

ATHERSYS, INC / NEW
Form 10-K
March 13, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark one)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2013

OR

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

For the transition period from _____ to _____

Commission file number 001-33876

Athersys, Inc.

(Exact name of registrant as specified in its charter)

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<p>Delaware (State or other jurisdiction of incorporation or organization)</p> <p>3201 Carnegie Avenue,</p> <p>Cleveland, Ohio (Address of principal executive offices)</p> <p>Registrant's telephone number, including area code (216) 431-9900</p>	<p>20-4864095 (I.R.S. Employer Identification No.)</p> <p>44115-2634 (Zip Code)</p>
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Securities registered pursuant to Section 12(b) of the Act:

<p>Title of each class Common Stock, par value \$0.001 per share</p>	<p>Name of each exchange on which registered NASDAQ Stock Market LLC</p>
<p>Securities registered pursuant to Section 12(g) of the Act: None</p>	

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. Yes No

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>

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

The aggregate market value at June 28, 2013, the last business day of the registrant's most recently completed second fiscal quarter, of shares of the registrant's common stock (based upon the closing price per share of \$1.66 of such stock as quoted on the NASDAQ Capital Market on such

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date) held by non-affiliates of the registrant was approximately \$89.4 million.

The registrant had 76,633,698 shares of common stock outstanding on March 1, 2014.

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PART I

ITEM 1. BUSINESS.

We are an international biotechnology company that is focused primarily in the field of regenerative medicine. We are committed to the discovery and development of best-in-class therapies designed to extend and enhance the quality of human life. We have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. Our MultiStem[®] cell therapy, a patented and proprietary allogeneic stem cell product, is our lead platform product and has been evaluated in two completed Phase 1 clinical trials and is currently being evaluated in two ongoing Phase 2 clinical trials, as well as an investigator-led Phase 1 trial. Our current clinical development programs are focused on treating inflammatory and immune disorders, neurological conditions, cardiovascular disease, and other conditions. We are also applying our pharmaceutical discovery capabilities to identify and develop small molecule compounds with potential applications in indications such as obesity, related metabolic conditions and certain neurological conditions. These represent major areas of clinical need, as well as substantial commercial opportunities.

We believe our MultiStem therapy represents a breakthrough in the field of regenerative medicine and stem cell therapy and could be used to treat a range of disease indications. MultiStem treatment enhances tissue repair and healing in multiple ways, including reducing inflammatory damage, protecting tissue that is at risk following acute or ischemic injury, and promoting formation of new blood vessels in regions of ischemic injury. These cells appear to be responsive to the environment in which they are administered, by homing to sites of injury and providing active disease response, while producing proteins that may provide benefit in both acute and chronic conditions. In contrast to traditional pharmaceutical products or biologics that generally act through a single biological mechanism of action, MultiStem therapy can enhance healing and tissue repair through multiple distinct mechanisms acting in parallel, such as by producing a range of therapeutic factors and dynamically responding to the needs of the body, resulting in a more effective therapeutic response.

The MultiStem product is unique among regenerative medicine approaches because it can be manufactured on a large scale, may be administered in an off-the-shelf manner with minimal processing, and can augment healing in multiple ways, providing biological potency and therapeutic effects that other cell therapy approaches may not be able to achieve. Additionally, MultiStem treatment has demonstrated a consistent safety profile in both preclinical and clinical studies. Like drugs and biologics, the product is cleared from the body over time, enhancing product safety relative to other types of stem cell therapy. While the product does not permanently engraft in the patient, the therapeutic effects of treatment with MultiStem cells appear to be quite durable.

We believe the therapeutic and commercial potential for MultiStem therapy to be very broad, applying to many areas of significant unmet medical need. We are pursuing opportunities in several potential multi-billion dollar markets. While traditional pharmaceuticals and traditional biologic therapies typically may be used to treat only a single disease or a narrowly defined set of related conditions, MultiStem cells appear to have far broader potential and could be developed in different formulations and with different delivery approaches to effectively treat a range of disease indications.

We have evaluated the use of MultiStem cells as a potential treatment in several disease areas. Working with an international network of leading investigators and prominent research and clinical institutions, and through our own internal efforts, we have explored the potential for MultiStem therapy to be used as a treatment of acute and chronic forms of inflammatory and immune disorders, neurological conditions, cardiovascular disease, certain pulmonary conditions and other areas of unmet medical need.

To date, we have successfully advanced MultiStem therapies into five clinical stage programs, which address areas of significant medical need and represent major commercial market opportunities. MultiStem cells have been evaluated as a potential treatment for heart attack patients in a completed Phase 1 clinical trial. We are preparing to initiate a Phase 2 clinical study late in 2014 for the administration of MultiStem cells to patients that have suffered a myocardial infarction. In 2013, we were awarded a grant from the National Institutes of Health for up to \$2.8 million to support funding this clinical program. Additionally, we have evaluated in a completed Phase 1 clinical study the potential for MultiStem therapy to prevent or reduce graft-versus-host disease, or GvHD, and other complications, and to provide supportive care to patients undergoing a hematopoietic stem cell transplant to treat leukemia or related conditions. We are preparing to advance our GvHD program into the next phase of clinical development and have had several interactions with the United States Food and Drug Administration, or FDA, and similar international agencies regarding study design and the potential to accelerate the path to product approval. Based on current plans, we are preparing to start this Phase 2/3 study in 2014, but the initiation will depend on the progress in other clinical trials and the achievement of certain business development and financial objectives. Our MultiStem therapy for GvHD has been designated an orphan drug by both the FDA and the European Medicines Agency, or EMA, which may provide market exclusivity and other substantial potential incentives and benefits.

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MultiStem therapy is also being evaluated in several other ongoing clinical trials. Our partner, Pfizer Inc., or Pfizer, is conducting a Phase 2 clinical study of MultiStem cells administered to patients with ulcerative colitis, or UC, a common form of inflammatory bowel disease, or IBD. We announced enrollment completion in December 2013, and we anticipate that preliminary results will be announced in the spring of 2014. In another Phase 2 trial, we are evaluating the potential for MultiStem treatment of patients who have suffered neurological damage from an ischemic stroke. We are targeting to complete enrollment, which is taking place in the United States and Europe, around the end of summer 2014 and release of the preliminary results as soon as they are available. Finally, a research collaborator and leading transplantation center in Europe is conducting a small, exploratory institutional-sponsored Phase 1 study to evaluate the administration of MultiStem cells to patients undergoing a liver transplant.

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Our development approach has historically involved establishing collaborative relationships with leading research and clinical centers in the United States and internationally. This has enabled us to methodically advance multiple programs in areas of defined unmet medical need in a resource efficient manner. Furthermore, by emphasizing the potential application of our technologies in areas of significant clinical need, we believe we are well positioned to utilize recent regulatory initiatives that are designed to promote the rapid and cost effective development of innovative new therapies. These include recent initiatives in the United States being implemented by the FDA involving the broadened application of the accelerated approval pathway, and the new Breakthrough Therapies framework, as well as the new accelerated Regenerative Medicine regulatory framework in Japan that could enable rapid conditional authorization of regenerative medicine therapies. We believe such initiatives could accelerate the development and commercialization of products like MultiStem cells, if clinical results demonstrate appropriate safety and therapeutic effectiveness, thereby increasing shareholder value.

In addition to our MultiStem programs, we have applied our pharmaceutical discovery capabilities to identify and develop novel pharmaceuticals to treat obesity, related metabolic conditions such as diabetes, and certain neurological indications such as schizophrenia. Further, small molecule compounds that may be used to enhance the production or therapeutic effectiveness of MultiStem or related products are under development. These compounds may increase biological potency for certain indications and lead to second or third generation products in the regenerative medicine area. Our 5HT2c agonist program for obesity works by the same mechanism as Lorcaserin[®], which was approved by the FDA in 2012 for the treatment of obesity. We believe our compounds may have the potential for providing superior weight loss performance, while also achieving a superior safety and tolerability profile. In addition, we have demonstrated that our compounds are complementary with other agents that have been approved by the FDA for treating obesity. Furthermore, we have evaluated certain compounds in preclinical models of schizophrenia that exhibit an attractive selectivity profile and also observed that these compounds exhibit potent effects. We may elect to enter into a partnership to advance the development of our 5HT2c agonist program, either for the treatment of obesity, schizophrenia, or both indications, as well as for certain programs involving MultiStem.

We were incorporated in Delaware on October 24, 1995. On June 8, 2007, we merged with a wholly owned subsidiary of BTHC VI, Inc., a Delaware corporation, and, on August 31, 2007, BTHC VI, Inc. changed its name to Athersys, Inc.

Business Strategy

Our principal business objective is to discover, develop and commercialize novel therapeutic products for disease indications that represent significant areas of clinical need and commercial opportunity. The key elements of our strategy are outlined below:

Efficiently Conduct Clinical Development to Establish Clinical Proof of Concept and Biological Activity with our Lead Product Candidates. We are conducting a number of clinical studies with the intent to establish proof of concept and/or proof of biological activity in a number of important disease areas where the cell therapies would be expected to have benefit in inflammatory and immune system dysfunctions, neurological conditions and cardiovascular disease. Our focus is on conducting well-designed studies early in the clinical development process to establish a robust foundation for subsequent development, partnering activity and expansion into complementary areas. We are committed to a rigorous clinical and regulatory framework, which we believe has helped us to advance our programs efficiently, providing high quality, transparent regulatory submissions. Our discussions with the FDA have resulted in a successful regulatory partnership that has helped to advance our programs efficiently.

Continue to Refine and Improve our Manufacturing and Related Processes and Deepen our Understanding of Therapeutic Mechanisms of Action. A key aspect of MultiStem cells is their expansion capacity *ex vivo* relative to other cell types. This allows for large scale production of the clinical product, which enables greater consistency, specificity and cost of goods advantages over other cell therapies. We plan to build on this intrinsic biological advantage by continuing to advance and optimize our production and process development approaches, further developing new manufacturing techniques including our bioreactor platform, and optimizing the plant-to-bedside supply chain to support late-stage development and commercialization of MultiStem therapy. Additionally, we will continue to refine our understanding of our products' activities and mechanisms of action to enable optimization of administration and dosing and to prepare the foundation for product enhancements and next generation opportunities.

Enter into Arrangements with Business Partners to Accelerate Development and Value Creation. In addition to our internal development efforts, an important part of our product development strategy is to work with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercial access. We have entered into licensing and product co-development arrangements with qualified commercial partners to achieve these

objectives. We anticipate that this strategy will help us to develop a portfolio of high quality product development opportunities, enhance

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our clinical development and commercialization capabilities, and increase our ability to generate value from our proprietary technologies. Over the past decade, we have entered into technology licensing arrangements and established product commercialization and co-development partnerships with companies such as Pfizer, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Johnson & Johnson, Wyeth Pharmaceuticals, Inc., Angiotech Pharmaceuticals, Inc., or Angiotech, and RTI Surgical, Inc., or RTI. Licensing partnerships generate revenue and provide capital that allows us to advance our programs further in development.

Efficiently Explore New High Potential Therapeutic Applications, Leveraging Third-Party Research Collaborations and our Results from Related Areas. Our product candidates have shown promise in multiple disease areas, including in treating inflammatory and immune disorders, neurological conditions, cardiovascular disease, and other areas. We are committed to exploring potential clinical indications where our therapies may achieve best-in-class profile, and where we can effectively address significant unmet medical needs. In order to achieve this goal, over the past decade, we have established collaborative research relationships with investigators from many leading research and clinical institutions across the United States and Europe, including the Cleveland Clinic, Case Western Reserve University, University of Minnesota, Georgia Regents University, the University of Oregon Health Sciences Center, the University of Texas Health Science Center at Houston, the University of Pittsburgh Medical Center, the Katholieke Universiteit Leuven, or KUL, University of Regensburg, and other institutions. Through this network of collaborations, we have studied MultiStem therapy in a range of preclinical models that reflect various types of human disease or injury in the cardiovascular, neurological, and immunological areas. These collaborative relationships have enabled us to cost effectively explore where MultiStem cells may have therapeutic relevance, and how it may be utilized to advance treatment over current clinical care. Additionally, we have shown that we can leverage clinical safety data and preclinical results from some programs to support accelerated clinical development efforts in other areas, saving substantial development time and resources compared to traditional drug development where generally each program is separately developed.

Continue to Expand our Intellectual Property Portfolio. We have a broad intellectual property estate that covers our proprietary products and technologies, as well as methods of production and methods of use. Our intellectual property is important to our business and we take significant steps to protect its value. We have ongoing research and development efforts, both through internal activities and through collaborative research activities with others, which aim to develop new intellectual property and enable us to file patent applications that cover new applications of our existing technologies or product candidates, including MultiStem cells and other opportunities. We currently have approximately 130 patents related to our stem cell technologies and cell therapy applications providing protection in the United States, Europe, Japan and other areas, and we have 53 patents associated with our other technologies and small molecule programs.

Our Current Programs

By applying our proprietary MultiStem cell therapy product, we have established therapeutic product development programs treating inflammatory and immune disorders, neurological conditions, cardiovascular disease, and other conditions. To date, we have advanced five programs to the clinical development stage, including the following:

Inflammatory Bowel Disease: MultiStem therapy is being evaluated in a Phase 2 clinical study involving administration of MultiStem to patients suffering from UC, the most common form of IBD. This double blind, placebo controlled trial being conducted with our partner, Pfizer, in UC patients that have an inadequate response or are refractory to current treatment, completed enrolling patients in December 2013. We expect to report with Pfizer the initial results in the spring of 2014.

Ischemic Stroke: In our ongoing Phase 2 clinical study, we are evaluating the administration of MultiStem cell therapy to patients that have suffered an ischemic stroke. In contrast to treatment with thrombolytics, which must be administered within 3 to 4 hours after a stroke, we are treating patients one to two days after the stroke has occurred. In preclinical studies, administration of a single dose of MultiStem cells, even several days after a stroke, resulted in significant and durable improvements. This double blind, placebo-controlled trial is being conducted at leading stroke centers across the United States and Europe. The study is expected to enroll approximately 136 patients. We are targeting to complete enrollment around the end of summer 2014 and release the preliminary results as soon as they are available.

Acute Myocardial Infarction: We have evaluated the administration of MultiStem to patients that have suffered an acute myocardial infarction, or AMI, in a Phase 1 clinical study. In 2010, we announced preliminary results for this study, demonstrating a favorable safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment. This data was published in a leading peer reviewed scientific journal in 2012. One-year follow-up data suggested that the benefit observed was sustained over time. We are preparing for a Phase 2 clinical study of MultiStem administration to heart attack victims and are planning to initiate late 2014. In 2013, we were awarded a grant for up to \$2.8 million to support funding this clinical program.

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Hematopoietic Stem Cell Transplant / GvHD: We completed a Phase 1 clinical study of the administration of MultiStem cells to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a hematopoietic stem cell, or HSC, transplant. Such patients are at significant risk for serious complications, including GvHD, an imbalance of immune system function caused by transplanted immune cells that attack various tissues and organs in the patient. In 2011 and in 2012, we released data from the study, which demonstrated the safety of MultiStem cells in this indication and suggested that the MultiStem therapy may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. The MultiStem therapy has been designated an orphan drug by both the FDA and EMA, which may provide market exclusivity and other substantial potential incentives and benefits. We have had several interactions with the FDA and international agencies regarding study design and the potential to accelerate the path to product approval. Based on current plans, we intend to be ready to start this study in 2014, but study initiation will depend on the progress in our other clinical trials and the achievement of certain business development and financial objectives.

