ATHERSYS, INC / NEW
Form 10-K
March 12, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2012

OR

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

For the transition period from _____ to _____

Commission file number 001-33876

Athersys, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-4864095**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3201 Carnegie Avenue, Cleveland, Ohio	**44115-2634**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code (216) 431-9900

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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 x No ¨

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 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 ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller Reporting Company x

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

The aggregate market value at June 30, 2012, the last 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 $1.61 of such stock as quoted on the NASDAQ Capital Market on such

date) held by non-affiliates of the registrant was approximately $44.3 million.

The registrant had 53,508,632 shares of common stock outstanding on March 1, 2013.

Documents Incorporated By Reference.

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant s definitive Proxy Statement with respect to the 2013 Annual Meeting of Stockholders.

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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. We are developing our lead platform product, MultiStem®, a patented and proprietary allogeneic stem cell product that has been evaluated in two completed Phase I clinical trials and is currently being evaluated in two ongoing Phase II clinical trials. Our current clinical development programs are focused on treating inflammatory and immune disorders, neurological conditions, cardiovascular disease, and other conditions. These represent major areas of clinical need, as well as substantial commercial opportunities.

We believe MultiStem 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 is a patented and proprietary product that 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. The cells comprising MultiStem appear to be responsive to the environment in which they are administered, homing to sites of injury, 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 can enhance healing and tissue repair through multiple distinct mechanisms acting in parallel, such as by producing a range of therapeutic factors, 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 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 appear to be quite durable.

We believe the therapeutic and commercial potential for MultiStem to be very broad, applying to multiple areas of significant unmet medical need. We are pursuing opportunities in several potential multi-billion dollar markets. While traditional pharmaceuticals or traditional biologic therapies typically may be used to treat only a single disease or narrowly defined set of related conditions, MultiStem appears 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 as a potential treatment in multiple 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 to be used in acute and chronic forms of inflammatory and immune disorders, neurological conditions, cardiovascular disease, certain pulmonary conditions, and other areas.

To date, we have successfully advanced MultiStem into five clinical stage programs, each of which addresses a significant area of medical need and represents a large commercial market opportunity. MultiStem has been evaluated in two completed clinical trials, one exploring the potential to treat patients that have suffered a heart attack and the other evaluating the potential to prevent or reduce graft-versus-host disease, or GvHD, as well as other complications, and to provide supportive care to patients being treated for leukemia or related conditions. MultiStem is currently being evaluated in two additional clinical programs in the inflammatory and immune disease and neurological areas. In one study, which is being conducted with our partner, Pfizer Inc, or Pfizer, MultiStem is being administered to patients with ulcerative colitis, a common form of inflammatory bowel disease, or IBD. In another ongoing study, we are evaluating the potential to treat patients that have suffered neurological damage from a stroke. In addition, a leading clinical center in Europe that is a research collaborator has recently received authorization to conduct an initial clinical trial evaluating administration of MultiStem in patients that have received a liver transplant.

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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 recently approved by the United States Food and Drug Administration, or FDA, 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, certain compounds that we developed may also have relevance in other disease areas, such as the treatment of schizophrenia. We are actively exploring partnership opportunities for our 5HT2c program in both the obesity and schizophrenia areas, 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. MultiStem represents a novel therapeutic modality for the treatment of inflammatory and immune system disorders, neurological conditions and cardiovascular disease, as well as in other areas. MultiStem may be administered like other biologics, intravenously, via catheter, or by local injection. The cells appear to be responsive to their environment, homing to sites of injury and producing proteins that may provide benefit in acute or chronic conditions. Additionally, MultiStem cell therapy may deliver therapeutic benefit through several distinct mechanisms of action, including reducing inflammatory damage, protecting tissue that is at risk following acute or ischemic injury, and promoting tissue repair, such as through formation of new blood vessels in regions of ischemic injury. 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 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 is its substantial expansion capacity *ex vivo* relative to other cell types. This enables 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. 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.

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Enter into Licensing or Product Co-Development Arrangements in Core Areas, while Out-Licensing Opportunities in Non-Core Areas. 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 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, Angiotech Pharmaceuticals, Inc., or Angiotech, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Johnson & Johnson, Wyeth Pharmaceuticals, Inc. and RTI Biologics, Inc., or RTI. These partnerships generate revenue and provide capital that allows us to advance certain 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 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, the Medical College of Georgia, 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, and other institutions. Through this network of collaborations, we have studied MultiStem 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 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 and other opportunities.

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 is being evaluated in an ongoing Phase II clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, or UC, the most common form of IBD. This study is a double blind, placebo controlled trial that began enrolling patients in 2011 and is being conducted with our partner, Pfizer, in UC patients who have an inadequate response or are refractory to current treatment. Enrollment of the trial is ongoing and designed to include approximately 130 patients, with initial results expected to be reported in the second half of 2013.

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Ischemic Stroke: In an ongoing Phase II clinical study, we are evaluating the administration of MultiStem to patients who 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, 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 may include sites in Europe. The study is expected to enroll approximately 136 patients. We completed the first patient cohorts, and the independent safety monitoring committee found in 2012 that MultiStem was safe and well tolerated at both of the doses evaluated. Patient enrollment of the trial is ongoing, and patients are being randomized to receive either high dose MultiStem or placebo. We anticipate announcing initial results for the study in the first half of 2014.

Acute Myocardial Infarction: We have evaluated the administration of MultiStem to patients who have suffered an acute myocardial infarction, or AMI, in a Phase I 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 have completed preliminary planning for a 150 patient Phase II trial that has been authorized by the FDA. Our plans to move the AMI program forward into subsequent development will depend on the availability of capital resources, progress in our other clinical studies and our business development activities.

Hematopoietic Stem Cell Transplant / GvHD: We completed a Phase I clinical study of the administration of MultiStem 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 in this indication and suggested that MultiStem may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. This program has been assigned orphan drug designation from the FDA, which provides us with seven years of market exclusivity upon approval and certain other benefits. We have met with the FDA to discuss the results of the clinical study and our proposed plans for the next phase of clinical development in this area. Based on current plans, we intend to be ready to start this study in the second half of 2013, but the 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 recently obtained authorization to initiate an institutional sponsored clinical trial exploring the administration of MultiStem in patients following a liver transplant. We plan to provide limited financial support for this investigator-sponsored Phase I study and provide the product to conduct the trial.

In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem 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 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 development activities are progressing, and we recently amended our agreement to accelerate $2.0 million of contingent milestone payments into 2012 in connection with technical support to assist RTI in its development efforts. We will also receive royalty revenue from product sales should they occur, as well as potential additional milestone payments.

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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 5HT2c 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 5HT2c agonists. We have also demonstrated our compounds are complementary with other agents 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 are in discussions with interested companies and 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.

Regenerative Medicine Programs

MultiStem A Novel Therapeutic Modality

We are developing a proprietary non-embryonic, allogeneic stem cell product candidate, MultiStem, 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 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 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 MultiStem 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 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.

MultiStem 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 MultiStem 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 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.

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 Cell, 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 current product platform as MultiStem. During several years of preclinical work, MultiStem has demonstrated the potential to address many of the fundamental limitations observed with traditional bone marrow or hematopoietic stem cell transplants.

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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 is administered without tissue matching or the requirement for immune suppressive drugs. MultiStem 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 MultiStem 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 has 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.

MultiStem for Treating Immune System Disorders, and Neurological Conditions and Cardiovascular Disease

Healthcare represents a significant part of the global economy. In the United States, it represented approximately 18% of all economic activity in 2009, or about $2.49 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.

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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, University of Minnesota, the National Institutes of Health, the Medical College of Georgia, the University of Oregon Health Sciences Center, the University of Texas Health Science Center at Houston, KUL and other institutions. Through this network of collaborations, we have studied MultiStem 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 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, the potential application of MultiStem 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 is safe and effective in animal models. As a result, we have advanced MultiStem 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 many patients, they have failed to adequately address the needs of many other patients that suffer from inflammatory and immune disorders.

In multiple studies, MultiStem has 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 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.

In 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem 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 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 Phase II clinical study being conducted with our partner, Pfizer, to administer MultiStem to patients suffering from UC, and we anticipate reporting initial trial results in the second half of 2013.

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Another area of focus is the use of MultiStem 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 has 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 the administration of MultiStem 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 I clinical trial examining the safety and tolerability of a single dose or repeat dosing of MultiStem 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.

In 2010, we announced that we had been granted orphan drug designation by the FDA for MultiStem in the prevention of GvHD. In April 2012, we met with the FDA to review the results from the Phase I trial and discuss plans for the next phase of clinical development, which could include a Phase II/III study of MultiStem for GvHD prophylaxis and HSC transplant support. We have submitted our proposed plan for such a study, which is currently under consideration by the FDA. Based on current plans, we intend to be ready to start this study in the second half of 2013, but the initiation 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 the use of MultiStem 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.

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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.

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 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 to treat chronic conditions such as Multiple Sclerosis, or MS, or Parkinson s disease. Our research has shown that MultiStem conveys 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 may have relevance to multiple forms of neurological injury and disease.

Our initial clinical focus in the neurological area involves evaluating administration of MultiStem 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 both the University of Minnesota, the Medical College of Georgia, 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 treatment with MultiStem. Published research has demonstrated that administration of MultiStem 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.

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Based on the research conducted by us and our collaborators, we believe MultiStem 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 administration of MultiStem 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 a 136-patient Phase II clinical trial exploring the administration of MultiStem to patients that have suffered an ischemic stroke. In this trial, MultiStem is administered 24 to 36 hours 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 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. Early in 2012, we announced 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.

We are also conducting preclinical work exploring the application of MultiStem in other neurological indications. In 2010, we announced that 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 treatment of spinal cord injury, or SCI, with MultiStem. In October 2012, we presented data at the Annual Society for Neuroscience meeting that demonstrated that intravenous administration of MultiStem 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 to treat chronic progressive MS based on initial results in preclinical models. In October 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.

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 1,255,000 patients suffer a heart attack each year, and approximately 5.7 million individuals in the United States are currently suffering from heart failure. Another eight million suffer from peripheral arterial disease, which is associated with significant morbidity and mortality. 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.

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In a Phase I clinical trial, we have explored the use of MultiStem as a treatment for damage caused by AMI. Myocardial infarction is one of the leading causes of death and disability in the United States. Myocardial infarction 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. According to the American Heart Association 2012 Statistical Update, there were approximately 935,000 cases of myocardial infarction that occurred in the United States in 2008 and approximately 7.9 million individuals living in the United States that had previously suffered a heart attack. In addition, there were approximately 812,000 deaths that occurred from all forms of cardiovascular disease, including 462,000 individuals that died as a result of coronary heart disease or heart failure. 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 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 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 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. In 2008, we initiated a multicenter, open-label Phase I clinical trial in this indication, and the study is now completed. In July 2010, we announced the preliminary results from this trial, which showed that MultiStem was well tolerated at all dose levels and exhibited a favorable safety profile. In addition, patients that received treatment with MultiStem exhibited meaningful improvements in cardiovascular function, including left ventricular ejection fraction, wall motion scores, and other parameters. These results were published electronically by *Circulation Research* in November 2011.

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 who 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 who 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 gained rapid and widespread acceptance in the clinical marketplace and 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. The activation of 5HT2b by Redux is believed to have caused significant cardiovascular problems in a number of patients and, as a result, Redux was withdrawn from the market in 1997.

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Since the withdrawal of Redux from the market, 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.

Recently, 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 are currently exploring partnering opportunities for this program and may elect to enter into a partnership to advance the development of this program for the treatment of obesity and related indications, schizophrenia, or multiple 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.

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 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.

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Collaborations and Partnerships

Pfizer

In 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem 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 and support 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, 2012. 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 III 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 a $5.0 million license fee in installments, of which $3.0 million was received in 2010 and 2011, and $2.0 million was received in 2012 in connection with an amendment that accelerated these payments in connection with our providing certain technical support to RTI. 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, 2012. In addition, we will receive tiered royalties on worldwide commercial sales of implants using our technologies.

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. Angiotech made its final cost-sharing payment in 2011 in connection with collaboration activities and has no further obligations to us. Though the termination will affect our future costs of development for ongoing cardiovascular programs, such as AMI, it significantly improves our ability to explore cardiovascular and more comprehensive collaborative development and commercialization arrangements with other pharmaceutical, biotechnology and medical products companies. In the case of a new AMI collaboration, Angiotech will be entitled to a future payment from us equal to a percentage of cash license fee payments we receive within the first six months from a third-party related to such AMI collaboration, and is not entitled to other downstream payments, such as milestone payments, royalties or any profit-sharing payments. The future payment, if any, will be either (i) 15% of third-party license fees if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, but before we have spent $5.0 million on the clinical trial, and within 24 months of the termination agreement, or (ii) 10% of third-party license fees up to a maximum of $5.0 million to Angiotech if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, and after we have spent $5.0 million on the clinical trial, and within 36 months of the termination agreement.

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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 II clinical development a drug candidate discovered using a target provided by us, thereby triggering a clinical development milestone payment to us.

We remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb under our completed collaboration, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology, though there can be no assurance that we will achieve any such milestones or royalties. As of December 31, 2012, we received an aggregate amount of $1.8 million in milestone payments and $9.7 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. Though we expect Bristol-Myers Squibb to file for and be issued patents for products developed under the collaboration, we are not aware of any patents issued to Bristol-Myers Squibb covering any potential products related to the collaboration. 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.

Osiris Therapeutics, Inc., or Osiris, is currently engaged in Phase II and Phase III clinical trials involving Prochymal, an allogeneic stem cell product based on mesenchymal stem cells, or MSCs, that are obtained from healthy consenting donors, and are administered without tissue matching. However, in contrast to MultiStem, MSCs display greater donor to donor variability, limited expansion potential, and limited biological plasticity. In 2008, Osiris announced a partnership in which Genzyme acquired development rights to Prochymal and Chondrogen for certain markets outside the United States and Canada in exchange for $130 million in license fees, up to $1.25 billion in clinical and sales milestones, and royalties. In 2011, Sanofi U.S., or Sanofi, acquired Genzyme, and in October 2012, Sanofi announced that the partnership had been terminated, and Osiris had regained commercial development rights to Prochymal and Chondrogen.

