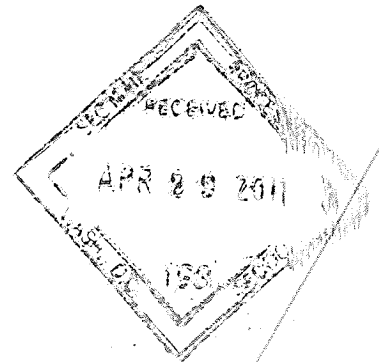


# REACHING MILESTONES



11007304



## ATHERSYS ANNUAL REPORT 2010



# GAINING MOMENTUM

# HIGHLIGHTS

**Athersys is a clinical stage biopharmaceutical company with a growing pipeline of potential best-in-class therapeutics designed to treat significant unmet medical needs and extend and enhance the quality of human life.**

**The Company is developing MultiStem<sup>®</sup>, a patented, adult-derived "off-the-shelf" stem cell product platform for multiple disease indications, including damage caused by myocardial infarction, ischemic stroke and inflammatory bowel disease, as well as support for patients receiving hematopoietic stem cell transplants to treat certain cancers. The Company's portfolio also includes orally active pharmaceutical product candidates for the treatment of obesity and related metabolic conditions.**

**Athersys has forged several key strategic alliances and collaborations with leading pharmaceutical and biotechnology companies, as well as world-renowned research institutions in the United States and Europe, to further develop its platform and products and enable the Company to reduce development risks and costs.**

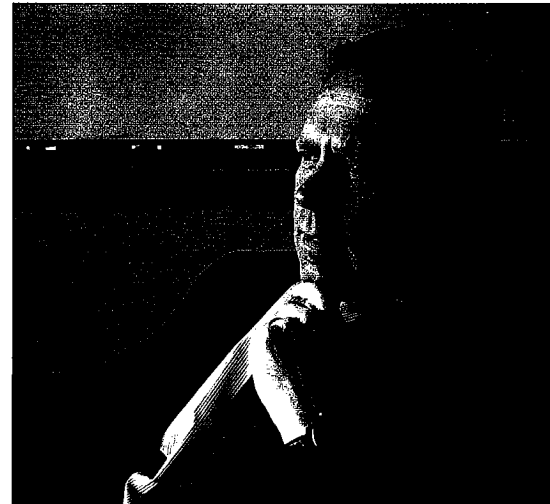
- ▶ Enrolled the first patient in a randomized, double-blind, placebo-controlled, multi-center Phase II clinical study, being conducted in collaboration with Pfizer Inc., designed to evaluate the safety and efficacy of MultiStem<sup>®</sup> for the treatment of ulcerative colitis, the most common form of inflammatory bowel disease.
- ▶ Completed patient enrollment for the single ascending dose arm of a Phase I clinical safety study administering MultiStem to patients being treated for leukemia or other blood-borne cancers and receiving a hematopoietic stem cell transplant. The multiple ascending dose portion of this graft-versus-host disease (GVHD) study is ongoing.
- ▶ Received orphan drug designation for MultiStem from the U.S. Food and Drug Administration (FDA) for the use of MultiStem for the prevention of GVHD, which, in the event of product approval and commercialization, would provide added market exclusivity.
- ▶ Reported top-line data from a Phase I clinical trial of MultiStem in acute myocardial infarction (AMI). The study results, based on four months of post-treatment patient data, demonstrate that MultiStem was well tolerated at all dose levels and suggest improvement in heart function in treated patients.
- ▶ Entered a collaborative agreement with RTI Biologics, Inc. to develop and commercialize biologic implants based on Athersys' Multipotent Adult Progenitor Cell (MAPC<sup>®</sup>) technology exclusively for certain orthopedic applications.
- ▶ Expanded European operations through our Belgium subsidiary, ReGenesys BVBA, building on our research and development activities in Europe both independently and with our collaborators. Our first patient in Europe was dosed in 2011 in our GVHD trial, and our IBD trial will include multiple clinical centers in Europe.
- ▶ Awarded key United States patents enhancing our intellectual property estate.
- ▶ Recorded revenues of \$8.9 million, including \$2.3 million of grant revenues related to our development programs, and a net loss of \$11.4 million for the year ended December 31, 2010.
- ▶ Ended the year with \$15.2 million in cash, cash equivalents and available-for-sale securities, to which Athersys added \$11.8 million in net proceeds from a registered direct offering of common stock and warrants in February 2011.

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MY FELLOW STOCKHOLDERS,

**W**e at Athersys are committed to developing best-in-class therapeutic products that can advance clinical care and address significant, unmet medical needs by providing safer, more effective treatments than those that are currently available. In 2010, we made significant progress in several key programs, including those involving MultiStem<sup>®</sup>, our patented and proprietary stem cell product.

MultiStem is currently being developed for indications in multiple areas, notably the treatment of cardiovascular disease, neurological indications, and disorders involving the immune system, including inflammatory bowel disease (IBD), which we are evaluating as part of a worldwide collaboration with Pfizer.



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## Immunology

### IBD / Ulcerative Colitis

Throughout 2010, our close collaboration with our colleagues at Pfizer Regenerative Medicine has led to rapid progress and advancement of our IBD program. In November, approximately 10 months after the Pfizer partnership was established, the FDA authorized the initiation of a Phase II clinical trial to evaluate the safety and efficacy of administration of MultiStem for the treatment of ulcerative colitis.

This randomized, double-blind, Phase II study is designed to enroll approximately 126 patients with moderate to severe ulcerative colitis. Subjects will receive multiple doses of either MultiStem or placebo over a several-week period. Endoscopic evaluation will occur for each patient at the beginning of the study and after eight weeks,



Barium x-ray of the colon, frontal view, showing ulcerative colitis in a 60 year old man

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## Inflammatory Bowel Disease

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Inflammatory bowel disease (IBD) includes two chronic diseases that cause inflammation of the intestines: ulcerative colitis and Crohn's disease.

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Although the diseases have some features in common, there are some important differences.

Ulcerative colitis is an inflammatory disease of the large intestine, or colon. In ulcerative colitis, the inner lining of the intestine becomes inflamed and develops open, painful wounds called ulcers. Ulcerative colitis is often the most severe in the rectal area, which can cause frequent diarrhea. Mucus and blood often appear in the stool if the lining of the colon is damaged.

