

ATHERSYS, INC / NEW  
Form 10-K  
March 13, 2014  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark one)

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

For the fiscal year ended December 31, 2013

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-33876

**Athersys, Inc.**

(Exact name of registrant as specified in its charter)

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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

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

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

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

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

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

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

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

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

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

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

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

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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

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

**Table of Contents**

**TABLE OF CONTENTS**

**PART I**

<u>Item 1. Business</u>	3
<u>Item 1A. Risk Factors</u>	18
<u>Item 1B. Unresolved Staff Comments</u>	30
<u>Item 2. Properties</u>	30
<u>Item 3. Legal Proceedings</u>	30
Item 3A. Executive Officers of the Registrant	30
<u>Item 4. Mine Safety Disclosures</u>	30

**PART II**

<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	31
<u>Item 6. Selected Financial Data</u>	32
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	33
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	44
<u>Item 8. Financial Statements and Supplementary Data</u>	44
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</u>	63
<u>Item 9A. Controls and Procedures</u>	63
<u>Item 9B. Other Information</u>	63

**PART III**

<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	64
<u>Item 11. Executive Compensation</u>	67
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	80
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	82
<u>Item 14. Principal Accountant Fees and Services</u>	83

**PART IV**

<u>Item 15. Exhibits and Financial Statement Schedules</u>	84
--	----

---

**Table of Contents**

**PART I**

**ITEM 1. BUSINESS.**

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

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

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

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

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

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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

---

## **Table of Contents**

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

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

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

## **Business Strategy**

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

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

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

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

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



## **Table of Contents**

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

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

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

### **Our Current Programs**

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

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

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

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



---

## **Table of Contents**

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

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

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

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

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

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

### ***Regenerative Medicine Programs***

#### ***MultiStem – A Novel Therapeutic Modality***

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

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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.

---

## Table of Contents

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

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

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

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

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

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

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

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

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



**Table of Contents***MultiStem for Treating Immune System Disorders, Neurological Conditions and Cardiovascular Disease*

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

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

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

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

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

**Immunological Disorders – MultiStem for IBD and HSC Transplant Support**

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

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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



**Table of Contents**

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

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

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

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

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

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

**Neurological Injury and Disease – MultiStem for Ischemic Stroke**

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

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



---

**Table of Contents**

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

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

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

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

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

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

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

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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.

---

## **Table of Contents**

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

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

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

### **Cardiovascular Disease Evaluating MultiStem for Treating Damage from a Heart Attack**

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

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

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

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

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



---

## **Table of Contents**

### ***Pharmaceutical Programs***

#### *Novel 5HT2c agonists for the treatment of obesity and other conditions*

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

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

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

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

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

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

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

#### *Other Small Molecule Programs & Key Technologies*

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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



## **Table of Contents**

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

### **Collaborations and Partnerships**

#### ***Pfizer***

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

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

#### ***RTI***

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

#### ***Angiotech***

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



---

## **Table of Contents**

### ***Bristol-Myers Squibb***

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

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

### **Competition**

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

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

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

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

There are many other companies that have previously attempted or are attempting to develop novel treatments for obesity, and a wide range of approaches are being taken. Some of these companies include large, multinational pharmaceutical companies such as Bristol-Myers Squibb, Merck & Co., Inc., Roche, Sanofi, GlaxoSmithKline plc, or GlaxoSmithKline, Eli Lilly and Company and others. There are also a variety of biotechnology companies developing treatments for obesity, including Orexigen Therapeutics, Neurosearch, Amgen Inc., or Amgen, Regeneron Pharmaceuticals, Inc., Nastech Pharmaceutical Company, Alizyme plc, Amylin Pharmaceuticals, Inc., Neurocrine Biosciences, Inc., Shionogi & Co., Ltd., Metabolic Pharmaceuticals Limited, Kyorin Pharmaceutical Co., Ltd., and others. It is likely that, given the magnitude of the market opportunity, many companies will continue to focus on the obesity area, and that competition will remain high. If we are successful at developing a 5HT<sub>2c</sub> 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.



## **Table of Contents**

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

### **Intellectual Property**

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

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

We have established a broad intellectual property portfolio related to our small molecule product candidates and functional genomics technologies. We have a broad patent estate with claims directed to compositions, methods of making, and methods of using our small molecule drug candidates. We have six United States patents and three patent applications with broad claims directed to selective 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 36 issued patents (16 United States patents and 20 international patents) relating to compositions and methods for the RAGE technology that currently provide patent coverage through as late as 2020, and five United States patents relating to human proteins and candidate drug targets that we identified through the application of RAGE and to our other technologies that currently provide patent coverage through as late as 2022. The RAGE technology was developed by Dr. John Harrington and other Athersys scientists internally in the mid-1990s.

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

### **Research and Development**

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

---

## **Table of Contents**

### **Government Regulation**

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

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

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

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

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

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

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

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

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

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

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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.

## **Table of Contents**

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

## **Employees**

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

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

## **Available Information**

We use the Investors section of our web site, [www.athersys.com](http://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](http://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.



---

## **Table of Contents**

### **ITEM 1A. RISK FACTORS**

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

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

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

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

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

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

our ability to raise capital to fund our operations;

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

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

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

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

the time and cost involved in obtaining regulatory approvals;

the cost of manufacturing our product candidates;

expenses related to complying with GMP of therapeutic product candidates;

**Table of Contents**

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

competing technological and market developments;

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

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

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

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

the level of our sales and marketing expenses; and

our ability to introduce and sell new products.

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

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

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

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

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

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

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

---

**Table of Contents**

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.

---

**Table of Contents**

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

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

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

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

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

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

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

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

---

## **Table of Contents**

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

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

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

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

test short-term safety and tolerability;

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

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

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

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

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

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





---

## **Table of Contents**

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

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

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

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

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

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

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

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

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

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

## Table of Contents

*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 licensors' 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.

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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.

---

**Table of Contents**

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

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

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

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

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

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

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

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

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

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



## **Table of Contents**

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

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

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

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

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

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

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

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

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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;

**Table of Contents**

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

convenience and ease of administration;

pricing;

perceived efficacy and side effects;

marketing;

availability of alternative treatments;

levels of reimbursement and insurance coverage; and

activities by our competitors.

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

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

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

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

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



## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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

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

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

## **Table of Contents**

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

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

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

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

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

changes and limits in import and export controls;

increases in custom duties and tariffs;

changes in currency exchange rates;

economic and political instability;

changes in government regulations and laws;

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

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

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

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

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

## **Table of Contents**

***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;

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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

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

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

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

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

**Table of Contents**

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

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

**ITEM 3. LEGAL PROCEEDINGS**

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

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

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

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

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

 **Holders**

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

**Dividend Policy**

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

**Unregistered Sales of Equity Securities and Use of Proceeds**

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

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

Period	Total Number of Shares Purchased (1)	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly	Maximum Number of Shares that May Yet Be Purchased
--------	--	------------------------------------	--	--

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

		Announced Plans	Under the Plans
October		\$	
November			
December	65,732	2.06	
<b>Total</b>	<b>65,732</b>	<b>\$ 2.06</b>	

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



**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

(in thousands, except share and per share data)

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

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

---

## **Table of Contents**

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

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

#### **Overview**

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

#### *Current Programs*

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

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

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

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

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

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

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

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

---

## **Table of Contents**

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

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

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

### *Financial*

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

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

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

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

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

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

### **Results of Operations**

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



**Table of Contents**

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

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

**Revenues**

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

**Research and development expenses**

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

**General and administrative expenses**

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

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

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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

**Table of Contents**

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

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

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

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

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

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

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

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



primarily due to expiring grants being replaced with new grants.

## **Table of Contents**

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

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

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

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

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

## **Liquidity and Capital Resources**

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

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

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

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

---

**Table of Contents**

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 connection with this private placement, our former lenders were entitled to a milestone payment in the amount of \$900,000, of which 75% was settled in 2012 through the issuance of our common stock at \$1.94 per share at our election.

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.

We entered into an equity purchase agreement with Aspire Capital in 2011, which provided that Aspire Capital was committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. Under the agreement, we had 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. As of September 30, 2013, we had sold all the remaining shares that were available under the 8,000,000 shares of common stock registered for resale under the equity facility. In aggregate since its inception in 2011, we received gross proceeds of approximately \$12.9 million under the agreement, which was due to expire in January 2014.

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

During the quarter ended December 31, 2013, we sold 300,000 shares under the Aspire equity purchase agreement at an average price per share of \$1.69 per share, and no shares were sold in the quarter ended December 31, 2012. During the years ended December 31, 2013 and 2012, we sold 6,566,666 and 800,000 shares, respectively, to Aspire Capital at average prices of \$1.70 and \$1.57 per share, respectively. As of December 31, 2013, we have received proceeds of approximately \$13.4 million in aggregate under the Aspire equity purchase agreements since 2011.

During the year ended December 31, 2013, we received proceeds of approximately \$402,000 from the exercise of warrants aggregating in the issuance of 397,826 shares of common stock. We did not receive any proceeds from the exercise of warrants in the year ended December 31, 2012. As of March 1, 2014, we received proceeds of approximately \$938,000 from the exercise of warrants in 2014.

In connection with our equity offerings, our former lenders were entitled to milestone payments until any remaining balance of an original \$2.25 million milestone was paid. 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 at our election.

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, 2013. 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 any worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase 3 clinical development.

In 2011, we reached an agreement with Angiotech to terminate the collaboration agreement and license between the parties, reflecting a change in Angiotech's business and financial strategy. As a result of the termination, we regained ownership of all rights for developing our stem cell technologies and products for cardiovascular disease indications, including AMI, congestive heart failure, chronic ischemia, and peripheral vascular disease, and Angiotech no longer has any license rights or options with respect to our technologies and products. As part of the termination agreement, if we enter into a new AMI collaboration before November 14, 2014, and at the time of the collaboration, we have made

certain progress in development, Angiotech could be eligible for 10% of any third-party license fees up to a maximum of \$5.0 million. Angiotech is not entitled to other downstream payments, such as milestone payments, royalties or any profit-sharing payments.

---

## **Table of Contents**

Under the terms of our RTI agreement, we received \$5.0 million of license fee payments in 2010-2012. In accordance with the agreement, we are also eligible to receive an additional \$35.5 million in cash payments upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved, and no milestone payments have been received as of December 31, 2013. In addition, we will receive tiered royalties on worldwide commercial sales of implants using our technologies. RTI commenced its commercialization activities in 2014.

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 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, 2013, we had drawn \$166,000 of this financing with a total balance of \$176,000.

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

In 2011, we entered into an alliance with Fast Forward, a nonprofit subsidiary of the National Multiple Sclerosis Society, pursuant to which Fast Forward is funding the development of MultiStem for the treatment of multiple sclerosis through the filing of an IND. Fast Forward has committed \$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 and manufacturing process development. At December 31, 2013, we had available cash and cash equivalents of \$31.9 million and after giving effect to our January 2014 registered direct offering, we had more than \$50 million of available cash and cash equivalents. 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 continue to generate additional funding to meet our needs, through business development opportunities, 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.



**Table of Contents***Cash Flow Analysis*

Net cash used in operating activities was \$22.8 million, \$17.7 million and \$14.5 million in 2013, 2012 and 2011, 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 2014 compared to 2013 in connection with increased clinical development activities for our MultiStem product candidates and platform. Net cash used in operating activities has fluctuated significantly on a quarter-to-quarter basis over the past few years primarily due to the receipt of collaboration fees and payment of specific clinical trial costs, such as clinical manufacturing campaigns, contract research organization costs, and manufacturing process development projects.

Net cash (used in) provided by investing activities was \$(0.4) million, \$3.9 million and \$8.6 million in 2013, 2012 and 2011, 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 \$385,000, \$347,000 and \$590,000 in 2013, 2012 and 2011, respectively. We expect that our capital equipment expenditures will continue at similar levels in 2014 compared to 2013.

Financing activities provided cash of \$29.6 million in 2013 related to the December 2013 registered direct offering, the exercise of common stock warrants, and usage of the Aspire Capital equity purchase facility. Financing activities provided cash of \$30.5 million in 2012 related to the March 2012 private placement, the October 2012 public offering, and usage of the Aspire Capital equity purchase facility, and provided cash of \$12.6 million in 2011 related to the February 2011 registered direct offering and the initial Aspire Capital investment in 2011.

Investors in certain of our equity offerings have received warrants to purchase shares of our common stock, of which an aggregate of 8,909,027 warrants remain outstanding at December 31, 2013 with a weighted average exercise price of \$2.04 per share. During 2013, we received \$402,000 from the exercise of warrants by our investors.

Our contractual payment obligations as of December 31, 2013 are as follows:

**Payment due by Period**

<b>Contractual Obligations</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 3 Years</b>	<b>3 5 Years</b>	<b>More than 5 Years</b>
Operating leases for facilities and equipment leases	\$ 933,000	\$ 483,000	\$ 450,000	\$	\$
Note payable (1)	176,000		176,000		
	\$ 1,109,000	\$ 483,000	\$ 626,000		

(1) Consists of a loan pursuant to an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic, which is forgivable upon the achievement of a certain milestone.