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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. In 2010, Mesoblast announced a partnership with Cephalon, Inc., or Cephalon, 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. In 2011, Teva Pharmaceuticals announced that it had acquired Cephalon.

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. Recently, 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 5HT2c 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.

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 who 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 130 patents for our technologies.

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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 acquired ownership of part of our stem cell technology and intellectual property as a result of our 2003 acquisition of a holding company, which held the rights to the technology originally discovered at the University of Minnesota. We also have an exclusive license to additional MAPC-related inventions (or in other words, improvements) developed by the University of Minnesota through May 2009, and, under a collaborative research agreement with KUL, we have an exclusive license to MAPC-related inventions developed at KUL using the MAPC technology or intellectual property or that result from sponsored research funded by us. We also own and license additional intellectual property develop by us and others. Our broad intellectual property portfolio consists of more than 80 issued patents (of which twelve are United States patents) and more than 170 global patent applications around our stem cell technology and MultiStem product platform. This includes nine United States patents and more than 40 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 functional genomics technologies and small molecule product candidates. 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 two patent applications with broad claims directed to selective 5HT2c 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 35 issued patents (sixteen United States patents and nineteen international patents) and three patent applications relating to compositions and methods for the RAGE technology that currently provide patent coverage through as late as 2017, and four United States patents and four patent applications relating to human proteins and candidate drug targets that we identified through the application of RAGE and 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 $19.6 million in 2012, $18.9 million in 2011 and $14.8 million in 2010.

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 European Medicines Agency and Committee on Proprietary Medicinal Products to standardize review and approval across EU member nations.

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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 I 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 I through completion of Phase III 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.

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, 2012, we employed 48 full-time employees, including 16 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 $15 million in 2012, $14 million in 2011 and $11 million in 2010. As of December 31, 2012, we had an accumulated deficit of $234 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 $18 million in 2012, $14 million in 2011 and $11 million in 2010.

At December 31, 2012, we had $26 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 or at a purchase price of less than $1.45. Even if we are able to access the remaining $17.7 million under the purchase agreement as of December 31, 2012, 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 MultiStem 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 II or large scale Phase III 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 III 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 who 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, as well as other executive and scientific officers, including 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.

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.

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.

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.

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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, Osiris, Aastrom, Stem Cells Inc., Cytori, Mesoblast, 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.

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.

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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:

- 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;
- 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.

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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.

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, interference, opposition, protest, reexamination or any other potentially adverse governmental, ex parte or inter-party proceeding 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. If we become 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 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.

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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;

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.

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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 121,100 and is subject to adjustments based on an inflationary index. Our total rent expense for all properties was $415,000 in 2012.

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 3A. EXECUTIVE OFFICERS OF THE REGISTRANT

The information under this Item is furnished pursuant to Instruction 3 to Item 401(b) of Regulation S-K.

There exists no arrangement or understanding between any executive officer and any other person pursuant to which such executive officer was elected. Each executive officer serves until his or her successor is elected and qualified.

The following sets forth the name, age, current position and principal occupation and employment during the past five years of our executive officers.

Gil Van Bokkelen, Ph.D.

Age: 52

Dr. Van Bokkelen co-founded Athersys in October 1995 and has served as our Chief Executive Officer and Chairman since August 2000. Dr. Van Bokkelen served as Chief Executive Officer and Director since Athersys founding. Prior to May 2006, he also served as Athersys President. From 2010 through 2012, Dr. Van Bokkelen served as the Chairman of the Alliance for Regenerative Medicine, a Washington D.C. based consortium of companies, patient advocacy groups, disease foundations, and clinical and research institutions that are committed to the advancement of the field of regenerative medicine, and now serves *ex officio*. He is also the Chairman of the Board of Governors for the National Center for Regenerative Medicine, and has served on a number of other boards, including the Biotechnology Industry Organization s ECS board of directors (from 2001 to 2004, and from 2008 to present). He received his Ph.D. in Genetics from Stanford University, his B.A. in Economics from the University of California at Berkeley, and his B.A. in Molecular Biology from the University of California at Berkeley. Dr. Van Bokkelen brings to the Board leadership, extensive business, operating, financial and scientific experience, and tremendous knowledge of our Company and the biopharmaceutical industry. Dr. Van Bokkelen also brings his broad strategic vision for our Company to the Board of Directors and his service as the Chairman and CEO of Athersys creates a critical link between management and the Board, enabling the Board to perform its oversight function with the benefit of management s perspectives on the business. In addition, having the CEO, and Dr. Van Bokkelen, in particular, on our Board of Directors provides our Company with ethical, decisive and effective leadership.

William (BJ) Lehmann, Jr., J.D.

Age: 47

Mr. Lehmann joined Athersys in September 2001 and has served as our President and Chief Operating Officer since June 2006. Prior to that time, Mr. Lehmann was Athersys Executive Vice President of Corporate Development and Finance from August 2002 until June 2006, when he became Athersys President and Chief Operating Officer. From 1994 to 2001, Mr. Lehmann was with McKinsey & Company, Inc., an

international management consulting firm, where he worked extensively with new technology and service-based businesses in the firm s Business Building practice. Prior to joining McKinsey, he worked at Wilson, Sonsini, Goodrich & Rosati, a Silicon Valley law firm, and worked with First Chicago Corporation, a financial institution. Mr. Lehmann received his J.D. from Stanford University, his M.B.A. from the University of Chicago, and his B.A. from the University of Notre Dame.

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John J. Harrington, Ph.D.

Age: 45

Dr. Harrington co-founded Athersys in October 1995 and has served as our Chief Scientific Officer, Executive Vice President and Director since our founding. Dr. Harrington led the development of the RAGE technology as well as its application for gene discovery, drug discovery and commercial protein production applications. He is a listed inventor on over 20 issued or pending United States patents, has authored numerous scientific publications, and has received numerous awards for his work, including being named one of the top international young scientists by MIT Technology Review in 2002. Dr. Harrington has overseen the therapeutic product development programs at Athersys since their inception, and during his career, he has also held positions at Amgen and Scripps Clinic. He received his B.A. in Biochemistry and Cell Biology from the University of California at San Diego and his Ph.D. in Cancer Biology from Stanford University. Dr. Harrington s scientific experience and deep understanding of our Company, combined with his drive for innovation and excellence, position him well to serve on the Board of Directors.

Robert J. Deans, Ph.D.

Age: 61

Dr. Deans joined Athersys in February 2003 to lead the Company s regenerative medicine research and development activities and has served as our Executive Vice President since June 2011. Prior to that time, Dr. Deans was Vice President of Regenerative Medicine, until he was named Senior Vice President of Regenerative Medicine in June 2006, and Executive Vice President in June 2011. Dr. Deans is highly regarded as an expert in stem cell therapeutics, with over twenty years of experience in this field. From 2001 to 2003, Dr. Deans worked for early-stage biotechnology companies. Dr. Deans was formerly the Vice President of Research at Osiris, a biotechnology company, from 1998 to 2001 and Director of Research and Development with the Immunotherapy Division of Baxter International, Inc., a global healthcare company, from 1992 to 1998. Dr. Deans was also previously on faculty at USC Medical School in Los Angeles, between 1981 and 1998, in the departments of Microbiology and Neurology at the Norris Comprehensive Cancer Center. Dr. Deans was an undergraduate at MIT, received his Ph.D. at the University of Michigan, and did his post-doctoral work at UCLA in Los Angeles.

Laura K. Campbell, CPA

Age: 49

Ms. Campbell joined Athersys in January 1998 and has served as our Vice President of Finance since June 2006. Ms. Campbell joined Athersys initially as Controller, followed by Director of Finance and Senior Director of Finance, and has served as Vice President of Finance since June 2006. Prior to joining Athersys, she was at Ernst & Young LLP, a public accounting firm, for 11 years, in the firm s audit practice. During her tenure with Ernst & Young LLP, Ms. Campbell specialized in entrepreneurial services and the biotechnology industry sector and participated in several initial public offerings. Ms. Campbell received her B.S., with distinction, in Business Administration from The Ohio State University.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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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, 2012:		
First Quarter	$ 2.33	$ 1.49
Second Quarter	$ 1.71	$ 1.25
Third Quarter	$ 1.75	$ 1.35
Fourth Quarter	$ 1.47	$ 0.95
Year ended December 31, 2011:		
First Quarter	$ 3.08	$ 2.35
Second Quarter	$ 3.10	$ 2.50
Third Quarter	$ 2.86	$ 1.00
Fourth Quarter	$ 2.42	$ 1.13

Holders

As of March 1, 2013, the number of holders of record was approximately 613. Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co., 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**.**

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ITEM 6. SELECTED FINANCIAL DATA

(in thousands, except per share data)

	Year Ended December 31,				
	2012	**2011**	**2010**	**2009**	**2008**
Consolidated Statement of Operations Data:					
Revenues:					
Contract revenue	$ 7,380	$ 9,015	$ 6,685	$ 1,079	$ 1,880
Grant revenue	1,328	1,329	2,254	1,080	1,225
Total revenues	8,708	10,344	8,939	2,159	3,105
Costs and expenses:					
Research and development	19,636	18,930	14,779	11,920	16,500
General and administrative	4,753	4,916	5,387	5,621	5,479
Depreciation	320	278	284	233	218
Loss from operations	(16,001)	(13,780)	(11,511)	(15,615)	(19,092)
Other (expense) income:					
Other income (expense), net	1,232	(51)	(69)	(126)	(46)
Interest income	34	85	203	375	1,146
Net loss	**$ (14,735)**	**$ (13,746)**	**$ (11,377)**	**$ (15,366)**	**$ (17,992)**
Basic and diluted net loss per share	**$ (0.45)**	**$ (0.59)**	**$ (0.60)**	**$ (0.81)**	**$ (0.95)**
Weighted average shares outstanding, basic and diluted	32,556,781	23,239,019	18,929,749	18,928,379	18,927,988

	December 31,				
	2012	**2011**	**2010**	**2009**	**2008**
Consolidated Balance Sheet Data:					
Cash and cash equivalents	**$ 25,533**	$ 8,785	$ 2,105	$ 11,167	$ 12,552
Available-for-sale securities, short-tem		3,999	13,076	10,135	15,460
Working capital	**21,831**	7,014	9,106	16,291	26,789
Available-for-sale securities, long-term				5,080	3,601
Total assets	**27,603**	15,701	19,106	28,331	33,877
Warrant liabilities and note payable	**2,878**	983			
Total stockholders equity	**20,247**	7,298	9,005	18,957	31,563

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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 on the field of regenerative medicine. We have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. We are developing our lead platform product, MultiStem®, a patented and proprietary allogeneic stem cell product that has been evaluated in two completed Phase I clinical trials and is currently being evaluated in two ongoing Phase II clinical trials. 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.

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 is being evaluated in an ongoing Phase II clinical study involving administration of MultiStem to patients suffering from UC, the most common form of IBD. This study is being conducted with our partner, Pfizer, in UC patients who have an inadequate response or are refractory to current treatment, and is a double blind, placebo controlled trial that began enrolling patients in 2011. Enrollment of the trial is ongoing and designed to include approximately 130 patients, with initial results expected to be reported in the second half of 2013.

Ischemic Stroke: In an ongoing Phase II clinical study, we are evaluating the administration of MultiStem to patients who 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, 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 may include sites in Europe. The study is expected to enroll approximately 136 patients. We completed the first patient cohorts, and the independent safety monitoring committee found in 2012 that MultiStem was safe and well tolerated at both of the doses evaluated. Patient enrollment is ongoing and for the remainder of the trial, patients are being randomized to receive either high dose MultiStem or placebo. We anticipate announcing initial results for the study in the first half of 2014.

Acute Myocardial Infarction: We have evaluated the administration of MultiStem in a Phase I clinical study to patients who have suffered an AMI. 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 completed preliminary planning for a Phase II trial, and a 150 patient study has been authorized by the FDA. Our plans to move the AMI program forward into subsequent development will depend on the availability of capital resources, progress in our other clinical studies and our business development activities.

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Hematopoietic Stem Cell Transplant / GvHD: We completed a Phase I clinical study of the administration of MultiStem to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a 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 in this indication and suggested that MultiStem may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. This program has been assigned orphan drug designation from the FDA, which provides us with seven years of market exclusivity upon approval and certain other benefits. We met with the FDA to discuss the results of the clinical study and our proposed plans for the next phase of clinical development in this area. Based on current plans, we intend to be ready to start this study in the second half of 2013, but the 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 recently obtained authorization to initiate an institutional sponsored clinical trial exploring the administration of MultiStem in patients following a liver transplant. We plan to provide limited financial support for this investigator-sponsored Phase I study and provide the product to conduct the trial.

In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem 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 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 in the bone graft substitutes market using our stem cell technologies. RTI s product development activities are progressing, and in 2012, we amended our agreement to accelerate $2.0 million of contingent milestone payments into 2012 in connection with technical support to assist RTI in its development efforts. We will also receive royalty revenue from product sales should they occur, as well as potential additional milestone payments.

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 5HT2c 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 5HT2c agonists. We have also demonstrated our compounds are complementary with other agents and believe these compounds could achieve best in class weight loss, as well as 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 are in discussions with interested companies and 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.

Financial

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of $234 million at December 31, 2012. 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 private 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.

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 additional 2,970,300 shares of common stock, solely to cover over-allotments. The exercise of the full over-allotment option generated an additional $2.8 million of net proceeds.

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In March 2012, we completed a private placement financing generating net proceeds of approximately $8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of $2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of $2.07 per fixed combination. The warrants have anti-dilution price protection, subject to certain exceptions. As a result of the October 2012 public offering and in accordance with the terms of the warrants, we sought and obtained stockholder approval in February 2013 to reduce the exercise price of these warrants to $1.01 per share.