Crohn's disease differs from ulcerative colitis in that it can affect any part of the gastrointestinal tract, from mouth to anus. Crohn's disease most commonly affects the terminal ileum, the last part of the small intestine, and parts of the large intestine. Crohn's disease causes inflammation that extends much deeper into the layers of the intestinal wall and generally tends to involve the entire bowel wall, in contrast to ulcerative colitis which affects only the lining of the bowel.

Over two million people in the United States, Europe and Japan suffer from this debilitating set of conditions. Many patients ultimately require surgical intervention to alleviate pain and suffering, but surgery does not address the underlying cause of the disease. Athersys and Pfizer believe MultiStem could address the significant unmet medical needs of IBD patients by overcoming the limitations of currently available therapies for ulcerative colitis and Crohn's disease.

*Sources: Datamonitor, Reuters Business Insights*

with a subsequent clinical assessment at 16 weeks and patient follow-up for 12 months. The study is being conducted at clinical centers in North America and Europe, with support provided by our Belgium subsidiary, ReGenesys, for clinical activities in Europe. Enrollment is ongoing, and the first patient was treated in the first quarter of 2011.

We were able to rapidly advance MultiStem directly into this Phase II ulcerative colitis study because of the consistent safety profile exhibited by MultiStem in extensive preclinical and initial clinical studies in other indications. This rapid advancement represents an important aspect of our development strategy. By establishing a foundation of safety data in certain initial indications, we believe we are well positioned to advance other indications into mid-stage clinical development, where we can evaluate biological activity and therapeutic effectiveness as we generate additional safety data.

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## **Hematopoietic Stem Cell Transplant Support / GVHD**

We also continue to advance our ongoing Phase I clinical trial of MultiStem in the area of transplantation and oncology treatment support. This study is evaluating MultiStem for hematopoietic stem cell transplant support in patients with leukemia and other blood-born cancers.

The first treatment arm of this study is a dose escalation arm, which involved administering a single dose of MultiStem two days after the initial hematopoietic stem cell transplant. Patients received a single dose of MultiStem at either a low, medium or high dose level, and were then evaluated at 30 and 100 days post treatment. We met our goal of completing enrollment for this arm of the study in 2010, and the last patient was dosed in late December. The last patient follow-up visit was conducted in mid-April, and we expect to have top-line results from the study by mid-2011.

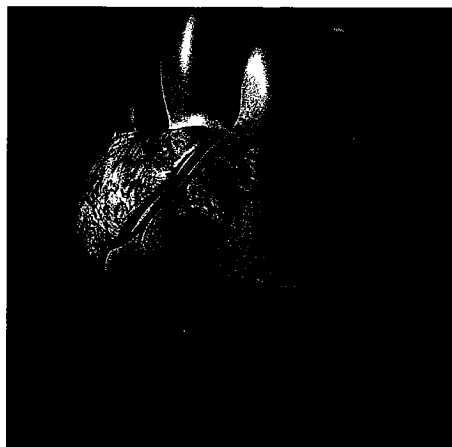


The second arm of this study involves administration of multiple doses of MultiStem at weekly intervals for up to one month following the initial hematopoietic stem cell transplant. As with the single ascending dose portion of the study, the primary endpoint for this Phase I trial is safety. We are on track to complete the enrollment for

the multi-dose arm of the study in 2011 and will present top-line results from the trial after the corresponding follow-up visits are completed.

For both treatment arms of this Phase I study, we are evaluating multiple secondary endpoints including engraftment, severity of GVHD, infection and survival. GVHD is a common condition associated with bone marrow transplantation in which immune cells from the transplanted marrow recognize the transplant recipient as foreign and mount an immunological attack. The effects of such an attack can be debilitating or fatal. We received Orphan Drug Designation from the FDA for MultiStem in the prevention of GVHD in 2010.

Illustration of a normal heart and coronary blood vessels



## **Cardiovascular Disease**

Heart disease remains the leading cause of death in the United States and many other parts of the world. In acute myocardial infarction (AMI), which is more commonly referred to as a heart attack, patients experience a blockage that impedes blood flow, resulting in damage to the heart. We believe that MultiStem has great potential for treating various forms of cardiovascular disease, including damage caused by AMI. In preclinical studies conducted with independent research labs, we observed that administration of MultiStem to the damaged region of the heart reduced tissue damage, lessened inflammation, promoted formation of new blood vessels in the region of injury, and enhanced recovery.

As a result of these and other studies, we initiated an ongoing Phase I clinical trial evaluating administration of MultiStem to patients that have suffered an AMI. Interim data presented at the annual Transcatheter Cardiovascular Therapeutics conference in Washington, D.C. in September showed a consistent safety profile and

also provided some encouraging signs of improvement in cardiovascular function among patients with significantly compromised heart function at the time of treatment. We expect to present additional data from the one-year patient follow-up evaluations in 2011. Working with our partner, Angiotech Pharmaceuticals, Inc., we intend to advance our AMI program into a Phase II clinical trial later this year.

As a result of an aging population, the number of individuals suffering from heart disease is expected to increase dramatically in the years ahead. We believe that MultiStem has broad potential to treat cardiovascular disease and could enhance recovery and tissue repair through multiple mechanisms, improving clinical outcomes and patient quality of life. Other forms of cardiovascular disease where MultiStem could have therapeutic relevance include congestive heart failure, peripheral artery disease, and other forms of vascular disease. We are collaborating with independent investigators and their research teams to explore these and other potential applications of MultiStem to treat cardiovascular disease.