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 \$197,000 is subject to adjustments based on an inflationary index. Our total rent expense for all properties was \$491,000 in 2013.

**Off-Balance Sheet Arrangements**

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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.

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



---

## **Table of Contents**

### ***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 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 affect revenues that we have earned through December 31, 2013. 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.

We recognize 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.

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

## **Table of Contents**

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 that 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.

### ***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.

### ***Fair Value of Warrant Liabilities***

The estimated fair value of warrants accounted for as liabilities, representing a level 3 fair value measure, is 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 our historical volatility for warrants issued after January 1, 2013, or for warrants issued prior to 2013, using the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization, each of which using a Black-Scholes pricing model. The fair value of certain warrants is determined using probability weighted-average assumptions that give consideration to contractual terms in the warrants, such as an exercise price repricing feature, as defined.

**Table of Contents**

**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:

our ability to raise capital to fund our operations;

the timing of the results of Pfizer's Phase 2 clinical study involving MultiStem cell therapy to ulcerative colitis patients;

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 of our product candidates;

uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the prevention of GvHD and the treatment of IBD, AMI, stroke and other disease indications;

changes in external market factors;

changes in our industry's overall performance;

changes in our business strategy;

our ability to protect and defend our intellectual property and related business operations, including the successful prosecution of our patent applications and enforcement of our patent rights, and operate our business in an environment of rapid technology and intellectual property development;

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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;

the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in Japan;

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.

**Table of Contents**

**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. When appropriate based on 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, 2013, 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, 2013, 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**

**Table of Contents**

Athersys, Inc.

Consolidated Financial Statements

Years Ended December 31, 2013, 2012 and 2011

**Contents**

<u>Reports of Independent Registered Public Accounting Firm</u>	46
<u>Consolidated Balance Sheets as of December 31, 2013 and 2012</u>	48
<u>Consolidated Statements of Operations and Comprehensive Loss for each of the years ended December 31, 2013, 2012 and 2011</u>	49
<u>Consolidated Statements of Stockholders' Equity for each of the years ended December 31, 2013, 2012 and 2011</u>	50
<u>Consolidated Statements of Cash Flows for each of the years ended December 31, 2013, 2012 and 2011</u>	51
<u>Notes to Consolidated Financial Statements</u>	52

**Table of Contents**

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, 2013 and 2012, 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, 2013. Our audits also included the financial statement schedule listed in the Index at Item 15(a) (2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Athersys, Inc. at December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Athersys, Inc.'s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated March 13, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Cleveland, Ohio

March 13, 2014



**Table of Contents**

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Athersys, Inc.

We have audited Athersys, Inc.'s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (the COSO criteria). Athersys Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting in Item 9A. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Athersys, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2013 and 2012, 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, 2013 of Athersys, Inc. and our report dated March 13, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Cleveland, Ohio

March 13, 2014

**Table of Contents**

Athersys, Inc.

Consolidated Balance Sheets

*(In Thousands, Except Share and Per Share Amounts)*

	December 31,	
	2013	2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 31,948	\$ 25,533
Accounts receivable	520	490
Prepaid expenses and other	387	286
Total current assets	32,855	26,309
Equipment, net	1,333	1,294
Total assets	\$ 34,188	\$ 27,603
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,243	\$ 1,767
Accrued compensation and related benefits	1,067	827
Accrued clinical trial costs	88	950
Accrued expenses	884	934
Deferred revenue	86	
Total current liabilities	4,368	4,478
Note payable	176	169
Warrant liabilities	9,823	2,709
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at December 31, 2013 and December 31, 2012		
Common stock, \$0.001 par value; 150,000,000 and 100,000,000 shares authorized at December 31, 2013 and December 31, 2012, respectively, 70,749,212 and 53,058,632 shares issued at December 31, 2013 and December 31, 2012, respectively, and 70,683,480 and 53,058,632 shares outstanding at December 31, 2013 and December 31, 2012, respectively		
	71	53
Additional paid-in capital	284,323	253,889
Treasury stock, at cost; 65,732 shares at December 31, 2013	(135)	
Accumulated deficit	(264,438)	(233,695)
Total stockholders' equity	19,821	20,247
Total liabilities and stockholders' equity	\$ 34,188	\$ 27,603

*See accompanying notes.*

**Table of Contents**

Athersys, Inc.

## Consolidated Statements of Operations and Comprehensive Loss

*(In Thousands, Except Share and Per Share Amounts)*

	Year Ended December 31,		
	2013	2012	2011
<b>Revenues</b>			
Contract revenue	\$ 755	\$ 7,380	\$ 9,015
Grant revenue	1,683	1,328	1,329
Total revenues	2,438	8,708	10,344
<b>Costs and expenses</b>			
Research and development (including stock compensation expense of \$639, \$150 and \$205 in 2013, 2012 and 2011, respectively)	20,484	19,636	18,930
General and administrative (including stock compensation expense of \$884, \$331 and \$347 in 2013, 2012 and 2011, respectively)	6,065	4,753	4,916
Depreciation	346	320	278
Total costs and expenses	26,895	24,709	24,124
Loss from operations	(24,457)	(16,001)	(13,780)
Other income (expense), net	38	(1,138)	(778)
(Expense) income from change in fair value of warrants	(6,324)	2,404	812
<b>Net loss</b>	<b>\$ (30,743)</b>	<b>\$ (14,735)</b>	<b>\$ (13,746)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.53)</b>	<b>\$ (0.45)</b>	<b>\$ (0.59)</b>
<b>Weighted average shares outstanding, basic and diluted</b>	<b>57,674,833</b>	<b>32,556,781</b>	<b>23,239,019</b>
Items included in other comprehensive income (loss):			
Proportional share of comprehensive (loss) income of equity method investment		(28)	28
Unrealized loss on available-for-sale securities			(26)
Other comprehensive (loss) income items		(28)	2
<b>Comprehensive loss</b>	<b>\$ (30,743)</b>	<b>\$ (14,763)</b>	<b>\$ (13,744)</b>

*See accompanying notes.*

**Table of Contents**

Athersys, Inc.

## Consolidated Statements of Stockholders' Equity

*(In Thousands, Except Share Amounts)*

	Accumulated								
	Preferred Stock Number of Shares Stated Value	Common Stock Number of Shares Par Value	Additional Paid-in Capital	Treasury Stock	Other Comprehensive Income	Accumulated Deficit	Total Stockholders Equity		
Balance at January 1, 2011	\$	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		28,561,553	29	27,202				27,231	
Issuance of common stock under equity compensation plans		9,819							
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	
Stock based compensation				1,523				1,523	
Issuance of common stock from warrant exercises		397,826		797				797	
Issuance of common stock and warrants, net of issuance costs		16,899,999	17	28,113	137			28,267	
Issuance of common stock under equity compensation plans		327,023	1	1	(272)			(270)	
Net loss							(30,743)	(30,743)	
<b>Balance at December 31, 2013</b>	<b>\$</b>	<b>70,683,480</b>	<b>\$ 71</b>	<b>\$ 284,323</b>	<b>\$ (135)</b>	<b>\$</b>	<b>\$ (264,438)</b>	<b>\$ 19,821</b>	

*See accompanying notes.*

**Table of Contents**

Athersys, Inc.

## Consolidated Statements of Cash Flows

*(In Thousands)*

	Year Ended December 31,		
	2013	2012	2011
<b>Operating activities</b>			
Net loss	\$ (30,743)	\$ (14,735)	\$ (13,746)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	346	320	278
Realized gain on investments and available-for-sale securities		(183)	(55)
Stock-based compensation	1,523	481	552
Issuance of common stock to former lenders		1,005	683
Change in fair value of warrant liabilities	6,324	(2,404)	(812)
Amortization of premium on available-for-sale securities and other	7	14	58
Changes in operating assets and liabilities:			
Accounts receivable	(30)	199	1,745
Prepaid expenses and other assets	(101)	580	(511)
Accounts payable and accrued expenses	(196)	198	983
Deferred revenue	86	(3,140)	(3,664)
Net cash used in operating activities	(22,784)	(17,665)	(14,489)
<b>Investing activities</b>			
Purchase of available-for-sale securities			(12,508)
Proceeds from maturities of available-for-sale securities		4,237	21,672
Purchases of equipment	(385)	(347)	(590)
Net cash (used in) provided by investing activities	(385)	3,890	8,574
<b>Financing activities</b>			
Proceeds from note payable		166	
Purchase of treasury stock	(272)		
Proceeds from exercise of warrants	402		
Proceeds from issuance of common stock and warrants, net	29,454	30,357	12,595
Net cash provided by financing activities	29,584	30,523	12,595
Increase in cash and cash equivalents	6,415	16,748	6,680
Cash and cash equivalents at beginning of year	25,533	8,785	2,105
Cash and cash equivalents at end of year	\$ 31,948	\$ 25,533	\$ 8,785

*See accompanying notes.*

---

**Table of Contents**

*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 affect revenues that we have earned through December 31, 2013. 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.

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.

## **Table of Contents**

### *Athersys, Inc.*

#### *Notes to Consolidated Financial Statements (continued)*

We recognize 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.

#### **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 that 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, 2013.

#### **Investments in Available-for-Sale Securities**

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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.



## **Table of Contents**

### **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.

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.

### **Patent Costs and Rights**

Costs of prosecuting and maintaining patents and patent rights are expensed as incurred. As of December 31, 2013, 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.

### **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 or liquidated damages are accounted for as liabilities. We classify these warrant liabilities on the consolidated balance sheet as non-current liabilities. The warrant liabilities are 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 liabilities at fair value. The fair value is estimated using the expected volatility based on our historical volatility for warrants issued after January 1, 2013, or for warrants issued prior to 2013, using the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization. The fair value of the warrants is determined using probability weighted-average assumptions, when appropriate. Changes in the fair market value of the warrant are reflected in the consolidated statement of operations as other income (expense).

### **Treasury Stock**

Treasury stock is recorded at cost and any difference between the cost basis and the selling price of treasury stock is recognized as additional paid-in capital. Treasury stock is relieved on a first-in-first-out basis at actual cost. At December 31, 2013, we had 65,732 shares of common stock held in treasury and available for reissuance.

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

Unrealized gains and losses on our available-for-sale securities, if any, and the proportional share of comprehensive income and loss of our equity method investment, which was liquidated in 2012, 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, 2013, 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.

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements (continued)***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 that 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.

The following weighted-average input assumptions were used in determining the fair value of the Company's stock options:

	<b>2013</b>	<b>December 31, 2012</b>	2011
Volatility	<b>109.2%</b>	117.3%	125.7%
Risk-free interest rate	<b>1.5%</b>	0.8%	1.5%
Expected life of option	<b>6.14 years</b>	5.72 years	5.96 years
Expected dividend yield	<b>0.0%</b>	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, 2013 and 2012. 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:

	<b>Year ended December 31,</b>		
	<b>2013</b>	2012	2011

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

Outstanding options	<b>5,129,579</b>	4,058,184	4,499,601
Restricted stock units	<b>2,449,346</b>	70,814	39,300
Outstanding warrants	<b>8,909,027</b>	5,806,853	6,435,496
	<b>16,487,952</b>	9,935,851	10,974,397

**Reclassifications**

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

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements (continued)***C. Equipment**

	December 31,	
	2013	2012
Equipment consists of (in thousands):		
Laboratory equipment	\$ 6,703	\$ 6,741
Office equipment and leasehold improvements	2,814	3,842
	<b>9,517</b>	10,583
Accumulated depreciation	<b>(8,184)</b>	(9,289)
	<b>\$ 1,333</b>	\$ 1,294

In 2013, we disposed of approximately \$1.5 million of obsolete laboratory equipment, office equipment and leasehold improvements, all of which was fully depreciated.

**D. Financial Instruments***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.

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

Description	Balance as of December 31, 2013	Fair Value Measurements at December 31, 2013 Using Quoted Prices in Active Markets for Identical		
		Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liabilities	\$ 9,823	\$	\$	\$ 9,823

  

Description	Balance as of December 31,	Fair Value Measurements at December 31, 2012 Using Quoted Prices in		
		Significant Other Observable	Significant Unobservable Inputs (Level	

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

	2012	Active Markets for Identical Assets (Level 1)	Inputs (Level 2)	3)
Warrant liabilities	\$ 2,709	\$	\$	\$ 2,709

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.

