If the Company is able to obtain such additional financings such financing may be dilutive to current shareholders. The Company has the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of capital stock, or debt obligations which may be convertible into any one or more classes or series of capital stock. The Company is authorized to issue 150,000,000 shares of common stock and 7,000,000 shares of preferred stock. Such securities may generally be issued without the approval or other consent of the Company's stockholders.

Risks Relating to Intellectual Property and Government Regulation

The Company may not be able to withstand challenges to its intellectual property rights, such as patents, should contests be initiated in court or at the U.S Patent and Trademark Office.

The Company relies on its intellectual property, including its issued and applied-for patents, as the foundation of its business. The intellectual property rights of the Company may come under challenge, and no assurances can be given that, even though issued, the Company's current and potential future patents will survive claims commencing in the court system alleging invalidity or infringement of other patents. For example, in 2005, the Company's neural stem cell technology was challenged in the U.S. Patent and Trademark Office. Although the Company prevailed in this particular matter upon re-examination by the patent office, these cases are complex, lengthy and expensive, and could potentially be adjudicated adversely to the Company, removing the protection afforded by an issued patent. The viability of the Company's business would suffer if such patent protection were limited or eliminated. Moreover, the costs associated with defending or settling intellectual property claims would likely have a material adverse effect on the Company. At present, there is new litigation with StemCells, Inc. which is in its initial stages and any likely outcome is difficult to predict. It is not known when nor on what basis the litigation with StemCells, Inc. will be concluded.

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

Considerable research in the area of stem cell therapies is being performed in countries outside of the United States, and a number of the Company's competitors are located in those countries. The laws protecting intellectual property in some of those countries may not provide protection for the Company's trade secrets and intellectual property adequate to prevent its competitors from misappropriating the Company's trade secrets or intellectual property. If the Company's trade secrets or intellectual property are misappropriated in those countries, the Company may be without adequate remedies to address the issue and its business may be materially impacted.

The Company's products may not receive FDA approval, which would prevent the Company from commercially marketing its products and producing revenues.

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacture and marketing of pharmaceutical products through lengthy and detailed laboratory, pre-clinical and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these

regulations typically takes several years or more and varies substantially based upon the type, complexity and novelty of the proposed product. On December 18, 2008, the Company submitted its first IND, application to the FDA. The Company cannot assure you when or if such IND application will be granted. Nor can the Company assure you that if the IND is granted, whether the Company will successfully complete any clinical trials in connection with such IND application. Further, the Company cannot yet accurately predict when it might first submit any product license application for FDA approval or whether any such product license application would be granted on a timely basis, if at all. As a result, the Company cannot assure you that FDA approvals for any products developed by it will be granted on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals could have a material adverse effect on the marketing of the Company's products and its ability to generate product revenue.

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

Our research and development efforts, as well as any future clinical trials, and the manufacturing and marketing of any products we may develop, will be subject to, and restricted by, extensive regulation by governmental authorities in the United States and other countries. The process of obtaining FDA and other necessary regulatory approvals is lengthy, expensive and uncertain. FDA and other legal and regulatory requirements applicable to the development and manufacture of the cells and cell lines required for our preclinical and clinical products could substantially delay or prevent us from producing the cells needed to initiate additional clinical trials. We or our collaborators may fail to obtain the necessary approvals to commence clinical testing or to manufacture or market our potential products in reasonable time frames, if at all. In addition, the U.S. Congress and other legislative bodies may enact regulatory reforms or restrictions on the development of new therapies that could adversely affect the regulatory environment in which we operate or the development of any products we may develop.

We base our research and development on the use of human stem cells obtained from human tissue. The U.S. federal and state governments and other jurisdictions impose restrictions on the acquisition and use of human tissue, including those incorporated in federal Good Tissue Practice, or cGTP, regulations. These regulatory and other constraints could prevent us from obtaining cells and other components of our products in the quantity or of the quality needed for their development or commercialization. These restrictions change from time to time and may become more onerous. Additionally, we may not be able to identify or develop reliable sources for the cells necessary for our potential products — that is, sources that follow all state and federal laws and guidelines for cell procurement. Certain components used to manufacture our stem and progenitor cell product candidates will need to be manufactured in compliance with the FDA's Good Manufacturing Practices, or cGMP. Accordingly, we will need to enter into supply agreements with companies that manufacture these components to cGMP standards. There is no assurance that we will be able to enter into any such agreements.