In November 2011, we entered into an equity purchase agreement, which provides that Aspire Capital is 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. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price. During the quarter ended December 31, 2012, we sold no shares under the Aspire Purchase Agreement, and during the year ended December 31, 2012, we sold 800,000 shares to Aspire Capital at an average price of $1.57 per share. As of March 1, 2013, we received aggregate proceeds of approximately $2.9 million under the Aspire Purchase Agreement since its inception.

In February 2011, we completed a registered direct offering with net proceeds of $11.8 million through the issuance of 4,366,667 shares of common stock and five-year warrants to purchase 1,310,000 shares of common stock with an exercise price of $3.55 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.3 of a share of common stock at an offering price of $3.00 per fixed combination.

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. The sources of funding including federal, state and European organizations and are generally focused on the advancement of our preclinical MultiStem programs, as well as process development and manufacturing activities.

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 fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property prosecution 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, 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,		
	2012	**2011**	**2010**
Contract revenue	$ 7,380	$ 9,015	$ 6,685
Grant revenue	1,328	1,329	2,254
	$ 8,708	$ 10,344	$ 8,939

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Research and development expenses

	Year ended December 31,		
Type of expense	**2012**	**2011**	**2010**
Personnel costs	$ 5,097	$ 4,641	$ 4,124
Research supplies	1,435	1,316	1,218
Facilities	964	944	870
Clinical and preclinical development costs	8,053	7,495	4,394
Sponsored research	1,381	1,408	1,149
Patent legal fees	1,373	1,703	1,477
Other	1,183	1,218	1,002
Stock-based compensation	150	205	545
	$ 19,636	$ 18,930	$ 14,779

General and administrative expenses

	Year ended December 31,		
Type of expense	**2012**	**2011**	**2010**
Personnel costs	$ 2,162	$ 1,927	$ 1,897
Facilities	280	270	279
Legal and professional fees	798	1,008	1,007
Other	1,182	1,364	1,283
Stock-based compensation	331	347	921
	$ 4,753	$ 4,916	$ 5,387

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 and RTI. Our contract revenues reflect the amortization of Pfizer payments, including a $6.0 million non-refundable 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 also include the final $2.0 million license payments from RTI that was recognized in the fourth quarter of 2012. Our contract revenues may also include license fees, milestone payments and royalties on compounds developed by Bristol-Myers Squibb using one of our technologies. As a result of the end of these performance periods and absent any new collaborations, we expect our contract revenues to decline significantly in 2013 and to be comprised of reimbursements from Pfizer for outsourced central processing costs for the clinical product, potential RTI royalty payments, and potential license and milestone payments from Bristol-Myers Squibb. 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. Our grant revenues may fluctuate from period to period based on the timing of grant-related activities and the expiration and award of grants.

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 sponsored research costs of $27,000, and a decrease in stock compensation expense of $55,000. Our clinical and preclinical development costs relate primarily to costs associated with our MultiStem clinical trials, and include increases in contract research organization costs and clinical consulting costs in 2012, partially offset by less clinical manufacturing costs during the period. Also in 2012, we incurred less preclinical study costs and more process development costs for our MultiStem manufacturing process as compared to 2011. 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 impact over the past two years of the addition personnel

supporting our preclinical and clinical programs. This increase in research supplies related primarily to supplies for process development activities and increased personnel. The decrease in patent legal costs resulted from reduced patent prosecution costs during the period. Sponsored research costs decreased primarily due to a decrease in grant-funded programs that require collaboration with certain academic research institutions. We expect our 2013 annual research and development expenses to be higher than the 2012 expenses based on our planned clinical development and 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.

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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. We expect our general and administrative expenses to continue at similar levels in 2013.

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 increases and decreases in our warrant liabilities, cash and stock-based milestone payments to our former lenders in connection with our equity offerings that were completed in 2012, foreign currency gains and losses related to our activities in Europe, and any realized gains and losses on the sale of our assets. We recognized income of $2.4 million and $0.8 million in 2012 and 2011, respectively, from the valuation of our warrant liabilities. Cash and stock-based milestone payments to our former lenders were $1.3 million and $0.9 million in 2012 and 2011, respectively. Also, in 2012, we recognized a gain of $183,000 related to an equity-method investment that was liquidated.

Interest Income. Interest income represents interest earned on our cash and available-for-sale securities. Interest income decreased to $34,000 in 2012 from $85,000 in 2011 due to the decline in our investment balances as they were used to fund our operations. We expect our 2013 interest income to reflect the impact of declining cash balances resulting from our ongoing and planned clinical and preclinical development, and interest earned on proceeds from any new financings or business transactions.

Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

Revenues. Revenues increased to $10.3 million for the year ended December 31, 2011 from $8.9 million for 2010. Contract revenue increased $2.3 million for the year ended December 31, 2011 compared to the year ended December 31, 2010 primarily as a result of our arrangements with Pfizer and RTI. Our contract revenues reflect the amortization of Pfizer payments, including a $6.0 million non-refundable up-front license fee, over the estimated performance period, 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. Our contract revenues may also include license fees, milestone payments and royalties on compounds developed by Bristol-Myers Squibb using one of our technologies. Grant revenue decreased $0.9 million for the year ended December 31, 2011 compared to the year ended December 31, 2010 primarily due to the timing of expenditures that are reimbursed with grant proceeds and a grant received in October 2010 from the Internal Revenue Service under section 48D of the Internal Revenue Code aggregating $733,000 for qualifying therapeutic discovery investments.

Research and Development Expenses. Research and development expenses increased to $18.9 million for the year ended December 31, 2011 from $14.8 million in 2010. The increase of approximately $4.1 million related primarily to an increase in clinical and preclinical development costs of $3.1 million, an increase in personnel costs of $517,000, an increase in sponsored research costs of $259,000, an increase in patent legal fees of $226,000, an increase in other costs of $216,000, and an increase in research supply and facilities costs of $172,000 for the year ended December 31, 2011 compared to 2010. These increases were partially offset by a decrease in stock-based compensation expense of $340,000, which declined as a result of a significant number of options becoming fully vested in 2010. The increase in clinical and preclinical development costs for the year ended December 31, 2011 related primarily to costs associated with our MultiStem clinical trials, including increased manufacturing and process development costs. Our clinical costs for the year ended December 31, 2011 and 2010 are reflected net of Angiotech s cost-sharing amount of $312,000 and $628,000, respectively. The Angiotech collaboration was terminated late in 2011. The increase in personnel costs related to the addition over the past twelve months of personnel supporting our preclinical and clinical programs, and annual merit increases in salaries. Sponsored research costs increased primarily due to an increase in grant-funded programs that require collaboration with certain academic research institutions. Patent legal fees increased related to international patent prosecution activities. 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.

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General and Administrative Expenses. General and administrative expenses decreased to $4.9 million in 2011 from $5.4 million in 2010. The $471,000 decrease in 2011 compared to 2010 was due primarily to a decrease in stock-based compensation expense of $574,000 from a significant number of options becoming fully vested in 2010, partially offset by an increase in other expenses of $81,000.

Depreciation. Depreciation expense remained fairly consistent at $278,000 in 2011 and $284,000 in 2010.

Other Income (Expense), net. Other income (expense), net, includes increases and decreases in our warrant liabilities, cash and stock-based milestone payments to our former lenders in connection with our equity offerings, foreign currency gains and losses related to our activities in Europe, and any realized gains and losses on the sale of our assets. We recognized income of $0.8 million in 2011 from the valuation of our warrant liabilities. Cash and stock-based milestone payments to our former lenders were $0.9 million in 2011.

Interest Income. Interest income represents interest earned on our cash and available-for-sale securities. Interest income decreased to $85,000 in 2011 from $203,000 in 2010 due to the decline in our investment balances as they were used to fund our operations.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and available-for-sale securities. At December 31, 2012, we had $25.5 million in cash and cash equivalents. We have primarily financed our operations through equity financings, business collaborations and grant funding. 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 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 additional 2,970,300 shares of common stock, solely to cover over-allotments. The exercise of the full over-allotment option generated an additional $2.8 million of net proceeds.

In March 2012, we completed a private placement financing generating net proceeds of approximately $8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of $2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of $2.07 per fixed combination. The warrants have anti-dilution price protection, subject to certain exceptions. As a result of the October 2012 public offering and in accordance with the terms of the warrants, we sought and obtained stockholder approval in February 2013 to reduce the exercise price of these warrants to $1.01 per share.

In November 2011, we entered into an equity purchase agreement, which provides that Aspire Capital is 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. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price. As of March 1, 2013, we received aggregate proceeds of $2.9 million under the equity purchase agreement since its inception ($1.3 million for the year ended December 31, 2012).

In February 2011, we completed a registered direct offering with net proceeds of $11.8 million through the issuance of 4,366,667 shares of common stock and five-year warrants to purchase 1,310,000 shares of common stock with an exercise price of $3.55 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.3 of a share of common stock at an offering price of $3.00 per fixed combination.

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In connection with our equity offerings, our former lenders were entitled to milestone payments until the remaining balance of an original $2.25 million milestone was paid in cash and stock. We made cash and stock-based milestone payments of $1.3 million to our former lenders during the year ended December 31, 2012, which settled the final balance of this contingent obligation, paying 75% of the milestone through the issuance of our common stock. The former lenders also received in 2007 seven-year warrants to purchase 149,026 shares of common stock with an exercise price of $5.00. The exercise of such warrants could provide us with cash proceeds. No warrants were exercised as of December 31, 2012.

Under the terms of our agreement with Pfizer, we are 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 any milestones. No significant milestone payments have been received as of December 31, 2012. 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 III clinical development.

In November 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. In the case of a new AMI collaboration, Angiotech will be entitled to a future payment from us equal to a percentage of cash license fee payments we receive within the first six months from a third-party related to such AMI collaboration, and is not entitled to other downstream payments, such as milestone payments, royalties or any profit-sharing payments. The future payment, if any, will be either (i) 15% of third-party license fees if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, but before we have spent $5.0 million on the clinical trial, and within 24 months of the termination agreement, or (ii) 10% of third-party license fees up to a maximum of $5.0 million to Angiotech if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, and after we have spent $5.0 million on the clinical trial, and within 36 months of the termination agreement.

Under the terms of our RTI agreement, we received $5.0 million of license fee payments. In accordance with the partnership 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 milestone payments have been received as of December 31, 2012. In addition, we will receive tiered royalties on worldwide commercial sales of implants using our technologies.

We remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb under our completed 2001 collaboration, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology, though there can be no assurance that we will achieve any such milestones or royalties.

In April 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic Foundation in which we are entitled to proceeds of up to $500,000 in the form of a forgivable loan to fund certain remaining preclinical work using MultiStem to treat congestive heart failure and for preparing the program for an investigational new drug application, or IND with the FDA. Interest on the loan accrues at a fixed rate of 4.25% per annum, and is added to the outstanding principal. The loan will be forgiven based on the achievement of a certain milestone, unrelated to the preclinical work, within three to four years. As of December 31, 2012, we had drawn $166,000 of this financing.

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In February 2012, we were awarded grant funding aggregating $3.6 million to further advance our MultiStem product programs and cell therapy platform. Specifically, we were awarded a Small Business Innovation Research Fast-Track grant of up to $1.9 million from the National Institute of Neurological Disorders and Stroke to develop MultiStem for the treatment of TBI. In addition, our subsidiary based in Belgium was awarded a $1.2 million (0.9 million) grant from Belgium s Agency for Innovation by Science and Technology to further develop cell therapy formulations and manufacturing capabilities, as well as the aforementioned $0.5 million in funding from the Global Cardiovascular Innovation Center to work in other areas, such as using MultiStem to treat chronic cardiovascular disease.

In 2011, we entered into an alliance with Fast Forward, a nonprofit subsidiary of the National Multiple Sclerosis Society, pursuant to which Fast Forward will fund the development of MultiStem for the treatment of multiple sclerosis through the filing of an IND. Fast Forward will commit up to $640,000 to fund the advancement of the program to clinical development stage. In return, upon successful achievement of certain development and commercialization milestones, we would remit certain milestone payments to Fast Forward.

When we hold investments, our available-for-sale securities typically include United States government obligations and corporate debt securities. We have been investing conservatively due to the ongoing economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments and have held our investments until maturity. All available-for-sale securities had matured as of December 31, 2012. Also, although the unfavorable market and economic conditions have resulted in a decrease to our market capitalization, there has been no impairment to the value of our assets. Our fixed assets are used for internal research and development and, therefore, are not impacted by these external factors.

We will require substantial additional funding in order to continue our research and product development programs, including preclinical evaluation and clinical trials of our product candidates. At December 31, 2012, we had available cash and cash equivalents of $25.5 million, which included the net proceeds from our October 2012 public offering. As a result, we intend to meet our short-term liquidity needs with available cash. Over the longer term, we will make use of available cash, but will have to generate additional funding to meet our needs. We are actively exploring business development opportunities for certain of our MultiStem programs and our small molecule 5HT2c program, as well as grant-funding opportunities. Additionally, we are raising capital from time to time through the equity purchase agreement with Aspire Capital, subject to its volume and price limitations. We also manage our cash by deferring certain discretionary costs and stage certain development costs to extend our operational runway, as needed. Over time, we may consider the sale of additional equity securities, or possibly borrowing from financing institutions.

Our capital requirements over time depend on a number of factors, including progress in our clinical development programs, our clinical and preclinical pipeline of additional opportunities and their stage of development, additional external costs such as payments to contract research organizations and contract manufacturing organizations, additional personnel costs, and the costs in filing and prosecuting patent applications and enforcing patent claims. The availability of funds impacts our ability to advance multiple clinical programs concurrently, and any shortfall in funding could result in our having to delay or curtail research and development efforts. Further, these requirements may change at any time due to technological advances, business development activity or competition from other companies. We cannot assure you that adequate funding will be available to us or, if available, that it will be available on acceptable terms.