We are also collaborating with a leading transplant group at the University of Regensburg in Germany that has initiated a small institutional sponsored clinical trial exploring the administration of MultiStem cells in patients following a liver transplant. We are providing the clinical product and some financial support to conduct the trial.

In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem therapy in other inflammatory and immune, neurological and cardiovascular disease areas, as well as certain other indications. We conduct such work both through our own internal research efforts and through a broad network of collaborations we have established with investigators at leading research institutions across the United States and in Europe.

We are in discussions with third parties about collaborating in the development of MultiStem therapy for certain programs and may enter into one or more business partnership(s) to advance these programs.

We have also collaborated with RTI on the development of products for certain orthopedic applications using our stem cell technologies in the bone graft substitutes market. RTI's product commercialization activities are underway in 2014, and we will receive royalty revenue from product sales and other payments upon the successful achievement of certain commercial milestones.

We are also engaged in the development of novel small molecule therapies to treat obesity and other conditions, such as schizophrenia. Currently, we are focused on the development of potent, highly selective compounds that act through stimulation of a specific receptor in the brain, the 5HT_{2c} serotonin receptor. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit favorable attributes, including outstanding receptor selectivity, as well as greater potency and activity than other 5HT_{2c} agonists. We have also demonstrated our compounds are complementary with other agents that have been approved by the FDA and believe these compounds could achieve best in class weight loss, along with a superior safety and tolerability profile. Furthermore, we have evaluated certain compounds in preclinical models of schizophrenia that exhibit an attractive selectivity profile and also observed that these compounds exhibit potent effects. We may elect to enter into a partnership to advance the development of our 5HT_{2c} agonist program, either for the treatment of obesity, schizophrenia, or both indications, as well as for certain programs involving MultiStem.

Regenerative Medicine Programs

MultiStem – A Novel Therapeutic Modality

We are developing our MultiStem therapy, a proprietary non-embryonic, allogeneic stem cell product candidate, that we believe has potential utility for treating a broad range of diseases and could have widespread application in the field of clinical regenerative medicine. Unlike traditional bone marrow transplants or other stem cell therapies, MultiStem cells may be manufactured on a large scale and may be administered without tissue matching or the need for immune suppression, analogous to type O blood. Potential applications of MultiStem therapy include the treatment of cardiovascular disease, neurological disease or injury and conditions involving the immune system, including autoimmune disease and other conditions. We believe that the MultiStem therapy represents a significant advancement in the field of stem cell therapy and could have broad clinical application. We currently have open Investigational New Drug applications, or INDs, for the study of MultiStem administration in distinct clinical indications, and a collaborating institution recently obtained authorization in Europe to initiate a clinical program through an investigator sponsored clinical trial application, obtained with our permission and support.

The MultiStem product is a patented biologic product that is manufactured from human stem cells obtained from adult bone marrow, although these cells may alternatively be obtained from other tissue sources, which are also covered under our intellectual property. The product consists of a special class of human stem cells that have the ability to express a range of therapeutically relevant proteins and other factors, as well as form multiple cell types. Factors expressed by the cells have the potential to deliver a therapeutic benefit in several ways, such as the reduction of inflammation, regulation of immune system function, protection of damaged or injured tissue, the formation of new blood vessels in regions

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of ischemic injury and augmentation of tissue repair and healing in other ways. Like drugs, these cells may be stored for an extended period of time (in frozen form) and used off-the-shelf. Following administration, the cells have been shown to express multiple therapeutically relevant proteins, but unlike a traditional transplant, are subsequently cleared from the body over time, analogous to a drug or biologic.

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The therapeutic benefit of bone marrow transplantation has been recognized for decades, and its clinical use has grown since Congress passed the National Organ Transplant Act in 1984 and the National Marrow Donor Registry was established in 1990. However, widespread bone marrow or stem cell transplantation has yet to become a reality. Some of the limitations that have prevented broader clinical application of bone marrow or stem cell transplantation include the requirement for tissue matching between donor and recipient, the typical need for one donor for each patient (a reflection of the inability to expand cells in a controlled and reproducible manner), frequent use of immune suppressive drugs to avoid rejection or immune system complications, the inability to efficiently produce significant quantities of stem cells and a range of potential safety issues.

A stem cell therapy that has the potential to address the challenges mentioned above could represent a breakthrough in the field of regenerative medicine, since it could greatly expand the clinical application of stem cell therapy or other forms of regenerative medicine. In 2003, we acquired technology originally developed at the University of Minnesota related to a novel stem cell type, Multipotent Adult Progenitor Cells, or MAPC®, that may be isolated from adult bone marrow as well as other tissue sources. Over the past several years, we have further developed this technology and the manufacturing of these cells for use in ongoing clinical trials. We refer to the lead cell therapy as the MultiStem product platform. During several years of preclinical work, MultiStem cells have demonstrated the potential to address many of the fundamental limitations observed with traditional bone marrow or hematopoietic stem cell transplants.

We believe that MultiStem represents a potential best-in-class stem cell therapy because it exhibits each of the following characteristics based on research and development conducted to date:

Broad plasticity and multiple potential mechanisms of action. MultiStem cells have a demonstrated ability in animal models to form a range of cell types and also appear to be able to deliver therapeutic benefit by producing factors that protect tissues against damage and inflammation, as well as enhancing or playing a direct role in revascularization or tissue regeneration.

Large scale production. Unlike conventional stem cells, such as blood-forming or hematopoietic stem cells, mesenchymal stem cells, or other cell types, MultiStem cells may be produced on a large scale, processed, and cryogenically preserved, and then used clinically in a rapid and efficient manner. Material obtained from a single donor may be used to produce hundreds of thousands or millions of individual doses, representing a yield far greater than other stem cells have been able to achieve.

Off-the-shelf utility. Unlike traditional bone marrow or hematopoietic stem cell transplants that require extensive genetic matching between donor and recipient, MultiStem administration does not require tissue matching or immune suppressive drugs. The MultiStem product is administered as a cryogenically preserved allogeneic product, meaning that these cells are not genetically matched between donor and recipient. This feature, combined with the ability to establish large MultiStem banks, could make it practical for clinicians to efficiently deliver stem cell therapy to a large number of patients.

Safety. Other stem cell types, such as undifferentiated embryonic stem cells or induced pluripotent stem cells have shown the capacity to form ectopic tissue or teratomas, which are tumor-like growths. These could pose serious safety risks to patients. In contrast, MultiStem cells have shown a consistent and outstanding safety profile that has been compiled over several years of preclinical study in a range of animal models by a variety of investigators and that is supported by emerging clinical data.

At each step of the MultiStem production process, cells are analyzed according to pre-established criteria to ensure that a consistent, well characterized product candidate is produced. Cells are harvested from a pre-qualified, healthy, consenting donor and these cells are then expanded to form a master cell bank from which we subsequently produce clinical grade material. We have demonstrated the ability to harvest cells that meet our rigorous criteria from healthy donors with a high degree of consistency. Furthermore, in multiple animal models, MultiStem has been shown to be non-immunogenic, and is administered without the genetic matching that is typically required for conventional bone marrow or stem cell transplantation.

The distinctive profile of the MultiStem product allows us to pursue multiple high value commercial opportunities from a single product platform. Based upon work that we and independent collaborators have conducted over the past several years, we believe that MultiStem cells have the potential to treat a range of distinct disease indications, including ischemic injury and cardiovascular disease, certain types of neurological conditions or injury, autoimmune disease, transplant support (including in oncology patients and solid organ transplant areas), and a range of orphan disease indications. As a result, we believe we will be able to leverage our foundation of safety and efficacy data to add clinical indications efficiently, enabling us to reduce development costs and timelines substantially.

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Healthcare represents a significant part of the global economy. In the United States, it represented approximately 17.2% of all economic activity in 2012, or about \$2.8 trillion dollars annually. However, the United States, along with many other nations, is experiencing an unprecedented demographic shift that is resulting in a significantly expanded population of older individuals. According to United States Census data, in the next few years there will be a dramatic increase in the number of individuals over the age of 65, as this segment of the population increases from 40.2 million individuals in 2010 to more than 72 million people in 2030, representing an increase of approximately 80%. The aging of the population will create enormous financial pressure on the healthcare system in the United States and other countries around the world, resulting in significant clinical challenges, but also resulting in substantial commercial opportunities.

Data from the National Center for Health Statistics shows that as people get older, they are more susceptible to a variety of age related conditions, including heart disease, stroke, certain forms of cancer, diabetes, progressive neurological disorders, various chronic inflammatory and immune conditions, renal disease and a range of others. As a consequence, as people get older they spend far more on healthcare on average they spend three to seven times more on healthcare annually at age 65 than when they were younger and more healthy. According to the Alliance for Aging Research, 83% of healthcare spending is associated with chronic conditions, and other research shows that 62% of healthcare spending is associated with multiple chronic conditions. Traditional medical approaches have failed to adequately address this problem.

We have worked with independent investigators at a number of leading institutions, such as the Cleveland Clinic, Case Western Reserve University, University of Minnesota, the National Institutes of Health, the Georgia Regents University, the University of Oregon Health Sciences Center, the University of Texas Health Science Center at Houston, KUL, the University of Pittsburgh Medical Center, University of Regensburg and other institutions. Through this network of collaborations, we have studied MultiStem cells in a range of preclinical models that reflect various types of human disease or injury in the cardiovascular, neurological, and immunological areas. To date, we and our collaborators have published research results illustrating the potential benefits of MultiStem therapy in a range of indications including myocardial infarction, vascular disease, ischemic stroke, traumatic brain injury, or TBI, brain damage due to restricted blood flow in newborns, spinal cord injury, and bone marrow transplant support/GvHD. In addition, we have explored and intend to further explore MultiStem administration in the treatment of a range of other conditions, including other forms of cardiovascular disease, neurological conditions, and immune related disorders.

As stated above, we have consistently observed that MultiStem cells are safe and effective in animal models. As a result, we have advanced MultiStem therapy to clinical development stage in four clinical indications or disease areas: treatment of IBD (initially focused on UC); support in the hematologic malignancy setting to reduce certain complications associated with traditional bone marrow or HSC transplantation; treatment for stroke caused by a blockage of blood flow in the brain; and treatment of damage caused by myocardial infarction. Additionally, in collaboration with a leading transplant center in Europe, a fifth program in the solid organ transplant area has been advanced to clinical development.

We may expand to other clinical indication areas as results warrant and resources permit.

Immunological Disorders – MultiStem for IBD and HSC Transplant Support

Inflammatory and immune disorders represent a significant burden to society. There are over 80 recognized autoimmune disorders, which are conditions caused by an acute or chronic imbalance in the immune system. In these conditions, cells of the immune system begin to attack certain tissues or organs in the body, resulting in tissue damage and loss of function. Some inflammatory and immune conditions are associated with age-related conditions (e.g., rheumatoid arthritis), but some are due to other causes that may be genetic, environmental or a combination of both (e.g., Type 1 diabetes, IBD). Still other conditions may reflect complications associated with the treatment of other conditions (e.g., GvHD, a frequent complication associated with transplant procedures used to treat leukemia or related blood-borne cancers). Each of these conditions shares certain biological characteristics, in that the immune system imbalance results from the inappropriate activation of certain populations of immune cells that subsequently results in significant tissue damage and destruction. This immune imbalance may result in a complex cascade of inflammation that can result in pain, progressive tissue deterioration and loss of function. While currently available immunomodulatory drugs have proven to be effective for some patients, they have failed to adequately address the needs of many other patients that suffer from inflammatory and immune disorders.

In multiple studies, MultiStem cells have shown potent immunomodulatory properties, including the ability to reduce active inflammation through various modes of action, stimulate tissue repair and restore immune system balance. Accordingly, we believe that MultiStem therapy could have broad application in the area of treating immune system disorders, including certain autoimmune diseases and other conditions, including GvHD, which is a frequent immunological complication associated with bone marrow or HSC transplantation.

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In 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem therapy for the treatment of IBD for the worldwide market. IBD is a group of inflammatory and autoimmune conditions that affect the colon and small intestine, typically resulting in severe abdominal pain, weight loss, vomiting and diarrhea. The most common forms of the disease include UC

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and Crohn's disease, which are estimated to affect four million people or more in the United States, five major European markets (United Kingdom, Germany, France, Italy and Spain) and Japan. Chronic IBD can be a severely debilitating condition, and advanced cases may require surgery to remove the affected region of the bowel, and may also require temporary or permanent colostomy or ileostomy. In many cases, surgery does not achieve a permanent cure, and patients suffer a return of the disease. In 2011, enrollment commenced in our double-blind, placebo-controlled Phase 2 clinical study evaluating MultiStem administration to patients suffering from UC, and enrollment was completed in December 2013. We anticipate reporting initial trial results in the spring of 2014.

Another area of focus is the use of MultiStem cells as adjunctive treatment for HSC/bone marrow transplant used as therapy in hematologic malignancy. For many types of cancer, such as leukemia or other blood-borne cancers, treatment typically involves radiation therapy or chemotherapy, alone or in combination. Such treatment can substantially deplete the cells of the blood and immune system, by reducing the number of stem cells in the bone marrow from which they arise. The more intense the radiation treatment or chemotherapy, the more severe the resulting depletion is of the bone marrow, blood, and immune system. Other tissues may also be affected, such as cells in the digestive tract and in the pulmonary system. The result may be severe anemia, immunodeficiency, substantial reduction in digestive capacity, and other problems that may result in significant disability or death.

One strategy for treating the depletion of bone marrow is to perform a peripheral blood stem cell transplant or a bone marrow transplant. This approach may augment the patient's ability to form new blood and immune cells and provide a significant survival advantage. However, finding a closely matched donor is frequently difficult or even impossible. Even when such a donor is found, in many cases there are immunological complications, such as GvHD, which may result in serious disability or death.

Working with leading experts in the stem cell and bone marrow transplantation field, we have studied MultiStem in animal models of radiation therapy and GvHD. In multiple animal models, MultiStem cells have been shown to be non-immunogenic, even when administered without the genetic matching that is typically required for conventional bone marrow or stem cell transplantation. Furthermore, in animal model systems testing immune reactivity of T-cells against unrelated donor tissue, MultiStem has been shown to suppress the T-cell-mediated immune responses that are an important factor in causing GvHD. MultiStem-treated animals also displayed a significant increase in survival relative to controls. As a result, we believe that MultiStem administration in conjunction with or following standard HSC transplantation may have the potential to reduce the incidence or severity of complications and may enhance gastrointestinal function, which is frequently compromised as a result of radiation treatment or chemotherapy.

We completed a Phase 1 clinical trial examining the safety and tolerability of a single dose or repeat dosing of MultiStem cells administered intravenously to patients receiving a bone marrow or hematopoietic stem cell transplant as part of their treatment of leukemia or other hematological condition. The trial was an open label, multicenter trial that involved leading experts in the field of bone marrow transplantation. In February 2012, we announced the top-line results from the trial. We observed a consistent safety profile in both the single and multiple dose arms of the study, and at all dose levels tested. Although the trial was not specifically designed to demonstrate efficacy, we also observed clinically meaningful improvement in medically important parameters relative to historical clinical experience, including reduced incidence and severity of acute GvHD, improved relapse free survival, no graft failures, and enhanced engraftment rates relative to other forms of treatment.