Noncompliance with applicable requirements both before and after approval, if any, can subject us, our third party suppliers and manufacturers and our other collaborators to administrative and judicial sanctions, such as, among other things, warning letters, fines and other monetary payments, recall or seizure of products, criminal proceedings, suspension or withdrawal of regulatory approvals, interruption or cessation of clinical trials, total or partial suspension of production or distribution, injunctions, limitations on or the elimination of claims we can make for our products, refusal of the government to enter into supply contracts or fund research, or government delay in approving or refusal to approve new drug applications.

Because the Company must obtain regulatory approval to market the products in the United States and other countries, the Company cannot predict whether or when it will be permitted to commercialize its products.

Federal, state and local governments and agencies in the United States (including the FDA) and governments in other countries have significant regulations in place that govern many of the Company's activities. The Company is or may become subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with its research and development work. The preclinical testing and clinical trials of the products that the Company is proposing to develop are subject to extensive government regulation that may prevent the Company from creating commercially viable products from its discoveries. In addition, the sale by the Company of any commercially viable product will be subject to government regulation from several standpoints, including manufacturing, advertising, marketing, promoting, selling, labeling and distributing. If, and to the extent that, the Company is unable to comply with these regulations, its ability to earn revenues will be materially and negatively impacted.

Risks Relating to the Company's Business

The Company relies on stem cell technologies that it may not be able to commercially develop, which will prevent the Company from generating revenues, operating profitably or providing investors any return on their investment.

The Company has concentrated its research on its stem cell technologies, and the Company's ability to generate revenue and operate profitably will depend on it being able to develop these technologies for human applications. These are emerging technologies with, as yet, limited human applications. The Company cannot guarantee that it will be able to develop its stem cell technologies or that such development will result in products or services with any significant commercial utility. The Company anticipates that the commercial sale of such products or services, and royalty/licensing fees related to its technology, will be the Company's primary sources of revenues. If the Company is unable to develop its technologies, investors will likely lose their entire investment.

Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of these therapies creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third party reimbursement, and market acceptance. For example, the pathway to regulatory approval for cell-based therapies, including our product candidates, may be more complex and lengthy than the pathway for conventional drugs. These challenges may prevent us from developing and commercializing products on a timely or profitable basis or at all.

Our Inability to complete pre-clinical and clinical testing and trials will impair the viability of the Company.

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

Because the results of preclinical studies are not necessarily predictive of future results, we can provide no assurances that, even if our product candidates are successful in preclinical studies, such product candidates will have favorable results in clinical trials or receive regulatory approval.

Positive results from preclinical studies should not be relied upon as evidence that clinical trials will succeed. Even if our product candidates achieve positive results in clinical studies, we will be required to demonstrate through clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. If any product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, then we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon our development efforts of any of our product candidates, then we may not be able to generate sufficient revenues to become profitable, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.

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

Our product candidates will require preclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. Delays in the commencement of clinical testing of our product candidates could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

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

• delays in demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;

•

delays in reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

- delays in manufacturing quantities of a product candidate sufficient for clinical trials;
- delays in obtaining approval of an Investigational New Drug Application ("IND") from the United States Food and Drug Administration ("FDA") or similar foreign approval;
- delays in obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- Insufficient financial resources.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial.

Even if we successfully initiate and complete clinical trials for any product candidate, there are no assurances that we will be able to submit or obtain FDA approval of a biologics license application.

There can be no assurance that if our clinical trials of any potential product candidate are successfully initiated and completed, we will be able to submit an Biologics License Application ("BLA") to the FDA or that any BLA we submit will be approved by the FDA in a timely manner, if at all. If we are unable to submit a BLA with respect to any future product candidate, or if any BLA we submit is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject BLAs and requires additional clinical trials, even when product candidates performed well or achieved favorable results in clinical trials. If we fail to commercialize any future product candidate in clinical trials, we may be unable to generate sufficient revenues to attain profitability and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

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

The manufacturing of cell-based therapeutic products is a complicated and difficult process, dependent upon substantial know-how and subject to the need for continual process improvements to be competitive. We depend almost exclusively on third party manufacturers to supply our cells. In addition, our suppliers' ability to scale-up manufacturing to satisfy the various requirements of our planned clinical trials, such as GTP, GMP and release testing requirements, is uncertain. Manufacturing irregularities or lapses in quality control could have a serious adverse effect on our reputation and business, which could cause a significant loss of stockholder value. Many of the materials that we use to prepare our cell-based products are highly specialized, complex and available from only a limited number of suppliers or are derived from a biological origin. At present, some of our material requirements are single sourced, and the loss of one or more of these sources may adversely affect our business if we are unable to obtain alternatives or alternative sources at all or upon terms that are acceptable to us.