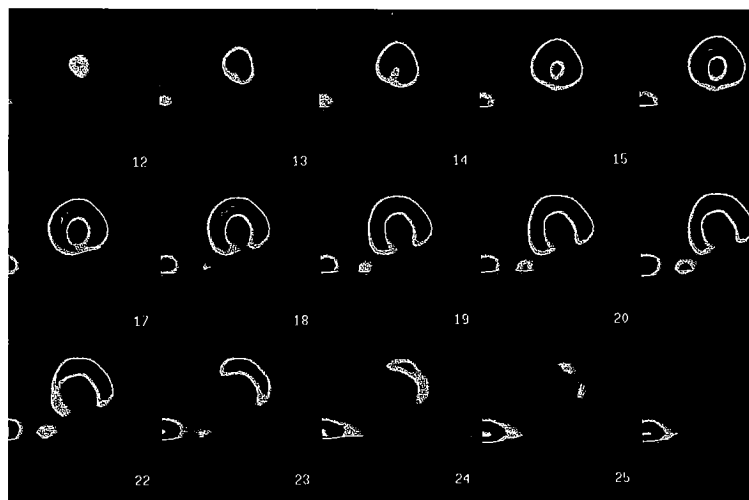
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## **Cardiovascular Disease: A major cost driver in healthcare**

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**C**ardiovascular disease affects an estimated 82.6 million individuals in the United States. In a study published in February 2011 in the scientific journal, *Circulation*, the American Heart Association (AHA) estimated that cardiovascular disease currently accounts for approximately \$273 billion in annual direct costs in the United States, representing approximately 17% of total national healthcare costs. As a direct result of an aging population, the AHA projects that the economic impact of cardiovascular disease will more than triple in the next 20 years, to more than \$818 billion in annual direct costs. By 2030, more than 40% of the United States population is expected to have some form of cardiovascular disease.

*Source: American Heart Association and Circulation*



SPECT scans of the heart showing a myocardial infarction (heart attack) located on the inferior wall



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## **Neurological Disease and Injury**

By continuing to conduct research on MultiStem, both in-house and with a team of independent experts, we have broadened and deepened our understanding of the various ways in which MultiStem can have a profound effect on promoting tissue repair and healing in a range of neurological indications including stroke, traumatic brain injury, spinal cord injury and other areas.

Stroke represents a leading cause of serious long-term disability in the United States and many other countries around the world. Unfortunately, current therapies for stroke are limited and require that the patient be treated within several hours after the stroke occurs. These therapies include the administration of anti-clotting agents that can help restore blood flow to the brain if the patient is treated in time. Unfortunately, in most instances, the patient is unable to get to the hospital in time, and the use of such therapies is no longer possible as the risk of bleeding in the brain sub-

stantially increases over time. Generally, only 3 to 5 percent of those who suffer a stroke reach the hospital in time to be considered for treatment with anti-clotting therapies.

The long-term effects of a stroke can be devastating. Many stroke patients require rehabilitative therapy, and many require long-term or even permanent institutional care, or have to be cared for by a family member. The American Heart Association estimates that annual cost of stroke care in the United States alone exceeds \$73 billion – a number that is expected to grow dramatically in the years ahead.

We believe MultiStem has great potential for treating damage caused by a stroke. Based on results from studies that we and our collaborators have conducted, we believe the potential therapeutic benefits may be achieved through the regulated expression of proteins or other factors that can:

- ▶ Protect damaged or injured neurons;
- ▶ Reduce the inflammation common in ischemic injury;
- ▶ Promote new blood vessel formation; and
- ▶ Augment tissue repair and healing.

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In 2010, we published results from preclinical work conducted with independent neurology researchers at the Medical College of Georgia that demonstrated intravenous administration of MultiStem up to one week after a stroke enabled robust and durable recovery. More recently, at the American Heart Association International Stroke Conference in February 2011, medical researchers from the Department of Neurology of the University of Texas Health Science Center at Houston presented additional research results that demonstrated the multiple benefits of MultiStem when administered in preclinical models of ischemic stroke. Researchers observed that intravenous administration of MultiStem one day after a stroke reduced inflammatory damage in the brain and resulted in a significant improvement in motor skills. In addition, in animals receiving MultiStem, there was substantially less cell death and markedly less inflammation compared to control animals that received placebo.

Interestingly, control animals treated with placebo showed a reduction in spleen size and an increase in inflam-

matory cytokines in the blood, whereas animals treated with MultiStem showed normal spleen size and increased levels of anti-inflammatory cytokines in the blood. The spleen is believed to play a significant role in promoting and sustaining the inflammation that can result in substantial long-term damage following brain injury.

Based on the results from these and other studies, we are actively preparing for a Phase II clinical trial to evaluate the safety and efficacy of administering MultiStem for the treatment of ischemic stroke in humans. We have FDA authorization to evaluate MultiStem administered to stroke patients, but have revised our original design to include an initial assessment of MultiStem's efficacy. We intend to begin patient enrollment for this study in the second half of 2011.

Through our network of collaborations, we also continue to make progress in other neurological areas. In September 2010, collaborators from the University of Texas Houston Medical center published results in the journal *Experimental Neurology*



MRI of the brain, axial section, showing damage from an ischemic stroke

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## Ischemic Stroke

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**I**schemic stroke occurs as a result of an obstruction within a blood vessel supplying blood to the brain. The underlying condition for this type of obstruction is the development of fatty deposits lining the vessel walls, a condition called atherosclerosis.

Approximately 800,000 individuals in the United States suffer a stroke each year, and ischemic stroke accounts for 87% of all stroke cases. Stroke is a leading cause of death and serious disability globally and represents a major unmet medical need. It is estimated that the direct and indirect costs of stroke exceed \$73 billion annually in the United States alone. Given the aging population in the United States and many other parts of the world, the clinical, economic and social impact of stroke is projected to grow dramatically in the next several decades.

Sources: American Heart Association, American Stroke Association

demonstrating that administration of MultiStem following traumatic brain injury reduced tissue damage and helped preserve the blood brain barrier. In another neurologic breakthrough, a preclinical study published in *The Journal of Neuroscience* in January 2011 demonstrated the regenerative benefit of MultiStem therapy after spinal cord injury. This was the first time an adult stem cell has been shown capable of modifying multiple aspects of the wound response following a spinal cord injury, while simultaneously altering the inflammatory response to mitigate secondary injury in the central nervous system and increasing the regenerative potential of the damaged neurons themselves.

These and other studies provide significant insights as to how MultiStem could have broad relevance across a range of significant unmet medical needs. By establishing clinical proof of concept in carefully selected indications in the immunological, cardiovascular and neurological areas, we believe that we are establishing a broad foundation of data that will lead to development of additional high-value opportunities.

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## **5HT2c Agonist for Obesity and Related Metabolic Conditions**

Beyond MultiStem, Athersys is actively advancing its drug development program for obesity and related metabolic conditions. Our primary focus is the development of potent, selective compounds that stimulate the 5HT2c receptor in the brain that regulates appetite and, therefore, food intake. The role of this receptor in regulating appetite is well understood in both animal models and humans and is extensively validated clinically.