We have been granted orphan drug designation by the FDA and EMA for MultiStem treatment in the prevention of GvHD. We met with the FDA to review the results from the Phase 1 trial and discuss plans for the next phase of clinical development, which we intend to be a Phase 2/3 study of MultiStem for GvHD prophylaxis and HSC transplant support. Based on FDA feedback, we are currently working to finalize our trial design as we plan and prepare for trial initiation. Based on current plans, we intend to be ready to start this study in 2014, but the initiation of the trial will depend on the progress in our clinical trials and the achievement of certain business development and financial objectives.

Neurological Injury and Disease – MultiStem for Ischemic Stroke

Another focus of our regenerative medicine program is MultiStem administration for the treatment of neurological injury as a result of acute or chronic conditions. Neurological injury and disease represents an area of significant unmet medical need, a major burden on the healthcare system, and also represents a huge commercial opportunity.

Many neurological conditions require extensive long-term therapy, and many require extended hospitalization and/or institutional care, creating an enormous cost burden. Stroke represents an area where the clinical need is particularly significant, since it represents a leading cause of death and significant long term disability. Currently, there are approximately 800,000 individuals in the United States that suffer a stroke each year, more than two million stroke victims in the United States, Europe and Japan, combined, and approximately 15 million people that suffer a stroke each year globally. The vast majority of these (approximately 85% to 90%) are ischemic strokes, that are caused by a blockage of blood flow in the brain, that cuts off the supply of oxygen and nutrients, and can result in tissue loss and neurological damage, as well as long term or permanent disability. The remaining 10% to 15% are hemorrhagic strokes, which occur when a blood vessel bursts and bleeding into the brain ensues.

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Studies show that in recent years there has been a dramatic rise in ischemic strokes among young adults (i.e., individuals in the 25 to 45 age group), which is likely due to a combination of rising rates of obesity and other factors. Unfortunately, current therapeutic options for ischemic stroke victims are limited, as the only available therapy, a clot dissolving agent or thrombolytic, must be administered within several hours of the occurrence of the stroke. As a consequence of this limited time window, only a small percentage of stroke victims are treated with the currently available therapy most simply receive supportive or palliative care. The long-term costs of stroke are substantial, with many patients requiring extended hospitalization, extended physical therapy or rehabilitation (for those patients that are capable of entering such programs), and many require long-term institutional or family care. Similarly, there are other acute and progressive neurological conditions that require substantial healthcare resources, with limited existing treatment options that are only marginally clinically effective.

We have published research with independent collaborating investigators that demonstrates that MultiStem administration conveys biological benefits in preclinical models of ischemic stroke, as well as other models of neurological damage and injury, including TBI, neonatal hypoxic ischemia (a cause of neurological damage in infants), and spinal cord injury. We have also conducted preclinical work in other neurological areas, and have been awarded grants to support work in areas such as the indications described above and for evaluating the potential of MultiStem cells to address chronic conditions such as Multiple Sclerosis, or MS, or Parkinson's disease. Our research has shown that MultiStem cells convey benefits through distinct mechanisms, including reducing inflammatory damage, protecting at risk tissue at the site of injury, and through direct neurotrophic effects that stimulate the recovery of damaged neurons. As a result, we believe that MultiStem therapy may have relevance to multiple forms of neurological injury and disease.

Our initial clinical focus in the neurological area involves evaluating MultiStem administration to treat ischemic stroke. Ischemic stroke is a leading cause of death and disability globally, and accounts for approximately 85% of all strokes. Recent progress toward the development of safer and more effective treatments for ischemic stroke has been disappointing. Despite the fact that ischemic stroke is one of the leading causes of death and disability in the United States, there has been little progress toward the development of treatments that improve the prognosis for stroke victims. The only FDA-approved drug currently available for ischemic stroke is the anti-clotting factor, tPA. According to current clinical guidelines, tPA must be administered to stroke patients within several hours after the occurrence of the ischemic stroke to remove the clot while minimizing potential risks, such as bleeding into the brain. Administration of tPA after three to four hours is not recommended, since it can cause cerebral bleeding or even death. Given this limited therapeutic window, it is estimated that less than 5% of ischemic stroke victims in the United States currently receive treatment with tPA.

In preclinical studies conducted by investigators, including at the University of Minnesota, the Georgia Regents University, and the University of Texas Health Science Center at Houston, significant functional improvements have been observed in rodents that have undergone an experimentally induced stroke, or that have incurred significant neurological damage due to similar types of ischemic events, such as a result of neonatal hypoxic ischemia or TBI, and then received MultiStem treatment. Published research has demonstrated that MultiStem administration even one week after a surgically induced stroke results in substantial long-term therapeutic benefit, as evidenced by the improvement of treated animals compared with controls in a battery of tests examining mobility, strength, fine motor skills, and other aspects of neurological functional improvement.

Based on the research conducted by us and our collaborators, we believe MultiStem treatment conveys significant benefits through several mechanisms, including reduction of inflammation and immune system modulation in the ischemic area, and the protection and rescue of damaged or injured cells, including neuronal tissue. Research results presented at the 2011 and 2012 American Heart Association International Stroke Conference by collaborators from the University of Texas Health Science Center at Houston demonstrated that MultiStem administration 24 hours following a stroke reduced inflammatory damage in the brain and resulted in significant functional improvement, and that some of these results were achieved by reducing the inflammatory response emanating from the spleen. These results confirm that MultiStem treatment is well tolerated, does not require immunosuppression and results in a robust and durable therapeutic benefit, and are consistent with prior results that show MultiStem can provide significant benefits even when administered up to one week after the initial stroke event.

We are currently enrolling patients in the United States and Europe in a 136-patient, double-blind, placebo-controlled Phase 2 clinical trial exploring the administration of MultiStem to patients that have suffered an ischemic stroke. In this trial, MultiStem is administered one to two days after a stroke has occurred. If shown to be safe and effective, this would represent a significant extension of the treatment window relative to existing standard of care and could provide an important new therapeutic option for stroke patients. We believe that the potential market for a new therapy to treat stroke could be \$15 to \$20 billion or more annually.

We are also interested in the application of MultiStem for other neurological indications that represent areas of significant unmet medical need, such as TBI, which represents the leading cause of disability among children and young adults, and a leading cause of death. Approximately 1.7 million cases of TBI are seen in the United States each year, nearly half a million cases of which are children age 0 to 14 years old. The United States Center for Disease Control and Prevention, or CDC, estimates that more than 5.3 million individuals are living with a disability and have a long-term or lifelong need for help to perform activities of daily living as a result of a TBI. The annual direct and indirect costs for TBI are approximately \$60 billion a year, according to the National Institute of Neurological Disorders and Stroke, which is part of the National

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Institutes of Health. In preclinical studies of TBI, administration of MultiStem dramatically reduced the extent of damage caused by a TBI, and promoted accelerated healing of the blood-brain barrier.

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In 2012, we announced grant funding of up to \$3.6 million to further advance our MultiStem programs and cell therapy platform, including further development of MultiStem therapy for the treatment of TBI and further development of our cell therapy formulations and manufacturing capabilities. We received authorization in 2013 to advance our TBI program into the second phase of the two-stage federal grant award.

We are also conducting preclinical work exploring the application of MultiStem treatment in other neurological indications. In 2010, we and collaborators at the Center for Stem Cell and Regenerative Medicine and Case Western Reserve University were awarded \$1.0 million through the Ohio Third Frontier Biomedical Program to support preclinical and translational research into the MultiStem treatment of spinal cord injury, or SCI. In 2012, we presented data at the Annual Society for Neuroscience meeting that demonstrated that intravenous MultiStem administration one day after SCI results in statistically significant and sustained improvements in gross locomotor function, fine locomotor function and bladder control compared to control treated animals.

In 2011, we announced the award of grant funding of up to \$640,000 to investigate the potential for MultiStem treatment for chronic progressive MS based on initial results in preclinical models. In 2012, in collaboration with scientists from Case Western Reserve University, and with the support of Fast Forward and the National Multiple Sclerosis Society, we reported research results that demonstrate the potential benefits of MultiStem therapy for treating MS. In standard preclinical models of MS, researchers observed that MultiStem administration results in sustained behavioral improvements, arrests the demyelination process that is central to the pathology of MS, and supports remyelination of affected axons. We have advanced our MS program with Fast Forward into the second phase of the two-stage grant in 2013.

Cardiovascular Disease Evaluating MultiStem for Treating Damage from a Heart Attack

Cardiovascular disease is an area of significant clinical need that is expected to expand significantly in the years ahead. Despite treatment advances in recent years, cardiovascular disease remains the leading cause of death, and represents one of the leading causes of disability around the world. In the United States, approximately 915,000 people suffer a heart attack each year, and approximately 5.1 million individuals in the United States are currently suffering from heart failure in 2009, according to the American Heart Association 2013 Statistical Update. Another 8.5 million people suffer from peripheral arterial disease, which is associated with significant morbidity and mortality. In addition, there were approximately 788,000 deaths that occurred from all forms of cardiovascular disease, including 443,000 individuals that died as a result of coronary heart disease or heart failure. According to projections published recently by the American Heart Association in February 2011 in the journal *Circulation*, aggregate costs for treating heart disease in the United States are expected to soar in the coming years. In 2010, annual direct costs for treating cardiovascular disease were \$273 billion, but by 2030 these are expected to nearly triple, to a projected \$818 billion per year. This increase will occur primarily as a result of the aging population, and may not fully reflect the impact of the dramatic escalation in obesity rates that has occurred for both adults and children in recent years, which could further exacerbate the long-term challenges and increase costs associated with cardiovascular disease and other conditions.

In a Phase 1 clinical trial, we have explored MultiStem treatment for damage caused by AMI. Myocardial infarction is one of the leading causes of death and disability in the United States and is caused by the blockage of one or more arteries that supply blood to the heart. Such blockages can be caused, for example, by the rupture of an atherosclerotic plaque deposit. A variety of risk factors are associated with an elevated risk of myocardial infarction or atherosclerosis, including age, high blood pressure, smoking, sedentary lifestyle and genetics. While advances in the diagnosis, prevention and treatment of heart disease have had a positive impact, there is clearly room for improvement myocardial infarction remains a leading cause of death and disability in the United States and the rest of the world.

MultiStem treatment has been studied in validated animal models of AMI, including at both the Cleveland Clinic and the University of Minnesota. Investigators demonstrated that the administration of allogeneic MultiStem cells into the hearts of animals damaged by experimentally induced heart attacks resulted in significant functional improvement in cardiac output and other functional parameters compared with animals that received placebo or no treatment. Furthermore, the administration of immunosuppressive drug was not required and provided no additional benefit in this study, and supports the concept of using MultiStem cells as an allogeneic product.

Working with a contract research organization, we completed additional preclinical studies in established pig models of AMI using catheter delivery and examining various factors such as the route and method of MultiStem administration, dose ranging, and timing of treatment. We conducted a multicenter, open-label Phase 1 clinical trial in this indication and announced in 2010 the preliminary results, which showed that MultiStem treatment was well tolerated at all dose levels and exhibited a favorable safety profile. In addition, patients that received MultiStem treatment exhibited meaningful improvements in cardiovascular function, including left ventricular ejection fraction, wall motion scores, and other parameters. These results were published by *Circulation Research* in 2012.

We are preparing for a Phase 2 clinical study of MultiStem administration to patients that have suffered a myocardial infarction and are planning to initiate the study in 2014. In 2013, we were awarded a grant from the National Institutes of Health for up to \$2.8 million to support funding the program.

Table of Contents***Pharmaceutical Programs******Novel 5HT2c agonists for the treatment of obesity and other conditions***

Obesity is a substantial contributing factor to a range of diseases that represent the major causes of death and disability in the developed world today. Individuals that are clinically obese have elevated rates of cardiovascular disease, stroke, certain types of cancer and diabetes. According to the CDC, the incidence of obesity in the United States has increased at an epidemic rate during the past 20 years. CDC now estimates that almost 70% of all Americans are overweight, including more than one-third that are considered clinically obese. The percentage of young people that are overweight has more than tripled since 1980. There has also been a dramatic rise in the rate of obesity in Europe and Asia. Despite the magnitude of this problem, current approaches to clinical obesity are largely ineffective, and we are aware of relatively few new therapeutic approaches in clinical development.

We are developing novel pharmaceutical treatments for obesity, which are compounds designed to act by stimulating a key receptor in the brain that regulates appetite and food intake – the 5HT2c receptor. The role of this receptor in regulating food intake is well understood in both animal models and humans. In 1996, Wyeth launched the anti-obesity drug Redux® (dexfenfluramine), a non-specific serotonin receptor agonist that was used with the stimulant phentermine in a combination commonly known as fen-phen. This diet drug combination was shown to be highly effective at regulating appetite, reducing food intake, and causing significant weight loss. Unfortunately, in addition to stimulating the 5HT2c receptor, Redux also stimulated the 5HT2b receptor that is found in the heart, and Redux was withdrawn from the market in 1997.

Since the withdrawal of Redux, several groups have published research and clinical data that implicate stimulation of the 5HT2b receptor as the underlying cause of the cardiovascular problems. These findings suggest that highly selective compounds that stimulate the 5HT2c receptor, but that do not appreciably stimulate the 5HT2b receptor, could be developed that maintain the desired appetite suppressive effects without the cardiovascular toxicity. Recent clinical data supports this hypothesis and also suggests that the 5HT2c agonists may also cause a statistically significant reduction in the amount of sugar in the blood, as measured by fasting blood glucose and HbA1c levels, which are both clinically relevant measures for patients suffering from diabetes.

In 2012, the FDA approved Lorcaserin, a 5HT2c agonist, for the treatment of obesity. We believe this represents a significant event for our program because it illustrates that the FDA recognizes and agrees with the concept that 5HT2c agonists that display appropriate selectivity, biological activity and clinical safety are approvable for indications such as obesity.

Our drug development program is focused on creating potent and selective orally administered compounds that stimulate the 5HT2c receptor, but that avoid the 5HT2b receptor and other receptors, such as 5HT2a, or other receptors that could cause adverse side effects. Based on extensive preclinical studies that we have conducted with compounds that we have generated, we have demonstrated the ability to develop compounds that are highly potent and selective for the 5HT2c receptor, and that lack activity at either 5HT2a or 5HT2b. We believe that clinical trials will demonstrate that this achievement represents a significant advance in the field, and that the potency and selectivity profile displayed by compounds we are developing will result in substantially better efficacy and a cleaner safety and tolerability profile, as well as a more convenient dosing schedule than other 5HT2c agonist programs including Lorcaserin. We also evaluated certain of our compounds when administered as a monotherapy or in conjunction with other weight loss agents, and have observed effectiveness with both approaches. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit outstanding receptor selectivity and are working toward the selection of a clinical development candidate for this program.

Certain potent and highly selective compounds that we have developed display a profile that we believe may have utility in treating schizophrenia. We evaluated some of these compounds in preclinical models of schizophrenia and have observed that they exhibit efficacy in these models.

We may elect to enter into a partnership to advance the development of our 5HT2c agonist program, either for the treatment of obesity, schizophrenia, or both indications.

Other Small Molecule Programs & Key Technologies

In addition to our other programs, we believe that there are significant opportunities for synergy between our small molecule platform and related capabilities and our MultiStem technology. Specifically, we believe that substantial opportunities exist for identifying and utilizing small molecule modulators of therapeutically relevant biological activity exhibited by MultiStem or other stem cell types. We believe that applying our capabilities in both areas could lead to next generation product development opportunities, including more potent stem cell based therapies that have been optimized for use in specific indication areas.