We expect to continue to incur substantial losses through at least the next several years and may incur losses in subsequent periods. The amount and timing of our future losses are highly uncertain. Our ability to achieve and thereafter sustain profitability will be dependent upon, among other things, successfully developing, commercializing and obtaining regulatory approval or clearances for our technologies and products resulting from these technologies.

Cash Flow Analysis

Net cash used in operating activities was $17.7 million, $14.5 million and $10.6 million in 2012, 2011 and 2010, respectively, and represented the use of cash in funding preclinical and clinical development activities. We expect that net cash used in operating activities will increase in 2013 compared to 2012 in connection with increased research and development expenses of our MultiStem clinical trials and later stage clinical development. Net cash used in operating activities has fluctuated significantly over the past few years primarily due to the receipt of collaboration fees and payment of specific clinical trial costs, such as clinical manufacturing and contract research organization costs.

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Net cash provided by investing activities was $3.9 million, $8.6 million and $1.5 million in 2012, 2011 and 2010, respectively. The fluctuations from period to period were due to the timing of purchases and maturity dates of investments and the purchase of equipment. Purchases of equipment were $347,000, $590,000 and $390,000 in 2012, 2011 and 2010, respectively. We expect that our capital equipment expenditures will continue at similar levels in 2013 compared to 2012.

Financing activities provided cash of $30.5 million in 2012 primarily related to the March private placement and the October 2012 public offering, $12.6 million in 2011 related to the February 2011 registered direct offering and the initial Aspire Capital investment in November 2011, and financing activities neither used nor provided cash in 2010.

Investors in our March 2012 private placement received five-year warrants to purchase an aggregate of 4,347,827 shares of common stock with an exercise price of $2.07 per share, with anti-dilution price protection, subject to certain exceptions. As a result of the October 2012 public offering and in accordance with the terms of the warrants, we sought and obtained stockholder approval in February 2013 to reduce the exercise price of these warrants to $1.01 per share. Also, investors in our February 2011 registered direct offering received five-year warrants to purchase an aggregate of 1,310,000 shares of common stock with an exercise price of $3.55 per share. The exercise of such warrants could provide us with cash proceeds. No warrants have been exercised at December 31, 2012.

Our contractual payment obligations as of December 31, 2012 are as follows:

Payment due by Period

Contractual Obligations	Total	Less than 1 Year	1 3 Years	3 5 Years	More than 5 Years
Operating leases for facilities and equipment leases	$ 1,334,000	$ 444,000	$ 890,000	$	$

We lease office and laboratory space under operating leases. Our lease for our corporate offices and laboratories 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 lease office and laboratory space for our Belgian subsidiary that currently expires in July 2015 and includes options to renew annually through July 2022, and the annual rent of $159,000 is subject to adjustments based on an inflationary index. Our total rent expense for all properties was $415,000 in 2012.

We have no off-balance sheet arrangements.

Critical Accounting Policies and Management Estimates

The SEC defines critical accounting policies as those that are, in management s view, important to the portrayal of our financial condition and results of operation and demanding of management s judgment. Our discussion and analysis of financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates on experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates.

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A discussion of the material implications of uncertainties associated with the methods, assumptions and estimates underlying our critical accounting polices is as follows:

Revenue Recognition

Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, manufacturing revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under Accounting Standards Codification, or ASC, 605-25, *Multiple-Element Arrangements.* Effective January 1, 2011, we adopted ASU 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13, which amended the guidance in ASC 605-25 on the accounting for arrangements involving the delivery of more than one element. Pursuant to the new standard, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has stand alone value to the customer. The arrangement s consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

We adopted this new accounting standard on a prospective basis for agreements containing multiple elements entered into on or after January 1, 2011, and for any agreements entered into prior to January 1, 2011, but materially modified on or after that date.

The primary impact of adopting the new standard is expected to be the earlier recognition of revenue for multiple element arrangements. The adoption of ASU 2009-13 did not have a material impact on our consolidated results of operations for the year ended December 31, 2011, or on our financial position as of December 31, 2011. The impact of adopting this new accounting standard is dependent on the terms and conditions of any future arrangements that we may enter into that include multiple elements and arrangements entered into prior to January 1, 2011 that are materially modified. Depending on the terms of any such arrangements, the adoption of this accounting standard may have a material impact on our consolidated results of operations or financial position as it may have the potential effect of less revenue deferral for new collaborations than we have historically experienced. We recognized revenue of $7.9 million for the year ended December 31, 2011 and deferred revenue of $3.1 million as of December 31, 2011 pertaining to collaborations which were entered into prior to our adoption of ASU 2009-13 and which were not modified on or after January 1, 2011. The performance period for our multiple element arrangements has concluded.

For agreements entered into prior to January 1, 2011 and not materially modified thereafter, we continue to apply our prior accounting policy with respect to such arrangements. Under this policy, the deliverables under the arrangement are evaluated to assess whether they have standalone value and objective and reliable evidence of fair value, and if so, are accounted for as a single unit. We then recognize revenue for each unit based on the culmination of the earnings process under ASC 605-S25, issued as Staff Accounting Bulletin, or SAB, Topic 13, and our estimated performance period for the single units of accounting based on the specific terms of each collaborative agreement. We subsequently adjust the estimated performance periods, if appropriate, on a prospective basis based upon available facts and circumstances. Future changes in estimates of the performance period may materially impact the timing of future revenue recognized. Amounts received prior to satisfying the revenue recognition criteria for contract revenues are recorded as deferred revenue in the accompanying balance sheets. Reimbursement amounts (other than those accounted for using collaboration accounting) paid to us are recorded on a gross basis in the statements of operations as contract revenues.

Effective January 1, 2011, we adopted ASU 2010 17, *Revenue Recognition Milestone Method*. The adoption of the new standard did not have a material impact on our consolidated results of operations for the year ended December 31, 2011 or on our financial position as of December 31, 2011 as we had been recognizing revenue from at-risk, performance milestones that are substantive in the period that the milestone is achieved, as defined in the respective contracts.

We entered into collaboration agreements with Pfizer and RTI that contain multiple elements and deliverables. For a description of the collaboration agreement and the determination of contract revenues, see Note E to our audited consolidated financial statements incorporated by reference into this prospectus.

Also included in contract revenue are license fees received from Bristol-Myers Squibb, which are specifically set forth in the license and collaboration agreement as amounts due to us based on our completion of certain tasks (e.g., delivery and acceptance of a cell line) and development milestones (e.g., clinical trial Phases), and as such, are not based on estimates that are susceptible to change. Such amounts are invoiced and recorded as revenue as tasks are completed and as milestones are achieved.

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Similarly, grant revenue consists of funding under cost reimbursement programs primarily from federal and state sources for qualified research and development activities performed by us, and as such, are not based on estimates that are susceptible to change. Such amounts are invoiced (unless prepaid) and recorded as revenue as tasks are completed.

Collaborative Arrangements

Collaborative arrangements that involve cost or future profit sharing are reviewed to determine the nature of the arrangement and the nature of the collaborative parties businesses. The arrangements are also reviewed to determine if one party has sole or primary responsibility for an activity, or whether the parties have shared responsibility for the activity. If responsibility for an activity is shared and there is no principal party, then the related costs of that activity are recognized by us on a net basis in the statement of operations (e.g., total cost less reimbursement from collaborator). If we are deemed to be the principal party for an activity, then the costs and revenues associated with that activity are recognized on a gross basis in the statement of operations. The accounting may be susceptible to change if the nature of a collaborator s business changes. Currently, our only collaboration accounted for on a net basis is our cost-sharing collaboration with Angiotech, which was terminated in 2011.

Clinical Trial Costs

Clinical trial costs are accrued based on work performed by outside contractors, who manage and perform the trials. We obtain initial estimates of total costs based on enrollment of subjects, project management estimates and other activities. Actual costs are typically charged to us and recognized as the tasks are completed by the contractor, and if we are invoiced based on progress payments as opposed to actual costs, we develop estimates of work completed to date. Accrued clinical trial costs may be subject to revisions as clinical trials progress, and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

Investments in Available-for-Sale Securities

We determine the appropriate classification of investment securities at the time of purchase and re-evaluate such designation as of each balance sheet date. Our investments typically consist primarily of United States government obligations and corporate debt securities, which are classified as available-for-sale and are valued based on quoted prices in active markets for identical assets (Level 1). Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported as a component of accumulated other comprehensive income. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization or accretion is included in interest income. Realized gains and losses on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest earned on securities classified as available-for-sale is included in interest income. Since the elements related to accounting for these investments are reflected on monthly statements, the amounts are not based on estimates that are susceptible to change. None of our financial assets are in markets that are not active.

Stock-Based Compensation

We recognize stock-based compensation expense on the straight-line method and use a Black-Scholes option-pricing model to estimate the grant-date fair value of share-based awards. The expected term of options granted represent the period of time that option grants are expected to be outstanding. We use the simplified method to calculate the expected life of option grants given our limited history and determine volatility by using our historical stock volatility. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates and if our expectations on forfeitures changes. If actual forfeitures vary from the estimate, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

All of the aforementioned estimates and assumptions are evaluated on a quarterly basis and may change as facts and circumstances warrant. Changes in these assumptions can materially affect the estimate of the fair value of our share-based payments and the related amount recognized in our financial statements.

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. These forward-looking statements relate to, among other things, the expected timetable for development of our product candidates, our growth strategy, and our future financial performance, including our operations, economic performance, financial condition, prospects, and other future events. We have attempted to identify forward-looking statements by using such words as anticipates, believes, can, continue, could, estimates, expects, intends, may, plans, potential, should, suggest, expressions. These forward-looking statements are only predictions and are largely based on our current expectations. These forward-looking statements appear in a number of places in this annual report.

In addition, a number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. Some of the more significant known risks that we face are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as human therapeutics, including the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues. The following risks and uncertainties may cause our actual results, levels of activity, performance, or achievements to differ materially from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements:

- uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem for the treatment of IBD, AMI, stroke and other disease indications, and the prevention of GvHD;
- our ability to raise capital to fund our operations;
- final results from our MultiStem clinical trials;
- the possibility of delays in, adverse results of, and excessive costs of the development process;
- our ability to successfully initiate and complete clinical trials and obtain all necessary regulatory approvals to commercialize our product candidates;
- changes in external market factors;
- changes in our industry s overall performance;
- changes in our business strategy;
- our ability to protect our intellectual property portfolio;
- our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;
- our ability to meet milestones under our collaboration agreements;
- our collaborators ability to continue to fulfill their obligations under the terms of our collaboration agreement;

our possible inability to execute our strategy due to changes in our industry or the economy generally;

changes in productivity and reliability of suppliers;

the success of our competitors and the emergence of new competitors; and

the risks mentioned elsewhere in this annual report on Form 10-K under Item 1A, Risk Factors.

Although we currently believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee our future results, levels of activity or performance. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. You are advised, however, to consult any further disclosures we make on related subjects in our reports on Forms 10-Q, 8-K and 10-K furnished to the SEC. You should understand that it is not possible to predict or identify all risk factors. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties.

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ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our exposure to interest rate risk is related to our investment portfolio and our borrowings. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Due in part to these factors, our future investment income may fall short of expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates. We invest our excess cash primarily in debt instruments of the United States government and its agencies and corporate debt securities, and as of December 31, 2012, we had no investments. We have been investing conservatively due to the current economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments.

We enter into loan arrangements with financial institutions when needed and when available to us. At December 31, 2012, we had no borrowings outstanding other than a forgivable note payable associated with local grant funding bearing fixed, forgivable interest of 4.25% per annum.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Athersys, Inc.

Consolidated Financial Statements

Years Ended December 31, 2012, 2011 and 2010

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Athersys, Inc.

We have audited the accompanying consolidated balance sheets of Athersys, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, stockholders equity and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Athersys, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U. S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Cleveland, Ohio

March 12, 2013

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Athersys, Inc.

Consolidated Balance Sheets

(In Thousands, Except Share and Per Share Amounts)

	December 31, 2012	2011
Assets		
Current assets:		
Cash and cash equivalents	**$ 25,533**	$ 8,785
Available-for-sale securities		3,999
Accounts receivable	**490**	689
Prepaid clinical trial costs		629
Prepaid expenses and other	**286**	332
Total current assets	**26,309**	14,434
Equipment, net	**1,294**	1,267
Total assets	**$ 27,603**	$ 15,701
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 1,767**	$ 2,301
Accrued compensation and related benefits	**827**	444
Accrued clinical trial costs	**950**	872
Accrued expenses	**934**	663
Deferred revenue		3,140
Total current liabilities	**4,478**	7,420
Note payable	**169**	
Warrant liabilities	**2,709**	983
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at December 31, 2012 and December 31, 2011		
Common stock, $0.001 par value; 100,000,000 shares authorized, 53,058,632 and 24,487,260 shares issued and outstanding at December 31, 2012 and December 31, 2011, respectively	**53**	24
Additional paid-in capital	**253,889**	226,206
Accumulated other comprehensive income		28
Accumulated deficit	**(233,695)**	(218,960)
Total stockholders equity	**20,247**	7,298
Total liabilities and stockholders equity	**$ 27,603**	$ 15,701

See accompanying notes.