Our aim is to develop an orally administered pill that reduces appetite by stimulating the 5HT2c receptor, but does not stimulate other receptors that could cause adverse side effects. These include the 5HT2b and 5HT2a receptors, which are associated with cardiovascular toxicity, dizziness, nausea and headaches. We have successfully developed highly selective novel compounds that meet these criteria.

We believe that the potency and selectivity profile displayed by our candidate compounds will result in better efficacy and a cleaner safety profile in clinical trials, as well as a more convenient dosing schedule than other 5HT2c agonist compounds. By achieving our goal of developing potent, selective compounds, we believe that we will be able to develop a best-in-class drug to assist patients in treating obesity and achieve a healthier lifestyle. We are

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## **Obesity: A Growing Epidemic**

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**O**besity is a substantial contributing factor to a range of diseases that represent the major causes



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actively evaluating which compounds we want to advance into further development, while continuing to explore potential partnering opportunities in this and other areas.

**I**n closing, we are encouraged by the steady and consistent progress we have achieved to date and are optimistic about continued success in the development of our best-in-class therapeutic products. We ended the year with more than \$15 million

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.

The Centers for Disease Control and Prevention estimates that nearly two-thirds of all Americans are overweight. There has been a dramatic rise in the rate of obesity in Europe and Asia as well. And, contrary to conventional wisdom, the obesity epidemic is not restricted to industrialized societies. The World Health Organization estimates that in developing countries, over 115 million people suffer from obesity-related problems.

*Sources: Centers for Disease Control and Prevention, World Health Organization*

in cash, cash equivalents and available-for-sale securities, and strengthened our balance sheet in early 2011 with \$11.8 million of net proceeds raised through the issuance of common stock and warrants. Given this and our strong collaborations with companies like Pfizer, we believe Athersys is well positioned to advance a number of promising programs further into the development process.

We appreciate your continued support and confidence, as well as the contributions and commitment of our employees and network of collaborators, as we pursue our goals. We look forward to an exciting year ahead as we continue to advance our portfolio, develop therapies to address significant unmet medical needs, and create substantial value for our stockholders.

Sincerely,

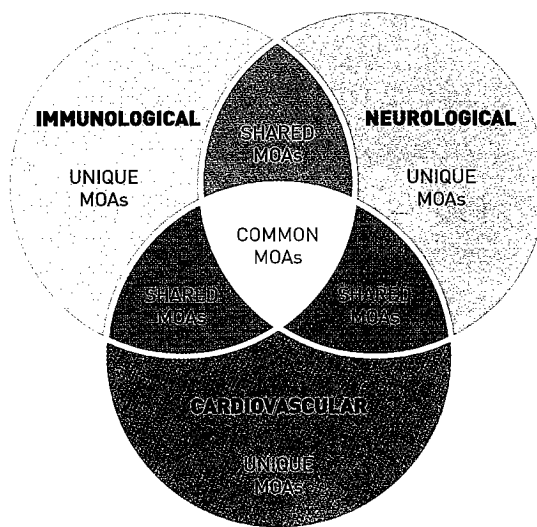


Gil Van Bokkelen  
Chairman and Chief Executive Officer

# MULTISTEM®: PROVIDING BENEFIT IN MULTIPLE WAYS

**MultiStem provides benefit** in a disease area generally **through multiple mechanisms of action (MOAs)**. For instance, in heart attack models, MultiStem drives improvement through a reduction of post-ischemia inflammation, the generation of new blood vessels to improve blood flow, and the protection of cells at risk from the heart attack.

The **MOAs** relevant to a particular disease may be **common to related diseases and across disease** categories, suggesting that success in one disease or therapeutic area can be leveraged in other areas to maximize development efficiency and value creation.

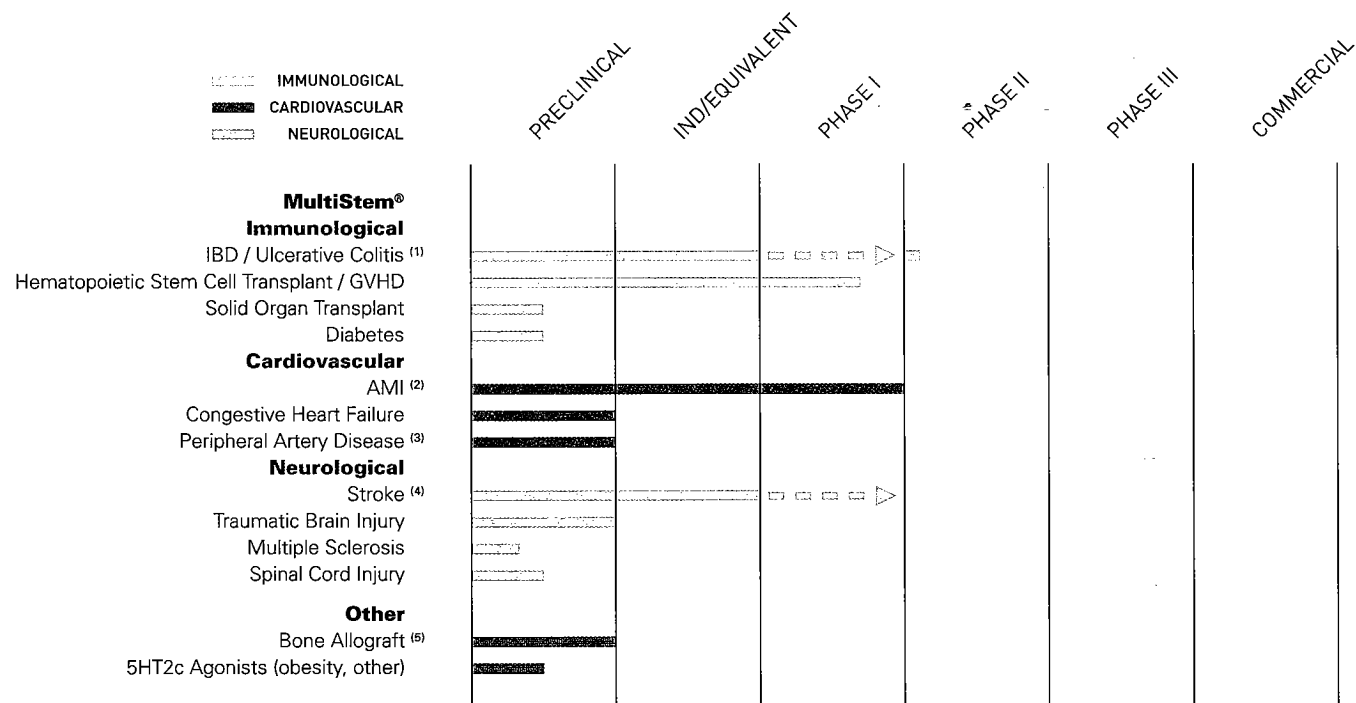


## THERAPEUTIC PIPELINE

Through the application of our proprietary technologies, we have established a pipeline of highly differentiated therapeutic candidates that we believe have best-in-class potential.