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In addition to our current product development programs, we developed our patented RAGE® technology that provides us with the ability to produce human cell lines that express specific, biologically well validated drug targets without relying upon cloned and isolated gene sequences. While our RAGE technology is not a therapeutic product, it is a commercial technology that we have successfully applied for the benefit of our partners and that we have also used for our own internal drug development programs. Modern drug screening approaches typically require the physical isolation and structural modification of a gene of interest, an

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approach referred to as gene cloning, in order to create a cell line that expresses a drug target of interest. Researchers may then use the genetically modified cell line to identify pharmaceutical compounds that inhibit or stimulate the target of interest. The RAGE technology enables us to turn on or amplify the expression of a drug target without having to physically clone or isolate the gene. In effect, the technology works through the random insertion of tiny, proprietary genetic switches that randomly turn genes on without requiring their physical isolation, or any advance knowledge of their structure. This technology provides us with broad freedom to work with targets that may be otherwise unavailable as a result of intellectual property restrictions on the use of specific cloned and isolated genes. In recent years, we have produced cell lines that express drug targets in a range of disease areas such as metabolic disease, infectious disease, oncology, cardiovascular disease, inflammation, and central nervous system disorders. Many of these were produced for drug development programs at major pharmaceutical companies that we have collaborated with, such as Bristol-Myers Squibb, and some have been produced for our internal drug development programs.

Collaborations and Partnerships***Pfizer***

In 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem therapy for the treatment of IBD for the worldwide market. Under the terms of the agreement, we received a non-refundable up-front cash payment of \$6.0 million from Pfizer and research funding during the initial phase of the collaboration that ended in 2012. In addition, we are also eligible to receive milestone payments of up to \$105 million upon the successful achievement of certain development, regulatory and commercial milestones, though there can be no assurance that we will achieve these milestones, and no significant milestone payments were received as of December 31, 2013. We are responsible for manufacturing and Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase 3 clinical development.

The Pfizer collaboration does not have a specific termination date, but will terminate upon the last to expire royalty term, unless terminated earlier by either party. Either party can terminate the agreement for an uncured material breach or default. Pfizer is permitted to terminate the agreement upon advance written notice to us if we sustain certain turnover levels for employees working on the program, if our license with the University of Minnesota is terminated, if we experience a specified change of control event, or in its sole discretion. We can terminate the agreement if a certain milestone event has not occurred by a defined period of time, or if we reasonably believe that Pfizer has failed to satisfy its obligations to progress the development of the program. Following termination of the agreement by us, all licenses granted to Pfizer to develop and commercialize MultiStem for IBD will terminate, other than certain more limited research licenses, and ownership of regulatory and clinical data will revert to us. Following termination of the agreement by Pfizer, the licenses granted to Pfizer will remain in effect according to their terms, unless the termination is due to our breach, employee turnover or termination of the license with University of Minnesota, in which case payments to us will be reduced from what was otherwise payable. Also, if Pfizer terminates in its sole discretion, then Pfizer retains its obligation to fund our research and development costs as set forth in the agreement.

RTI

In 2010, we entered into an agreement with RTI to develop and commercialize MAPC technology-based biologic implants for certain orthopedic applications in the bone graft substitutes market. Under the terms of our RTI agreement, we received \$5.0 million of license fees in installments during 2010-2012. In accordance with the agreement, we are also eligible to receive an additional \$35.5 million in cash payments upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved, and no significant milestone payments were received as of December 31, 2013. In addition, we will receive tiered royalties on worldwide commercial sales of implants using our technologies beginning in 2014, since RTI recently commenced its commercialization activities.

Angiotech

In 2011, we reached an agreement with Angiotech to terminate the collaboration agreement and license between the parties, reflecting a change in Angiotech's business and financial strategy. As a result of the termination, we regained ownership of all rights for developing our stem cell technologies and products for cardiovascular disease indications, including AMI, congestive heart failure, chronic ischemia, and peripheral vascular disease, and Angiotech no longer has any license rights or options with respect to our technologies and products. As part of the termination agreement, if we enter into a new AMI collaboration before November 14, 2014, and at the time of the collaboration, we have made certain progress in development, Angiotech could be eligible for 10% of any third-party license fees up to a maximum of \$5.0 million. Angiotech is not entitled to other downstream payments, such as milestone payments, royalties or any profit-sharing payments.

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Bristol-Myers Squibb

In 2000, we entered into a collaboration with Bristol-Myers Squibb to provide cell lines expressing well validated drug targets produced using our RAGE technology for compound screening and development. This initial collaboration was expanded in 2002 and again in 2006, and was in its final phase as amended in 2009. Bristol-Myers Squibb uses the cell lines in its internal drug development programs and, in exchange, we receive license fee and milestone payments and will be entitled to receive royalties on the sale of any approved products. Depending on the use of a cell line by Bristol-Myers Squibb and the progress of drug development programs benefiting from the use of such a cell line, we may receive as much as approximately \$5.5 million per cell line in additional license fees and milestone payments, though we cannot assure you that any further milestones will be achieved or that we will receive any additional milestone payments. In 2008, Bristol-Myers Squibb successfully advanced into Phase 2 clinical development a drug candidate discovered using a target provided by us, thereby triggering a clinical development milestone payment to us. As of December 31, 2013, we received an aggregate amount of \$2.1 million in milestone payments and \$9.8 million in license fees since the inception of our collaboration with Bristol-Myers Squibb.

The Bristol-Myers Squibb collaboration does not have a specific termination date, but will terminate when Bristol-Myers Squibb no longer has an obligation to pay us royalties, which obligation generally continues until the later of the expiration of the Bristol-Myers Squibb patent covering an approved product and ten years after commercial sales of that product began. If either party breaches its material obligations and fails to cure that breach within 60 days after notice from the non-breaching party, the non-breaching party may terminate the collaboration.

Competition

We face significant competition with respect to the various dimensions of our business. With regard to our efforts to develop MultiStem as a novel stem cell therapy, currently, there are a number of companies that are actively developing stem cell products, which encompass a range of different cell types, including embryonic stem cells, umbilical cord stem cells, adult-derived stem cells and processed bone marrow derived cells.

Mesoblast Limited, or Mesoblast, is currently engaged in clinical trials evaluating the safety and efficacy of Revascor, an allogeneic stem cell product based on mesenchymal stem cell precursors that are obtained from healthy consenting donors. These cells also appear to display limited expansion potential and biological plasticity. Additionally, Mesoblast is developing Prochymal, a mesenchymal stem cell product candidate that it acquired from Osiris Therapeutics, Inc. in 2013. In 2010, Mesoblast announced a partnership with Cephalon, Inc., or Cephalon, now owned by Teva Pharmaceuticals, Inc., in which Cephalon paid an upfront license fee of \$130 million, and agreed to invest an additional \$220 million in equity for a 19.9% stake in Mesoblast. In addition, total regulatory milestone payments to Mesoblast could reach \$1.7 billion, assuming that the agreement results in commercial treatments for conditions including congestive heart failure, AMI, Parkinson's disease and Alzheimer's disease.

Other public companies are developing stem-related therapies, including Aastrom Biosciences, Inc., or Aastrom, Stem Cells Inc., Johnson & Johnson, Celgene Corporation, or Celgene, Advanced Cell Technology, Inc., CRYO-CELL International, Inc., Pluristem Therapeutics, Inc., or Pluristem, and Cytori Therapeutics, Inc., or Cytori. In addition, private companies, such as Gamida Cell Ltd., Plureon Corporation, NeoStem, Inc., Tigenix NV and others, are also developing cell therapy related products or capabilities. Given the magnitude of the potential opportunity for stem cell therapy, we expect competition in this area to intensify in the coming years.

We also face competition in our efforts to develop compounds for the treatment of obesity. In 2012, two new treatments were approved by the FDA for the treatment of obesity, Belviq (Lorcaserin), which was developed by Arena Pharmaceuticals, Inc., or Arena, and Qsymia (a proprietary combination of phentermine and topiramate), which was developed by Vivus, Inc., or Vivus. Prior to these recent approvals, there was one approved therapeutic product on the market for obesity, Xenical (also known as Alli), which is marketed by F. Hoffman LaRoche Ltd., or Roche. Potential side effects associated with taking Xenical / Alli include cramping, intestinal discomfort, flatulence, diarrhea, and leakage of oily stool. Another obesity drug, Meridia, was approved for clinical use and marketed by Abbott Pharmaceuticals, but was withdrawn from the market due to concerns regarding increased risk of cardiovascular disease and stroke among patients taking the drug.

There are many other companies that have previously attempted or are attempting to develop novel treatments for obesity, and a wide range of approaches are being taken. Some of these companies include large, multinational pharmaceutical companies such as Bristol-Myers Squibb, Merck & Co., Inc., Roche, Sanofi, GlaxoSmithKline plc, or GlaxoSmithKline, Eli Lilly and Company and others. There are also a variety of biotechnology companies developing treatments for obesity, including Orexigen Therapeutics, Neurosearch, Amgen Inc., or Amgen, Regeneron Pharmaceuticals, Inc., Nastech Pharmaceutical Company, Alizyme plc, Amylin Pharmaceuticals, Inc., Neurocrine Biosciences, Inc., Shionogi & Co., Ltd., Metabolic Pharmaceuticals Limited, Kyorin Pharmaceutical Co., Ltd., and others. It is likely that, given the magnitude of the market opportunity, many companies will continue to focus on the obesity area, and that competition will remain high. If we are successful at developing a 5HT_{2c} agonist as a safe and effective treatment for obesity, it is likely that other companies will attempt to develop safer and more effective compounds in the same class, or will attempt to combine therapies in an effort to establish a safer and more effective therapeutic product.

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We believe our most significant competitors are fully integrated pharmaceutical companies and biotechnology companies that have substantially greater financial, technical, sales, marketing, and human resources than we do. These companies may succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products. In addition, our competitors may develop technologies and products that are cheaper, safer or more effective than those being developed by us or that would render our technology obsolete. Furthermore, some of these companies may feel threatened by our activities and attempt to delay or impede our efforts to develop our products or apply our technologies.

Intellectual Property

We rely on a combination of patent applications, patents, trademarks, and contractual provisions to protect our proprietary rights. We believe that to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. Currently, we require our officers, employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, and other advisors to execute confidentiality agreements in connection with their employment, consulting, or advisory relationships with us, where appropriate. We also require our employees, consultants, and advisors that we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, developed using our property, or which relate to our business. We currently have over 180 patents for our technologies.

We have a broad patent estate with claims directed to compositions, methods of production, and methods of use of certain non-embryonic stem cells and related technologies. We have developed, acquired and exclusively licensed intellectual property covering our cell therapy product candidates and other applications in the field. Our broad intellectual property portfolio consists of more than 130 issued patents (of which seventeen are United States patents) and more than 170 global patent applications around our stem cell technology and MultiStem product platform. This includes fourteen United States patents and more than 90 international patents that apply to MAPC and related products, such as MultiStem. The current intellectual property estate, which incorporates additional filings and may broaden over time, could provide coverage for our stem cell product candidates, manufacturing processes and methods of use through 2030 and beyond. Furthermore, an extended period of market exclusivity may apply for certain products (e.g., exclusivity periods for orphan drug designation or biologics).

We have established a broad intellectual property portfolio related to our small molecule product candidates and functional genomics technologies. We have a broad patent estate with claims directed to compositions, methods of making, and methods of using our small molecule drug candidates. We have six United States patents and three patent applications with broad claims directed to selective 5HT_{2c} agonists discovered at Athersys that currently provide patent coverage through as late as 2029. From our Histamine H₃ program, we have six United States patents with broad claims directed to compounds discovered at Athersys from two distinct chemical series that currently provide patent coverage through as late as 2028. In addition, we currently have 36 issued patents (16 United States patents and 20 international patents) relating to compositions and methods for the RAGE technology that currently provide patent coverage through as late as 2020, and five United States patents relating to human proteins and candidate drug targets that we identified through the application of RAGE and to our other technologies that currently provide patent coverage through as late as 2022. The RAGE technology was developed by Dr. John Harrington and other Athersys scientists internally in the mid-1990s.

We believe that we have broad freedom to use and commercially develop our technologies and product candidates. However, if successful, a patent infringement suit brought against us may force us or any of our collaborators or licensees to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property, unless that party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Research and Development

Our research and development costs, which consist primarily of costs associated with external clinical trial costs, preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property application processes, and laboratory supply and reagent costs, were \$20.5 million in 2013, \$19.6 million in 2012 and \$18.9 million in 2011.

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Government Regulation

Any products we may develop and our research and development activities are subject to stringent government regulation in the United States by the FDA and, in many instances, by corresponding foreign and state regulatory agencies. The European Union, or EU, has vested centralized authority in the EMA and Committee on Proprietary Medicinal Products to standardize review and approval across EU member nations. In Japan, the Pharmaceuticals and Medical Device Agency, or PDMA, a division of the Ministry of Health, Labour and Welfare, or MHLW, regulates the development and commercialization of medical therapies. Recently, Japan's parliament enacted new legislation to promote the safe and accelerated development of treatments using stem cells. The new regenerative medicine law and revised pharmaceutical affairs law define products containing stem cells as regenerative medicine products and allow for the conditional approval of such products if safety has been confirmed in clinical trials, even if their efficacy has not been fully demonstrated. The legislation creates a new, faster pathway for cell therapy product approval, and offers the potential to enable more rapid entry in the Japanese market. The MHLW has been directed to develop and adopt new rules and procedures to implement this legislation.

These regulatory agencies enforce comprehensive statutes, regulations and guidelines governing the drug development process. This process involves several steps. Initially, a company must generate preclinical data to show safety before human testing may be initiated. In the United States, a drug company must submit an IND to the FDA prior to securing authorization for human testing. The IND must contain adequate data on product candidate chemistry, toxicology and metabolism and, where appropriate, animal research testing to support initial safety.

A Clinical Trial Agreement, or CTA, is the European equivalent of the IND. CTA requirements are issued by each competent authority within the European Union and are enacted by local laws and Directives.

Any of our product candidates will require regulatory approval and compliance with regulations made by United States and foreign government agencies prior to commercialization in such countries. The process of obtaining FDA or foreign regulatory agency approval has historically been extremely costly and time consuming. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale, and distribution of biologics and new drugs.

The standard process required by the FDA before a pharmaceutical agent may be marketed in the United States includes:

preclinical tests in animals that demonstrate a reasonable likelihood of safety and effectiveness in human patients;

submission to the FDA of an IND, which must become effective before clinical trials in humans can commence. If Phase 1 clinical trials are to be conducted initially outside the United States, a different regulatory filing is required, depending on the location of the trial;

adequate and well controlled human clinical trials to establish the safety and efficacy of the drug or biologic in the intended disease indication;

for drugs, submission of a New Drug Application, or NDA, or a Biologic License Application, or BLA, with the FDA; and

FDA approval of the NDA or BLA before any commercial sale or shipment of the drug.

Preclinical studies can take several years to complete, and there is no guarantee that an IND based on those studies will become effective to permit clinical trials to begin. The clinical development phase generally takes five to seven years, or longer, to complete (i.e., from the initiation of Phase 1 through completion of Phase 3 studies), and such sequential studies may overlap or be combined. After successful completion of clinical trials for a new drug or biologic product, FDA approval of the NDA or BLA must be obtained. This process requires substantial time and effort and there is no assurance that the FDA will accept the NDA or BLA for filing and, even if filed, that the FDA will grant approval. In the past, the FDA's approval of an NDA or BLA has taken, on average, one to two years, but in some instances may take substantially longer. If questions regarding safety or efficacy arise, additional studies may be required, followed by a resubmission of the NDA or BLA. Review and approval of an NDA or BLA can take up to several years.