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Athersys, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In Thousands, Except Share and Per Share Amounts)

	Year Ended December 31,		
	2012	2011	2010
Revenues			
Contract revenue	**$ 7,380**	$ 9,015	$ 6,685
Grant revenue	**1,328**	1,329	2,254
Total revenues	**8,708**	10,344	8,939
Costs and expenses			
Research and development (including stock compensation expense of $150, $205 and $545 in 2012, 2011and 2010, respectively)	**19,636**	18,930	14,779
General and administrative (including stock compensation expense of $331, $347 and $921 in 2012, 2011 and 2010, respectively)	**4,753**	4,916	5,387
Depreciation	**320**	278	284
Total costs and expenses	**24,709**	24,124	20,450
Loss from operations	**(16,001)**	(13,780)	(11,511)
Other expense, net	**(1,172)**	(863)	(69)
Income from change in fair value of warrants	**2,404**	812	
Interest income	**34**	85	203
Net loss	**$ (14,735)**	$ (13,746)	$ (11,377)
Basic and diluted net loss per common share	**$ (0.45)**	$ (0.59)	$ (0.60)
Weighted average shares outstanding, basic and diluted	**32,556,781**	23,239,019	18,929,749
Items included in other comprehensive income (loss):			
Proportional share of comprehensive (loss) income of equity method investment	**(28)**	28	
Unrealized (loss) gain on available-for-sale securities		(26)	(45)
Other comprehensive (loss) income items	**(28)**	2	(45)
Comprehensive loss	**$ (14,763)**	$ (13,744)	$ (11,422)

See accompanying notes.

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Athersys, Inc.

Consolidated Statements of Stockholders Equity

(In Thousands, Except Share Amounts)

	Preferred Stock		Common Stock		Additional	Accumulated Other		Total
	Number of Shares	Stated Value	Number of Shares	Par Value	Paid-in Capital	Comprehensive Income	Accumulated Deficit	Stockholders Equity
Balance at January 1, 2010		$	18,929,333	$ 19	$ 212,704	$ 71	$ (193,837)	$ 18,957
Stock based compensation					1,466			1,466
Issuance of common stock			1,345		4			4
Net loss							(11,377)	(11,377)
Other comprehensive income (loss) items						(45)		(45)
Balance at December 31, 2010			18,930,678	19	214,174	26	(205,214)	9,005
Stock based compensation					552			552
Issuance of common stock and warrants, net of issuance costs			5,556,582	5	11,480			11,485
Net loss							(13,746)	(13,746)
Other comprehensive income (loss) items						2		2
Balance at December 31, 2011			24,487,260	24	226,206	28	(218,960)	7,298
Stock based compensation					**481**			**481**
Issuance of common stock and warrants, net of issuance costs			**28,571,372**	**29**	**27,202**			**27,231**
Net loss							**(14,735)**	**(14,735)**
Other comprehensive income (loss) items						**(28)**		**(28)**
Balance at December 31, 2012		$	**53,058,632**	**$ 53**	**$ 253,889**	**$**	**$ (233,695)**	**$ 20,247**

See accompanying notes.

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Athersys, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

	Year Ended December 31,		
	2012	2011	2010
Operating activities			
Net loss	**$ (14,735)**	$ (13,746)	$ (11,377)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	**320**	278	284
Realized gain on investments and available-for-sale securities	**(183)**	(55)	
Stock-based compensation	**481**	552	1,466
Issuance of common stock to former lenders	**1,005**	683	
Change in fair value of warrant liabilities	**(2,404)**	(812)	
Amortization of premium on available-for-sale securities and other	**11**	58	225
Changes in operating assets and liabilities:			
Accounts receivable	**199**	1,745	(1,853)
Prepaid expenses and other assets	**580**	(511)	(63)
Accounts payable and accrued expenses	**201**	983	562
Deferred revenue	**(3,140)**	(3,664)	165
Net cash used in operating activities	**(17,665)**	(14,489)	(10,591)
Investing activities			
Purchase of available-for-sale securities		(12,508)	(8,834)
Proceeds from maturities of available-for-sale securities	**4,237**	21,672	10,753
Purchases of equipment	**(347)**	(590)	(390)
Net cash provided by investing activities	**3,890**	8,574	1,529
Financing activities			
Proceeds from note payable	**166**		
Proceeds from issuance of common stock and warrants, net	**30,357**	12,595	
Net cash provided by financing activities	**30,523**	12,595	
Increase (decrease) in cash and cash equivalents	**16,748**	6,680	(9,062)
Cash and cash equivalents at beginning of year	**8,785**	2,105	11,167
Cash and cash equivalents at end of year	**$ 25,533**	$ 8,785	$ 2,105

See accompanying notes.

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Athersys, Inc.

Notes to Consolidated Financial Statements

A. Background

We are an international biopharmaceutical company that is focused primarily in the field of regenerative medicine and operate in one business segment. Our operations consist primarily of research and product development activities.

B. Accounting Policies

Principles of Consolidation

The consolidated financial statements include our accounts and results of operations and those of our wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Investments in joint ventures are accounted for using the equity method when we do not control the investee, but have the ability to exercise significant influence over the investee s operations and financial policies. We liquidated our investment in our joint venture in January 2012 and recognized a gain of $183,000.

Revenue Recognition

Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, manufacturing revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under Accounting Standards Codification (ASC) 605-25, *Multiple-Element Arrangements.* Effective January 1, 2011, we adopted ASU 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13), which amended the guidance in ASC 605-25 on the accounting for arrangements involving the delivery of more than one element. Pursuant to the new standard, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has stand-alone value to the customer. The arrangement s consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

We adopted this new accounting standard on a prospective basis for agreements containing multiple elements entered into on or after January 1, 2011, and for any agreements entered into prior to January 1, 2011, but materially modified on or after that date.

The primary impact of adopting the new standard is expected to be the earlier recognition of revenue for multiple element arrangements. The adoption of ASU 2009-13 did not have a material impact on our consolidated results of operations for the years ended December 31, 2011 and 2012, or on our financial position as of December 31, 2011 and 2012. The impact of adopting this new accounting standard is dependent on the terms and conditions of any future arrangements that we may enter into that include multiple elements and arrangements entered into prior to January 1, 2011 that are materially modified. Depending on the terms of any such arrangements, the adoption of this accounting standard may have a material impact on our consolidated results of operations or financial position as it may have the potential effect of less revenue deferral for new collaborations than we have historically experienced. We recognized revenue of $7.9 million for the year ended December 31, 2011 and deferred revenue of $3.1 million as of December 31, 2011 pertaining to collaborations which were entered into prior to our adoption of ASU 2009-13 and which were not modified on or after January 1, 2011. The performance period for our multiple element arrangements concluded in 2012.

For agreements entered into prior to January 1, 2011 and not materially modified thereafter, we continue to apply our prior accounting policy with respect to such arrangements. Under this policy, the deliverables under the arrangement are evaluated to assess whether they have standalone value and objective and reliable evidence of fair value, and if so, are accounted for as a single unit. We then recognize revenue for each unit based on the culmination of the earnings process under ASC 605-S25, issued as Staff Accounting Bulletin (SAB) Topic 13, and our estimated performance period for the single units of accounting based on the specific terms of each collaborative agreement. We subsequently adjust the estimated performance periods, if appropriate, on a prospective basis based upon available facts and circumstances. Future changes in estimates of the performance period may materially impact the timing of future revenue recognized. Amounts received prior to satisfying the revenue recognition criteria for contract revenues are recorded as deferred revenue in the accompanying balance sheets. Reimbursement amounts (other than those accounted for using collaboration accounting) paid to us are recorded on a gross basis in the statements of operations as contract revenues.

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

Effective January 1, 2011, we adopted ASU 2010 17, *Revenue Recognition Milestone Method*. The adoption of the new standard did not have a material impact on our consolidated results of operations for the year ended December 31, 2011 or on our financial position as of December 31, 2011 as we had been recognizing revenue from at-risk, performance milestones that are substantive in the period that the milestone is achieved, as defined in the respective contracts.

Also included in contract revenue are license fees received from Bristol-Myers Squibb, which are specifically set forth in the license and collaboration agreement as amounts due to us based on our completion of certain tasks (e.g., delivery and acceptance of a cell line) and development milestones (e.g., clinical trial phases), and as such, are not based on estimates that are susceptible to change. Such amounts are invoiced and recorded as revenue as tasks are completed and as milestones are achieved.

Similarly, grant revenue consists of funding under cost reimbursement programs primarily from federal and state sources for qualified research and development activities performed by us, and as such, are not based on estimates that are susceptible to change. Such amounts are invoiced (unless prepaid) and recorded as revenue as tasks are completed.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents are primarily invested in money market funds and commercial paper. The carrying amount of our cash equivalents approximates fair value due to the short maturity of the investments.

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

B. Accounting Policies, continued

Research and Development

Research and development expenditures, which consist primarily of costs associated with external clinical and preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property application processes, and laboratory supply and reagent costs, including direct and allocated overhead expenses, are charged to expense as incurred.

Collaborative Arrangements

Collaborative arrangements that involve cost or future profit sharing are reviewed to determine the nature of the arrangement and the nature of the collaborative parties businesses. The arrangements are also reviewed to determine if one party has sole or primary responsibility for an activity, or whether the parties have shared responsibility for the activity. If responsibility for an activity is shared and there is no principal party, then the related costs of that activity are recognized by us on a net basis in the statement of operations (e.g., total cost less reimbursement from collaborator). If we are deemed to be the principal party for an activity, then the costs and revenues associated with that activity are recognized on a gross basis in the statement of operations. The accounting may be susceptible to change if the nature of a collaborator s business changes. Our only collaboration accounted for on a net basis was our cost-sharing collaboration with Angiotech Pharmaceuticals, Inc. (Angiotech), which was terminated in 2011.

Clinical Trial Costs

Clinical trial costs are accrued based on work performed by outside contractors, who manage and perform the trials. We obtain initial estimates of total costs based on enrollment of subjects, project management estimates and other activities. Actual costs are typically charged to us and recognized as the tasks are completed by the contractor, and if we are invoiced based on progress payments as opposed to actual costs, we develop estimates of work completed to date. Accrued clinical trial costs may be subject to revisions as clinical trials progress, and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

Royalties

We may be required to make future royalty payments to certain parties based on product sales under license agreements. We did not pay any royalties during the three-year period ended December 31, 2012.

Investments in Available-for-Sale Securities

We determine the appropriate classification of investment securities at the time of purchase and re-evaluate such designation as of each balance sheet date. Our investments typically consist of United States government obligations and corporate debt securities, which are classified as available-for-sale and are valued based on quoted prices in active markets for identical assets (Level 1). Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of applicable tax, reported as a component of accumulated other comprehensive income. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization or accretion is included in interest income. Realized gains and losses on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest earned on securities classified as available-for-sale is included in interest income. None of our financial assets are in markets that are not active.

Long-Lived Assets

Equipment is stated at acquired cost less accumulated depreciation. Laboratory and office equipment are depreciated on the straight-line basis over the estimated useful lives (three to ten years). Leasehold improvements are amortized over the shorter of the lease term or estimated useful

life.

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

B. Accounting Policies, continued

Long-lived assets are evaluated for impairment when events or changes in circumstances indicate that the carrying amount of the asset or related group of assets may not be recoverable. If the expected future undiscounted cash flows are less than the carrying amount of the asset, an impairment loss is recognized at that time. Measurement of impairment may be based upon appraisal, market value of similar assets or discounted cash flows.

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

B. Accounting Policies, continued

Patent Costs and Rights

Costs of prosecuting and maintaining patents and patent rights are expensed as incurred. As of December 31, 2012, we have filed for broad intellectual property protection on our proprietary technologies. We currently have numerous United States patent applications and corresponding international patent applications related to our technologies, as well as many issued United States and international patents.

Comprehensive Income (Loss)

Unrealized gains and losses on our available-for-sale securities are the only components of accumulated other comprehensive income.

Concentration of Credit Risk

Our accounts receivable are generally comprised of amounts due from collaborators and granting authorities and are subject to concentration of credit risk due to the absence of a large number of customers. At December 31, 2012, the majority of our accounts receivable are due from granting authorities. We do not require collateral from these customers.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Stock-Based Compensation

We recognize stock-based compensation expense on the straight-line method and use a Black-Scholes option-pricing model to estimate the fair value of option awards. The expected term of options granted represent the period of time that option grants are expected to be outstanding. We use the simplified method to calculate the expected life of option grants given our limited history of exercise activity and determine volatility by using our historical stock volatility. The fair value of our restricted stock units are equal to the closing price of our common stock on the date of grant and is expensed over the vesting period on a straight-line basis. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. If actual forfeitures vary from the estimate, we recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

All of the aforementioned estimates and assumptions are evaluated on a quarterly basis and may change as facts and circumstances warrant. Changes in these assumptions can materially affect the estimate of the fair value of our share-based payments and the related amount recognized in our financial statements.

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

B. Accounting Policies, continued

The following weighted-average input assumptions were used in determining the fair value of the Company s stock-based compensation awards:

	December 31,		
	2012	2011	2010
Volatility	**117.3%**	125.7%	119.5%
Risk-free interest rate	**0.8%**	1.5%	1.0%
Expected life of option	**5.72 years**	5.96 years	4.09 years
Expected dividend yield	**0.0%**	0.0%	0.0%

Income Taxes

Deferred tax liabilities and assets are determined based on the differences between the financial reporting and tax basis of assets and liabilities and are measured using the tax rate and laws currently in effect. We evaluate our deferred income taxes to determine if a valuation allowance should be established against the deferred tax assets or if the valuation allowance should be reduced based on consideration of all available evidence, both positive and negative, using a more likely than not standard.

We had no liability for uncertain income tax positions as of December 31, 2012 and 2011. Our policy is to recognize potential accrued interest and penalties related to the liability for uncertain tax benefits, if applicable, in income tax expense. Net operating loss and credit carryforwards since inception remain open to examination by taxing authorities, and will for a period post utilization.

Net Loss per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. We have outstanding options and warrants that are not used in the calculation of diluted net loss per share because to do so would be anti-dilutive. The following instruments were excluded from the calculation of diluted net loss per share because their effects would be anti-dilutive:

	Year ended December 30,		
	2012	**2011**	**2010**
Outstanding options	**4,058,184**	4,499,601	4,308,013
Restricted stock units	**70,814**	39,300	0
Outstanding warrants	**5,806,853**	6,435,496	5,125,496
	9,935,851	10,974,397	9,433,509

Reclassifications

Certain prior year amounts have been reclassified to conform with current year presentations.