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 is estimated using the expected volatility based on our historical volatility for warrants issued after January 1, 2013, or for warrants issued prior to 2013, using the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization. The fair value of the warrants is determined using probability weighted-average assumptions, when appropriate. The warrants issued in our December 2013 offering were issued in two series, since 1,401,218 of the total 3,500,000 warrants issued are not exercisable until June 3, 2014. The following inputs were used at December 31, 2013:

	A Warrants Issued December 2013	B Warrants Issued December 2013	Warrants Issued March 2012	Warrants Issued February 2011
Expected volatility	53.3%	51.7%	71.4%	73.3%
Risk-free interest rate	0.13%	0.13%	0.78%	0.38%
Expected life	1.25 years	0.82 years	3.20 years	2.09 years
<b>Fair value at December 31, 2013</b>				
<b>(in thousands)</b>	<b>\$ 1,232</b>	<b>\$ 650</b>	<b>\$ 6,944</b>	<b>\$ 997</b>

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements (continued)*

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

	<b>Year ended December 31, 2013</b>
Balance January 1, 2013	\$ 2,709
Issuance of warrants December 2013	1,186
Settlements	(396 )
Loss included in other income (expense), net, for the period	6,324
<b>Balance December 31, 2013</b>	<b>\$ 9,823</b>

*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 \$197,000, subject to adjustments based on an inflationary index

Aggregate rent expense was approximately \$491,000, \$415,000 and \$397,000 in 2013, 2012 and 2011, respectively. The future annual minimum lease commitments at December 31, 2013 are approximately \$483,000 for 2014, \$383,000 for 2015, \$67,000 for 2016, and \$0 for 2017.

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 United States 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, 2013 and 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 2012. In 2011, milestone expense was \$0.9 million.

We paid no interest during the three years ended December 31, 2013.

**E. Collaborations and Revenue Recognition***Pfizer*

In 2009, we entered into a collaboration with Pfizer Inc. ( Pfizer ) to develop and commercialize our MultiStem<sup>®</sup> 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 3 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.

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements (continued)**Angiotech*

In 2011, we reached an agreement with Angiotech to terminate the collaboration agreement and license between the parties, reflecting a change in Angiotech's business and financial strategy. As a result of the termination, we regained ownership of all rights for developing our stem cell technologies and products for cardiovascular disease indications, including AMI, congestive heart failure, chronic ischemia, and peripheral vascular disease, and Angiotech no longer has any license rights or options with respect to our technologies and products. As part of the termination agreement, if we enter into a new AMI collaboration before November 14, 2014, and at the time of the collaboration, we have made certain progress in development, Angiotech could be eligible for 10% of any third-party license fees up to a maximum of \$5.0 million. Angiotech is not entitled to other downstream payments, such as milestone payments, royalties or any profit-sharing payments. Prior to the termination of the collaboration, our clinical costs were recorded net of Angiotech's cost-share reimbursements, which amounted to \$312,000 in 2011.

*RTI Surgical, Inc.*

In 2010, we entered into an agreement with RTI Surgical, Inc. (RTI), formerly RTI Biologics, Inc., 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, 2013, we had 150.0 million shares of common stock (100.0 million shares at December 31, 2012) and 10.0 million shares of undesignated preferred stock authorized. No shares of preferred stock have been issued as of December 31, 2013.

The following shares of common stock were reserved for future issuance:

	<b>December 31</b>	
	<b>2013</b>	<b>2012</b>
Stock-based compensation plans	<b>11,020,510</b>	5,490,181
Warrants to purchase common stock - former lenders	<b>149,026</b>	149,026
Warrants to purchase common stock - 2011 offering	<b>1,310,000</b>	1,310,000
Warrants to purchase common stock - 2012 offering	<b>3,950,001</b>	4,347,827



Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

Warrants to purchase common stock	2013 offering	<b>3,500,000</b>	
		<b>19,929,537</b>	11,297,034

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

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements (continued)*

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

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

*Aspire Capital*

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.

In October 2013, we terminated the expiring 2011 equity purchase agreement with Aspire Capital and entered into a new equity purchase agreement with Aspire Capital to purchase up to an aggregate of \$25.0 million of shares of our common stock over a new two-year period. The terms of the 2013 equity facility are similar to the previous arrangement, and we issued 333,333 shares of our common stock to Aspire Capital as a commitment fee in October 2013 and filed a registration statement for the resale of 10,000,000 shares of common stock in connection with the new equity facility. In 2013, we sold an aggregate 6,566,666 shares to Aspire Capital at an average price of \$1.70 per share under both equity purchase agreements (300,000 shares were sold during the quarter ended December 31, 2013 at an average price of \$1.69 per share). As of December 31, 2013, we have received aggregate proceeds of approximately \$13.4 million under both equity purchase agreements since their inception.

*Warrant Liabilities*

The warrants we issued in the December 2013 registered direct offering contain a provision for a cash payment in the event that the shares are not delivered to the holder within two trading days. The cash payment equals \$10 per day per \$2,000 of warrant shares for each day late. 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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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.

The warrants have been classified as liabilities, as opposed to equity, due to the potential adjustment to the exercise price that could result upon late delivery of the shares or 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.

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements (continued)*

As of December 31, 2013, 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
3,950,001	\$1.01	March 14, 2017
3,500,000	\$2.50	March 31, 2015
<b>8,909,027</b>		

**G. Stock-Based Compensation**

We have two incentive plans that authorized an aggregate of 11,500,000 shares of common stock for awards to employees, directors and consultants, which reflects an increase in shares authorized of 6,000,000 that was approved in 2013. 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, 2013, a total of 479,490 shares of common stock have been issued under our equity incentive plans.

As of December 31, 2013, a total of 3,441,585 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 7,578,925 shares of common stock were outstanding. We recognized \$1,523,000, \$481,000 and \$552,000 of stock-based compensation expense in 2013, 2012 and 2011, respectively.

*Stock Options*

The weighted average fair value of options granted in 2013, 2012 and 2011 was \$1.42, \$1.21 and \$2.30 per share, respectively. The total fair value of options vested during 2013, 2012 and 2011 was \$585,000, \$420,000 and \$570,000, respectively. At December 31, 2013, total unrecognized estimated compensation cost related to unvested stock options was approximately \$1,686,000, which is expected to be recognized by mid-2017 using the straight-line method. The weighted average contractual life of unvested options at December 31, 2013 was 9.34 years. The aggregate intrinsic value of fully vested option shares and option shares expected to vest as of December 31, 2013 was \$402,000.

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

	Number of Options	Weighted Average Exercise Price
Outstanding January 1, 2011	4,308,013	\$ 4.73
Granted	213,588	2.61
Forfeited / Terminated / Expired	(22,000)	3.46
Outstanding December 31, 2011	4,499,601	4.63
Granted	290,150	1.44
Forfeited / Expired	(731,567)	4.92

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

Outstanding December 31, 2012	4,058,184	4.36
Granted	1,336,928	1.71
Exercised	(1,312)	1.26
Forfeited / Expired	(264,221)	3.36
<b>Outstanding December 31, 2013</b>	<b>5,129,579</b>	<b>\$ 3.72</b>
<b>Vested during 2013</b>	<b>383,808</b>	<b>\$ 1.86</b>
<b>Vested and exercisable at December 31, 2013</b>	<b>3,896,383</b>	<b>\$ 4.35</b>

Exercise Price		December 31, 2013					
		Options Outstanding			Options Vested and Exercisable		
		Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
\$1.13	2.94	1,988,579	8.18	\$ 1.86	756,133	6.28	\$ 2.08
\$3.10	5.00	3,033,500	3.37	\$ 4.88	3,032,750	3.37	\$ 4.88
\$5.28	7.80	107,500	5.98	\$ 5.28	107,500	5.98	\$ 5.28
		<b>5,129,579</b>			<b>3,896,383</b>		

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements (continued)**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 January 1, 2011		\$
Granted	39,300	2.69
Outstanding December 31, 2011	39,300	2.69
Granted	56,716	1.43
Vested-common stock issued	(9,819)	2.69
Forfeited/expired	(15,383)	1.88
Outstanding December 31, 2012	70,814	1.86
Granted	2,851,964	1.71
Vested-common stock issued	(468,359)	1.72
Forfeited/expired	(5,073)	1.77
<b>Outstanding December 31, 2013</b>	<b>2,449,346</b>	<b>\$ 1.71</b>
<b>Vested/Issued cumulative at December 31, 2013</b>	<b>478,178</b>	<b>\$ 1.74</b>

The weighted average fair value of restricted stock units granted in 2013 was \$1.71 per share. The total fair value of restricted stock units vested during 2013, 2012 and 2011 was \$805,000, \$26,000 and \$0, respectively. At December 31, 2013, total unrecognized estimated compensation cost related to unvested restricted stock units was approximately \$3,954,000, which is expected to be recognized by mid-2017 using the straight-line method.

**H. Income Taxes**

We had net operating loss and research and development tax credit carryforwards of approximately \$26,382,000 and \$1,473,000, respectively, at December 31, 2013, and approximately \$71,522,000 and \$4,176,000, respectively at December 31, 2012. Such losses and credits may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2033 and 2034.

Additionally, as of December 31, 2013, we have net operating loss carryforwards of approximately \$34,521,000 ( Section 382 Limited NOL ) that are limited to an annual net operating loss carryforward of \$1,833,000. This limitation under Section 382 of the Internal Revenue Code was a result of our equity offering in October 2012. The Section 382 Limited NOL may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2014 and 2031.

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

	December 31,	
	2013	2012
Net operating loss carryforwards	<b>\$ 8,970</b>	<b>\$ 24,318</b>

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

Net operating loss carryforwards Section 382 Limited NOL	<b>11,737</b>	2,277
Research and development credit carryforwards	<b>1,473</b>	4,176
Compensation expense	<b>3,353</b>	2,948
Other	<b>509</b>	503
Total deferred tax assets	<b>26,042</b>	34,222
Valuation allowance for deferred tax assets	<b>(26,042)</b>	(34,222)
Net deferred tax assets	<b>\$</b>	<b>\$</b>

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements (continued)*

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, 2013.

**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 make employer contributions to this plan, and the expense was approximately \$97,000 in 2013, \$98,000 in 2012, and \$88,000 in 2011.

**J. Quarterly Financial Data (unaudited)**

The following table presents quarterly data for the years ended December 31, 2013 and 2012, in thousands, except per share data:

	2013				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Revenues	\$ 326	\$ 571	\$ 621	\$ 920	\$ 2,438
Net loss	\$ (9,388)	\$ (5,946)	\$ (5,614)	\$ (9,795)	\$ (30,743)
Basic and diluted net loss per common share	\$ (0.18)	\$ (0.11)	\$ (0.10)	\$ (0.15)	\$ (0.53)

	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)

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.



**Table of Contents****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, 2013, 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 1992 framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation under the 1992 framework in Internal Control Integrated Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2013. The effectiveness of our internal control over financial reporting as of December 31, 2013 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report, which is included in Item 8 of this annual report on Form 10-K and incorporated herein by reference.

**Changes in internal control:** During the fourth quarter of 2013, 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 17, 2014, 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, 2014 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, 2014 through December 31, 2014. 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	60%	100%
President & Chief Operating Officer	45%	80%
Executive Vice President & Chief Scientific Officer	45%	80%
Executive Vice President, Regenerative Medicine	40%	60%
Vice President of Finance	30%	60%

A summary of the plan is attached to this annual report on Form 10-K as Exhibit 10.55 and is hereby incorporated herein by reference thereto.

**Table of Contents****PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The persons listed below are the directors and executive officers of the Company as of March 13, 2014.

<b>Name</b>	<b>Age</b>	<b>Current Position and Office</b>
Gil Van Bokkelen, Ph.D.	53	Chief Executive Officer, Chairman and Director
William (B.J.) Lehmann, Jr., J.D.	48	President and Chief Operating Officer
John J. Harrington, Ph.D.	46	Chief Scientific Officer, Executive Vice President and Director
Robert Deans, Ph.D.	62	Executive Vice President of Regenerative Medicine
Laura K. Campbell, CPA	50	Vice President of Finance
Lee E. Babiss, Ph.D.	58	Director (Lead Director)
Ismail Kola, Ph.D.	57	Director
Lorin J. Randall	70	Director
Kenneth H. Traub	52	Director
Jack L. Wyszomierski	58	Director

*Executive Officers and Directors*

**Gil Van Bokkelen, Ph.D.** Dr. Van Bokkelen has served as our Chief Executive Officer and Chairman since August 2000. Dr. Van Bokkelen co-founded Athersys, Inc. in 1995 and served as Chief Executive Officer and Director since the Company's founding. Prior to May 2006, he also served as the Company's President. Dr. Van Bokkelen served as the Chairman of the Alliance for Regenerative Medicine from 2010 through 2012, 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 School of Medicine, 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 Chief Executive Officer 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 Chief Executive Officer, and Dr. Van Bokkelen, in particular, on our Board of Directors provides our Company with ethical, decisive and effective leadership.

**John J. Harrington, Ph.D.** Dr. Harrington co-founded Athersys in 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 is also focused on the clinical development and manufacturing of MultiStem®. 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.

*Executive Officers*

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

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.

**Table of Contents**

**Robert J. Deans, Ph.D.** 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.** 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 Contoller, followed by Director of Finance and Senior Director of Finance, and currently serves as Vice President of Finance. 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.