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In addition to obtaining FDA approval for each product, each drug manufacturing facility must be inspected and approved by the FDA. All manufacturing establishments are subject to inspections by the FDA and by other federal, state, and local agencies, and must comply with good manufacturing practices, or GMP, requirements. We do not currently have any GMP manufacturing capabilities, and will rely on contract manufacturers to produce material for any clinical trials that we may conduct.

We must also obtain regulatory approval in other countries in which we intend to market any drug. The requirements governing conduct of clinical trials, product licensing, pricing, and reimbursement vary widely from country to country. FDA approval does not ensure regulatory approval in other countries. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In some countries, the sale price of the drug must also be approved. The pricing review period often begins after market approval is granted. Even if a foreign regulatory authority approves a drug product, it may not approve satisfactory prices for the product.

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In addition to regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other present and potential future federal, state, or local regulations. Our research and development involves the controlled use of hazardous materials, chemicals, biological materials, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials currently comply in all material respects with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our available resources.

Employees

We believe that our success will be based on, among other things, the quality of our clinical programs, our ability to invent and develop superior and innovative technologies and products, and our ability to attract and retain capable management and other personnel. We have assembled a high quality team of scientists, clinical development managers, and executives with significant experience in the biotechnology and pharmaceutical industries.

As of December 31, 2013, we employed 56 full-time employees, including 17 with Ph.D. degrees. In addition to our employees, we also use the service and support of outside consultants and advisors. None of our employees is represented by a union, and we believe relationships with our employees are good.

Available Information

We use the Investors section of our web site, www.athersys.com, as a channel for routine distribution of important information, including news releases, analyst presentations and financial information. We post filings as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC, including our annual, quarterly, and current reports on Forms 10-K, 10-Q, and 8-K; our proxy statements; and any amendments to those reports or statements. All such postings and filings are available on the Investors section of our web site free of charge. In addition, this web site allows investors and other interested persons to sign up to automatically receive e-mail alerts when we post news releases and financial information on our web site. The SEC also maintains a web site, www.sec.gov, that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The content on any web site referred to in this annual report on Form 10-K is not incorporated by reference into this annual report unless expressly noted.

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ITEM 1A. RISK FACTORS

The statements in this section, as well as statements described elsewhere in this annual report, or in other SEC filings, describe risks that could materially and adversely affect our business, financial condition and results of operations, which could also cause the trading price of our equity securities to decline. These risks are not the only risks that we face. Our business, financial condition and results of operations could also be affected by additional factors that are not presently known to us or that we currently consider to be immaterial to our operations.

We have incurred losses since inception and we expect to incur significant net losses in the foreseeable future and may never become profitable.

Since our inception in 1995, we have incurred significant losses and negative cash flows from operations. We incurred net losses of \$31 million in 2013, \$15 million in 2012 and \$14 million in 2011. As of December 31, 2013, we had an accumulated deficit of \$264 million and anticipate incurring additional losses for at least the next several years. We expect to spend significant resources over the next several years to enhance our technologies and to fund research and development of our pipeline of potential products. To date, substantially all of Athersys' revenue has been derived from corporate collaborations, license agreements and government grants. In order to achieve profitability, we must develop products and technologies that can be commercialized by us or through our existing or future collaborations. Our ability to generate revenues and become profitable will depend on our ability, alone or with potential collaborators, to timely, efficiently and successfully complete the development of our product candidates. We have never earned revenue from selling a product and we may never do so, as none of our product candidates have been approved for sale, since they are currently being tested in humans and animal studies. We cannot assure you that we will ever earn revenue or that we will ever become profitable. If we sustain losses over an extended period of time, we may be unable to continue our business.

We will need substantial additional funding to develop our products and for our future operations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development activities or may be unable to continue our business.

The development of our product candidates will require a commitment of substantial funds to conduct the costly and time-consuming research, which may include preclinical and clinical testing, necessary to obtain regulatory approvals and bring our products to market. Net cash used in our operations was \$23 million in 2013, \$18 million in 2012 and \$14 million in 2011.

At December 31, 2013, we had \$32 million of cash, cash equivalent and investments, and we will need substantially more to advance our product candidates through development. Furthermore, we will need to add additional capital to fund our operations through the completion of our current clinical trials. Our future capital requirements will depend on many factors, including:

our ability to raise capital to fund our operations;

the progress and costs of our research and development programs, including our ability to develop our current portfolio of therapeutic products, or discover and develop new ones;

our ability, or our partners ability and willingness, to advance partnered products or programs, and the speed in which they are advanced;

the cost of prosecuting, defending and enforcing patent claims and other intellectual property rights;

the progress, scope, costs, and results of our preclinical and clinical testing of any current or future pharmaceutical or MultiStem-related products;

the time and cost involved in obtaining regulatory approvals;

the cost of manufacturing our product candidates;

expenses related to complying with GMP of therapeutic product candidates;

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costs of financing the purchases of additional capital equipment and development technologies;

competing technological and market developments;

our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements;

the amount and timing of payments or equity investments that we receive from collaborators or changes in or terminations of future or existing collaboration and licensing arrangements and the timing and amount of expenses we incur to supporting these collaborations and license agreements;

costs associated with the integration of any new operation, including costs relating to future mergers and acquisitions with companies that have complementary capabilities;

expenses related to the establishment of sales and marketing capabilities for products awaiting approval or products that have been approved;

the level of our sales and marketing expenses; and

our ability to introduce and sell new products.

The extent to which we utilize our existing equity purchase agreement with Aspire Capital Fund, LLC, or Aspire Capital, as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the purchase agreement on any given day and during the term of the agreement is limited. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the purchase agreement during the continuance of an event of default. Even if we are able to access the remaining \$24.5 million under the purchase agreement as of December 31, 2013, we will still need additional capital to fully implement our business, operating and development plans.

We have secured capital historically from grant revenues, collaboration proceeds, and debt and equity offerings. We will need to secure substantial additional capital to fund our future operations. We cannot be certain that additional capital will be available on acceptable terms or at all. In recent years, it has been difficult for companies to raise capital due to a variety of factors, which may or may not continue. To the extent we raise additional capital through the sale of equity securities, including to Aspire Capital, the ownership position of our existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

Failure to successfully address ongoing liquidity requirements will have a material adverse effect on our business. If we are unable to obtain additional capital on acceptable terms when needed, we may be required to take actions that harm our business and our ability to achieve cash flow in the future, including possibly the surrender of our rights to some technologies or product opportunities, delaying our clinical trials or curtailing or ceasing operations.

We are heavily dependent on the successful development and commercialization of MultiStem products, and if we encounter delays or difficulties in the development of this product candidate, our business could be harmed.

Our success is heavily dependent upon the successful development of MultiStem products for certain diseases and conditions involving acute or ischemic injury or immune system dysfunction. Our business could be materially harmed if we encounter difficulties in the development of this product candidate, such as:

delays in the ability to manufacture the product in quantities or in a form that is suitable for any required preclinical studies or clinical trials;

delays in the design, enrollment, implementation or completion of required preclinical studies and clinical trials;

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an inability to follow our current development strategy for obtaining regulatory approval from the FDA because of changes in the regulatory approval process;

less than desired or complete lack of efficacy or safety in preclinical studies or clinical trials; and

intellectual property constraints that prevent us from making, using, or commercializing the product candidate.

Our product candidates are in an early stage of development and we currently have no therapeutic products approved for sale. If we are unable to develop, obtain regulatory approval or market any of our product candidates, our financial condition will be negatively affected, and we may have to curtail or cease our operations.

Many factors, known and unknown, can adversely affect clinical trials and the ability to evaluate a product's efficacy. During the course of treatment, patients can die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Even if unrelated to our product, certain events can nevertheless adversely impact our clinical trials. As a result, our ability to ultimately develop and market the products and obtain revenues would suffer.

Even promising results in preclinical studies and initial clinical trials do not ensure successful results in later clinical trials, which test broader human use of our products. Many companies in our industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials.

We are in the early stage of product development, and we are dependent on the application of our technologies to discover or develop therapeutic product candidates. We currently do not sell any approved therapeutic products and do not expect to have any products commercially available for several years, if at all. You must evaluate us in light of the uncertainties and complexities affecting an early stage biotechnology company. Our product candidates require additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals or clearances before marketing. To date, no one to our knowledge has commercialized any therapeutic products using our technologies and we might never commercialize any product using our technologies and strategy. In addition, we may not succeed in developing new product candidates as an alternative to our existing portfolio of product candidates. If our current product candidates are delayed or fail, or we fail to successfully develop and commercialize new product candidates, our financial condition may be negatively affected, and we may have to curtail or cease our operations.

We may not successfully maintain our existing collaborative and licensing arrangements, or establish new ones, which could adversely affect our ability to develop and commercialize our product candidates.

A key element of our business strategy is to commercialize some of our product candidates through collaborations with other companies. Our strategy includes establishing collaborations and licensing agreements with one or more pharmaceutical, biotechnology or device companies, preferably after we have advanced product candidates through the initial stages of clinical development. However, we may not be able to establish or maintain such licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

Our agreements with our collaborators and licensees may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply, or commercialization of certain product candidates, or could require or result in litigation or arbitration. Moreover, disagreements could arise with our collaborators over rights to intellectual property or our rights to share in any of the future revenues of products developed by our collaborators. These kinds of disagreements could result in costly and time-consuming litigation. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators.

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Currently, our material collaborations and licensing arrangements are our collaboration with Pfizer to develop and commercialize MultiStem for the treatment of IBD, and our collaboration with RTI to develop and commercialize MAPC technology-based biologic implants for certain orthopedic applications in the bone graft substitutes market, and our license with the University of Minnesota pursuant to which we license certain aspects of the MAPC technology. These arrangements do not have specific termination dates; rather, each arrangement terminates upon the occurrence of certain events.

If our collaborators do not devote sufficient time and resources to successfully carry out their contracted duties or meet expected deadlines, we may not be able to advance our product candidates in a timely manner or at all.

Our success depends on the performance by our collaborators of their responsibilities under our collaboration arrangements. Some potential collaborators may not perform their obligations in a timely fashion or in a manner satisfactory to us. Typically, we cannot control the amount of resources or time our collaborators may devote to our programs or potential products that may be developed in collaboration with us. We are currently involved in multiple research and development collaborations with academic and research institutions. These collaborators frequently depend on outside sources of funding to conduct or complete research and development, such as grants or other awards. In addition, our academic collaborators may depend on graduate students, medical students, or research assistants to conduct certain work, and such individuals may not be fully trained or experienced in certain areas, or they may elect to discontinue their participation in a particular research program, creating an inability to complete ongoing research in a timely and efficient manner. As a result of these uncertainties, we are unable to control the precise timing and execution of any experiments that may be conducted.

Additionally, our current or future corporate collaborators will retain the ability to pursue other research, product development or commercial opportunities that may be directly competitive with our programs. If these collaborators elect to prioritize or pursue other programs in lieu of ours, we may not be able to advance product development programs in an efficient or effective manner, if at all. If a collaborator is pursuing a competitive program and encounters unexpected financial or capability limitations, they may be motivated to reduce the priority placed on our programs or delay certain activities related to our programs or be unwilling to properly fund their share of the development expenses for our programs. Any of these developments could harm our product and technology development efforts, which could seriously harm our business.

We may experience delays in clinical trials and regulatory approval relating to our products that could adversely affect our financial results and our commercial prospects for our pharmaceutical or stem cell products.

In addition to the regulatory requirements for our pharmaceutical programs, we will also require regulatory approvals for each distinct application of our stem cell product. In each case, we will be required to conduct clinical trials to demonstrate safety and efficacy of MultiStem, or various products that incorporate or use MultiStem. For product candidates that advance to clinical testing, we cannot be certain that we or a collaborator will successfully complete the clinical trials necessary to receive regulatory product approvals. This process is lengthy and expensive.

We intend to seek approval for our product candidates through the FDA approval process. To obtain regulatory approvals, we must, among other requirements, complete clinical trials showing that our products are safe and effective for a particular indication. Under the approval process, we must submit clinical and non-clinical data to demonstrate the medication is safe and effective. For example, we must be able to provide data and information, which may include extended pharmacology, toxicology, reproductive toxicology, bioavailability and genotoxicity studies, to establish suitability for Phase 2 or large scale Phase 3 clinical trials.

All of our product candidates are at an early stage of development. As these programs enter and progress through early stage clinical development, or complete additional non-clinical testing, an indication of a lack of safety or lack of efficacy may result in the early termination of an ongoing trial, or may cause us or any of our collaborators to forego further development of a particular product candidate or program. The FDA or other regulatory agencies may require extensive clinical trials or other testing prior to granting approval, which could be costly and time consuming to conduct. Any of these developments would hinder, and potentially prohibit, our ability to commercialize our product candidates. We cannot assure you that clinical trials will in fact demonstrate that our products are safe or effective.

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Additionally, we may not be able to find acceptable patients or may experience delays in enrolling patients for our currently planned or any future clinical trials. The FDA or we may suspend our clinical trials at any time if either believes that we are exposing the subjects participating in the trials to unacceptable health risks. The FDA or institutional review boards and/or institutional biosafety committees at the medical institutions and healthcare facilities where we seek to sponsor clinical trials may not permit a trial to proceed or may suspend any trial indefinitely if they find deficiencies in the conduct of the trials.

Product development costs to us and our potential collaborators will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. We expect to continue to rely on third-party clinical investigators at medical institutions and healthcare facilities to conduct our clinical trials, and, as a result, we may face additional delaying factors outside our control. Significant delays may adversely affect our financial results and the commercial prospects for our product candidates and delay our ability to become profitable.

The results seen in animal testing of our product candidates may not be replicated in humans.

This annual report discusses the safety and efficacy seen in preclinical testing of our lead product candidates, including MultiStem, in animals, but we may not see positive results when our other product candidates undergo clinical testing in humans in the future. Preclinical studies and Phase I clinical trials are not primarily designed to test the efficacy of a product candidate in humans, but rather to:

test short-term safety and tolerability;

study the absorption, distribution, metabolism and elimination of the product candidate;

study the biochemical and physiological effects of the product candidate and the mechanisms of the drug action and the relationship between drug levels and effect; and

understand the product candidate's side effects at various doses and schedules.

Success in preclinical studies or completed clinical trials does not ensure that later studies or trials, including continuing non-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. The rate of failure in drug development is quite high, and many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Product candidates may fail to show desired safety and efficacy in larger and more diverse patient populations in later stage clinical trials, despite having progressed through early stage trials. Negative or inconclusive results from any of our ongoing preclinical studies or clinical trials could result in delays, modifications, or abandonment of ongoing or future clinical trials and the termination of our development of a product candidate. Additionally, even if we are able to successfully complete pivotal Phase 3 clinical trials, the FDA still may not approve our product candidates.

Even if we obtain regulatory approval of any of our product candidates, the approved products may be subject to post-approval studies and will remain subject to ongoing regulatory requirements. If we fail to comply, or if concerns are identified in subsequent studies, our approval could be withdrawn and our product sales could be suspended.