This chart presents a snapshot of selected therapeutic development programs at Athersys.

We will continue to identify opportunities to develop therapies that we believe are innovative and offer significant benefit to patients, as well as create value for our stockholders.



<sup>(1)</sup> Program is part of a development collaboration with Pfizer Inc.

<sup>(2)</sup> Program is supported through collaboration with Angiotech Pharmaceuticals, Inc.

<sup>(3)</sup> Includes applications in peripheral vascular disease and critical limb ischemia.

<sup>(4)</sup> We intend to initiate clinical development in stroke with a Phase II study.

<sup>(5)</sup> Allotransplant program being developed as part of a collaboration with RTI Biologics, Inc.

**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, 2010**

**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)

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

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

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$.001 per share	NASDAQ Stock Market LLC

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

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

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer," large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller Reporting Company

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 30, 2010, the last day of the registrant's most recently completed second quarter, of shares of the registrant's common stock (based upon the closing price per share of \$2.91 of such stock as quoted on the NASDAQ Capital Market on such date) held by non-affiliates of the registrant was approximately \$44.3 million.

The registrant had 23,502,581 shares of common stock outstanding on March 25, 2011.

Documents Incorporated By Reference.

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant's definitive Proxy Statement with respect to the 2011 Annual Meeting of Stockholders.

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## PART I

### ITEM 1. BUSINESS.

We are a biopharmaceutical company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human life. Through the application of our proprietary technologies, we have established a pipeline of therapeutic product development programs in multiple disease areas. We are committed to developing therapeutic products that we believe have best-in-class potential, meaning therapeutic candidates that have the potential to be safer, more effective products than the current standard of care or other products in development, and that may have other advantages, such as superior scalability or ease of administration. Our current product development portfolio consists of MultiStem®, a patented and proprietary stem cell product that we are developing as a treatment for multiple disease indications and that has been evaluated in one fully enrolled clinical trial and is currently being evaluated in two ongoing clinical trials, and has been authorized for use in a fourth clinical trial. In addition, we are developing novel pharmaceuticals to treat indications such as obesity and related metabolic conditions such as diabetes. We are also focused on the development of small molecule compounds with potential applications in other areas, including the treatment of certain neurological conditions, and for the modulation of stem cells or related applications in the regenerative medicine area.

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.

#### **Recent Developments**

In February 2011, we completed a registered direct offering generating 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.

#### **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 develop product candidates in established areas of significant clinical need.* We are focused on the development of best-in-class product candidates with differentiated profiles, meaning improved safety and/or efficacy relative to current standards of care. Our intention is to develop our products for ultimate commercialization by us, our partners or licensees after they have received approval from the U.S. Food and Drug Administration, or FDA, and/or other regulatory agencies.
- *Apply our proprietary technologies toward the identification, validation, and development of therapeutic product candidates.* We will continue to use our proprietary technologies to identify and validate therapeutic product candidates. We believe our technologies, including MultiStem and RAGE (Random Activation of Gene Expression)®, provide us with a competitive advantage in discovery and product development by allowing us to move product candidates quickly from the discovery phase into clinical trials. We select candidates for internal development based on several factors, including the required regulatory approval pathway, the potential market into which the product may be sold and our ability to feasibly fund development activities.
- *Enter into licensing or co-development arrangements for certain product candidates.* 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 commercialization capabilities. We have entered into multiple licensing and product co-development arrangements with qualified commercial partners to achieve these objectives. We anticipate that this strategy will help us to develop a portfolio of high quality product development opportunities, enhance our clinical development and commercialization capabilities, and increase our ability to generate value from our proprietary technologies.

- *Continue to expand our intellectual property portfolio.* 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.
- *Out-license non-core applications of our technologies.* Certain elements of our technologies may not be relevant to the key elements of our corporate strategy. We believe these applications may have significant potential value, however, and may provide capital to us that can be applied to our other development efforts. Where appropriate, we may seek to license non-core applications of our technologies to others to realize this value.

### **Our Current Programs**

By applying our proprietary cell therapy platform, MultiStem, we have established therapeutic product development programs in the areas of treating cardiovascular disease, neurological disease, and immune system disorders. To date, we have advanced four programs to clinical development stage, including:

- An ongoing Phase II clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, the most common form of inflammatory bowel disease, or IBD. This study was authorized by the FDA in November 2010 and is being conducted with our partner, Pfizer Inc., or Pfizer. This trial began enrolling patients in the study in February 2011;
- A Phase I clinical study involving administration of MultiStem to patients that have suffered an acute myocardial infarction, or AMI, more commonly referred to as a heart attack. We announced initial results for this study in July 2010, demonstrating a consistent safety profile and encouraging signs of improvement in heart function among patients who had received treatment after experiencing a heart attack and exhibiting severely compromised heart function. We intend to initiate a Phase II study in 2011 with our partner, Angiotech Pharmaceuticals, Inc., or Angiotech, to evaluate the safety and efficacy of MultiStem administration to AMI patients;
- An ongoing Phase I clinical study involving administration of MultiStem to patients suffering from leukemia or certain other blood-borne cancers, in which patients undergo radiation therapy and then receive a hematopoietic stem cell, or HSC, transplant. Such patients are at risk for serious complications, including graft versus host disease, or GVHD, which is an imbalance of immune system function caused by transplanted immune cells that attack various tissues and organs in the patient. In January 2011, we announced that we had successfully completed enrollment for the single ascending dose portion of this clinical trial and expect to announce preliminary results in the second-quarter of 2011. In addition, the multiple ascending dose portion of this study is ongoing.
- An FDA authorized Phase I clinical study to evaluate administration of MultiStem to patients that have suffered an ischemic stroke. We are currently working with our clinical advisors to modify the proposed study design, including increasing the size of the study so that we can evaluate safety and efficacy.