*Directors*

**Lee E. Babiss, Ph.D.** Dr. Babiss has served as Lead Director since October 2013 and as a Director since August 2010. Dr. Babiss is currently Chief Scientific Officer and Executive Vice President of Discovery Innovation of PPD, Inc., a contract research organization, where he has served since February 2010, and Chief Executive Officer of X-Rx, a majority-owned subsidiary of PPD, Inc., providing strategic direction and scientific leadership in support of drug discovery. Dr. Babiss was formerly President and Director of Global Pharmaceutical Research at Roche, a pharmaceutical company, from 1998 until his appointment at PPD, Inc. Prior to Roche, Dr. Babiss spent seven years with Glaxo, Inc., now GlaxoSmithKline, a pharmaceutical company, where he held senior positions, including Vice President of Biological Sciences and Genetics. Dr. Babiss received his doctorate in Microbiology from Columbia University and completed his postdoctoral fellowship at the Rockefeller University, where he served as an assistant and associate professor. Dr. Babiss has received numerous fellowship awards and grants and serves on several scientific advisory committees and boards. Dr. Babiss has published over 60 peer-reviewed scientific papers.

Dr. Babiss brings over 20 years of experience developing and leading research and development programs. His strategic leadership and product development knowledge provide a valuable perspective to the Board.

**Ismail Kola, Ph.D.** Dr. Kola has served as a Director since October 2010. Dr. Kola is currently Executive Vice President of UCB S.A. in Belgium, a biopharmaceutical company dedicated to the development of innovative medicines focused on the fields of central nervous system and immunology disorders, and President of UCB New Medicines, UCB's discovery research through proof-of-concept organization, since November 2009. Dr. Kola was formerly Senior Vice President, Discovery Research and Early Clinical Research & Experimental Medicine at Schering-Plough Research Institute, the pharmaceutical research arm of Schering-Plough Corporation, a pharmaceutical company, and Chief Scientific Officer at Schering-Plough Corporation, from March 2007 until his appointment at UCB. Prior to Schering-Plough, Dr. Kola held senior positions from January 2003 to March 2007 at Merck, a pharmaceutical company, where he was Senior Vice President and Site Head, Basic Research. From 2000 to 2003, Dr. Kola was Vice President, Research, and Global Head, Genomics Science and Biotechnology, at Pharmacia Corporation, a pharmaceutical company. Prior to his position with Pharmacia, Dr. Kola spent 15 years as Professor of Human Molecular Genetics and was Director of the Centre for Functional Genomics and Human Disease at Monash Medical School in Australia. Dr. Kola received his Ph.D. in Medicine from the University of Cape Town, South Africa, his B.Sc. from the University of South Africa, and his B.Pharm. from Rhodes University, South Africa. Dr. Kola served on the board of directors of Astex Therapeutics (NASDAQ: ASTX) since May 2010 until its sale to Otsuka Pharmaceuticals in October 2013, and currently serves on the board of directors of Biotie Therapies (and previously Synosia who merged with Biotie) since February 2011, and previously served on the board of directors of Ondek Pty Ltd from 2009 to 2011, and Promega Corporation from 2003 to 2007. Dr. Kola has authored 160 technical publications in scientific and medical journals and is the named inventor on at least a dozen patents. Dr. Kola holds Adjunct Professorships of Medicine at Washington University in St. Louis, Missouri, and Monash University Medical School; a Foreign Adjunct Professorship at the Karolinska Institute in Stockholm, Sweden; and was elected William Pitt Fellow at Pembroke College, Cambridge University, United Kingdom in 2008. Dr. Kola has also been appointed a Visiting Professor at Oxford University, Nuffield School of Medicine, Oxford UK, since September 2012.

For more than 20 years, Dr. Kola has created a bridge between the scientific and academic worlds through various projects funded by renowned institutes, and Dr. Kola's experience and leadership in taking numerous drugs from the research stage to market or late stage development brings a unique and valuable perspective to our Board.



**Table of Contents**

**Lorin J. Randall.** Mr. Randall has served as a Director since September 2007. Mr. Randall is an independent financial consultant and previously was Senior Vice President and Chief Financial Officer of Eximias Pharmaceutical Corporation, a development-stage drug development company, from 2004 to 2006. From 2002 to 2004, Mr. Randall served as Senior Vice President and Chief Financial Officer of i-STAT Corporation, a publicly-traded manufacturer of medical diagnostic devices that was acquired by Abbott Laboratories in 2004. From 1995 to 2001, Mr. Randall was Vice President and Chief Financial Officer of CFM Technologies, Inc., a publicly-traded manufacturer of semiconductor manufacturing equipment. Mr. Randall currently serves on the boards of directors of Acorda Therapeutics, Inc. (NASDAQ: ACOR) since 2006, where he serves as chairman of the audit committee and is a member of the compensation and nominations and governance committees, Nanosphere, Inc. (NASDAQ: NSPH) since 2008, where he serves as chairman of the audit committee, and Tengion, Inc. (OTCQB: TNGN) since 2008, where he serves as chairman of the audit committee and a member of the compensation committee. He previously served on the board of directors of Opexa Therapeutics, Inc. (NASDAQ: OPXA) from 2007 to 2009, where he served as chair of the audit committee. Mr. Randall received a B.S. in accounting from The Pennsylvania State University and an M.B.A. from Northeastern University.

Mr. Randall's strong financial and human resources background and his service on the audit and compensation committees of other companies provides expertise to the Board, including an understanding of financial statements, compensation policies and practices, corporate finance, developing and maintaining effective internal controls, accounting, employee benefits, investments and capital markets. These qualities also formed the basis for the Board's decision to appoint Mr. Randall as chairman of the Audit Committee and the Compensation Committee.

**Kenneth H. Traub.** Mr. Traub has served as our Director since June 2012. Mr. Traub is currently the President and Chief Executive Officer of Ethos Management LLC since 2009, which specializes in investing in and enabling companies to execute strategies to build and unlock stockholder value, and Mr. Traub is also currently general partner of Rosemark Capital, a private equity firm since 2013. Mr. Traub served as President, Chief Executive Officer and director of American Bank Note Holographics, Inc., or ABNH, a global leader in product and document security, from 1999 until its sale in 2008 to JDS Uniphase Corporation, or JDSU, a provider of optical products and measurement solutions for the communications industry. Mr. Traub managed the turnaround, growth and sale of ABNH, and under his leadership, ABNH's stockholders achieved a gain exceeding 1000 percent. Following the sale of ABNH, Mr. Traub served as Vice President of JDSU in 2008. In 1994, Mr. Traub co-founded Voxware, Inc., a pioneer in Voice over IP communication technologies and acted as its Executive Vice President, Chief Financial Officer and director until June 1998. Prior to Voxware, he was Vice President of Finance of Trans-Resources, Inc. Mr. Traub currently serves on the boards of directors of the following publicly traded companies: (i) MRV Communications, Inc. (OTC: MRVC) since November 2011 and as Chairman since January 2012, where he is a member of the audit committee, compensation committee and nominating and governance committee; (ii) DSP Group, Inc. (NASDAQ: DSPG) since May 2012 where he is a member of the compensation committee and strategic committee; (iii) Vitesse Semiconductor Corp. (NASDAQ: VTSS) since March 2013, where he is a member of the compensation committee; and (iv) Xyratex Limited (NASDAQ: XRTX) since June 2013, where he is a member of the audit committee. Mr. Traub also served on the board of Phoenix Technologies Ltd. (NASDAQ:PTEC) from November 2009 through its sale in December 2010, where he was a member of the audit committee and compensation committee, served on the board of MIPS Technologies, Inc. (NASDAQ: MIPS) from November 2011 through its sale in February 2013, where he was a member of the audit and governance committee, and served on the board of iPass, Inc. (NASDAQ: IPAS) from June 2009 through June 2013, where he was a member of the compensation committee and the corporate governance and nominating committee. Mr. Traub received a M.B.A. from Harvard Business School in 1988 and a B.A. from Emory University in 1983.

As a director for Athersys, Mr. Traub contributes his extensive experience and expertise in managing and growing companies to maximize shareholder value.

**Jack L. Wyszomierski.** Mr. Wyszomierski has served as a Director since June 2010 and is currently retired. From 2004 until his retirement in June 2009, Mr. Wyszomierski served as the Executive Vice President and Chief Financial Officer of VWR International, LLC, a supplier and distributor of laboratory supplies, equipment and supply chain solutions to the global research laboratory industry. From 1982 to 2004, Mr. Wyszomierski held positions of increasing responsibility within the finance group at Schering-Plough Corporation, a pharmaceutical company, culminating with his appointment as Executive Vice President and Chief Financial Officer in 1996. Prior to joining Schering-Plough, he was responsible for capitalization planning at Joy Manufacturing Company, a producer of mining equipment, and was a management consultant at Data Resources, Inc., a distributor of economic data. Mr. Wyszomierski currently serves on the board of directors of Xoma Corporation (NASDAQ: XOMA) since 2010, where he also serves as chairman of the compensation committee and as a member of the audit committee, and Exelixis, Inc. (NASDAQ: EXEL) since 2004, where he serves as chairman of the audit committee. Mr. Wyszomierski was also a member of the board of directors and chairman of the audit committee at Unigene Laboratories, Inc. (OTC: UGNE) from 2012 to 2013. Mr. Wyszomierski holds a M.S. in Industrial Administration and a B.S. in Administration, Management Science and Economics from Carnegie Mellon University.

Mr. Wyszomierski's extensive financial reporting, accounting and finance experience and his service on the audit committees of other public companies, as well as his experience in the healthcare and life sciences industries, provides financial expertise to the Board, including an understanding of financial statements, corporate finance, developing and maintaining effective internal controls, accounting, investments and capital markets.



---

## **Table of Contents**

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Based solely on a review of reports of ownership, reports of changes of ownership and written representations under Section 16(a) of the Exchange Act that were furnished to the Company during or with respect to fiscal year 2013 by persons who were, at any time during fiscal year 2013, Directors or officers of the Company or beneficial owners of more than 10% of the outstanding shares of common stock, all filing requirements for reporting persons were met.

### **Code of Ethics**

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](http://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.

### **Audit Committee**

The Audit Committee is responsible for overseeing the accounting and financial reporting processes of the Company and the audits of the financial statements of the Company. The Audit Committee is also directly responsible for the appointment, compensation, retention and oversight of the work of the Company's independent auditors, including the resolution of disagreements between management and the auditors regarding financial reporting. Additionally, the Audit Committee approves all related-party transactions that are required to be disclosed pursuant to Item 404 of Regulation S-K. The current members of the Audit Committee are Lorin J. Randall, Kenneth H. Traub and Jack L. Wyszomierski. The Board of Directors has determined that each of Mr. Randall, Mr. Traub and Mr. Wyszomierski is an audit committee financial expert, as defined in Item 407(d)(5)(ii) of Regulation S-K, and an independent director, as defined in the NASDAQ listing standards.

## **ITEM 11. EXECUTIVE COMPENSATION**

### **Compensation Discussion and Analysis**

#### ***Executive Summary***

This section discusses the principles underlying our executive compensation policies and decisions and the most important factors relevant to an analysis of these policies and decisions. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our named executive officers, which include Dr. Gil Van Bokkelen, our Chief Executive Officer, Ms. Laura Campbell, our Vice President of Finance, Mr. William (B.J.) Lehmann, Jr., our President and Chief Operating Officer, Dr. John Harrington, our Executive Vice President and Chief Scientific Officer, and Dr. Robert Deans, our Executive Vice President of Regenerative Medicine, and places in perspective the data presented in the compensation tables and narratives that follow.

We are an international biotechnology company that is focused primarily in the field of regenerative medicine. Our MultiStem cell therapy has been evaluated in two completed Phase 1 clinical trials and is currently being evaluated in two ongoing Phase 2 clinical trials, as well as an investigator-led Phase 1 trial. 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. As further discussed in this section, our compensation and benefit programs help us attract, retain and motivate individuals who will maximize our business results by working to meet or exceed established company or individual objectives. In addition, we reward our executive officers for meeting certain developmental milestones, such as completing advancements in product candidate development, strategic partnerships or other financial transactions that add to the capital resources of the Company or create value for stockholders.

The following are the highlights of our 2013 compensation and benefit programs:

increased the base salaries of our named executive officers;



paid cash bonuses to our named executive officers;

granted stock options to our named executive officers under a newly implemented annual equity compensation program;

## **Table of Contents**

terminated incentive agreements established in 2005 that would have provided our named executive officers with bonus opportunities in the event of a financing transaction, merger or acquisition, or asset sale transaction and, in exchange, granted restricted stock units to the executives that vest over three years; and

amended our Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (Amended and Restated Effective June 18, 2013), or LTIP, to, among other things, increase the shares of common stock available thereunder.

The following discussion and analysis of our compensation and benefit programs for 2013 should be read together with the compensation tables and related disclosures that follow this section. This discussion includes forward-looking statements based on our current plans, considerations, expectations and determinations about our compensation program. Actual compensation decisions that we may make for 2014 and beyond may differ materially from our recent past.