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

The use of stem cells for research and therapy has been the subject of debate regarding related ethical, legal and social issues. Negative public attitudes toward stem cell therapy could result in greater governmental regulation of stem cell therapies, which could harm our business. For example, concerns regarding such possible regulation could impact our ability to attract collaborators and investors. Existing and potential U.S. government regulation of human tissue may lead researchers to leave the field of stem cell research or the country altogether, in order to assure that their careers will not be impeded by restrictions on their work. Similarly, these factors may induce graduate students to choose other fields less vulnerable to changes in regulatory oversight, thus exacerbating the risk that we may not be able to attract and retain the scientific personnel we need in the face of competition among pharmaceutical, biotechnology and health care companies, universities and research institutions for what may become a shrinking class of qualified individuals.

The Company may be subject to litigation that will be costly to defend or pursue and uncertain in its outcome.

The Company's business may bring it into conflict with its licensees, licensors, or others with whom it has contractual or other business relationships or with its competitors or others whose interests differ from the Company's. If the Company is unable to resolve those conflicts on terms that are satisfactory to all parties, the Company may become involved in litigation brought by or against it. That litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of the Company's business. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require the Company to pay damages, enjoin it from certain activities, or otherwise affect its legal or contractual rights, which could have a significant adverse effect on its business. By way of example, in May of 2008, we filed a complaint against StemCells Inc., alleging that U.S. Patent No. 7,361,505 (the "'505 patent"), allegedly exclusively licensed to StemCells, Inc., is invalid, not infringed and unenforceable. On the same day, StemCells, Inc. filed a complaint alleging that we had infringed, contributed to the infringement of, and or induced the infringement of two patents owned by or exclusively licensed to StemCells relating to stem cell culture compositions. At present, the litigation is in its initial stages and any likely outcome is difficult to predict.

The Company may not be able to obtain third-party patient reimbursement or favorable product pricing, which would reduce its ability to operate profitably.

The Company's ability to successfully commercialize certain of its proposed products in the human therapeutic field may depend to a significant degree on patient reimbursement of the costs of such products and related treatments at acceptable levels from government authorities, private health insurers and other organizations, such as health

maintenance organizations. The Company cannot assure you that reimbursement in the United States or foreign countries will be available for any products it may develop or, if available, will not be decreased in the future, or that reimbursement amounts will not reduce the demand for, or the price of, its products with a consequent harm to the Company's business. The Company cannot predict what additional regulation or legislation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such regulation or legislation may have on the Company's business. If additional regulations are overly onerous or expensive or if health care related legislation makes its business more expensive or burdensome than originally anticipated, the Company may be forced to significantly downsize its business plans or completely abandon its business model.

The Company's products may be expensive to manufacture, and they may not be profitable if the Company is unable to control the costs to manufacture them.

The Company's products may be significantly more expensive to manufacture than most other drugs currently on the market today due to a fewer number of potential manufacturers, greater level of needed expertise and other general market conditions affecting manufacturers of stem cell based products. The Company would hope to substantially reduce manufacturing costs through process improvements, development of new science, increases in manufacturing scale and outsourcing to experienced manufacturers. If the Company is not successful in these and other initiatives, and depending on the pricing of the product, its profit margins may be significantly less than that of most drugs on the market today. In addition, the Company may not be able to charge a high enough price for any cell therapy product it develops, even if they are safe and effective, to make a profit. If the Company is unable to realize significant profits from its potential product candidates, its business would be materially harmed.

In order to secure market share and generate revenues, the Company's proposed products must be accepted by the health care community, which can be very slow to adopt or unreceptive to new technologies and products.

The Company's proposed products and those developed by its collaborative partners, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept and utilize these products. The products that the Company is attempting to develop represent substantial departures from established treatment methods and will compete with a number of more conventional drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any of the Company's developed products will depend on a number of factors, including:

- the Company's establishment and demonstration to the medical community of the clinical efficacy and safety of its proposed products;
- the Company's ability to create products that are superior to alternatives currently on the market;
- the Company's ability to establish in the medical community the potential advantage of its treatments over alternative treatment methods; and