In addition to our current and anticipated clinical development activities, we are engaged in preclinical development and evaluation of MultiStem in other disease indications in the cardiovascular, neurological and immune disorder areas. 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 also engaged in the development of novel small molecule therapies to treat obesity and related metabolic conditions, including diabetes, as well as other conditions. Currently we are focused on the development of potent, highly selective compounds that act through stimulation of a specific receptor in the brain that controls appetite — the 5HT<sub>2c</sub> serotonin receptor. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit outstanding selectivity and intend to select a clinical development candidate for this program in 2011.

## ***Regenerative Medicine Programs***

### *MultiStem — A Novel Allogeneic Approach to Stem Cell Therapy and Regenerative Medicine*

We are developing a proprietary nonembryonic, allogeneic stem cell product candidate, MultiStem, that we believe has potential utility for treating a broad range of diseases and could have widespread application in the field of clinical regenerative medicine. Unlike traditional bone marrow transplants or other stem cell therapies, MultiStem may be manufactured on a large scale (with hundreds of thousands to millions of doses obtained from a single healthy donor), and may be administered without tissue matching or the need for immune suppression, analogous to type O blood. Potential applications of MultiStem include the treatment of cardiovascular disease, neurological disease or injury, and conditions involving the immune system, including autoimmune disease and other conditions. We believe that MultiStem represents a significant advancement in the field of stem cell therapy and could have broad clinical application. We currently have open Investigational New Drug applications, or INDs, for the study of MultiStem in four distinct clinical indications.

MultiStem is a patented biologic product that is manufactured from human stem cells obtained from adult bone marrow. The product consists of a special class of human stem cells that have the ability to express a range of therapeutically relevant proteins and other factors, as well as form multiple cell types. Factors expressed by MultiStem have the potential to deliver a therapeutic benefit in several ways, such as the reduction of inflammation, regulation of immune system function, protection of damaged or injured tissue, the formation of new blood vessels in regions of ischemic injury and augmenting 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 express multiple therapeutically relevant proteins and are subsequently cleared from the body over time.

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, the Multipotent Adult Progenitor Cell, or MAPC, which may be isolated from adult bone marrow as well as other nonembryonic tissues. Over the past several years, we have further developed this technology and the manufacturing of these cells for use in ongoing clinical trials. Our current product platform is referred to as MultiStem. During several years of preclinical work, MultiStem has demonstrated the potential to address many of the fundamental limitations observed with traditional bone marrow or hematopoietic stem cell transplants.

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 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 through multiple mechanisms, such as 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, MultiStem cells may be produced on a large scale, processed, and cryogenically preserved, and then used clinically in a rapid and efficient manner. Material obtained from a single donor may be used to produce hundreds of thousands or millions of individual doses, representing a yield far greater than other stem cells have been able to achieve.

- *“Off-the-shelf” utility.* Unlike traditional bone marrow or hematopoietic stem cell transplants that require extensive genetic matching between donor and recipient, MultiStem is administered without tissue matching or the requirement for immune suppressive drugs. MultiStem is administered as a cryogenically preserved allogeneic product, meaning that these cells are not genetically matched between donor and recipient. This feature, combined with the ability to establish large MultiStem banks, could make it practical for clinicians to efficiently deliver stem cell therapy to a large number of patients.
- *Safety.* Other stem cell types, such as embryonic stem cells, can pose serious safety risks, such as the formation of ectopic tissue or tumor-like growths. In contrast, MultiStem cells have an 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 donor and then expanded to form a Master Cell Bank from which we subsequently produce clinical grade material. 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.

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

#### *MultiStem for Cardiovascular Disease, Immune System Disorders, and Neurological Conditions*

Working with independent investigators at a number of leading institutions, such as the University of Minnesota, the Cleveland Clinic, the National Institutes of Health, the Medical College of Georgia, the University of Oregon Health Sciences Center and the Katholieke Universiteit Leuven, we have studied MultiStem in a range of *in vitro* and preclinical animal models that reflect various types of human disease or injury in the cardiovascular, neurological and immunological areas. To date, we have published research results illustrating the potential benefits of MultiStem in a range of indications including myocardial infarction, vascular disease, ischemic stroke, traumatic brain injury, brain damage due to restricted blood flow in newborns, spinal cord injury, and bone marrow transplant support/GVHD. In addition, we have explored and intend to further explore, the potential application of MultiStem in the treatment of a range of other conditions, including other forms of cardiovascular disease, neurological conditions, and immune related disorders.

As stated above, we have consistently observed that MultiStem is safe and effective in animal models. As a result, we have advanced MultiStem to clinical development stage in four clinical indications or disease areas: treatment of IBD (initially focused on ulcerative colitis); treatment of damage caused by myocardial infarction; support in the hematologic malignancy setting to reduce certain complications associated with traditional bone marrow or HSC transplantation; and treatment for stroke caused by a blockage of blood flow in the brain.

We have advanced four programs to clinical development stage, including:

- A Phase I clinical study involving administration of MultiStem to patients that have suffered an AMI with our partner, Angiotech, and we intend to initiate in 2011 a Phase II study to evaluate the safety and efficacy of MultiStem administration to AMI patients;
- An ongoing Phase I clinical study involving administration of MultiStem to patients suffering from leukemia or certain other blood-borne cancers, in which patients undergo radiation therapy and then receive a HSC transplant and are at risk for serious complications, including GVHD. We have successfully completed enrollment for the single ascending dose portion of this trial and the multiple ascending dose portion of this study is ongoing;

- An ongoing Phase II clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, the most common form of IBD with our partner, Pfizer. This trial began enrolling patients in the study in February 2011; and
- An FDA authorized Phase I clinical study to evaluate administration of MultiStem to patients that have suffered an ischemic stroke, and we are working with our clinical advisors to modify the proposed study design so that we can evaluate safety and efficacy.