If we are successful at obtaining regulatory approval for MultiStem or any of our other product candidates, regulatory agencies in the United States and other countries where a product will be sold may require extensive additional clinical trials or post-approval clinical studies that are expensive and time consuming to conduct. In particular, therapeutic products administered for the treatment of persistent or chronic conditions, such as obesity, are likely to require extensive follow-up studies and close monitoring of patients after regulatory approval has been granted, for any signs of adverse effects that occur over a long period of time. These studies may be expensive and time consuming to conduct and may reveal side effects or other harmful effects in patients that use our therapeutic products after they are on the market, which may result in the limitation or withdrawal of our drugs from the market. Alternatively, we may not be able to conduct such additional trials, which might force us to abandon our efforts to develop or commercialize certain product candidates. Even if post-approval studies are not requested or required, after our products are approved and on the market, there might be safety issues that emerge over time that require a change in product labeling or that require withdrawal of the product from the market, which would cause our revenue to decline.

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Additionally, any products that we may successfully develop will be subject to ongoing regulatory requirements after they are approved. These requirements will govern the manufacturing, packaging, marketing, distribution, and use of our products. If we fail to comply with such regulatory requirements, approval for our products may be withdrawn, and product sales may be suspended. We may not be able to regain compliance, or we may only be able to regain compliance after a lengthy delay, significant expense, lost revenues and damage to our reputation.

We may rely on third parties to manufacture our MultiStem product candidate.

Our current business strategy relies on third parties to manufacture our MultiStem product candidates in accordance with good manufacturing practices established by the FDA, or similar regulations in other countries. These third parties may not deliver sufficient quantities of our MultiStem product candidates, manufacture MultiStem product candidates in accordance with specifications, or comply with applicable government regulations. Additionally, if the manufactured products fail to perform as specified, our business and reputation could be severely impacted.

We expect to enter into additional manufacturing agreements for the production of product materials. If any manufacturing agreement is terminated or any third party collaborator experiences a significant problem that could result in a delay or interruption in the supply of product materials to us, there are very few contract manufacturers that currently have the capability to produce our MultiStem product on acceptable terms, or on a timely and cost-effective basis. We cannot assure you that manufacturers on whom we will depend will be able to successfully produce our MultiStem product on acceptable terms, or on a timely or cost-effective basis. We cannot assure you that manufacturers will be able to manufacture our products in accordance with our product specifications or will meet FDA or other requirements. We must have sufficient and acceptable quantities of our product materials to conduct our clinical trials and ultimately to market our product candidates, if and when such products have been approved by the FDA for marketing. If we are unable to obtain sufficient and acceptable quantities of our product material, we may be required to delay the clinical testing and marketing of our products.

If we do not comply with applicable regulatory requirements in the manufacture and distribution of our product candidates, we may incur penalties that may inhibit our ability to commercialize our products and adversely affect our revenue.

Our failure or the failure of our potential collaborators or third party manufacturers to comply with applicable FDA or other regulatory requirements including manufacturing, quality control, labeling, safety surveillance, promoting and reporting may result in criminal prosecution, civil penalties, recall or seizure of our products, total or partial suspension of production or an injunction, as well as other regulatory action against our product candidates or us. Discovery of previously unknown problems with a product, supplier, manufacturer or facility may result in restrictions on the sale of our products, including a withdrawal of such products from the market. The occurrence of any of these events would negatively impact our business and results of operations.

If we are unable to attract and retain key personnel and advisors, it may adversely affect our ability to obtain financing, pursue collaborations or develop our product candidates.

We are highly dependent on our executive officers Gil Van Bokkelen, Ph.D., our Chief Executive Officer, William Lehmann, J.D., M.B.A., President and Chief Operating Officer, John Harrington, Ph.D., Chief Scientific Officer and Executive Vice President, Robert Deans, Ph.D., Executive Vice President, Regenerative Medicine, and Laura Campbell, CPA, Vice President of Finance, as well as other personnel.

These individuals are integral to the development and integration of our technologies and to our present and future scientific collaborations, including managing the complex research processes and the product development and potential commercialization processes. Given their leadership, extensive technical, scientific and financial expertise and management and operational experience, these individuals would be difficult to replace. Consequently, the loss of services of one or more of these named individuals could result in product development delays or the failure of our collaborations with current and future collaborators, which, in turn, may hurt our ability to develop and commercialize products and generate revenues.

Our future success depends on our ability to attract, retain and motivate highly qualified management and scientific, development and commercial personnel and advisors. If we are unable to attract and retain key personnel and advisors, it may negatively affect our ability to successfully develop, test and commercialize our product candidates.

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Our ability to compete may decline if we are not successful in adequately protecting our patented and other proprietary technologies.

Our success depends in part on our ability to obtain and maintain intellectual property that protects our technologies and our products. Patent positions may be highly uncertain and may involve complex legal and factual questions, including the ability to establish patentability of compounds and methods for using them for which we seek patent protection. We cannot predict the breadth of claims that will ultimately be allowed in our patent applications, if any, including those we have in-licensed or the extent to which we may enforce these claims against our competitors. We have filed multiple patent applications that seek to protect the composition of matter and method of use related to our programs. In addition, we are prosecuting numerous distinct patent families directed to composition, methods of production, and methods of use of MultiStem and related technologies. If we are unsuccessful in obtaining and maintaining these patents related to products and technologies, we may ultimately be unable to commercialize products that we are developing or may elect to develop in the future.

The degree of future protection for our proprietary rights is therefore highly uncertain and we cannot assure you that:

we were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies or product candidates upon which we rely;

others will not independently develop similar or alternative technologies or duplicate any of our technologies;

others did not publicly disclose our claimed technology before we conceived the subject matter included in any of our patent applications;

any of our pending or future patent applications will result in issued patents;

any of our patent applications will not result in interferences or disputes with third parties regarding priority of invention;

any patents that may be issued to us, our collaborators or our licensors will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;

we will develop additional proprietary technologies that are patentable;

the patents of others will not have an adverse effect on our ability to do business; or

new proprietary technologies from third parties, including existing licensors, will be available for licensing to us on reasonable commercial terms, if at all.

In addition, patent law outside the United States is uncertain and in many countries intellectual property laws are undergoing review and revision. The laws of some countries do not protect intellectual property rights to the same extent as domestic laws. It may be necessary or useful for us to participate in opposition proceedings to determine the validity of our competitors' patents or to defend the validity of any of our or our licensor's future patents, which could result in substantial costs and would divert our efforts and attention from other aspects of our business. With respect to certain of our inventions, we have decided not to pursue patent protection outside the United States, both because we do not believe it is cost effective and because of confidentiality concerns. Accordingly, our international competitors could develop and receive foreign patent protection for gene sequences and functions for which we are seeking United States patent protection, enabling them to sell products that we have developed.

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Technologies licensed to us by others, or in-licensed technologies, are important to our business. The scope of our rights under our licenses may be subject to dispute by our licensors or third parties. Our rights to use these technologies and to practice the inventions claimed in the licensed patents are subject to our licensors abiding by the terms of those licenses and not terminating them. In particular, we depend on certain technologies relating to our MultiStem technology licensed from the University of Minnesota, and the termination of this license could result in our loss of some of the rights that enable us to utilize this technology, and our ability to develop products based on MultiStem could be seriously hampered.

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In addition, we may in the future acquire rights to additional technologies by licensing such rights from existing licensors or from third parties. Such in-licenses may be costly. Also, we generally do not control the patent prosecution, maintenance or enforcement of in-licensed technologies. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we do over our internally developed technologies. Moreover, some of our academic institution licensors, collaborators and scientific advisors have rights to publish data and information to which we have rights. If we cannot maintain the confidentiality of our technologies and other confidential information in connection with our collaborations, our ability to protect our proprietary information or obtain patent protection in the future may be impaired, which could have a significant adverse effect on our business, financial condition and results of operations.

We may not have adequate protection for our unpatented proprietary information, which could adversely affect our competitive position.

In addition to patents, we will substantially rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. However, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. To protect our trade secrets, we may enter into confidentiality agreements with employees, consultants and potential collaborators. However, these agreements may not provide meaningful protection of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information. Likewise, our trade secrets or know-how may become known through other means or be independently discovered by our competitors. Any of these events could prevent us from developing or commercializing our product candidates.

We may be sued for product liability, which could adversely affect our business.

Because our business strategy involves the development and sale by either us or our collaborators of commercial products, we may be sued for product liability. We may be held liable if any product we develop and commercialize, or any product our collaborators commercialize that incorporates any of our technology, causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. In addition, the safety studies we must perform and the regulatory approvals required to commercialize our pharmaceutical products, will not protect us from any such liability.

We carry product liability insurance that includes coverage for human clinical trials. Currently, we carry a \$5 million per event, \$5 million annual aggregate coverage for both our products liability policy and our clinical trials protection. We also intend to seek product liability insurance for any approved products that we may develop or acquire. However, in the event there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any of our approved products. If such insurance is insufficient to protect us, our results of operations will suffer. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage.

Many potential competitors, including those who have greater resources and experience than we do, may develop products or technologies that make ours obsolete or noncompetitive.

We face significant competition with respect to our product candidates. With regard to our efforts to develop MultiStem as a novel stem cell therapy, currently, there are a number of companies that are actively developing stem cell products, which encompass a range of different cell types, including embryonic stem cells, adult-derived stem cells, and processed bone marrow derived cells. Our future success will depend on our ability to maintain a competitive position with respect to technological advances. Technological developments by others may result in our MultiStem product platform and technologies, as well as our pharmaceutical formulations, becoming obsolete.

We are subject to significant competition from pharmaceutical, biotechnology and diagnostic companies, academic and research institutions, and government or other publicly funded agencies that are pursuing or may pursue the development of therapeutic products and technologies that are substantially similar to our proposed therapeutic products and technologies, or that otherwise address the indications we are pursuing. Our most significant competitors include major pharmaceutical companies such as Pfizer, Roche, Johnson & Johnson, Sanofi and GlaxoSmithKline, as well as smaller biotechnology or biopharmaceutical companies such as Celgene, Mesoblast, Aastrom, Stem Cells Inc., Cytori, Pluristem, Arena Pharmaceuticals and Vivus. Most of our current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources, and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally.

Many of these companies have substantially greater capital resources, research and development resources and experience, manufacturing capabilities, regulatory expertise, sales and marketing resources, established relationships with consumer products companies and production facilities.

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Universities and public and private research institutions are also potential competitors. While these organizations primarily have educational objectives, they may develop proprietary technologies related to stem cells or secure patent protection that we may need for the development of our technologies and products. We may attempt to license these proprietary technologies, but these licenses may not be available to us on acceptable terms, if at all. Our competitors, either alone or with their collaborative partners, may succeed in developing technologies or products that are more effective, safer, more affordable or more easily commercialized than ours, and our competitors may obtain intellectual property protection or commercialize products sooner than we do. Developments by others may render our product candidates or our technologies obsolete.

Our current product discovery and development collaborators are not prohibited from entering into research and development collaboration agreements with third parties in any product field. Our failure to compete effectively would have a significant adverse effect on our business, financial condition and results of operations.

The availability, manner, and amount of reimbursement for our product candidates from government and private payers are uncertain, and our inability to obtain adequate reimbursement for any products could severely limit our product sales.

We expect that many of the patients who seek treatment with any of our products that are approved for marketing will be eligible for Medicare benefits. Other patients may be covered by private health plans. If we are unable to obtain or retain adequate levels of reimbursement from Medicare or from private health plans, our ability to sell our products will be severely limited. The application of existing Medicare regulations and interpretive coverage and payment determinations to newly approved products is uncertain and those regulations and interpretive determinations are subject to change. The Medicare Prescription Drug Improvement and Modernization Act, enacted in December 2003, provides for a change in reimbursement methodology that reduces the Medicare reimbursement rates for many drugs, which may adversely affect reimbursement for any products we may develop. Medicare regulations and interpretive determinations also may determine who may be reimbursed for certain services, and may limit the pool of patients our product candidates are being developed to serve.

Federal, state and foreign governments continue to propose legislation designed to contain or reduce health care costs. Legislation and regulations affecting the pricing of products like our potential products may change further or be adopted before any of our potential products are approved for marketing. Cost control initiatives by governments or third-party payers could decrease the price that we receive for any one or all of our potential products or increase patient coinsurance to a level that make our products under development become unaffordable. In addition, government and private health plans persistently challenge the price and cost-effectiveness of therapeutic products. Accordingly, these third parties may ultimately not consider any or all of our products under development to be cost effective, which could result in products not being covered under their health plans or covered only at a lower price. Any of these initiatives or developments could prevent us from successfully marketing and selling any of our products that are approved for commercialization.

Public perception of ethical and social issues surrounding the use of adult-derived stem cell technology may limit or discourage the use of our technologies, which may reduce the demand for our therapeutic products and technologies and reduce our revenues.

Our success will depend in part upon our ability to develop therapeutic products incorporating or discovered through our adult-derived stem cell technology. For social, ethical, or other reasons, governmental authorities in the United States and other countries may call for limits on, or regulation of the use of, adult-derived stem cell technologies. Although we do not use the more controversial stem cells derived from embryos or fetuses, claims that adult-derived stem cell technologies are ineffective, unethical or pose a danger to the environment may influence public attitudes. The subject of stem cell technologies in general has received negative publicity and aroused public debate in the United States and some other countries. Ethical and other concerns about our adult-derived stem cell technology could materially hurt the market acceptance of our therapeutic products and technologies, resulting in diminished sales and use of any products we are able to develop using adult-derived stem cells.

Even if we or our collaborators receive regulatory approval for our products, those products may never be commercially successful.

Even if we develop pharmaceuticals or MultiStem related products that obtain the necessary regulatory approval, and we have access to the necessary manufacturing, sales, marketing and distribution capabilities that we need, our success depends to a significant degree upon the commercial success of those products. If these products fail to achieve or subsequently maintain market acceptance or commercial viability, our business would be significantly harmed because our future royalty revenue or other revenue would be dependent upon sales of these products. Many factors may affect the market acceptance and commercial success of any potential products that we may discover, including:

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health concerns, whether actual or perceived, or unfavorable publicity regarding our obesity drugs, stem cell products or those of our competitors;

the timing of market entry as compared to competitive products;

the rate of adoption of products by our collaborators and other companies in the industry;

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any product labeling that may be required by the FDA or other United States or foreign regulatory agencies for our products or competing or comparable products;

convenience and ease of administration;

pricing;

perceived efficacy and side effects;

marketing;

availability of alternative treatments;

levels of reimbursement and insurance coverage; and

activities by our competitors.

If we are unable to create and maintain sales, marketing and distribution capabilities or enter into agreements with third parties to perform those functions, we will not be able to commercialize our product candidates.

We currently have no sales, marketing or distribution capabilities. Therefore, to commercialize our product candidates, if and when such products have been approved and are ready for marketing, we expect to collaborate with third parties to perform these functions. We will either need to share the value generated from the sale of any products and/or pay a fee to the contract sales organization. If we establish any such relationships, we will be dependent upon the capabilities of our collaborators or contract service providers to effectively market, sell, and distribute our product. If they are ineffective at selling and distributing our product, or if they choose to emphasize other products over ours, we may not achieve the level of product sales revenues that we would like. If conflicts arise, we may not be able to resolve them easily or effectively, and we may suffer financially as a result. If we cannot rely on the sales, marketing and distribution capabilities of our collaborators or of contract service providers, we may be forced to establish our own capabilities. We have no experience in developing, training or managing a sales force and will incur substantial additional expenses if we decide to market any of our future products directly. Developing a marketing and sales force is also time consuming and could delay launch of our future products. In addition, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete successfully against these companies.

We will use hazardous and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our products and processes will involve the controlled storage, use and disposal of certain hazardous and biological materials and waste products. We and our suppliers and other collaborators are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and exceed our financial resources. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs to comply with current or future environmental laws and regulations.

Disputes concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and extremely costly and could delay our research and development efforts.