### ***Compensation Objectives and Philosophy***

Our executive compensation programs are designed to:

recruit, retain, and motivate executives and employees that can help us achieve our core business goals;

provide incentives to promote and reward superior performance throughout the organization, which we refer to as Pay for Performance;

facilitate stock ownership and retention by our executives and other employees; and

promote alignment between executives and other employees and the long-term interests of stockholders.

The Compensation Committee seeks to achieve these objectives by:

establishing a compensation program that is market competitive and internally fair;

linking individual and corporate performance with certain elements of compensation through the use of equity grants, cash performance bonuses or other means of compensation, the value of which is substantially tied to the achievement of our Company goals; and

when appropriate, given the nature of our business, rewarding our executive officers for both Company and individual achievements with one-time performance awards.

At the 2013 Annual Meeting of Stockholders, approximately 95% of the votes cast were voted in favor of the approval of our named executive officer compensation. Our Compensation Committee believes that the stockholder vote reinforces the objectives and philosophy of our executive compensation programs.

### ***Components of Compensation***

Our executive compensation program includes the following elements:

base salary;

cash bonuses;

long-term equity incentive plan awards; and

retirement and health and other insurance benefits.

Our Compensation Committee has not adopted any formal or informal policies or guidelines for allocating compensation between long-term and currently paid-out compensation, between cash and non-cash compensation or among different forms of non-cash compensation. We consider competitive practices, relative management level and operating responsibilities of each executive officer when determining the compensation elements to reward his or her ability to impact short-term and long-term results.

---

## **Table of Contents**

### ***Role of the Chief Executive Officer***

Historically, our Chief Executive Officer has taken the lead in providing our Board of Directors with advice regarding executive compensation. For 2013, the Compensation Committee considered recommendations from our Chief Executive Officer regarding the compensation for and performance of our executive officers in relation to company-specific strategic goals that were established by the Compensation Committee and approved by the Board of Directors. These achievements related to potential bonus payments and salary increases. The Compensation Committee considers the recommendations made by our Chief Executive Officer because of his knowledge of the business and the performance of the other executive officers. The Compensation Committee is not bound by the input it receives from our Chief Executive Officer. Instead, the Compensation Committee exercises independent discretion when making executive compensation decisions. We describe and discuss the particular compensation decisions made by the Compensation Committee regarding the 2013 compensation of our named executive officers below under Elements of Executive Compensation.

### ***Role of the Independent Compensation Consultant***

From time to time, the Compensation Committee has retained the services of an independent compensation consultant, Arnosti Consulting, Inc., or Arnosti. During 2013, at the request of the Compensation Committee, Arnosti assisted the Compensation Committee in evaluating the base salaries to be paid to named executive officers and the annual equity awards to be granted companywide. Also during 2013, Arnosti provided peer company data and advice with respect to the increase of the shares of common stock available under the LTIP and the elimination of our 2005 incentive program with our named executive officers (see *Long-Term Incentive Program* later in this section). The Company pays the cost for Arnosti's services. However, the Compensation Committee retains the sole authority to direct, terminate or engage Arnosti's services. In 2013, the Compensation Committee considered and assessed all relevant factors, including but not limited to, those set forth in Rule 10C-1(b)(4)(i) through (vi) under the Exchange Act, that could give rise to a potential conflict of interest with respect to Arnosti's work. Based on this review, we are not aware of any conflict of interest that has been raised by the work performed by Arnosti.

### ***Elements of Executive Compensation***

**Base Salary.** We pay base salaries to provide executive officers with a competitive level of financial security. We establish base salaries for our executives based on the scope of their responsibilities, taking into account competitive market compensation paid by other companies for similar positions. Base salaries are generally reviewed annually, with adjustments based on the individual's responsibilities, performance and experience during the year. This review generally occurs each year following an annual review of individual performance.

In general, the Company and the executive team performed well in 2013 against many key goals and objectives, as measured against the metrics of key programmatic achievements (e.g., clinical and preclinical development), operational management and financial performance (e.g., adherence to budgetary goals and objectives, balance sheet), intellectual property (e.g., patent issuances and new filings, competitive positioning) and business development, among others. Each executive's performance was evaluated based on the Company's performance as a whole, combined with an evaluation of individual performance against specific goals and objectives relevant to his or her area of responsibility. Overall, the majority of corporate goals were achieved in 2013, taking into account that a business partnership was not achieved, which was, and continues to be, an important goal.

For 2013, the Compensation Committee and the Board of Directors approved an increase in base salary of 4.65% for 2013 as compared to 2012 for the Chief Executive Officer, an adjustment based on both performance and on competitive information provided to the Compensation Committee by Arnosti. Also for 2013, the Compensation Committee and the Board of Directors approved increases for each of the other named executive officer's salary for 2013 as compared to 2012 based primarily on Company performance for the year ended December 31, 2012. The increases were as follows: Mr. Lehmann 3.5%; Dr. Harrington 3.45%; Dr. Deans 3.42%; and Ms. Campbell 3.33%.

For 2014, the Compensation Committee and the Board of Directors approved an increase in base salary of 2.00% for 2014 as compared to 2013 for the Chief Executive Officer, an adjustment based on both performance and on competitive information provided to the Compensation Committee by Arnosti. Also for 2014, the Compensation Committee and the Board of Directors approved increases for each of the other named executive officer's salary for 2014 as compared to 2013 based primarily on Company performance for the year ended December 31, 2013. The increases are as follows: Mr. Lehmann 2.05%; Dr. Harrington 2.06%; Dr. Deans 2.04%; and Ms. Campbell 2.07%.

**Cash Bonuses.** Given the nature of our business, when appropriate, we reward our named executive officers with performance-related bonuses. We utilize annual incentive bonuses to reward officers and other employees for achieving financial and operational goals and for achieving individual annual performance objectives. These objectives relate generally to strategic factors, including advancement of our product candidates, identification and advancement of additional programs or product candidates, establishment and maintenance of key strategic relationships, and to financial factors, including raising capital, adherence to budgets and cash management.



**Table of Contents**

The Compensation Committee recommended and the Board approved a cash bonus incentive program for the year ended December 31, 2013 for our named executive officers. Under the 2013 incentive program, each participant was eligible to earn a target bonus of a specified percentage of the named executive officer's salary during the award term, weighted on the achievement of specific corporate goals, with the remainder based on individual/functional performance, as set forth below:

	Target Bonus	Weighted On	
		Corporate Goals	Functional Performance
Dr. Van Bokkelen	40%	100%	0%
Dr. Harrington	33%	80%	20%
Mr. Lehmann	33%	80%	20%
Dr. Deans	30%	60%	40%
Ms. Campbell	25%	60%	40%

The evaluation of goal achievement is at the discretion of Compensation Committee and Board of Directors based on input from the Chief Executive Officer (with respect to the named executive officers other than the Chief Executive Officer). The 2013 corporate goals included program and collaboration goals, progress on MultiStem clinical development, and execution against the established budget and operating plan. However, any bonus ultimately paid under the 2013 incentive program was to be at the discretion of the Board of Directors based on the recommendation of the Compensation Committee, after good faith consideration of executive officer performance, overall company performance, market conditions and cash availability. There was no formally adopted plan document for the 2013 incentive program, although the Compensation Committee recommended and the Board of Directors approved the specific corporate goals, target bonus levels and weightings between corporate and functional performance. The Compensation Committee and the Board of Directors agreed that each of the named executive officers would be entitled to a bonus under the 2013 incentive program as a result of individual performance and the achievement of operational and strategic objectives in 2013, specifically the achievement of patient enrollment goals for the Company's clinical trials and other program development and sector leadership goals, resulting in the payment of bonuses based on a percentage of such officers' 2013 base salaries as follows:

	Bonus Achieved	Cash Bonus Paid
Dr. Van Bokkelen	26.4%	\$ 118,800
Dr. Harrington	22.6%	\$ 83,500
Mr. Lehmann	22.6%	\$ 84,000
Dr. Deans	20.4%	\$ 65,000
Ms. Campbell	17.6%	\$ 42,000

For the year ending December 31, 2014, the Compensation Committee recommended and the Board of Directors approved a similar cash bonus incentive plan for our named executive officers. The 2014 plan includes the following changes to the target bonus percentage for our named executive officers.

	Target Bonus	Weighted On	
		Corporate Goals	Functional Performance
Dr. Van Bokkelen	60%	100%	0%
Dr. Harrington	45%	80%	20%
Mr. Lehmann	45%	80%	20%
Dr. Deans	40%	60%	40%
Ms. Campbell	30%	60%	40%

The 2014 corporate goals include advancing strategic partnership and program activities, advancing and achieving enrollment goals for our clinical programs for MultiStem, and executing against the established operating plan and capital acquisition objectives.

*Long-Term Incentive Program.* We believe that we can encourage superior long-term performance by our executive officers and employees through encouraging them to own, and assisting them with the acquisition of, our common stock. Our equity compensation plans provide our employees, including named executive officers, with incentives to help align their interests with the interests of our stockholders. We believe that the use of common stock and stock-based awards offers the best approach to achieving our objective of fostering a culture of ownership, which we believe will, in turn, motivate our named executive officers to create and enhance stockholder value. We have not adopted stock ownership guidelines, but our equity compensation plans provide a principal method for our executive officers to acquire equity in our company.



---

**Table of Contents**

Our equity compensation plans authorize us to grant, among other types of awards, options, restricted stock and restricted stock units, or RSUs, to our employees, Directors and consultants. Historically, we elected to use stock options as our primary long-term equity incentive vehicle. However, we began awarding RSUs to our non-executive employees in 2011 and to our named executive officers in 2013. We expect to continue to use equity-based awards as a long-term incentive vehicle because we believe:

equity-based awards align the interests of our executives with those of our stockholders, support a pay-for-performance culture, foster an employee stock ownership culture and focus the management team on increasing value for our stockholders;

the value of equity-based awards is based on our performance, because all the value received by the recipient of equity-based awards is based on the growth of our stock price;

equity-based awards help to provide a balance to the overall executive compensation program because, while base salary and our discretionary annual bonus program focus on short-term performance, vesting equity-based awards reward increases in stockholder value over the longer term; and

the vesting period of equity-based awards encourages executive retention and efforts to preserve stockholder value.

In 2013, we granted 540,000 stock options and 2,700,000 RSUs to our named executive officers, as well as stock options and RSUs to our other employees. We revised our long-term equity incentive program for our named executive officers in 2013, as described further below, in connection with the termination of an outdated incentive program and the initiation of an ordinary-course annual award program.

In 2005, in connection with a restructuring of our internal programs, the Board established the 2005 Incentive Program to retain and motivate our executives, which would have compensated the named executive officers in the event of a merger, acquisition or asset sale transaction. The 2005 Incentive Program became outdated for a variety of reasons, and, in 2013, the Compensation Committee and the Board determined that the 2005 Incentive Program should be eliminated in exchange for a one-time award of RSUs, and that an ordinary course annual award program for our named executive officers should be implemented. In April 2013, the Compensation Committee approved amendments whereby the named executive officers would agree to terminate their incentive agreements, and thereby the 2005 Incentive Program, in return for one-time grants of RSUs for their past service and performance, and for the ability to receive annual grants under our Amended LTIP. Each named executive officer entered into such a termination agreement and received the following number of RSUs in June 2013: 695,040 for Dr. Van Bokkelen; 570,551 for Dr. Harrington; 573,640 for Mr. Lehmann; 491,162 for Dr. Deans; and 369,607 for Ms. Campbell. These RSUs will vest ratably and quarterly over a three-year term. The Compensation Committee utilized the services of Arnosti to assist in the development of a fair and rational approach to the elimination of the 2005 Incentive Program and the number of one-time RSUs.

Annual equity awards in the ordinary course of business, which were initiated in June 2013 for our named executive officers once the 2005 Incentive Program was eliminated, are tied to factors such as performance, peer and market analysis, and total equity ownership level of each named executive officer, and further enhance the retention and long-term stock ownership features of our equity incentive program. In determining the number of stock-based awards to be granted to named executive officers, we review annually our named executive officers equity ownership positions, and we take into account the individual's scope of responsibility, ability to affect results and stockholder value, anticipated future contributions to increases in shareholder value, and the value of equity-based awards in relation to other elements of the individual named executive officer's total compensation. We also review competitive compensation data, an assessment of individual performance, a review of each named executive officer's existing long-term incentives, retention considerations and a subjective determination of the individual's potential to positively impact future stockholder value. Equity-based awards are granted from time to time by the Compensation Committee and the Board of Directors, with input from independent compensation consultants, as appropriate. The following stock option awards were granted to our named executive officers in June 2013 as part of the program for routine annual equity-based awards: 185,000 for Dr. Van Bokkelen; 100,000 for Dr. Harrington; 115,000 for Mr. Lehmann; 80,000 for Dr. Deans; and 60,000 for Ms. Campbell.