C. Equipment

Equipment consists of (in thousands):	December 31, 2012	2011
Laboratory equipment	**$ 6,741**	$ 6,430
Office equipment and leasehold improvements	**3,842**	3,806
	10,583	10,236
Accumulated depreciation	**(9,289)**	(8,969)
	$ 1,294	$ 1,267

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

D. Financial Instruments

Investments in Available-for-Sale Securities

Our available-for-sale securities typically include United States government obligations and corporate debt securities. As of December 31, 2011, all of our investments were in United States government obligations, including government-backed agencies, and we had no investments at December 31, 2012.

The following is a summary of available-for-sale securities (in thousands) at December 31, 2011:

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Estimated Fair Value
December 31, 2011:				
United States government obligations, including government-backed agencies	$ 3,999	$	$	$ 3,999

We had no realized gains or losses on the sale of available-for-sale securities for any of the periods presented. Unrealized gains and losses on our available-for-sale securities are excluded from earnings and are reported as a separate component of stockholders equity within accumulated other comprehensive income until realized. When available-for-sale securities are sold in the future, the cost of the securities will be specifically identified and used to determine any realized gain or loss. There was no net unrealized gain on available-for-sale securities as of December 31, 2012 and 2011.

Fair Value Measurements

We classify the inputs used to measure fair value into the following hierarchy:

Level 1	Unadjusted quoted prices in active markets for identical assets or liabilities.
Level 2	Unadjusted quoted prices in active markets for similar assets or liabilities, or unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are observable for the asset or liability.
Level 3	Unobservable inputs for the asset or liability.

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

D. Financial Instruments, continued

The following table provides a summary of the financial assets and liabilities measured at fair value on a recurring basis as follows: (in thousands):

		Fair Value Measurements at December 31, 2012 Using		
Description	**Balance as of December 31, 2012**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Warrant liabilities	**$ 2,709**	**$**	**$**	**$ 2,709**

		Fair Value Measurements at December 31, 2011 Using		
Description	**Balance as of December 31, 2011**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Available-for-sale securities	$ 3,999	$ 3,999	$	$
Warrant liabilities	$ 983	$	$	$ 983

We review and reassess the fair value hierarchy classifications on a quarterly basis. Changes from one quarter to the next related to the observability of inputs in a fair value measurement may result in a reclassification between fair value hierarchy levels. There were no reclassifications for all periods presented.

Fair value is based upon quoted market prices in active markets for our level 1 investments. The estimated fair value of warrants accounted for as liabilities, representing a level 3 fair value measure, was determined on the issuance date and subsequently marked to market at each financial reporting date. The fair value of the warrants is estimated using the expected volatility based on the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization, using a Black-Scholes pricing model. The fair value of the warrants issued in March 2012 is determined using probability weighted-average assumptions that give consideration to the exercise price repricing feature that is dependent upon the consummation of future qualified offerings, as defined, and requisite stockholder approval. The following inputs were used at December 31, 2012:

	Warrants Issued February 2011	**Warrants Issued March 2012**
Expected volatility	71.3%	80.7%
Risk-free interest rate	0.36%	0.72%
Expected life	3.08 years	4.20 years
Fair value at December 31, 2012	**$ 249**	**$ 2,460**

(in thousands)

A roll-forward of fair value measurements using significant unobservable inputs (Level 3) for the warrants is as follows (in thousands):

	Year ended December 31, 2012
Balance January 1, 2012	$ 983
Issuance of warrants March 2012	4,130
Settlements	
(Gain) included in other income (expense), net, for the period	(2,404)
Balance December 31, 2012	**$ 2,709**

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

D. Financial Instruments, continued

Financing Arrangements

We lease office and laboratory space under operating leases. The lease for our corporate offices and laboratories 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 lease office and laboratory space for our Belgian subsidiary, which currently expires in July 2015 and includes options to renew annually through July 2022, with annual rent of $159,000, subject to adjustments based on an inflationary index

Aggregate rent expense was approximately $415,000, $397,000 and $387,000 in 2012, 2011 and 2010, respectively. The future annual minimum lease commitments at December 31, 2012 are approximately $444,000 for 2013, $453,000 for 2014, $370,000 for 2015, and $67,000 for 2016.

In April 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic Foundation pursuant to which we are entitled to proceeds of up to $500,000 in the form of a forgivable loan to fund certain remaining preclinical work using MultiStem to treat congestive heart failure and for preparing the program for an investigational new drug application with the U.S. Food and Drug Administration. Interest on the loan accrues at a fixed rate of 4.25% per annum, and is added to the outstanding principal. The principal and interest on the loan will be forgiven based on the achievement of a certain milestone, unrelated to the preclinical work, within three to four years. As of December 31, 2012, we have drawn $166,000 of this financing, which is reflected on the balance sheet as a non-current note payable, including interest.

Our former lenders retained a right to receive remaining milestone payments up to $1.3 million as of December 31, 2011 (from an original amount of $2.25 million) upon the occurrence of certain events, and the final balance was settled in full in 2012 in connection with equity offerings during the year. We elected to pay 75% of the milestone payments in shares of common stock at the per-share offering prices in 2012 and $1.3 million in cash and stock-based milestone payments were recognized as other expense in the year. In 2011, milestone expense was $0.9 million and no milestone expense was incurred in 2010.

We paid no interest during the three years ended December 31, 2012.

E. Collaborations and Revenue Recognition

Pfizer

In 2009, we entered into a collaboration with Pfizer Inc. (Pfizer) to develop and commercialize our MultiStem® product candidate to treat inflammatory bowel disease (IBD) for the worldwide market. Under the terms of the agreement, we received a non-refundable up-front payment from Pfizer and research funding and support through June 2012. In addition, we are eligible to receive milestone payments upon the successful achievement of certain development, regulatory and commercial milestones, for which we evaluated the nature of the events triggering these contingent payments and concluded that these events constituted substantive milestones that will be recognized as revenue in the period in which the underlying triggering event occurs. In concluding that each milestone is substantive, we considered factors such as whether the associated consideration fairly represents either the level of effort required to reach the milestone or the value added to the product based on the achievement of such milestone. No significant milestone revenue has been recognized to date.

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 III clinical development.

We evaluated the facts and circumstances of the agreement and determined the Pfizer agreement had multiple deliverables that should be combined into a single unit of accounting. We recognized the license and technology access fee and research and development funding ratably on a straight-line basis over the estimated performance period, which was completed mid-2012, and measured manufacturing revenue beginning upon the culmination of the earnings process and recognized it over the performance period of the bundled unit of accounting.

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

Angiotech

In November 2011, we reached an agreement with Angiotech Pharmaceuticals, Inc. (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 such as acute myocardial infarction (AMI), and Angiotech no longer has any license rights with respect to our technologies. Angiotech made its final cost-sharing payment in 2011 in connection with collaboration activities and has no further obligations to us.

In the case of a new AMI collaboration, Angiotech will be entitled to a future payment from us equal to a percentage of cash license fee payments we receive within the first six months from a third-party related to such AMI collaboration, and is not entitled to other downstream payments. The future payment, if any, will be either (i) 15% of third-party license fees if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, but before we have spent $5.0 million on the clinical trial, and within 24 months of the termination agreement, or (ii) 10% of third-party license fees up to a maximum of $5.0 million to Angiotech if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, and after we have spent $5.0 million on the clinical trial, and within 36 months of the termination agreement. Prior to the termination of the collaboration, our clinical costs were recorded net of Angiotech s cost-share reimbursements, which amounted to $312,000 and $628,000 in 2011 and 2010, respectively.

RTI Biologics, Inc.

In 2010, we entered into an agreement with RTI Biologics, Inc. (RTI) to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market. Under the terms of the agreement, we received a $5.0 million license fee in installments, of which $3.0 million was guaranteed and received in 2010 and 2011, and $2.0 million was contingent upon future events and considered a substantive milestone at the inception of the agreement. We evaluated the facts and circumstances and determined the RTI agreement had obligations constituting deliverables and concluded that it has multiple deliverables, including deliverables relating to the grant of a license to our technology and performance of research and development services, and concluded that these deliverables should be combined into a single unit of accounting. We recognized the $3.0 million guaranteed license fee ratably on a straight-line basis over the estimated performance period, which was completed in 2011.

In September 2012, RTI agreed to make the remaining $2.0 million license fee payments by December 31, 2012, and we agreed to provide RTI with certain technical support through December 31, 2012. The $2.0 million consideration associated with the amendment was recognized over the performance period from September 2012 through December 2012.

We are also eligible to receive $35.5 million in cash payments upon the successful achievement of certain commercial milestones. We evaluated the nature of the events triggering these contingent payments and concluded that these events are substantive and that revenue will be recognized in the period in which each underlying triggering event occurs. In addition, we will receive tiered royalties on worldwide commercial sales, if any, of implants using our technologies. No milestone or royalty revenue has been recognized to date.

F. Capitalization and Warrant Liability

Capitalization

At December 31, 2012, we had 100.0 million shares of common stock and 10.0 million shares of undesignated preferred stock authorized. No shares of preferred stock have been issued as of December 31, 2012.

The following shares of common stock were reserved for future issuance (in thousands):

December 31

		2012	2011
Stock-based compensation plans		**5,490**	5,500
Warrants to purchase common stock	2007 offering		4,976
Warrants to purchase common stock	former lenders	**149**	149
Warrants to purchase common stock	2011 offering	**1,310**	1,310
Warrants to purchase common stock	2012 offering	**4,348**	
		11,297	11,935

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

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 additional 2,970,300 shares of common stock, solely to cover over-allotments. The exercise of the full over-allotment option generated an additional $2.8 million of net proceeds.

In March 2012, we completed a private placement financing generating net proceeds of approximately $8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of $2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of $2.07 per fixed combination, and the warrants include price protection in the event we sell stock below the exercise price, as defined. As a result of the October 2012 public offering and in accordance with the terms of the warrants, we sought and obtained stockholder approval in February 2013 to reduce the exercise price of these warrants to $1.01 per share.

In November 2011, we entered into an equity purchase agreement, which provides that Aspire Capital Fund, LLC (Aspire Capital) is 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. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price. As part of the agreement, Aspire Capital made an initial investment of $1.0 million in us through the purchase of 666,667 shares of our common stock at $1.50 per share in 2011, and received 266,667 additional shares as compensation for its commitment. In 2012, we sold an additional 800,000 shares to Aspire Capital at an average price of $1.57 per share (no shares were sold during the quarter ended December 31, 2012). As of December 31, 2012, we have received aggregate proceeds of approximately $2.3 million under the equity purchase agreement since its inception.

In February 2011, we completed a registered direct offering with net proceeds of $11.8 million through the issuance of 4,366,667 shares of common stock and five-year warrants to purchase 1,310,000 shares of common stock with an exercise price of $3.55 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.3 of a share of common stock at an offering price of $3.00 per fixed combination.

Warrant Liabilities

We account for common stock warrants as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. Registered common stock warrants that could require cash settlement are accounted for as liabilities. We classify these warrant liabilities on the consolidated balance sheet as a non-current liability, which is revalued at fair value at each balance sheet date subsequent to the initial issuance. We use the Black-Scholes valuation model to value the warrant liability at its fair value. Changes in the fair market value of the warrant are reflected in the consolidated statement of operations as other income (expense).

The warrants we issued in both the March 2012 private placement and the February 2011 registered direct offering each contain a provision for net cash settlement in the event that there is a fundamental transaction (e.g., merger, sale of substantially all assets, tender offer, or share exchange). If a fundamental transaction occurs in which the consideration issued consists of all cash or stock in a non-public company, then the warrant holder has the option to receive cash equal to a Black Scholes value of the remaining unexercised portion of the warrant. Further, the March 2012 warrants include price protection in the event we sell stock below the exercise price, as defined. As a result of the October 2012 public offering and in accordance with the terms of the warrants, we sought and obtained stockholder approval in February 2013 to reduce the exercise price of these 4,347,827 warrants to $1.01 per share.

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

The warrants have been classified as liabilities, as opposed to equity, due to the potential cash settlement upon the occurrence of certain events as described above, and are recorded at their fair values at each balance sheet date. See Note D.

As of December 31, 2012, we had the following outstanding warrants to purchase shares of common stock:

Number of Underlying Shares	Exercise Price	Expiration
149,026	$5.00	June 8, 2014
1,310,000	$3.55	February 2, 2016
4,347,827	$2.07	March 14, 2017
5,806,853		

G. Stock-Based Compensation

We have two incentive plans that authorized an aggregate of 5,500,000 shares of common stock for awards to employees, directors and consultants. These equity incentive plans authorize the issuance of equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units, and other stock-based awards to qualified employees, directors and consultants. As of December 31, 2012, a total of 9,819 shares of common stock have been issued under our equity incentive plans.

As of December 31, 2012, a total of 1,362,258 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 4,128,998 shares of common stock were outstanding (including 70,814 of restricted stock units and certain assumed options from 2007 covering 1,075 shares). We recognized $481,000, $552,000 and $1,466,000 of stock-based compensation expense in 2012, 2011 and 2010, respectively.

Stock Options

The weighted average fair value of options granted in 2012, 2011 and 2010 was $1.21, $2.30 and $2.22 per share, respectively. The total fair value of options vested during 2012, 2011 and 2010 was $420,000, $570,000 and $1,835,000, respectively. At December 31, 2012, total unrecognized estimated compensation cost related to unvested stock options was approximately $491,000, which is expected to be recognized by the end of 2016 using the straight-line method. The weighted average contractual life of unvested options at December 31, 2012 was 8.12 years. There is no aggregate intrinsic value of fully vested option shares and option shares expected to vest as of December 31, 2012 since the market value was less than the exercise price of the options at the end of the year.