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

**Cardiovascular Disease — Evaluating MultiStem for Heart Attack**

In a Phase I clinical trial, we have been exploring the use of MultiStem as a treatment for damage caused by myocardial infarction, or heart attack. Myocardial infarction is one of the leading causes of death and disability in the United States. Myocardial infarction is caused by the blockage of one or more arteries that supply blood to the heart. Such blockages can be caused, for example, by the rupture of an atherosclerotic plaque deposit. According to the American Heart Association 2010 Statistical Update, there were approximately 935,000 cases of myocardial infarction that occurred in the United States in 2006 and approximately 8.5 million individuals living in the United States that had previously suffered a heart attack. In addition, there were more than 831,000 deaths that occurred from various forms of cardiovascular disease, including 567,000 individuals that died as a result of a myocardial infarction or congestive heart failure. A variety of risk factors are associated with an elevated risk of myocardial infarction or atherosclerosis, including age, high blood pressure, smoking, sedentary lifestyle and genetics. While advances in the diagnosis, prevention and treatment of heart disease have had a positive impact, there is clearly room for improvement — myocardial infarction remains a leading cause of death and disability in the United States and the rest of the world.

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

Working with a contract research organization, we completed additional preclinical studies in established pig models of AMI using catheter delivery and examining various factors such as the route and method of MultiStem administration, dose ranging, and timing of treatment. In 2008, we initiated a multicenter, open-label Phase I clinical trial in this indication and we completed enrollment in 2010. In July 2010, we announced the interim results from this trial, which showed that MultiStem was well tolerated at all dose levels and exhibited a favorable safety profile. In addition, patients that received treatment with MultiStem exhibited meaningful improvements in cardiovascular function, including left ventricular ejection fraction, wall motion scores, and other parameters.

We are developing MultiStem for this indication in conjunction with our partner, Angiotech. We entered into a product co-development collaboration with Angiotech in 2006 for the potential application of MultiStem in multiple cardiovascular indications including myocardial infarction, peripheral vascular disease and certain other indications. Based on the results from the preclinical studies and Phase I clinical trial results, we intend to initiate a Phase II clinical trial involving administration of MultiStem to AMI patients in 2011.

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

In multiple studies, MultiStem has shown potent immunomodulatory properties, including the ability to reduce active inflammation and immune system imbalance. Accordingly, we believe that MultiStem could have broad application in the area of treating immune system disorders, including certain autoimmune diseases and other conditions, including GVHD, which is a frequent immunological complication associated with bone marrow or HSC transplantation.

In 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem for the treatment of IBD for the worldwide market. IBD is a group of inflammatory and autoimmune conditions that affect the colon and small intestine, typically resulting in severe abdominal pain, weight loss, vomiting and diarrhea. The most common forms of the disease include ulcerative colitis and Crohn's disease, which are estimated to affect more than 2.3 million people 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. Enrollment commenced in February 2011 in our Phase II clinical study being conducted with our partner, Pfizer, to administer MultiStem to patients suffering from ulcerative colitis.

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

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

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

In 2008, we initiated a Phase I clinical trial to examine the safety and tolerability of MultiStem in patients receiving a bone marrow or hematopoietic stem cell transplant related to their treatment for hematologic malignancy. The trial is an open label, multicenter trial that involves leading experts in the field of bone marrow transplantation. In January 2011, we announced that we had successfully completed enrollment for the single ascending dose portion of this clinical trial and established the maximum tolerated dose, and we expect to announce preliminary results in the second quarter of 2011. In addition, the multiple ascending dose portion of this study is ongoing.

#### **Neurological Disease — MultiStem for Ischemic Stroke**

Another focus of our regenerative medicine program is the use of MultiStem for the treatment of neurological injury as a result of ischemic stroke or other conditions. To date, we have published research with independent collaborating investigators that demonstrates that MultiStem conveys biological benefits in preclinical models of ischemic stroke, traumatic brain injury, neonatal hypoxic ischemia (a leading cause of cerebral palsy), and spinal cord injury. We have also conducted preclinical work in other neurological areas, and have been awarded grants to support work in areas such as the indications described above and for evaluating the potential of MultiStem to treat Parkinson's Disease. Research has shown that MultiStem conveys benefits through multiple distinct mechanisms, including reducing inflammatory damage, protecting at risk tissue at the site of injury, and through direct neurotrophic effects. As a result, we believe that MultiStem may have relevance to multiple forms of neurological injury and disease.

Our initial clinical focus in the neurological area involves evaluating administration of MultiStem to treat ischemic stroke. Ischemic stroke is a leading cause of death and disability globally, and accounts for approximately 85% of all strokes. Recent progress toward the development of safer and more effective treatments for ischemic stroke has been disappointing. Despite the fact that ischemic stroke is one of the leading causes of death and disability in the United States, affecting more than 700,000 new patients annually according to the United States Centers for Disease Control and Prevention, or CDC, 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 three 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 this time frame is not recommended, since it can cause bleeding or even death. Given this limited therapeutic window, it is estimated that less than 5% of ischemic stroke victims currently receive treatment with tPA.

In preclinical studies conducted by investigators, including at both the University of Minnesota and the Medical College of Georgia, significant functional improvements have been observed in rodents that have undergone an experimentally induced stroke, or that have incurred significant neurological damage as a result of neonatal hypoxic ischemia, and then received treatment with MultiStem. Published research has demonstrated that administration of MultiStem even one week after a surgically induced stroke results in substantial long-term therapeutic benefit, as evidenced by the improvement of treated animals compared with controls in a battery of tests examining mobility, strength, fine motor skills, and other aspects of neurological functional improvement. We believe that this benefit is achieved 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. More recent research results, presented at the 2011 American Heart Association International Stroke Conference by collaborators from the University of Texas Health Science Center at Houston, demonstrated that administration of MultiStem 24 hours following a stroke reduced inflammatory damage in the brain, and resulted in significant functional improvement, and that some of these results were achieved by reducing the inflammatory response emanating from the spleen. These results confirm that MultiStem treatment is well tolerated, does not require immunosuppression, and results in a robust and durable therapeutic benefit even when administered up to one week after the initial stroke event.

In 2008, we completed additional preclinical safety studies and submitted an IND for this application, which has been authorized by the FDA. The Phase I safety clinical trial authorized by the FDA is a double blind, placebo controlled study that allows for administration of MultiStem to patients 48 to 60 hours after the ischemic stroke, which, if shown to be safe and effective, would represent a significant extension of the treatment window relative to existing standard of care. However, since this study was authorized, we have generated additional preclinical and clinical data that demonstrates the consistent safety profile of MultiStem. Accordingly, we are focused on modifying the design of this study, including increasing the trial size, so that we can evaluate clinical safety and efficacy in a more robust manner.