*Retirement and Insurance Benefits.* Consistent with our compensation philosophy, we maintain benefits for our named executive officers, including medical, dental, vision, life and disability insurance coverage and the ability to contribute to a 401(k) retirement plan. The named executive officers and employees have the ability to participate in these benefits at the same levels. We began making employer contributions to our 401(k) retirement plan in 2011 and contributed approximately \$97,000 in 2013. We provide such retirement and health insurance benefits to our employees to retain qualified personnel.



## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

In addition, Dr. Van Bokkelen, Dr. Harrington, Mr. Lehmann, Dr. Deans and Ms. Campbell also receive Company-paid life insurance benefits in the amounts of \$2.0 million for Dr. Van Bokkelen, Dr. Harrington and Mr. Lehmann, and \$1.0 million for Dr. Deans and Ms. Campbell. These additional life insurance policies are provided to these officers due to their extensive travel requirements and contributions to the Company.

## **Table of Contents**

### ***Severance Arrangements***

See the disclosure under **Potential Payments Upon Termination or Change of Control** for more information about severance arrangements with our named executive officers. We provide such severance arrangements in order to assure that our executives will focus on the best interests of the business at all times, without undue concern for their own financial security.

### ***Employment Agreements and Arrangements***

We believe that entering into employment agreements with each of our named executive officers was necessary for us to attract and retain talented and experienced individuals for our senior level positions. In this way, the employment agreements help us meet the initial objective of our compensation program. Each agreement contains terms and arrangements that we agreed to through arms-length negotiation with our named executive officers. We view these employment agreements as reflecting the minimum level of compensation that our named executive officers require to remain employed with us, and thus the bedrock of our compensation program for our named executive officers. For more details of our employment agreements and arrangements, see the disclosure under **2013 Summary Compensation Table**.

### ***General Tax Deductibility of Executive Compensation***

We structure our compensation program to comply with Internal Revenue Code Section 162(m). Under Section 162(m) of the Code, there is a limitation on tax deductions of any publicly-held corporation for individual compensation to certain executives of such corporation exceeding \$1.0 million in any taxable year, unless the compensation is performance-based. The Compensation Committee manages our incentive programs to qualify for the performance-based exemption; however, it also reserves the right to provide compensation that does not meet the exemption criteria if, in its sole discretion, it determines that doing so advances our business objectives.

**Table of Contents****2013 Summary Compensation Table**

The following table and narrative set forth certain information with respect to the compensation earned during the fiscal year ended December 31, 2013 by our named executive officers.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (1) (\$)	Option Awards (2) (\$)	All Other Compensation (\$)	Total (4)
Gil Van Bokkelen,	2013	\$ 450,000	\$ 118,800	\$ 1,188,518	\$ 264,550	\$ 12,620	\$ 2,034,488
Chief Executive	2012	\$ 430,000	\$ 107,500	\$ 0	\$ 0	\$ 12,620	\$ 550,120
Officer (3)	2011	\$ 404,500	\$ 40,000	\$ 0	\$ 0	\$ 12,620	\$ 457,120
Laura Campbell,	2013	\$ 239,300	\$ 42,000	\$ 632,028	\$ 85,800	\$ 5,109	\$ 1,004,237
Vice President	2012	\$ 231,562	\$ 40,500	\$ 0	\$ 0	\$ 5,109	\$ 277,171
of Finance	2011	\$ 225,365	\$ 15,300	\$ 0	\$ 0	\$ 5,109	\$ 245,774
William (BJ) Lehmann, Jr.,	2013	\$ 371,400	\$ 84,000	\$ 980,924	\$ 164,450	\$ 4,673	\$ 1,605,447
President and Chief	2012	\$ 358,849	\$ 77,000	\$ 0	\$ 0	\$ 4,673	\$ 440,522
Operating Officer	2011	\$ 346,714	\$ 27,000	\$ 0	\$ 0	\$ 4,673	\$ 378,387
John Harrington,	2013	\$ 369,400	\$ 83,500	\$ 975,642	\$ 143,000	\$ 4,355	\$ 1,575,897
Chief Scientific Officer and	2012	\$ 357,116	\$ 77,800	\$ 0	\$ 0	\$ 4,355	\$ 439,271
Executive Vice President (3)	2011	\$ 346,714	\$ 27,000	\$ 0	\$ 0	\$ 4,355	\$ 378,069
Robert Deans,	2013	\$ 318,000	\$ 65,000	\$ 839,887	\$ 114,400	\$ 5,620	\$ 1,342,907
Executive Vice President,	2012	\$ 307,500	\$ 62,300	\$ 0	\$ 0	\$ 5,620	\$ 375,420
Regenerative Medicine	2011	\$ 292,898	\$ 24,300	\$ 0	\$ 0	\$ 5,620	\$ 322,818

- (1) Amounts for stock awards represent the grant date full value of restricted stock units that vest over a three-year period, and do not necessarily reflect compensation actually received by our named executive officers. The fair value of restricted stock unit awards is calculated in accordance with Accounting Standards Codification 718 ( ASC 718 ), excluding the impact of potential forfeitures. Assumptions used in the calculation of these amounts are included in Note B to the audited consolidated financial statements included herein for the fiscal year ended December 31, 2013.
- (2) Amounts for option awards do not necessarily reflect compensation actually received by our named executive officers. The amounts for option awards reflect the full grant date fair value of the equity awards made during the fiscal year ended December 31, 2013 in accordance with ASC 718, excluding the impact of potential forfeitures. Assumptions used in the calculation of these amounts are included in Note B to the audited consolidated financial statements included herein for the fiscal year ended December 31, 2013.
- (3) Drs. Van Bokkelen and Harrington also served as our Directors for 2013, 2012 and 2011 but did not receive any compensation as our Directors.

**Grants of Plan-Based Awards for 2013**

The following table sets forth plan-based equity awards granted to our named executive officers during 2013 under our equity compensation plans.

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

Name	Grant Date	All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards (\$/sh)	Grant Date Fair Value of Stock and Option Awards (\$ (3))
Gil Van Bokkelen	June 18, 2013 (1)	695,040			\$ 1,188,518
	June 18, 2013 (2)		185,000	\$ 1.43	\$ 264,550
Laura Campbell	June 18, 2013 (1)	369,607			\$ 632,028
	June 18, 2013 (2)		60,000	\$ 1.43	\$ 85,800

**Table of Contents**

William (BJ) Lehmann, Jr.	June 18, 2013 (1)	573,640			\$ 980,924
	June 18, 2013 (2)		115,000	\$ 1.43	\$ 164,450
John Harrington	June 18, 2013 (1)	570,551			\$ 975,642
	June 18, 2013 (2)		100,000	\$ 1.43	\$ 143,000
Robert Deans	June 18, 2013 (1)	491,162			\$ 839,887
	June 18, 2013 (2)		80,000	\$ 1.43	\$ 114,400

- (1) Restricted stock units granted under our Long-Term Incentive Plan.
- (2) Options granted under our Long-Term Incentive Plan.
- (3) The amounts in this column represent the grant date fair value of the options calculated in accordance with ASC 718, excluding the impact of potential forfeitures.

**Employment Agreements and Arrangements**

*Dr. Gil Van Bokkelen.* On December 1, 1998, we entered into a one-year employment agreement, effective April 1, 1998, with Dr. Gil Van Bokkelen, to serve initially as President and Chief Executive Officer. The agreement automatically renews for subsequent one-year terms on April 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Van Bokkelen was entitled to an initial base salary of \$150,000, which may be increased at the discretion of the Board of Directors, and an annual discretionary incentive bonus of up to 33% of his base salary. His salary for 2014 is \$459,000 and his target annual incentive bonus is 60% of his base salary. Dr. Van Bokkelen also received options to purchase shares of common stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. Dr. Van Bokkelen is also entitled to life insurance coverage for the benefit of his family in the amount of at least \$1.0 million (which is \$2.0 million for 2014) and is provided the use of a company automobile for business use. For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control. Dr. Van Bokkelen has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of 18 months thereafter, he is restricted from, among other things, competing with us.

*Dr. John J. Harrington.* On December 1, 1998, we entered into a one-year employment agreement, effective April 1, 1998, with Dr. John J. Harrington to serve initially as Executive Vice President and Chief Scientific Officer. The agreement automatically renews for subsequent one-year terms on April 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Harrington was entitled to an initial base salary of \$150,000, which may be increased at the discretion of the Board of Directors, and an annual discretionary incentive bonus of up to 33% of his base salary. His salary for 2014 is \$377,000 and his target annual incentive bonus is 45% of his base salary. Dr. Harrington also received options to purchase shares of common stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. Dr. Harrington is also entitled to life insurance coverage for the benefit of his family in the amount of at least \$1.0 million (which is \$2.0 million for 2014). For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control. Dr. Harrington has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of 18 months thereafter, he is restricted from, among other things, competing with us.

*Laura K. Campbell.* On May 22, 1998, we entered into a two-year employment agreement with Laura K. Campbell to serve initially as Controller. The agreement automatically renews for subsequent one-year terms on May 22 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Ms. Campbell was entitled to an initial base salary of \$70,200, which may be increased at the discretion of the Board of Directors. Her salary for 2014 is \$244,250 and her target annual incentive bonus is 30% of her base salary. Ms. Campbell also received options to purchase shares of common stock upon her employment that were terminated in 2007, and her current stock options are described in the table below. For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control.

*William (B.J.) Lehmann, Jr.* On January 1, 2004, we entered into a four-year employment agreement with Mr. Lehmann to serve initially as Executive Vice President of Corporate Development and Finance. The agreement automatically renews for subsequent one-year terms on January 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. The agreement was amended in 2013 to modify the duration of his severance arrangement, with no changes to the events triggering such severance. Under the terms of the agreement, Mr. Lehmann was entitled to an initial base salary of \$250,000, which may be increased at the discretion of the Board of Directors. His salary for 2014 is \$379,000 and his target annual incentive bonus is 45% of his base salary. Mr. Lehmann also received options to

## Table of Contents

purchase shares of common stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control. Mr. Lehmann has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of six months thereafter, he is restricted from, among other things, competing with us.

*Dr. Robert Deans.* On October 3, 2003, we entered into a four-year employment agreement with Dr. Robert Deans to serve initially as Vice President of Regenerative Medicine. The agreement automatically renews for subsequent one-year terms on October 3 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Deans was entitled to an initial base salary of \$200,000, which may be increased at the discretion of the Board of Directors, and an annual discretionary incentive bonus of up to 30% of his base salary. His salary for 2014 is \$324,500 and his target annual incentive bonus is 40% of his base salary. Dr. Deans also received options to purchase shares of common stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control. Dr. Deans has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of six months thereafter, he is restricted from, among other things, competing with us.

### *Equity Compensation Plans*

In June 2007, we adopted two equity compensation plans, which authorize the Board of Directors, or a committee thereof, to provide equity-based compensation in the form of stock options, restricted stock, RSUs and other stock-based awards, which are used to attract and retain qualified employees, Directors and consultants. Equity awards are granted from time to time under the guidance and approval of the Compensation Committee. Total awards under these plans, as amended, are currently limited to 11,500,000 shares of common stock, of which 3,441,585 shares remain available for issuance.

### *401(k) Plan*

We have a tax-qualified employee savings and retirement plan, also known as a 401(k) plan that covers all of our employees. Under our 401(k) plan, eligible employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit, which was \$17,500 in 2013, and have the amount of the reduction contributed to the 401(k) plan. The trustees of the 401(k) plan, at the direction of each participant, invest the assets of the 401(k) plan in designated investment options. We may make matching or profit-sharing contributions to the 401(k) plan in amounts to be determined by the Board of Directors. We made matching contributions to the 401(k) plan during fiscal 2013 at a maximum rate of fifty cents for every dollar of the first 6% of participant contributions, up to a dollar maximum of \$3,000 per participant, which amounted to approximately \$97,000 in 2013. The 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code, so that contributions to the 401(k) plan and income earned on the 401(k) plan contributions are not taxable until withdrawn, and so that any contributions we make will be deductible when made.

### **Outstanding Equity Awards at 2013 Fiscal Year-End**

The following table sets forth outstanding options held by our named executive officers at December 31, 2013.