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Our commercial success, if any, will be significantly harmed if we infringe the patent rights of third parties or if we breach any license or other agreements that we have entered into with regard to our technology or business.

We are aware of other companies and academic institutions that have been performing research in the areas of adult derived stem cells. In particular, other companies and academic institutions have announced that they have identified nonembryonic stem cells isolated from bone marrow or other tissues that have the ability to form a range of cell types, or display the property of pluripotency. To the extent any of these companies or academic institutions currently have, or obtain in the future, broad patent claims, such patents could block our ability to use various aspects of our discovery and development process and might prevent us from developing or commercializing newly discovered applications of our MultiStem technology, or otherwise conducting our business. In addition, it is possible that some of the pharmaceutical product candidates we are developing may not be patentable or may be covered by intellectual property of third parties.

We are not currently a party to any litigation with regard to our patent or trademark positions. However, the life sciences and other technology industries are characterized by extensive litigation regarding patents and other intellectual property rights. Many life sciences and other technology companies have employed intellectual property litigation as a way to gain a competitive advantage. To the extent we are involved in litigation, interference proceedings, oppositions, reexamination, protest or other potentially adverse intellectual property proceedings as a result of alleged infringement by us of the rights of others or as a result of priority of invention

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disputes with third parties, we might have to spend significant amounts of money, time and effort defending our position and we may not be successful. In addition, any claims relating to the infringement of third-party proprietary rights or proprietary determinations, even if not meritorious, could result in costly litigation, lengthy governmental proceedings, divert management's attention and resources, or require us to enter into royalty or license agreements that are not advantageous to us. If we do not have the financial resources to support such litigation or appeals, we may forfeit or lose certain commercial rights. Even if we have the financial resources to continue such litigation or appeals, we may lose. In the event that we lose, we may be forced to pay very substantial damages; we may have to obtain costly license rights, which may not be available to us on acceptable terms, if at all; or we may be prohibited from selling products that are found to infringe the patent rights of others.

Should any person have filed patent applications or obtained patents that claim inventions also claimed by us, we may have to participate in an interference proceeding declared by the relevant patent regulatory agency to determine priority of invention and, thus, the right to a patent for these inventions in the United States. Such a proceeding could result in substantial cost to us even if the outcome is favorable. Even if successful on priority grounds, an interference action may result in loss of claims based on patentability grounds raised in the interference action. Litigation, interference proceedings or other proceedings could divert management's time and efforts. Even unsuccessful claims could result in significant legal fees and other expenses, diversion of management's time and disruption in our business. Uncertainties resulting from initiation and continuation of any patent proceeding or related litigation could harm our ability to compete and could have a significant adverse effect on our business, financial condition and results of operations.

An adverse ruling arising out of any intellectual property dispute, including an adverse decision as to the priority of our inventions, could undercut or invalidate our intellectual property position. An adverse ruling could also subject us to significant liability for damages, including possible treble damages, prevent us from using technologies or developing products, or require us to negotiate licenses to disputed rights from third parties. Although patent and intellectual property disputes in the technology area are often settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and could include license fees and ongoing royalties. Furthermore, necessary licenses may not be available to us on satisfactory terms, if at all. Failure to obtain a license in such a case could have a significant adverse effect on our business, financial condition and results of operations.

To the extent we enter markets outside of the United States, our business will be subject to political, economic, legal and social risks in those markets, which could adversely affect our business.

There are significant regulatory and legal barriers in markets outside the United States that we must overcome to the extent we enter or attempt to enter markets in countries other than the United States. We will be subject to the burden of complying with a wide variety of national and local laws, including multiple and possibly overlapping and conflicting laws. We also may experience difficulties adapting to new cultures, business customs and legal systems. Any sales and operations outside the United States would be subject to political, economic and social uncertainties including, among others:

changes and limits in import and export controls;

increases in custom duties and tariffs;

changes in currency exchange rates;

economic and political instability;

changes in government regulations and laws;

absence in some jurisdictions of effective laws to protect our intellectual property rights; and

currency transfer and other restrictions and regulations that may limit our ability to sell certain products or repatriate profits to the United States.

Any changes related to these and other factors could adversely affect our business to the extent we enter markets outside the United States.

Foreign governments often impose strict price controls on approved products, which may adversely affect our future profitability in those countries, and the re-importation of drugs to the United States from foreign countries that impose price controls may adversely affect our future profitability.

Frequently foreign governments impose strict price controls on newly approved therapeutic products. If we obtain regulatory approval to sell products in foreign countries, we may be unable to obtain a price that provides an adequate financial return on our investment. Furthermore, legislation in the United States may permit re-importation of drugs from foreign countries into the United States, including re-importation from foreign countries where the drugs are sold at lower prices than in the United States due to foreign government-mandated price controls. Such a practice, especially if it is conducted on a widespread basis, may significantly reduce our potential United States revenues from any drugs that we are able to develop.

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If we elect not to sell our products in foreign countries that impose government mandated price controls because we decide it is uneconomical to do so, a foreign government or patent office may attempt to terminate our intellectual property rights in that country, enabling competitors to make and sell our products.

In some cases we may choose not to sell a product in a foreign country because it is uneconomical to do so under a system of government-imposed price controls, or because it could severely limit our profitability in the United States or other markets. In such cases, a foreign government or patent office may terminate any intellectual property rights we may obtain with respect to that product. Such a termination could enable competitors to produce and sell our product in that market. Furthermore, such products may be exported into the United States through legislation that authorizes the importation of drugs from outside the United States. In such an event, we may have to reduce our prices, or we may be unable to compete with low-cost providers of our drugs, and we could be financially harmed as a result.

We may encounter difficulties managing our growth, which could adversely affect our business.

At various times we have experienced periods of rapid growth in our employee numbers as a result of a dramatic increase in activity in technology programs, genomics programs, collaborative research programs, discovery programs, and scope of operations. At other times, we have had to reduce staff in order to bring our expenses in line with our financial resources. Our success will also depend on the ability of our officers and key employees to continue to improve our operational capabilities and our management information and financial control systems, and to expand, train and manage our work force.

If we acquire products, technologies or other businesses, we will incur a variety of costs, may have integration difficulties and may experience numerous other risks that could adversely affect our business.

To remain competitive, we may decide to acquire additional businesses, products and technologies. We currently have no commitments or agreements with respect to, and are not actively seeking, any material acquisitions. We have limited experience in identifying acquisition targets, successfully acquiring them and integrating them into our current infrastructure. We may not be able to successfully integrate any businesses, products, technologies or personnel that we might acquire in the future without a significant expenditure of operating, financial and management resources, if at all. In addition, future acquisitions could require significant capital infusions and could involve many risks, including, but not limited to the following:

we may have to issue convertible debt or equity securities to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock;

an acquisition may negatively impact our results of operations because it may require us to incur large one-time charges to earnings, amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or it may cause adverse tax consequences, substantial depreciation or deferred compensation charges;

we may encounter difficulties in assimilating and integrating the business, technologies, products, personnel or operations of companies that we acquire;

certain acquisitions may disrupt our relationship with existing collaborators who are competitive to the acquired business;

acquisitions may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient revenue to offset acquisition costs;

an acquisition may disrupt our ongoing business, divert resources, increase our expenses and distract our management;

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acquisitions may involve the entry into a geographic or business market in which we have little or no prior experience; and

key personnel of an acquired company may decide not to work for us.

Any of the foregoing risks could have a significant adverse effect on our business, financial condition and results of operations.

If we do not continue to meet the listing standards established by The NASDAQ Capital Market, the common stock may not remain listed for trading.

The NASDAQ Capital Market has established certain quantitative criteria and qualitative standards that companies must meet in order to remain listed for trading on these markets. We cannot guarantee that we will be able to maintain all necessary requirements for listing; therefore, we cannot guarantee that our common stock will remain listed for trading on The NASDAQ Capital Market or other similar markets.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our principal offices are located at 3201 Carnegie Avenue in Cleveland, Ohio. We currently lease approximately 45,000 square feet of space for our corporate offices and laboratories, with state-of-the-art laboratory space. The lease began in 2000 and currently expires in March 2016, and we have the option to renew annually through 2019. Our rent is \$267,000 per year and our rental rate has not changed since the lease inception in 2000. Also, we currently lease office and laboratory space for our Belgian subsidiary. The lease currently expires in July 2015, and we have an option to renew annually through July 2022. The annual rent in Belgium is 144,000 and is subject to adjustments based on an inflationary index. Our total rent expense for all properties was \$491,000 in 2013.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become subject to various legal proceedings that are incidental to the ordinary conduct of our business. Currently, there are no such proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock is traded on the NASDAQ Capital Market under the symbol ATHX. Set forth below are the high and low sale prices for our common stock on the NASDAQ Capital Market for the periods indicated.

	High	Low
Year ended December 31, 2013:		
Fourth Quarter	\$ 2.52	\$ 1.52
Third Quarter	\$ 1.99	\$ 1.47
Second Quarter	\$ 2.42	\$ 1.54
First Quarter	\$ 1.89	\$ 1.07
Year ended December 31, 2012:		
Fourth Quarter	\$ 1.47	\$ 0.95
Third Quarter	\$ 1.75	\$ 1.35
Second Quarter	\$ 1.71	\$ 1.25
First Quarter	\$ 2.33	\$ 1.49

 Holders

As of March 1, 2014, there were approximately 540 holders of record of our common stock. Additionally, shares of common stock are held by financial institutions as nominees for beneficial owners that are deposited into participant accounts at DTC, which are considered to be held of record by Cede & Co. and are included in the holders of record as one stockholder.

Dividend Policy

We would have to rely upon dividends and other payments from our wholly owned subsidiary, ABT Holding Company, to generate the funds necessary to make dividend payments, if any, on our common stock. ABT Holding Company, however, is legally distinct from us and has no obligation to pay amounts to us. The ability of ABT Holding Company to make dividend and other payments to us is subject to, among other things, the availability of funds and applicable state laws. However, there are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us. We did not pay cash dividends on our common stock during the past three years. We do not anticipate that we will pay any dividends on our common stock in the foreseeable future. Rather, we anticipate that we will retain earnings, if any, for use in the development of our business.

Unregistered Sales of Equity Securities and Use of Proceeds

During the quarter ended December 31, 2013, we sold an aggregate of 300,000 shares of common stock to Aspire Capital under an equity purchase agreement an average purchase price of \$1.69 per share. Each issuance of these unregistered shares qualifies as an exempt transaction pursuant to Section 4(2) of the Securities Act of 1933. Each issuance qualified for exemption under Section 4(2) of the Securities Act of 1933 because none involved a public offering. Each offering was not a public offering due to the number of persons involved, the manner of the issuance and the number of securities issued. In addition, in each case Aspire Capital had the necessary investment intent.

Information concerning our share repurchases made during the fourth quarter of 2013:

Period	Total Number of Shares Purchased (1)	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly	Maximum Number of Shares that May Yet Be Purchased
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		Announced Plans	Under the Plans
October		\$	
November			
December	65,732	2.06	
Total	65,732	\$ 2.06	

(1) All shares were surrendered or deemed surrendered to us in connection with our share-based compensation plans.

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(in thousands, except share and per share data)

	Year Ended December 31,				
	2013	2012	2011	2010	2009
Consolidated Statement of Operations Data:					
Revenues:					
Contract revenue	\$ 755	\$ 7,380	\$ 9,015	\$ 6,685	\$ 1,079
Grant revenue	1,683	1,328	1,329	2,254	1,080
Total revenues	2,438	8,708	10,344	8,939	2,159
Costs and expenses:					
Research and development	20,484	19,636	18,930	14,779	11,920
General and administrative	6,065	4,753	4,916	5,387	5,621
Depreciation	346	320	278	284	233
Loss from operations	(24,457)	(16,001)	(13,780)	(11,511)	(15,615)
Other (expense) income:					
Other income (expense), net	38	(1,138)	(778)	134	249
(Expense) income from change in fair value of warrants	(6,324)	2,404	812		
Net loss	\$ (30,743)	\$ (14,735)	\$ (13,746)	\$ (11,377)	\$ (15,366)
Basic and diluted net loss per share	\$ (0.53)	\$ (0.45)	\$ (0.59)	\$ (0.60)	\$ (0.81)
Weighted average shares outstanding, basic and diluted	57,674,833	32,556,781	23,239,019	18,929,749	18,928,379

	December 31,				
	2013	2012	2011	2010	2009
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 31,948	\$ 25,533	\$ 8,785	\$ 2,105	\$ 11,167
Available-for-sale securities, short-term			3,999	13,076	10,135
Working capital	28,487	21,831	7,014	9,106	16,291
Available-for-sale securities, long-term					5,080
Total assets	34,188	27,603	15,701	19,106	28,331
Warrant liabilities and note payable	9,999	2,878	983		
Total stockholders' equity	19,821	20,247	7,298	9,005	18,957

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

You should read the following discussion and analysis in conjunction with Item 8. Financial Statements and Supplementary Data included below in this annual report on Form 10-K.

Overview

We are an international biotechnology company that is focused primarily in the field of regenerative medicine. Our MultiStem cell therapy has been evaluated in two completed Phase 1 clinical trials and is currently being evaluated in two ongoing Phase 2 clinical trials, as well as an investigator-led Phase 1 trial. Our current clinical development programs are focused on treating inflammatory and immune disorders, neurological conditions, cardiovascular disease, and other conditions. We are also applying our pharmaceutical discovery capabilities to identify and develop small molecule compounds with potential applications in indications such as obesity, related metabolic conditions and certain neurological conditions.

Current Programs

By applying our proprietary MultiStem cell therapy product, we have established therapeutic product development programs treating inflammatory and immune disorders, neurological conditions, cardiovascular disease, and other conditions. To date, we have advanced five programs to the clinical development stage, including the following:

Inflammatory Bowel Disease: MultiStem therapy is being evaluated in a Phase 2 clinical study involving administration of MultiStem to patients suffering from UC, the most common form of IBD. This double blind, placebo controlled trial being conducted with our partner, Pfizer, in UC patients that have an inadequate response or are refractory to current treatment, completed enrolling patients in December 2013. We expect to report with Pfizer the initial results in the spring of 2014.

Ischemic Stroke: In our ongoing Phase 2 clinical study, we are evaluating the administration of MultiStem cell therapy to patients that have suffered an ischemic stroke. In contrast to treatment with thrombolytics, which must be administered within 3 to 4 hours after a stroke, we are treating patients one to two days after the stroke has occurred. In preclinical studies, administration of a single dose of MultiStem cells, even several days after a stroke, resulted in significant and durable improvements. This double blind, placebo-controlled trial is being conducted at leading stroke centers across the United States and Europe. The study is expected to enroll approximately 136 patients. We are targeting to complete enrollment around the end of summer 2014 and release the preliminary results as soon as they are available.

Acute Myocardial Infarction: We have evaluated the administration of MultiStem to patients that have suffered an acute myocardial infarction, or AMI, in a Phase 1 clinical study. In 2010, we announced preliminary results for this study, demonstrating a favorable safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment. This data was published in a leading peer reviewed scientific journal in 2012. One-year follow-up data suggested that the benefit observed was sustained over time. We are preparing for a Phase 2 clinical study of MultiStem administration to heart attack victims and are planning to initiate late 2014. In 2013, we were awarded a grant for up to \$2.8 million to support funding this clinical program.