A summary of our stock option activity and related information is as follows:

	Number of Options	Weighted Average Exercise Price
Outstanding January 1, 2010	4,001,149	$ 4.94
Granted	390,437	2.96
Exercised		

Forfeited / Terminated / Expired	(83,573)	6.39
Outstanding December 31, 2010	4,308,013	4.73
Granted	213,588	2.61
Exercised		
Forfeited / Expired	(22,000)	3.46
Outstanding December 31, 2011	4,499,601	4.63
Granted	290,150	1.44
Exercised		
Forfeited / Expired	(731,567)	4.92
Outstanding December 31, 2012	**4,058,184**	**$ 4.36**
Vested during 2012	**227,975**	**$ 2.38**
Vested and exercisable at December 31, 2012	**3,761,922**	**$ 4.54**

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

	December 31, 2012					
	Options Outstanding			Options Vested and Exercisable		
Exercise Price	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$1.23 2.96	838,609	6.21	2.18	568,034	5.08	2.33
$3.10 5.00	3,098,500	4.37	4.88	3,072,813	4.38	4.89
$5.28 7.80	120,000	7.09	5.28	120,000	7.09	5.28
$90.66	1,075	0.38	$ 90.66	1,075	0.38	$ 90.66
	4,058,184			**3,761,922**		

Restricted Stock Units

A summary of our restricted stock unit activity and related information is as follows:

	Number of Restricted Stock Units	Weighted Average Fair Value
Outstanding December 31, 2010		$
Granted	39,300	2.69
Vested/Issued		
Forfeited/Expired		
Outstanding December 31, 2011	39,300	$ 2.69
Granted	56,716	1.43
Vested/Issued	(9,819)	2.69
Forfeited/Expired	(15,383)	1.88
Outstanding December 31, 2012	**70,814**	**$ 1.86**
Vested/Issued during 2012	**9,819**	**$ 2.69**
Vested/Issued cumulative at December 31, 2012	**9,819**	**$ 2.69**

The weighted average fair value of restricted stock units granted in 2012 was $1.43 per share. Restricted stock units that vested during 2012 were 9,819 and none vested in 2011. At December 31, 2012, total unrecognized estimated compensation cost related to unvested restricted stock units was approximately $109,000, which is expected to be recognized by the end of 2016 using the straight-line method.

H. Income Taxes

We had net operating loss and research and development tax credit carryforwards of approximately $71,522,000 and $4,176,000, respectively, at December 31, 2012, and approximately $54,918,000 and $4,176,000, respectively at December 31, 2011. Such losses and credits may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2027 and 2032.

We have net operating loss carryforwards of approximately $6,698,000 (Pre-Merger NOL) that are limited for use under Section 382 of the Internal Revenue Code to an annual net operating loss carryforward of $464,000. The Pre-Merger NOL may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2013 and 2027. However, as a result of our most recent equity offerings, all of the net operating loss and credit carryforwards may be significantly limited for use under Section 382 of the Internal Revenue Code.

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Athersys, Inc.

Notes to Consolidated Financial Statements (continued)

Significant components of our deferred tax assets are as follows (in thousands):

	December 31,	
	2012	2011
Net operating loss carryforwards	**$ 24,318**	$ 18,672
Net operating loss carryforwards Pre-Merger NOL	**2,277**	2,435
Research and development credit carryforwards	**4,176**	4,176
License fee	**0**	684
Compensation expense	**2,948**	2,828
Other	**503**	477
Total deferred tax assets	**34,222**	29,272
Valuation allowance for deferred tax assets	**(34,222)**	(29,272)
Net deferred tax assets	**$**	$

Because of our cumulative losses, the deferred tax assets have been fully offset by a valuation allowance. We have not paid income taxes for the three-year period ended December 31, 2012.

I. Profit Sharing Plan and 401(k) Plan

We have a profit sharing and 401(k) plan that covers substantially all employees and allows for discretionary contributions by us. We began making employer contributions to this plan in 2011, and the expense was approximately $98,000 in 2012, $88,000 in 2011, and $0 in 2010.

J. Quarterly Financial Data (unaudited)

The following table presents quarterly data for the years ended December 31, 2012 and 2011, in thousands, except per share data:

	2012				
	First Quarter	**Second Quarter**	**Third Quarter**	**Fourth Quarter**	**Full Year**
Revenues	**$ 2,747**	**$ 2,657**	**$ 1,015**	**$ 2,289**	**$ 8,708**
Net loss	**$ (4,336)**	**$ (3,713)**	**$ (3,449)**	**$ (3,237)**	**$ (14,735)**
Basic and diluted net loss per common share	**$ (0.17)**	**$ (0.13)**	**$ (0.12)**	**$ (0.07)**	**$ (0.45)**

	2011				
	First Quarter	**Second Quarter**	**Third Quarter**	**Fourth Quarter**	**Full Year**
Revenues	$ 2,990	$ 2,435	$ 2,354	$ 2,565	$ 10,344
Net loss	$ (3,930)	$ (3,223)	$ (2,341)	$ (4,252)	$ (13,746)
Basic and diluted net loss per common share	$ (0.18)	$ (0.14)	$ (0.10)	$ (0.18)	$ (0.59)

Due to the effect of quarterly changes to outstanding shares of common stock and weightings, the annual loss per share will not necessarily equal the sum of the respective quarters.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures: An evaluation was carried out under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this annual report on Form 10-K. Based on that evaluation, these officers have concluded that as of December 31, 2012, our disclosure controls and procedures are effective.

Management s report on internal control over financial reporting: Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation under the framework in Internal Control Integrated Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2012.

Changes in internal control: During the fourth quarter of 2012, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On January 7, 2013, the Board of Directors of the Company, upon the recommendation of the Compensation Committee of the Board of Directors of the Company, approved a cash bonus incentive plan, or the Plan, for the year ended December 31, 2013 for the named executive officers of the Company. The Plan provides that each participant is eligible to earn a bonus during the award term of January 1, 2013 through December 31, 2013. The Plan provides for the following target bonus percentages of the named executive officer s salary during the award term, weighted as set forth below on the achievement of specified corporate goals, with the remainder based on individual/functional performance. The corporate goals include advancing the Company s clinical programs for MultiStem, advancement of strategic partnership and program activities, and executing against the established operating plan and capital acquisition objectives. There is no formally adopted plan document for the Plan.

Title	Target Bonus	Weighting on Corporate Goals
Chief Executive Officer	40%	100%
President & Chief Operating Officer	33%	80%
Executive Vice President & Chief Scientific Officer	33%	80%
Executive Vice President, Regenerative Medicine	30%	60%
Vice President of Finance	25%	60%

A summary of the plan is attached to this annual report on Form 10-K as Exhibit 10.54 and is hereby incorporated herein by reference thereto.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding Athersys directors, including the identification of the audit committee and the audit committee financial expert, is incorporated by reference to the information contained in Athersys Proxy Statement with respect to the 2013 Annual Meeting of Stockholders, or the 2013 Proxy Statement, under the headings Election of Directors and The Board of Directors and its Committees . Information concerning executive officers is contained in Item 3A of Part I of this annual report on Form 10-K under the heading Executive Officers of the Registrant .

The information regarding Section 16(a) beneficial ownership reporting compliance is incorporated by reference to the material under the heading Section 16(a) Beneficial Ownership Reporting Compliance in the 2013 Proxy Statement.

Athersys has adopted a code of ethics that applies to its principal executive officer, principal financial officer and principal accounting officer. Athersys code of ethics is posted under the Investors tab of its website at www.athersys.com. Athersys will post any amendments to, or waivers of, its code of ethics that apply to its principal executive officer, principal financial officer and principal accounting officer on its website.

ITEM 11. EXECUTIVE COMPENSATION

The information regarding executive officer and director compensation is incorporated by reference to the information contained in the 2013 Proxy Statement under the heading Executive Compensation .

The compensation committee report is incorporated by reference to the information contained in the 2013 Proxy Statement under the heading Compensation Committee Report .

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

The information regarding security ownership of certain beneficial owners and management is incorporated by reference to the information contained in the 2013 Proxy Statement under the heading Beneficial Ownership of Common Stock .

The information regarding compensation plans under which equity securities are authorized for issuance is incorporated by reference to the information contained in the 2013 Proxy Statement under the heading Equity Compensation Plan Information.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information regarding certain relationships and related transactions and director independence is incorporated by reference to the information contained in the 2013 Proxy Statement under the heading The Board of Directors and its Committees .

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information regarding fees paid to and services provided by our independent registered public accounting firm during the fiscal years ended December 31, 2012 and 2011 and the pre-approval policies and procedures of the audit committee is incorporated by reference to the information contained in the 2013 Proxy Statement under the heading Ratification of the Appointment of Independent Auditors .

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements:

The following consolidated financial statements of Athersys, Inc. are included in Item 8:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2012 and 2011

Consolidated Statements of Operations and Comprehensive Loss for each of the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Stockholders Equity for each of the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Cash Flow for each of the years ended December 31, 2012, 2011 and 2010

Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedules:

All schedules for which provision is made in the applicable accounting regulation of the SEC are not required under the related instructions or are not applicable and, therefore, omitted.

(a)(3) Exhibits.

Exhibit No.	Exhibit Description
3.1	Certificate of Incorporation of Athersys, Inc., as amended as of August 31, 2007 (incorporated herein by reference to Exhibit 3.1 to the registrant s Registration Statement on Form S-3/A (Registration No. 333-144433) filed with the Commission on October 10, 2007)
3.2	Bylaws of Athersys, Inc., as amended as of October 30, 2007 (incorporated herein by reference to Exhibit 3.1 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on October 31, 2007)
4.1	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on January 28, 2011)
4.2	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on March 15, 2012)
10.1*	Research Collaboration and License Agreement, dated as of December 8, 2000, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.2*	Cell Line Collaboration and License Agreement, dated as of July 1, 2002, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.2 to the registrant s Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007)
10.3*	Extended Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.3 to the registrant s Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007)

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10.4	License Agreement, effective as of May 5, 2006, by and between Athersys, Inc. and Angiotech (incorporated herein by reference to Exhibit 10.4 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.5	Sublicense Agreement, effective as of May 5, 2006, by and between Athersys, Inc. and Angiotech (incorporated herein by reference to Exhibit 10.5 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.6	Amended and Restated Registration Rights Agreement, dated as of April 28, 2000, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto (incorporated herein by reference to Exhibit 10.6 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.7	Amendment No. 1 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of January 29, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.7 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.8	Amendment No. 2 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of November 19, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, as amended, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.8 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.9	Amendment No. 3 to Amended and Restated Registration Rights Agreement, dated as of May 15, 2007, by and among Athersys, Inc. and the Existing Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.9 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.10	Athersys, Inc. Equity Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.11 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.11	Loan and Security Agreement, and Supplement, dated as of November 2, 2004, by and among Athersys, Inc., Advanced Biotherapeutics, Inc., Venture Lending & Leasing IV, Inc., and Costella Kirsch IV, L.P. (incorporated herein by reference to Exhibit 10.1 to the registrant s Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on November 14, 2007)
10.12	Second Amendment to Loan and Security Agreement, dated as of October 30, 2007, by and among ABT Holding Company, Advanced Biotherapeutics, Inc., Venture Lending and Leasing IV, Inc., and Costella Kirsch IV, L.P. (incorporated herein by reference to Exhibit 10.2 to the registrant s Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on November 14, 2007)
10.13	Amendment to Loan and Security Agreement, dated as of September 29, 2006, by and among Athersys, Inc., Advanced Biotherapeutics, Inc., Venture Lending & Leasing IV, Inc., and Costella Kirsch IV, L.P. (incorporated herein by reference to Exhibit 10.13 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.14	Amended and Restated Employment Agreement, dated as of December 1, 1998 but effective as of April 1, 1998, by and between Athersys, Inc. and Dr. Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.14 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)

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10.15	Amendment No. 1 to Amended and Restated Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.15 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.16	Non-Competition and Confidentiality Agreement, dated as of December 1, 1998, by and between Athersys, Inc. and Dr. Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.16 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.17	Amended and Restated Employment Agreement, dated as of December 1, 1998 but effective as of April 1, 1998, by and between Athersys, Inc. and Dr. John J. Harrington (incorporated herein by reference to Exhibit 10.17 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.18	Amendment No. 1 to Amended and Restated Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and John Harrington (incorporated herein by reference to Exhibit 10.18 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.19	Non-Competition and Confidentiality Agreement, dated as of December 1, 1998, by and between Athersys, Inc. and Dr. John J. Harrington (incorporated herein by reference to Exhibit 10.19 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.20	Employment Agreement, dated as of May 22, 1998, by and between Athersys, Inc. and Laura K. Campbell (incorporated herein by reference to Exhibit 10.20 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.21	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Laura Campbell (incorporated herein by reference to Exhibit 10.21 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.22	Employment Agreement, dated as of October 3, 2003, by and between Advanced Biotherapeutics, Inc. and Robert Deans, Ph.D. (incorporated herein by reference to Exhibit 10.25 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.23	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Robert Deans (incorporated herein by reference to Exhibit 10.26 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.24	Non-Competition and Confidentiality Agreement, dated as of October 3, 2003, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and Robert Deans (incorporated herein by reference to Exhibit 10.27 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.25	Employment Agreement, dated as of January 1, 2004, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.28 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)

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10.26	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.29 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.27	Non-Competition and Confidentiality Agreement, dated as of September 10, 2001, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.30 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.28	Form Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.31 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.29	Form Amendment No. 1 to Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.32 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.30	Securities Purchase Agreement, dated as of June 8, 2007, by and among Athersys, BTHC VI, Inc. and Investors (as defined therein) (incorporated herein by reference to Exhibit 10.33 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.31*	Exclusive License Agreement, dated as of May 17, 2002, by and between Regents of the University of Minnesota and MCL LLC, assumed by ReGenesys, LLC through operation of merger on November 4, 2003 (incorporated herein by reference to Exhibit 10.34 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.32*	Strategic Alliance Agreement, by and between Athersys, Inc. and Angiotech, dated as of May 5, 2006 (incorporated herein by reference to Exhibit 10.35 to the registrant s Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on October 9, 2007)
10.33	Amendment No. 1 to Cell Line Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.36 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.34	Form Indemnification Agreement for Directors, Officers and Directors and Officers (incorporated herein by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on August 6, 2007)
10.35	Summary of Athersys, Inc. 2011 Cash Bonus Incentive Plan (incorporated herein by reference to Exhibit 10.41 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011)
10.36	Summary of Athersys, Inc. 2012 Cash Bonus Incentive Plan (incorporated herein by reference to Exhibit 10.36 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2011 (Commission No. 001-33876) filed with the Commission on March 28, 2012)