Name (a)	Option Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Option Exercise Price (\$)(e)	Option Expiration Date (f)
Gil Van Bokkelen	23,125	161,875	\$ 1.71	June 18, 2023 (1)
	25,000	0	\$ 5.28	December 23, 2019 (2)
	712,500	0	\$ 5.00	June 8, 2017(3)
Laura Campbell	7,500	52,500	\$ 1.71	June 18, 2023(1)
	17,500	0	\$ 5.28	December 23, 2019 (2)
	200,000	0	\$ 5.00	June 8, 2017(3)

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

William (BJ) Lehmann	14,375	100,625	\$ 1.71	June 18, 2023 (1)
	22,500	0	\$ 5.28	December 23, 2019 (2)
	400,000	0	\$ 5.00	June 8, 2017(3)

**Table of Contents**

John Harrington	12,500	87,500	\$ 1.71	June 18, 2023 (1)
	22,500	0	\$ 5.28	December 23, 2019 (2)
	700,000	0	\$ 5.00	June 8, 2017 (3)
Robert Deans	10,000	70,000	\$ 1.71	June 8, 2017 (1)
	20,000	0	\$ 5.28	December 23, 2019 (2)
	240,000	0	\$ 5.00	June 8, 2017 (3)

- (1) Options were granted on June 18, 2013, vesting ratably over four years on a quarterly basis.
- (2) Options were granted on December 23, 2009 and vested ratably over one year on a quarterly basis, and thus were fully exercisable on December 24, 2010.
- (3) Options were granted on June 8, 2007 and vested at a rate of 40% on the grant date and vested 20% in each of the three years thereafter (on a quarterly basis), and thus were fully exercisable on June 8, 2010.

**2013 Options Exercised and Stock Vested**

None of our named executive officers exercised any stock options during 2013. The following table provides information on all stock awards vested and the value realized upon vesting, by the named executive officers during fiscal 2013:

Name	Stock Awards	
	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting (1) (\$)
Gil Van Bokkelen	115,840	\$ 222,413
Laura Campbell	61,602	\$ 118,276
William (BJ) Lehmann	95,608	\$ 183,567
John Harrington	95,092	\$ 182,577
Robert Deans	81,862	\$ 157,175

- (1) The value realized upon vesting is the product of multiplying the number of shares of common stock by the market value of the underlying shares on the vesting date.

**Potential Payments Upon Termination or Change in Control**

Under their employment agreements, the named executive officers may be entitled to certain potential payments upon termination. In the event that an executive officer is terminated without cause or terminates employment for good reason, as defined in the agreements, we would be obligated to pay full base salary for a defined period, subject to mitigation related to other employment. For Gil Van Bokkelen and John Harrington, the defined payment period is 18 months, for William (BJ) Lehmann, the defined payment period is twelve months, and for Laura Campbell and Robert Deans, the defined payment period is six months. We would also be obligated to continue the participation of Gil Van Bokkelen and John Harrington in all other medical, life and employee welfare benefit programs for a period of eighteen months at our expense, to the extent available and possible under the programs.

The agreements define cause to mean willful and continuous neglect of such executive officer's duties or responsibilities or willful misconduct by the executive officer that is materially and manifestly injurious to Athersys. Good reason includes, among other things, demotion, salary reduction, relocation, failure to provide an executive officer with adequate and appropriate facilities and termination by the executive officer within 90 days of a change in control. A change in control occurs when (1) a person or group of persons purchases 50% or more of our consolidated assets or a majority of our voting shares, or (2) if, following a public offering, the directors of Athersys immediately following the offering no longer constitute a majority of the Board of Directors. Upon a change in control, or if the named executive officer should die or become permanently disabled, all unvested stock options become immediately vested and exercisable. As of December 31, 2013, each of the named executive officers held unvested stock options, as reflected in the Outstanding Equity Awards at 2013 Fiscal Year-End table above.

In the event that an executive officer is terminated for cause or as a result of death, we would be obligated to pay full base salary and other benefits, including any unpaid expense reimbursements, through the date of termination, and would have no further obligations to the executive



officer. In the event that an executive officer is unable to perform duties as a result of a disability, we would be obligated to pay full base salary and other benefits until employment is terminated and for a period of twelve months from the date of such termination.

**Table of Contents**

The table below reflects the amount of compensation payable to each named executive officer in the event of termination of such executive's employment, pursuant to such executive's employment agreement. The amounts shown assume that such termination was effective as of December 31, 2013 and thus includes amounts earned through such time and are estimates of the amounts that would be paid out to executives upon their termination.

	<b>Executive Benefit and Payments Upon Separation</b>	<b>Termination Without Cause or Voluntary For Good Reason</b>
<b>Gil Van Bokkelen</b>		\$ 675,000
	Cash Severance Payment	
	Continuation of Benefits	\$ 25,848
	<b>Total</b>	<b>\$ 700,848</b>
<b>William (BJ) Lehmann, Jr.</b>		\$ 371,400
	Cash Severance Payment	
	Continuation of Benefits	\$
	<b>Total</b>	<b>\$ 371,400</b>
<b>John Harrington</b>		\$ 554,100
	Cash Severance Payment	
	Continuation of Benefits	\$ 25,848
	<b>Total</b>	<b>\$ 579,948</b>
<b>Robert Deans</b>		\$ 159,000
	Cash Severance Payment	\$ 159,000
	Continuation of Benefits	\$
	<b>Total</b>	<b>\$ 159,000</b>
<b>Laura Campbell</b>		\$ 119,650
	Cash Severance Payment	\$ 119,650
	Continuation of Benefits	\$
	<b>Total</b>	<b>\$ 119,650</b>

**Table of Contents****Director Compensation Table for 2013**

The following table summarizes compensation paid to our non-employee Directors in 2013:

Name(a)	Fees Earned or Paid in Cash (\$)(b)	Option Awards (\$)(1)(d)	Total (\$)(h)
Lee E. Babiss	\$ 58,250	\$ 41,400	\$ 99,650
Ismail Kola	\$ 42,000	\$ 41,400	\$ 83,400
Lorin J. Randall	\$ 68,500	\$ 41,400	\$ 109,900
Kenneth H. Traub	\$ 50,000	\$ 41,400	\$ 91,400
Jack L. Wyszomierski	\$ 56,000	\$ 41,400	\$ 97,400

- (1) Amounts in column (d) do not necessarily reflect compensation actually received by our Directors. The amounts in column (d) reflect the full grant date fair value of the equity awards made during the fiscal year ended December 31, 2013, in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in the notes to the 2013 audited consolidated financial statements included herein. The Directors had option awards outstanding as of December 31, 2013 for shares of common stock as follows: Lee Babiss 135,000; Ismail Kola 135,000; Lorin Randall 90,000; Kenneth Traub 60,000; and Jack Wyszomierski 135,000.

Under our Director compensation program for non-employee Directors, new Directors receive an initial stock option grant to purchase 50,000 shares (30,000 shares prior to September 2013) of common stock at fair market value on the date of grant, which vests at a rate of 50% in the first year (on a quarterly basis) and 25% in each of the two years (on a quarterly basis) thereafter.

Additionally, the non-employee Directors receive annually an option award to purchase 30,000 shares (15,000 shares prior to September 2013) of common stock at fair market value on the date of grant, which vests quarterly over a one-year period, with such anniversary awards issued in June of each year in connection with our annual stockholder meeting. In June 2013, Directors Babiss, Kola, Randall, Traub and Wyszomierski each received an anniversary stock option award of 15,000 shares. In September 2013, the Compensation Committee recommended, and the Board of Directors approved, an increase to the initial option award and the anniversary option award for a non-employee Director to 50,000 and 30,000 shares, respectively, after engaging Arnosti to conduct a market and peer analysis. As a result, each of Directors Babiss, Kola, Randall, Traub and Wyszomierski received an incremental anniversary stock option award of 15,000 shares in September 2013. The incremental awards vest over a one-year period beginning June 2013, on a quarterly basis. All initial and anniversary stock option awards granted to non-employee Directors have a term of ten years and upon the termination of the Director's service, the Director has 18 months in which to exercise the vested portion of his options prior to forfeiture.

Our Directors receive annual cash compensation retainers as set forth below, effective October 1, 2013:

Board Member	\$ 40,000
Lead Director	\$ 25,000
Audit Committee Chairman	\$ 15,000
Audit Committee Member	\$ 7,500
Compensation Committee Chairman	\$ 10,000
Compensation Committee Member	\$ 5,000
Nominations and Corporate Governance Committee Chairman	\$ 10,000
Nominations and Corporate Governance Committee Member	\$ 5,000

Prior to October 1, 2013, we did not appoint a lead director, and the annual retainers for the chairman and members of the Nominations and Corporate Governance Committee were \$6,000 and \$3,000, respectively. These annual retainers are paid in quarterly installments and Directors are reimbursed for reasonable out-of-pocket expenses incurred while attending Board and committee meetings.

**Compensation Committee Interlocks and Insider Participation**

In 2013, none of our Directors was a member of the board of directors of any other company where the relationship would be construed to constitute a committee interlock within the meaning of the rules of the SEC.



**Table of Contents**

**Compensation Committee Report**

The Compensation Committee has reviewed and discussed with management the Compensation Discussion and Analysis section above and based on this review, has recommended to the Athersys Board of Directors the inclusion of the Compensation Discussion and Analysis in this annual report on Form 10-K for the fiscal year ended December 31, 2013.

Compensation Committee

Board of Directors

Lee E. Babiss

Lorin J. Randall

Kenneth H. Traub

Jack W. Wyszomierski

**Table of Contents****ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS****EQUITY COMPENSATION PLAN INFORMATION**

The following table sets forth certain information regarding the Company's equity compensation plans as of December 31, 2013, unless otherwise indicated.

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding awards (a) (1)</b>	<b>Weighted-average exercise price of outstanding awards (b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</b>
Equity compensation plan approved by security holders	6,644,055	\$ 3.74	2,911,455
Equity compensation plan not approved by security holders (2)	934,870	\$ 3.60	530,130
<b>Total</b>	<b>7,578,925</b>		<b>3,441,585</b>

- (1) Included in column (a) are both stock options and restricted stock units awarded under our equity compensation plans.
- (2) The other shares of common stock included in this plan category are issued or issuable under our Equity Incentive Compensation Plan. The terms of our Equity Incentive Compensation Plan are substantially similar to the terms of the Current LTIP. For information on the terms of these plans, see Compensation Discussion and Analysis Elements of Executive Compensation Long-Term Incentive Program, as well as Compensation Discussion and Analysis Equity Compensation Plans in this annual report.

**Table of Contents****BENEFICIAL OWNERSHIP OF COMMON STOCK**

The following table sets forth certain information known to us regarding the beneficial ownership of our common stock as of February 28, 2014 (unless otherwise indicated below) by:

each person known by us to beneficially own more than 5% of our common stock;

each of our Directors;

each of the executive officers named in the Summary Compensation Table; and

all of our Directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock that could be issued upon the exercise of outstanding options and warrants held by that person that are exercisable within 60 days of February 28, 2014 are considered outstanding. These shares, however, are not considered outstanding when computing the percentage ownership of each other person.

Percentage ownership calculations for beneficial ownership for each person or entity are based on 76,633,698 shares of common stock outstanding as of February 28, 2014.

Except as indicated in the footnotes to this table and pursuant to state community property laws, each stockholder named in the table has sole voting and investment power for the shares shown as beneficially owned by them.

Name of Beneficial Owner	Number of Shares	Percent of Class
<b>Greater Than 5% Stockholders</b>		
First Eagle Investment Management, LLC <sup>(1)</sup>	4,207,600	5.5%
<b>Directors and Executive Officers</b>		
Gil Van Bokkelen <sup>(2)</sup>	1,137,879	1.5%
Lee Babiss <sup>(3)</sup>	127,500	*
John Harrington <sup>(4)</sup>	911,144	1.2%
Ismail Kola <sup>(5)</sup>	127,500	*
Lorin Randall <sup>(6)</sup>	82,500	*
Kenneth Traub <sup>(7)</sup>	61,250	*
Jack Wyszomierski <sup>(8)</sup>	127,500	*
Laura Campbell <sup>(9)</sup>	344,098	*
Robert Deans <sup>(10)</sup>	369,448	*
William (BJ) Lehmann, Jr. <sup>(11)</sup>	525,967	*
All Directors and executive officers as a group (10 persons)	3,814,786	5.0%

\* Less than 1%.

(1) A Schedule 13G/A filed with the SEC on February 14, 2014 reported that First Eagle Investment Management, LLC, or FEIM, an investment adviser registered under Section 203 of the Investment Advisers Act of 1940, is deemed to be the beneficial owner of 4,207,600 shares of common stock as a result of acting as investment adviser to various FEIM clients. FEIM has sole voting and dispositive power over 4,207,600 shares of common stock.

(2) Includes vested options for 772,187 shares of common stock at a weighted average exercise price of \$4.86 per share and 57,920 restricted stock units that vest on March 18, 2014.

## Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

- (3) Includes vested options for 127,500 shares of common stock at a weighted average exercise price of \$2.67 per share.
- (4) Includes vested options for 741,250 shares of common stock at a weighted average exercise price of \$4.93 per share and 47,546 restricted stock units that vest on March 18, 2014.
- (5) Includes vested options for 127,500 shares of common stock at a weighted average exercise price of \$2.45 per share.
- (6) Includes vested options for 82,500 shares of common stock at a weighted average exercise price of \$1.95 per share.
- (7) Includes vested options for 41,250 shares of common stock at a weighted average exercise price of \$1.58 per share.