Hematopoietic Stem Cell Transplant / GvHD: We completed a Phase 1 clinical study of the administration of MultiStem cells to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a hematopoietic stem cell, or HSC, transplant. Such patients are at significant risk for serious complications, including GvHD, an imbalance of immune system function caused by transplanted immune cells that attack various tissues and organs in the patient. In 2011 and in 2012, we released data from the study, which demonstrated the safety of MultiStem cells in this indication and suggested that the MultiStem therapy may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. The MultiStem therapy has been designated an orphan drug by both the FDA and EMA, which may provide market exclusivity and other substantial potential incentives and benefits. We have had several interactions with the FDA and international agencies regarding study design and the potential to accelerate the path to product approval. Based on current plans, we intend to be ready to start this study in 2014, but study initiation will depend on the progress in our other clinical trials and the achievement of certain business development and financial objectives.

We are also collaborating with a leading transplant group at the University of Regensburg in Germany that has initiated a small institutional sponsored clinical trial exploring the administration of MultiStem cells in patients following a liver transplant. We are providing the clinical product and some financial support to conduct the trial.

In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem therapy in other inflammatory and immune, neurological and cardiovascular disease areas, as well as certain other indications. We conduct such work both through our own internal research efforts and through a broad network of collaborations we have established with

investigators at leading research institutions across the United States and in Europe.

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We are in discussions with third parties about collaborating in the development of MultiStem therapy for certain programs and may enter into one or more business partnership(s) to advance these programs.

We have also collaborated with RTI on the development of products for certain orthopedic applications using our stem cell technologies in the bone graft substitutes market. We will receive royalty revenue from product sales beginning in 2014, since RTI recently commenced its commercialization activities, and we may receive other payments upon the successful achievement of certain commercial milestones.

We are also engaged in the development of novel small molecule therapies to treat obesity and other conditions, such as schizophrenia. We may elect to enter into a partnership to advance the development of our 5HT2c agonist program, either for the treatment of obesity, schizophrenia, or both indications, as well as for certain programs involving MultiStem.

Financial

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of \$264 million at December 31, 2013. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We have used the financing proceeds from equity and debt offerings and other sources of capital to develop our technologies, to discover and develop therapeutic product candidates, develop business collaborations and to acquire certain technologies and assets. During the years ended December 2013, 2012 and 2011, excluding issuances pursuant to our equity purchase arrangement with Aspire Capital described below, we completed registered direct, public and private equity offerings generating net proceeds of approximately \$18.4 million, \$29.2 million and \$11.8 million, respectively. Also, in January 2014, we generated net proceeds of approximately \$18.7 million in a registered direct offering.

In November 2011, we entered into an equity purchase agreement with Aspire Capital, which provided that Aspire Capital was committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. As part of the agreement, Aspire Capital made an initial investment of \$1.0 million in us and received 266,667 additional shares as compensation for its commitment. As of September 30, 2013, we had sold all the remaining shares that were available under the 8,000,000 shares of common stock registered for resale under the equity facility, which was due to expire early in 2014.

In October 2013, we terminated the expiring 2011 equity purchase agreement with Aspire Capital and entered into a new 2013 equity purchase agreement with Aspire Capital to purchase up to an aggregate of \$25.0 million of shares of our common stock over a new two-year period. The terms of the 2013 equity facility are similar to the previous arrangement, and we issued 333,333 shares of our common stock Aspire Capital as a commitment fee in October 2013 and filed a registration statement for the resale of 10,000,000 shares of common stock in connection with the new equity facility.

During the quarter ended December 31, 2013, we sold 300,000 shares under the Aspire equity purchase agreements, and no shares were sold in the quarter ended December 31, 2012. From its inception in November 2011 through December 31, 2013, we have received proceeds of approximately \$13.4 million, in aggregate, under the Aspire equity purchase arrangement since its inception in November 2011.

During the year ended December 31, 2013, we received proceeds of approximately \$402,000 from the exercise of warrants aggregating in issuances of 397,826 shares of common stock. As of March 1, 2014, we received proceeds of approximately \$938,000 from the exercise of warrants in 2014. No warrants were exercised in 2012 and 2011.

In August 2013, we were awarded a federal grant that is expected to provide up to \$2.8 million in support of a Phase 2 clinical study evaluating the administration of MultiStem to patients who have suffered an AMI. In 2012, we were awarded grant funding aggregating \$3.6 million to further advance our MultiStem programs and cell therapy platform, including further development of MultiStem for the treatment of TBI and further development of our cell therapy formulations and manufacturing capabilities, from federal, state and European organizations.

Results of Operations

Since our inception, our revenues have consisted of license fees, contract revenues and milestone payments from our collaborators, and grant proceeds primarily from federal, state and foundation grants. We have derived no revenue from the commercial sale of therapeutic products to date. Research and development expenses consist primarily of external clinical and preclinical study costs, manufacturing and process development costs, salaries and related personnel costs, legal expenses resulting from intellectual property

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prosecution and maintenance processes, facility costs, and laboratory supply and reagent costs. We expense research and development costs as they are incurred. We expect to continue to make significant investments in research and development to enhance our technologies, advance clinical trials of our product candidates, expand our regulatory affairs and product development capabilities, conduct preclinical studies of our product, and manufacture our product candidates. General and administrative expenses consist primarily of salaries and related personnel costs, board fees, legal and professional fees, and other corporate expenses. We expect to continue to incur substantial losses through at least the next several years.

The following table sets forth our revenues and expenses for the periods indicated. The following tables are stated in thousands.

Revenues

	Year ended December 31,		
	2013	2012	2011
Contract revenue	\$ 755	\$ 7,380	\$ 9,015
Grant revenue	1,683	1,328	1,329
	\$ 2,438	\$ 8,708	\$ 10,344

Research and development expenses

Type of expense	Year ended December 31,		
	2013	2012	2011
Personnel costs	\$ 5,590	\$ 5,097	\$ 4,641
Research supplies	1,484	1,435	1,316
Facilities	1,083	964	944
Clinical and preclinical development costs	7,459	8,053	7,495
Sponsored research	1,074	1,381	1,408
Patent legal fees	1,956	1,373	1,703
Other	1,199	1,183	1,218
Stock-based compensation	639	150	205
	\$ 20,484	\$ 19,636	\$ 18,930

General and administrative expenses

Type of expense	Year ended December 31,		
	2013	2012	2011
Personnel costs	\$ 2,339	\$ 2,162	\$ 1,927
Facilities	262	280	270
Legal and professional fees	1,050	798	1,008
Other	1,530	1,182	1,364
Stock-based compensation	884	331	347
	\$ 6,065	\$ 4,753	\$ 4,916

Year Ended December 31, 2013 Compared to Year Ended December 31, 2012

Revenues. Revenues decreased to \$2.4 million for the year ended December 31, 2013 from \$8.7 million for 2012, reflecting a \$4.0 million decrease in our Pfizer contract revenues and a \$2.2 million decrease in our RTI contract revenues. Our 2012 contract revenues included the

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amortization of Pfizer payments, including a \$6.0 million up-front license fee, research and development funding, and payments for manufacturing services over the estimated performance period that ended in June 2012. Absent any new collaborations,

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our ongoing contract revenues will be comprised of any clinical manufacturing and milestone payments from Pfizer, potential royalty and commercial milestone payments from RTI, and potential license fees, milestone payments and royalties from Bristol-Myers Squibb. Grant revenue increased \$355,000 for the year ended December 31, 2013 compared to the year ended December 31, 2012, primarily due to expiring grants being replaced with new, larger awards, as our grants are focused now on late-stage preclinical and early-stage clinical development programs. Our grant revenues may fluctuate from period to period based on the timing of grant-related activities and the award and expiration of grants.

Research and Development Expenses. Research and development expenses increased to \$20.5 million for the year ended December 31, 2013 from \$19.6 million for the year ended December 31, 2012. The increase of \$0.9 million is primarily comprised of an increase in patent legal fees of \$583,000, an increase in personnel costs of \$493,000, an increase in stock-based compensation expense of \$489,000, an increase in facility costs of \$119,000, and an increase in research supplies of \$49,000 for the year ended December 31, 2013 from the comparable period in 2012. These increases were partially offset by a decrease in clinical and preclinical development costs of \$594,000 and a decrease in sponsored research costs of \$307,000 in 2013 compared to 2012. The increase in patent legal fees resulted from increased patent expenses associated with patent prosecution, national filings, and interference and related other filings during 2013. The increase in personnel costs related to the addition over the past twelve months of personnel supporting our preclinical and clinical programs, an annual merit increase in salaries, and increased performance bonus payments. The increase in stock-based compensation in 2013 compared to 2012 related primarily to restricted stock units granted to our named executive officers in exchange for the termination of an old incentive agreement, which vest over a three-year period, and the issuance of stock options to our executives as part of the implementation of an annual equity incentive program. Our clinical and preclinical development costs primarily reflect costs associated with our MultiStem clinical trials and include contract research organization costs, clinical manufacturing costs, manufacturing process development costs and clinical consulting costs. The decrease in our clinical and preclinical costs in 2013 compared to 2012 relates primarily to fewer manufacturing campaigns and less contract research organization costs for our ongoing clinical studies, net of increased manufacturing process development costs. Sponsored research costs decreased due to fewer academic research institution costs being required under our grant-funded programs. We expect our 2014 annual research and development expenses to be higher than the 2013 expenses based on our planned clinical development and manufacturing process development activities, and such costs will vary over time based on clinical manufacturing campaigns and the timing and stage of clinical trials underway. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

General and Administrative Expenses. General and administrative expenses increased to \$6.1 million in 2013 from \$4.8 million in 2012. The \$1.3 million increase in 2013 compared to 2012 was due primarily to an increase of \$553,000 in stock-based compensation, an increase in other general and administrative costs of \$348,000 related to outside services and recruiting costs, an increase in legal and professional fees of \$252,000 related primarily to SEC filings, and an increase in personnel costs of \$177,000. The increase in stock-based compensation in 2013 compared to 2012 related primarily to restricted stock units granted to our named executive officers in exchange for the termination of an old incentive arrangement, which vest over a three-year period, and the issuance of stock options to our executives as part of the implementation of an annual equity incentive program. The increase in outside services related to an increase in investor relations costs and advisory fees, as well as our being designated an accelerated filer in 2013, resulting in additional external costs associated with the required attestation of internal controls. The increase in legal and professional fees related primarily to required additional SEC filings and related activities, and corporate advisory services. The increase in personnel costs related to the addition of personnel over the past twelve months, an annual merit increase in salaries, and increased performance bonus payments. We expect our general and administrative expenses to continue at similar levels in 2014.

Depreciation. Depreciation expense increased to \$346,000 in 2013 from \$320,000 in 2012 due to depreciation on new capital purchases.

Other Income (Expense), net. In 2013, we had net other income of \$38,000 compared to net other expense of \$1.1 million in 2012. Included in other income (expense), net, are interest income, foreign currency gains and losses, and any realized gains and losses on the sale of our assets. Also, included in 2012 were the final cash and stock-based milestone payments to our former lenders in connection with our equity offerings amounting to \$1.3 million, net of a gain of \$183,000 related to an equity-method investment that was liquidated in 2012.

(Expense) Income from Change in Fair Value of Warrants. Expense of \$6.3 million and income of \$2.4 million was recognized during the years ended 2013 and 2012, respectively, for the change in the valuation of our warrant liabilities.

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Revenues. Revenues decreased to \$8.7 million for the year ended December 31, 2012 from \$10.3 million for 2011. Contract revenue decreased \$1.6 million for the year ended December 31, 2012 compared to the year ended December 31, 2011 and reflects the impact of our arrangements with Pfizer, RTI and Bristol-Myers Squibb. Our contract revenues reflect the amortization of Pfizer payments, including a \$6.0 million up-front license fee, over the estimated performance period that ended in June 2012, as well as the amortization of a \$3.0 million guaranteed license fee from the RTI collaboration over the estimated performance period that ended in 2011 and the final \$2.0 million license payments from RTI that was recognized in the fourth quarter of 2012. Grant revenue remained consistent at \$1.3 million for the year ended December 31, 2012 and 2011

primarily due to expiring grants being replaced with new grants.

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Research and Development Expenses. Research and development expenses increased to \$19.6 million for the year ended December 31, 2012 from \$18.9 million for the year ended December 31, 2011. The increase of \$0.7 million related to an increase in clinical and preclinical development costs of \$558,000, an increase in personnel costs of \$456,000 and an increase in research supplies of \$119,000 for the year ended December 31, 2012 from the comparable period in 2011. These increases were partially offset by a decrease in patent legal fees of \$330,000, a decrease in stock compensation expense of \$55,000, and a decrease in sponsored research costs of \$27,000. Our clinical and preclinical development costs relate primarily to costs associated with our MultiStem clinical trials, and reflect increases in contract research organization costs and clinical consulting costs in 2012, partially offset by less clinical manufacturing costs during the year. Lastly, our clinical costs for the year ended December 31, 2011 were net of the now terminated Angiotech collaboration's cost-sharing amount of \$312,000. The increase in personnel costs related to an increase in salaries and bonus, and the addition of personnel supporting our preclinical and clinical programs. The increase in research supplies related primarily to supplies for increased personnel. The decrease in patent legal costs resulted from reduced patent prosecution costs during the year. Sponsored research costs decreased primarily due to a decrease in grant-funded programs that require collaboration with academic research institutions. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

General and Administrative Expenses. General and administrative expenses decreased to \$4.8 million in 2012 from \$4.9 million in 2011. The \$163,000 decrease in 2012 compared to 2011 was due primarily to a decrease in legal and professional fees of \$210,000 and a decrease in other general and administrative costs of \$182,000 related to outside services, partially offset by an increase in personnel costs of \$235,000.

Depreciation. Depreciation expense increased to \$320,000 in 2012 from \$278,000 in 2011 due to depreciation on new capital purchases.

Other Income (Expense), net. Other income (expense), net, includes cash and stock-based milestone payments that were completed in 2012 to our former lenders in connection with our equity offerings, amounting to \$1.3 million in 2012 and \$0.9 million in 2011, foreign currency gains and losses, and a gain of \$183,000 related to an equity-method investment that was liquidated in 2012.

(Expense) Income from Change in Fair Value of Warrants. We recognized income of \$2.4 million and \$0.8 million in 2012 and 2011, respectively, from the change in the valuation of our warrant liabilities.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and any available-for-sale securities. At December 31, 2013, we had \$31.9 million in cash and cash equivalents. We have primarily financed our operations through business collaborations, grant funding and equity financings. We conduct all of our operations through our subsidiary, ABT Holding Company. Consequently, our ability to fund our operations depends on ABT Holding Company's financial condition and its ability to make dividend payments or other cash distributions to us. There are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us.

In January 2014, we completed a registered direct offering generating net proceeds of approximately \$18.7 million through the issuance of 5,000,000 shares of common stock and warrants to purchase 1,500,000 shares of common stock with an exercise price of \$4.50 per share that expire on July 15, 2016. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.30 shares of common stock at an offering price of \$4.10 per fixed combination.

In December 2013, we completed a registered direct offering generating net proceeds of approximately \$18.4 million through the issuance of 10,000,000 shares of common stock and warrants to purchase 3,500,000 shares of common stock with an exercise price of \$2.50 per share that expire on March 31, 2015. Of the 3,500,000 warrants, 1,401,218 are not exercisable until June 3, 2014. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.35 shares of common stock at an offering price of \$2.00 per fixed combination.

In October 2012, we completed a public offering generating net proceeds of approximately \$18.3 million through the issuance of 19,802,000 shares of common stock at a price of \$1.01 per share. In November 2012, the underwriters exercised in full their right to purchase an addit