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10.37*	Collaboration and License Agreement, dated as of December 18, 2009, by and between Athersys, Inc., ABT Holding Company, and Pfizer (incorporated herein by reference to Exhibit 10.42 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2009 (Commission No. 001-33876) filed with the Commission on March 11, 2010)
10.38*	Stand-by License Agreement, dated as of December 18, 2009, by and between Regents of the University of Minnesota, ABT Holding Company and Pfizer (incorporated herein by reference to Exhibit 10.43 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2009 (Commission No. 001-33876) filed with the Commission on March 11, 2010)
10.39	Amendment dated as of March 31, 2009 to the Extended Collaboration and License Agreement, by and between Athersys, Inc. and Bristol-Myers Squibb Company effective January 1, 2006 (incorporated herein by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on April 9, 2009)
10.40	Amendment No. 4 to Amended and Restated Registration Rights Agreement, dated as of March 8, 2010, by and among Athersys, Inc. and the Existing Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.45 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2009 (Commission No. 001-33876) filed with the Commission on March 11, 2010)
10.41*	License and Technical Assistance Agreement, dated as of September 10, 2010, between ABT Holding Company and RTI (incorporated herein by reference to Exhibit 10.1 to the registrant s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on November 8, 2010)
10.42	Form of Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.47 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011)
10.43	Form of Nonqualified Stock Option Agreement for Non-Employee Directors (incorporated herein by reference to Exhibit 10.48 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011)
10.44	Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (Amended and Restated Effective June 16, 2011) (incorporated herein by reference to Exhibit 10.1 to registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on June 20, 2011
10.45	Form of Nonqualified Stock Option Agreement for Non-Employee Directors pursuant to the Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (Amended and Restated Effective June 16, 2011) (incorporated herein by reference to Exhibit 10.49 to the registrant s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 6, 2011)
10.46	Common Stock Purchase Agreement, dated as of November 11, 2011, by and between Athersys, Inc. and Aspire Capital Fund, LLC (incorporated herein by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on November 14, 2011)
10.47	Termination Agreement, dated as of November 11, 2011, by and between Athersys, Inc. and ABT Holding Company (f/k/a Athersys, Inc.) and Angiotech (incorporated by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on November 14, 2011)

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10.48	First Amendment to Common Stock Purchase Agreement, dated as of November 17, 2011, by and between Athersys, Inc. and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.47 to the registrant s Registration Statement on Form S-1(Commission No. 333-178418) filed with the Commission on December 9, 2011)
10.49	Form of Restricted Stock Unit Agreement (incorporated herein by reference to Exhibit 10.2 to the registrant s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on August 10, 2011)
10.50	Registration Rights Agreement, dated as of November 11, 2011, by and between Athersys, Inc. and Aspire Capital Fund, LLC (incorporated herein by reference to Exhibit 10.2 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on November 14, 2011)
10.51	Amendment No. 3 to Extended Collaboration and License Agreement, dated January 31, 2012, by and between ABT Holding Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.3 to the registrant s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 14, 2012)
10.52	First Amendment to License and Technical Assistance Agreement, dated September 17, 2012, by and between ABT Holding, Inc. and RTI Biologics, Inc. (incorporated herein by reference to Exhibit 10.52 to the registrant s Registration Statement on Form S-1/A (Commission No. 001-33876) filed with the Commission on October 23, 2012)
10.53	Registration Rights Agreement, dated as of March 9, 2012, by and between Athersys, Inc. and the signatories thereto (incorporated herein by reference to Exhibit 10.53 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on March 15, 2012)
10.54	Summary of Athersys, Inc. 2013 Cash Bonus Incentive Plan
21.1	List of Subsidiaries
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney
31.1	Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Laura K. Campbell, Vice President of Finance, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, and Laura Campbell, Vice President of Finance, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

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101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Confidential treatment requested as to certain portions, which portions have been filed separately with the SEC
Indicates management contract or compensatory plan, contract or arrangement in which one or more directors or executive officers of the registrant may be participants

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Cleveland, State of Ohio, on March 12, 2013.

ATHERSYS, INC.

By: /s/ Gil Van Bokkelen
Gil Van Bokkelen
Title: Chief Executive Officer

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

Signature	Title	Date
/s/ Gil Van Bokkelen Gil Van Bokkelen	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 12 , 2013
/s/ Laura K. Campbell Laura K. Campbell	Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)	March 12, 2013
* John J. Harrington	Executive Vice President, Chief Scientific Officer and Director	March 12, 2013
* Lorin J. Randall	Director	March 12, 2013
* Kenneth H. Traub	Director	March 12, 2013
* Jack L. Wyszomierski	Director	March 12, 2013
* Lee E. Babiss	Director	March 12, 2013
* Ismail Kola	Director	March 12, 2013

* Gil Van Bokkelen, by signing his name hereto, does hereby sign this Form 10-K on behalf of each of the above named and designated directors of the Company pursuant to Powers of Attorney executed by such persons and filed with the Securities and Exchange Commission.

By: /s/ Gil Van Bokkelen
Gil Van Bokkelen
Attorney-in-fact

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EXHIBIT INDEX

Exhibit No.	Exhibit Description
3.1	Certificate of Incorporation of Athersys, Inc., as amended as of August 31, 2007 (incorporated herein by reference to Exhibit 3.1 to the registrant s Registration Statement on Form S-3/A (Registration No. 333-144433) filed with the Commission on October 10, 2007)
3.2	Bylaws of Athersys, Inc., as amended as of October 30, 2007 (incorporated herein by reference to Exhibit 3.1 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on October 31, 2007)
4.1	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on January 28, 2011)
4.2	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on March 15, 2012)
10.1*	Research Collaboration and License Agreement, dated as of December 8, 2000, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.2*	Cell Line Collaboration and License Agreement, dated as of July 1, 2002, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.2 to the registrant s Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007)
10.3*	Extended Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.3 to the registrant s Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007)
10.4	License Agreement, effective as of May 5, 2006, by and between Athersys, Inc. and Angiotech (incorporated herein by reference to Exhibit 10.4 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.5	Sublicense Agreement, effective as of May 5, 2006, by and between Athersys, Inc. and Angiotech (incorporated herein by reference to Exhibit 10.5 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
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10.7	Amendment No. 1 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of January 29, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.7 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.8	Amendment No. 2 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of November 19, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, as amended, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.8 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)

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10.9	Amendment No. 3 to Amended and Restated Registration Rights Agreement, dated as of May 15, 2007, by and among Athersys, Inc. and the Existing Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.9 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.10	Athersys, Inc. Equity Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.11 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.11	Loan and Security Agreement, and Supplement, dated as of November 2, 2004, by and among Athersys, Inc., Advanced Biotherapeutics, Inc., Venture Lending & Leasing IV, Inc., and Costella Kirsch IV, L.P. (incorporated herein by reference to Exhibit 10.1 to the registrant s Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on November 14, 2007)
10.12	Second Amendment to Loan and Security Agreement, dated as of October 30, 2007, by and among ABT Holding Company, Advanced Biotherapeutics, Inc., Venture Lending and Leasing IV, Inc., and Costella Kirsch IV, L.P. (incorporated herein by reference to Exhibit 10.2 to the registrant s Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on November 14, 2007)
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10.14	Amended and Restated Employment Agreement, dated as of December 1, 1998 but effective as of April 1, 1998, by and between Athersys, Inc. and Dr. Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.14 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.15	Amendment No. 1 to Amended and Restated Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.15 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.16	Non-Competition and Confidentiality Agreement, dated as of December 1, 1998, by and between Athersys, Inc. and Dr. Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.16 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
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10.20	Employment Agreement, dated as of May 22, 1998, by and between Athersys, Inc. and Laura K. Campbell (incorporated herein by reference to Exhibit 10.20 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.21	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Laura Campbell (incorporated herein by reference to Exhibit 10.21 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.22	Employment Agreement, dated as of October 3, 2003, by and between Advanced Biotherapeutics, Inc. and Robert Deans, Ph.D. (incorporated herein by reference to Exhibit 10.25 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.23	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Robert Deans (incorporated herein by reference to Exhibit 10.26 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.24	Non-Competition and Confidentiality Agreement, dated as of October 3, 2003, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and Robert Deans (incorporated herein by reference to Exhibit 10.27 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.25	Employment Agreement, dated as of January 1, 2004, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.28 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.26	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.29 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.27	Non-Competition and Confidentiality Agreement, dated as of September 10, 2001, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.30 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.28	Form Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.31 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.29	Form Amendment No. 1 to Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.32 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.30	Securities Purchase Agreement, dated as of June 8, 2007, by and among Athersys, BTHC VI, Inc. and Investors (as defined therein) (incorporated herein by reference to Exhibit 10.33 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)

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10.31*	Exclusive License Agreement, dated as of May 17, 2002, by and between Regents of the University of Minnesota and MCL LLC, assumed by ReGenesys, LLC through operation of merger on November 4, 2003 (incorporated herein by reference to Exhibit 10.34 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.32*	Strategic Alliance Agreement, by and between Athersys, Inc. and Angiotech, dated as of May 5, 2006 (incorporated herein by reference to Exhibit 10.35 to the registrant s Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on October 9, 2007)
10.33	Amendment No. 1 to Cell Line Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.36 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.34	Form Indemnification Agreement for Directors, Officers and Directors and Officers (incorporated herein by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on August 6, 2007)
10.35	Summary of Athersys, Inc. 2011 Cash Bonus Incentive Plan (incorporated herein by reference to Exhibit 10.41 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011)
10.36	Summary of Athersys, Inc. 2012 Cash Bonus Incentive Plan (incorporated herein by reference to Exhibit 10.36 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2011 (Commission No. 001-33876) filed with the Commission on March 28, 2012)
10.37*	Collaboration and License Agreement, dated as of December 18, 2009, by and between Athersys, Inc., ABT Holding Company, and Pfizer (incorporated herein by reference to Exhibit 10.42 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2009 (Commission No. 001-33876) filed with the Commission on March 11, 2010)
10.38*	Stand-by License Agreement, dated as of December 18, 2009, by and between Regents of the University of Minnesota, ABT Holding Company and Pfizer (incorporated herein by reference to Exhibit 10.43 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2009 (Commission No. 001-33876) filed with the Commission on March 11, 2010)
10.39	Amendment dated as of March 31, 2009 to the Extended Collaboration and License Agreement, by and between Athersys, Inc. and Bristol-Myers Squibb Company effective January 1, 2006 (incorporated herein by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on April 9, 2009)
10.40	Amendment No. 4 to Amended and Restated Registration Rights Agreement, dated as of March 8, 2010, by and among Athersys, Inc. and the Existing Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.45 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2009 (Commission No. 001-33876) filed with the Commission on March 11, 2010)
10.41*	License and Technical Assistance Agreement, dated as of September 10, 2010, between ABT Holding Company and RTI (incorporated herein by reference to Exhibit 10.1 to the registrant s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on November 8, 2010)
10.42	Form of Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.47 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011)

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10.43	Form of Nonqualified Stock Option Agreement for Non-Employee Directors (incorporated herein by reference to Exhibit 10.48 to the registrant s Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011)
10.44	Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (Amended and Restated Effective June 16, 2011) (incorporated herein by reference to Exhibit 10.1 to registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on June 20, 2011
10.45	Form of Nonqualified Stock Option Agreement for Non-Employee Directors pursuant to the Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (Amended and Restated Effective June 16, 2011) (incorporated herein by reference to Exhibit 10.49 to the registrant s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 6, 2011)
10.46	Common Stock Purchase Agreement, dated as of November 11, 2011, by and between Athersys, Inc. and Aspire Capital Fund, LLC (incorporated herein by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on November 14, 2011)
10.47	Termination Agreement, dated as of November 11, 2011, by and between Athersys, Inc. and ABT Holding Company (f/k/a Athersys, Inc.) and Angiotech (incorporated by reference to Exhibit 10.1 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on November 14, 2011)
10.48	First Amendment to Common Stock Purchase Agreement, dated as of November 17, 2011, by and between Athersys, Inc. and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.47 to the registrant s Registration Statement on Form S-1 (Commission No. 333-178418) filed with the Commission on December 9, 2011)
10.49	Form of Restricted Stock Unit Agreement (incorporated herein by reference to Exhibit 10.2 to the registrant s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on August 10, 2011)
10.50	Registration Rights Agreement, dated as of November 11, 2011, by and between Athersys, Inc. and Aspire Capital Fund, LLC (incorporated herein by reference to Exhibit 10.2 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on November 14, 2011)
10.51	Amendment No. 3 to Extended Collaboration and License Agreement, dated January 31, 2012, by and between ABT Holding Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.3 to the registrant s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 14, 2012)
10.52	First Amendment to License and Technical Assistance Agreement, dated September 17, 2012, by and between ABT Holding, Inc. and RTI Biologics, Inc. (incorporated herein by reference to Exhibit 10.52 to the registrant s Registration Statement on Form S-1/A (Commission No. 001-33876) filed with the Commission on October 23, 2012)
10.53	Registration Rights Agreement, dated as of March 9, 2012, by and between Athersys, Inc. and the signatories thereto (incorporated herein by reference to Exhibit 10.53 to the registrant s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on March 15, 2012)
10.54	Summary of Athersys, Inc. 2013 Cash Bonus Incentive Plan
21.1	List of Subsidiaries

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23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney
31.1	Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Laura K. Campbell, Vice President of Finance, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, and Laura Campbell, Vice President of Finance, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Confidential treatment requested as to certain portions, which portions have been filed separately with the SEC
Indicates management contract or compensatory plan, contract or arrangement in which one or more directors or executive officers of the registrant may be participants