---

**Table of Contents**

- (8) Includes vested options for 127,500 shares of common stock at a weighted average exercise price of \$2.61 per share.
- (9) Includes vested options for 228,750 shares of common stock at a weighted average exercise price of \$4.86 per share and 30,801 restricted stock units that vest on March 18, 2014.
- (10) Includes vested options for 275,000 shares of common stock at a weighted average exercise price of \$4.84 per share and 40,930 restricted stock units that vest on March 18, 2014.
- (11) Includes vested options for 444,063 shares of common stock at a weighted average exercise price of \$4.85 per share and 47,804 restricted stock units that vest on March 18, 2014.

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

**Certain Relationships and Related Person Transactions**

We give careful attention to related person transactions because they may present the potential for conflicts of interest. We refer to related person transactions as those transactions, arrangements, or relationships in which:

we were, are or are to be a participant;

the amount involved exceeds \$120,000; and

any of our Directors, Director nominees, executive officers or greater-than five percent stockholders (or any of their immediate family members) had or will have a direct or indirect material interest.

To identify related person transactions in advance, we rely on information supplied by our executive officers, Directors and certain significant stockholders. We maintain a comprehensive written policy for the review, approval or ratification of related person transactions, and our Audit Committee reviews all related person transactions identified by us. The Audit Committee approves or ratifies only those related person transactions that are determined by it to be, under all of the circumstances, in the best interest of the Company and its stockholders. No related person transactions occurred in fiscal 2013 that required a review by the Audit Committee.

At times, Aspire Capital has beneficially owned more than 5% of our outstanding common stock. We entered into an equity purchase agreement with Aspire Capital in 2011, which provided that Aspire Capital was committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares. Under the agreement, we had 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. As a result of this transaction, combined with shares of our common stock that Aspire Capital held prior to the November 2011 transaction, Aspire Capital became one of our larger stockholders, owning more than 5% of our shares of our common stock outstanding at that time.

By September 30, 2013, we had sold all the remaining shares that were available under the 8,000,000 shares of common stock registered for resale under the equity facility, which was due to expire in January 2014. In October 2013, we terminated the expiring equity purchase agreement with Aspire Capital and entered into a new equity purchase agreement with Aspire Capital to purchase up to an aggregate of \$25.0 million of shares of our common stock over a new two-year period. The terms of the 2013 equity facility are similar to the previous arrangement, and we issued 333,333 shares of our common stock to Aspire Capital as a commitment fee in October 2013 and filed a registration statement for the resale of 10,000,000 shares of common stock in connection with the new equity facility.

In 2013, we sold an aggregate 6,566,666 shares to Aspire Capital at an average price of \$1.70 per share under both equity purchase agreements.

In our March 2012 private placement, Aspire Capital purchased an additional 966,184 shares of common stock and five-year warrants to purchase 966,184 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, for a total purchase price to Aspire Capital of approximately \$2.0 million. Also, in our October 2012 public offering, Aspire Capital purchased an additional 750,000 shares of common stock for a total purchase price to Aspire Capital of approximately \$0.8 million. As a result of our October 2012 public offering and in accordance with the antidilution provisions of the March 2012 warrants, we sought and obtained stockholder

approval in February 2013 to reduce the exercise price of the March 2012 warrants to \$1.01 per share.

---

## **Table of Contents**

Also, in our December 2013 registered direct offering, Aspire Capital purchased an additional 1.0 million shares of common stock and warrants to purchase 350,000 shares of common stock with an exercise price of \$2.50 per share that expire on March 31, 2015, a portion of which are not exercisable until June 3, 2014. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.35 shares of common stock at an offering price of \$2.00 per fixed combination, for a total purchase price to Aspire Capital of approximately \$2.0 million.

### **Director Independence**

The Board reviews the independence of each Director at least annually. During these reviews, the Board will consider transactions and relationships between each Director (and his or her immediate family and affiliates) and the Company and our management to determine whether any such transactions or relationships are inconsistent with a determination that the Director was independent. The Board conducted its annual review of Director independence to determine if any transactions or relationships exist that would disqualify any of the individuals who serve as a Director under the rules of the NASDAQ Capital Market or require disclosure under Securities and Exchange Commission, or SEC, rules. Based upon the foregoing review, the Board determined the following individuals are independent under the rules of the NASDAQ Capital Market: Lee E. Babiss, Ismail Kola, Lorin J. Randall, Kenneth H. Traub and Jack L. Wyszomierski. Currently, we have two members of management that also serve on the Board: Dr. Van Bokkelen, who is also our Chairman and Chief Executive Officer, and Dr. Harrington, who is our Executive Vice President and Chief Scientific Officer. Neither Dr. Van Bokkelen nor Dr. Harrington is considered independent under the independence rules of the NASDAQ Capital Market.

## **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

### **Principal Accountant Fees and Services**

***Audit Fees.*** Fees paid to Ernst & Young LLP for the audit of the annual consolidated financial statements included in the Company's Annual Reports on Form 10-K, for the reviews of the consolidated financial statements included in the Company's Forms 10-Q, and for services related to registration statements were \$639,100 for the fiscal year ended December 31, 2013 and \$500,400 for the fiscal year ended December 31, 2012. The increase related primarily to services for registration statements filed in 2013 and internal control attestation required in 2013.

***Audit-Related Fees.*** There were no fees paid to Ernst & Young LLP for audit-related services in 2013 and 2012.

***Tax Fees.*** Fees paid to Ernst & Young LLP associated with tax compliance and tax consultation were \$29,250 and \$25,000 for the fiscal years ended December 31, 2013 and 2012, respectively.

***All Other Fees.*** There were no other fees paid to Ernst & Young LLP in 2013 or 2012.

### **Audit Committee Pre-Approval Policies and Procedures**

The Audit Committee has adopted a formal policy on auditor independence requiring the pre-approval by the Audit Committee of all professional services rendered by the Company's independent auditor prior to the commencement of the specified services.

For the fiscal year ended December 31, 2013, 100% of the services described above were pre-approved by the Audit Committee in accordance with the Company's formal policy on auditor independence.

**Table of Contents****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:

Reports of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2013 and 2012

Consolidated Statements of Operations and Comprehensive Loss for each of the years ended December 31, 2013, 2012 and 2011

Consolidated Statements of Stockholders' Equity for each of the years ended December 31, 2013, 2012 and 2011

Consolidated Statements of Cash Flow for each of the years ended December 31, 2013, 2012 and 2011

Notes to Consolidated Financial Statements

## (a)(2) Financial Statement Schedules:

The following financial statement schedule of Athersys, Inc. is included:

## Schedule II Valuation and Qualifying Accounts

(In thousands)	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
<b>Year Ended December 31, 2013</b>				
Deducted from asset accounts:				
Allowance for doubtful accounts note receivable	\$ 330	\$	\$	\$ 330(A)
Tax valuation allowances	\$ 34,222	\$ 10,126	\$ 18,306 (B)	\$ 26,042
<b>Total 2013</b>	<b>\$ 34,552</b>	<b>\$ 10,126</b>	<b>\$ 18,306</b>	<b>\$ 26,372</b>
<b>Year Ended December 31, 2012</b>				
Deducted from asset accounts:				
Allowance for doubtful accounts note receivable	\$ 307	\$ 23	\$	\$ 330(A)
Tax valuation allowances	\$ 29,272	\$ 4,950	\$	\$ 34,222
<b>Total 2012</b>	<b>\$ 29,579</b>	<b>\$ 4,973</b>	<b>\$</b>	<b>\$ 34,552</b>
<b>Year Ended December 31, 2011</b>				
Deducted from asset accounts:				
Allowance for doubtful accounts note receivable	\$ 296	\$ 11	\$	\$ 307
Tax valuation allowances	\$ 23,908	\$ 5,364	\$	\$ 29,272
<b>Total 2011</b>	<b>\$ 24,204</b>	<b>\$ 5,375</b>	<b>\$</b>	<b>\$ 29,579</b>

- (A) Reserve on note receivable; Fully - reserved.
- (B) Deferred tax assets are fully offset by valuation allowances. As a result of the October 2012 equity offering, the Company lost the use of a significant portion of its net operating loss carryforwards generated prior to October 2012.

All other 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.

**Table of Contents**

(a)(3) Exhibits.

Exhibit No.	Exhibit Description
3.1	Certificate of Incorporation of Athersys, Inc., as amended as of June 28, 2013 (incorporated herein by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on August 13, 2013)
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)
4.3	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 November 29, 2013)
4.4	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 13, 2014)
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)
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)



**Table of Contents**

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	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)
10.12	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)
10.13	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)
10.14	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. 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)
10.15	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)
10.16	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)
10.17	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)
10.18	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)
10.19	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)
10.20	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)
10.21	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)
10.22	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)



**Table of Contents**

10.23	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)
10.24	Amendment No. 2 to Employment Agreement, dated as of January 24, 2014, by and between Advanced Biotherapeutics, Inc. and William Lehmann
10.25	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)
10.26	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)
10.27	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)
10.28	Form Amendment No. 2 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 10.2 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 20, 2013)
10.29*	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)
10.30	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)
10.31	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)

**Table of Contents**

10.32*	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)
10.33*	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)
10.34	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)
10.35	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)
10.36*	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)
10.37	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)
10.38	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)
10.39	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)
10.40	Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (Amended and Restated Effective June 18, 2013) (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 18, 2013)
10.41	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)
10.42	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)
10.43	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)
10.44	Common Stock Purchase Agreement, dated as of October 22, 2013, 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 October 23, 2013)

**Table of Contents**

10.45	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)
10.46	Form of Restricted Stock Unit Agreement (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 June 20, 2013)
10.47	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)
10.48	Registration Rights Agreement, dated as of October 22, 2013, 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 October 23, 2013)
10.49	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)
10.50	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)
10.51	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)
10.52	Summary of Athersys, Inc. 2013 Cash Bonus Incentive Plan (incorporated herein by reference to Exhibit 10.54 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2012 (Commission No. 001-33876) filed with the Commission on March 12, 2013)
10.53	Form of Securities Purchase Agreement (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 29, 2013)
10.54	Form of Securities Purchase Agreement (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 January 13, 2014)
10.55	Summary of Athersys, Inc. 2014 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
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

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

Indicates management contract or compensatory plan, contract or arrangement in which one or more directors or executive officers of the registrant may be participants

**Table of Contents**

**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 13, 2014.

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Gil Van Bokkelen	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 13 , 2014
Gil Van Bokkelen		
/s/ Laura K. Campbell	Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)	March 13, 2014
Laura K. Campbell		
*	Executive Vice President, Chief Scientific Officer and Director	March 13, 2014
John J. Harrington		
*		
Lorin J. Randall	Director	March 13, 2014
*		
Kenneth H. Traub	Director	March 13, 2014
*		
Jack L. Wyszomierski	Director	March 13, 2014
*		
Lee E. Babiss	Director	March 13, 2014
*		
Ismail Kola	Director	March 13, 2014

\* 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

**Table of Contents**

**EXHIBIT INDEX**

Exhibit No.	Exhibit Description
3.1	Certificate of Incorporation of Athersys, Inc., as amended as of June 28, 2013 (incorporated herein by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on August 13, 2013)
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)
4.3	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 November 29, 2013)
4.4	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 13, 2014)
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)

**Table of Contents**

- 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 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)

**Table of Contents**

10.12	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)
10.13	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)
10.14	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. 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)
10.15	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)
10.16	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)
10.17	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)
10.18	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)
10.19	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)
10.20	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)
10.21	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)
10.22	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)



**Table of Contents**

10.23	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)
10.24	Amendment No. 2 to Employment Agreement, dated as of January 24, 2014, by and between Advanced Biotherapeutics, Inc. and William Lehmann
10.25	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)
10.26	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)
10.27	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)
10.28	Form Amendment No. 2 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 10.2 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 20, 2013)
10.29*	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)
10.30	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)
10.31	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)

**Table of Contents**

10.32*	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)
10.33*	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)
10.34	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)
10.35	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)
10.36*	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)
10.37	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)
10.38	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)
10.39	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)
10.40	Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (Amended and Restated Effective June 18, 2013) (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 18, 2013)
10.41	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)
10.42	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)
10.43	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)
10.44	Common Stock Purchase Agreement, dated as of October 22, 2013, 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 October 23, 2013)

**Table of Contents**

10.45	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)
10.46	Form of Restricted Stock Unit Agreement (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 June 20, 2013)
10.47	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)
10.48	Registration Rights Agreement, dated as of October 22, 2013, 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 October 23, 2013)
10.49	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)
10.50	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)
10.51	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)
10.52	Summary of Athersys, Inc. 2013 Cash Bonus Incentive Plan (incorporated herein by reference to Exhibit 10.54 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2012 (Commission No. 001-33876) filed with the Commission on March 12, 2013)
10.53	Form of Securities Purchase Agreement (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 29, 2013)
10.54	Form of Securities Purchase Agreement (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 January 13, 2014)
10.55	Summary of Athersys, Inc. 2014 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
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

Edgar Filing: ATHERSYS, INC / NEW - Form 10-K

Indicates management contract or compensatory plan, contract or arrangement in which one or more directors or executive officers of the registrant may be participants