### ***Pharmaceutical Programs***

#### *Novel 5HT2c agonists for the treatment of obesity and related 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 66% of all Americans are overweight, including more than 30% that are considered clinically obese. The percentage of young people who are overweight has more than tripled since 1980. There has also been a dramatic rise in the rate of obesity in Europe and Asia. Despite the magnitude of this problem, current approaches to clinical obesity are largely ineffective, and we are aware of relatively few new therapeutic approaches in clinical development.

We are developing novel pharmaceutical treatments for obesity, which are compounds designed to act by stimulating a key receptor in the brain that regulates appetite and food intake — the 5HT2c receptor. The role of this receptor in regulating food intake is well understood in both animal models and humans. In 1996, Wyeth Pharmaceuticals launched the anti-obesity drug Redux<sup>®</sup> (dexfenfluramine), a non-specific serotonin receptor agonist

that was used with the stimulant phentermine in a combination commonly known as fen-phen. This diet drug combination gained rapid and widespread acceptance in the clinical marketplace and was shown to be highly effective at regulating appetite, reducing food intake, and causing significant weight loss. Unfortunately, in addition to stimulating the 5HT2c receptor, Redux also stimulated the 5HT2b receptor that is found in the heart. The activation of 5HT2b by Redux is believed to have caused significant cardiovascular problems in a number of patients and, as a result, Redux was withdrawn from the market in 1997. In 1996, doctors wrote 18 million monthly prescriptions for drugs constituting the fen/phen combination. In that same year, these drugs generated sales of greater than \$400 million, serving as a benchmark for the substantial market opportunity for an effective drug to treat clinical obesity.

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

We initiated a drug development program focused on creating potent and selective compounds that stimulate the 5HT2c receptor, but that avoid the 5HT2b receptor and other receptors, such as 5HT2a. Our specific goal has been to develop an orally administered pill that reduces appetite by stimulating the 5HT2c receptor, but that does not stimulate the 5HT2b receptor, the 5HT2a receptor, 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 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 in clinical trials, as well as a more convenient dosing schedule than other 5HT2c agonist programs. Our goal is to select a clinical candidate for this program in 2011.

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

In addition to our current product development programs, we developed our patented RAGE technology that provides us with the ability to produce human cell lines that express specific, biologically well validated drug targets without relying upon cloned and isolated gene sequences. While our RAGE technology is not a product, it is a commercial technology that we have successfully applied for the benefit of our partners and that we have also used for our own internal drug development programs. Modern drug screening approaches typically require the physical isolation and structural modification of a gene of interest, an approach referred to as gene cloning, in order to create a cell line that expresses a drug target of interest. Researchers may then use the genetically modified cell line to identify pharmaceutical compounds that inhibit or stimulate the target of interest. The RAGE technology enables us to turn on or amplify the expression of a drug target without having to physically clone or isolate the gene. In effect, the technology works through the random insertion of tiny, proprietary genetic switches that randomly turn genes on without requiring their physical isolation, or any advance knowledge of their structure. This technology provides us with broad freedom to work with targets that may be otherwise unavailable as a result of intellectual property restrictions on the use of specific cloned and isolated genes. Over the past several 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 the fourth quarter of 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem for the treatment of IBD for the worldwide market. Under the terms of the agreement, we received a non-refundable up-front cash payment of \$6 million from Pfizer and will receive research funding and support during the initial phase of the collaboration. 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 any milestones, and no milestones were received as of December 31, 2010. We will be responsible for manufacturing and Pfizer will pay us for manufacturing product for clinical development and commercialization purposes. Pfizer will have responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase III clinical development.

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

### *Angiotech*

In May 2006, we established a collaboration with Angiotech that is focused on co-developing MultiStem for the treatment of damage caused by myocardial infarction and peripheral vascular disease. In support of the collaboration, Angiotech invested \$10.0 million in us and we may also receive up to \$3.75 million of additional equity investments and \$63.75 million of aggregate cash payments based upon the successful achievement of specified clinical development and commercialization milestones, though there can be no assurance that we will achieve any milestones. To date, other than the initial investment of \$10.0 million in the Company by Angiotech in installments in 2006 and 2007, we have not received any additional payments from Angiotech as equity investments or milestone payments.

Under the terms of the collaboration, the parties are jointly funding clinical development activities, whereby preclinical costs are borne solely by Athersys, costs for Phase I and Phase II clinical trials are borne 50% by Athersys and 50% by Angiotech, costs for the first Phase III clinical trial will be borne 33% by Athersys and 67% by Angiotech, and costs for any Phase III clinical trials subsequent to the first Phase III clinical trial will be borne 25% by Athersys and 75% by Angiotech. We have received \$2.4 million from Angiotech as its cumulative share of clinical development cost reimbursements, representing billings through September 30, 2010. We have lead responsibility for preclinical and early clinical development and manufacturing of the MultiStem product, and Angiotech will take the lead on pivotal and later clinical trials and commercialization. We will receive nearly half of the net profits from the sale of any jointly developed, approved products. In addition, we will retain the commercial rights to MultiStem for all other therapeutic applications, including treatment of stroke or other neurological indications, bone marrow transplantation and oncology support, blood and immune system disorders, autoimmune disease, and other indications that we may elect to pursue.

The Angiotech collaboration does not have a specific termination date, but will terminate upon the earliest to occur of the following:

- if at least one cell therapy product has obtained regulatory approval and we and Angiotech have shared profits with respect to sales of at least one cell therapy product, the date that there has been no sales for 12 months of any cell therapy product that has been the subject of profit-sharing, unless a clinical development candidate is in at least a Phase III clinical or later; and
- the later of (1) the expiration date of the last-to-expire patent licensed to Angiotech and (2) the 15-year anniversary, which would be May 2021.

Currently, the expiration date of the last-to-expire patent licensed to Angiotech is in 2025. Additional patent applications that are under active prosecution are also part of the collaboration, and we continue to develop intellectual property and prosecute filed patent applications that, once issued, would likely extend patent coverage and may be licensed to Angiotech under the collaboration.

Neither we nor Angiotech may terminate the collaboration at will; however, either party may elect at certain points to not move forward with individual product development programs. 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. Angiotech has a right to immediately terminate the collaboration upon certain bankruptcy events involving us. Angiotech also has the right to terminate the collaboration upon 120 days' prior notice if Angiotech, in its reasonable judgment, determines that: (1) a primary endpoint in a clinical trial within a clinical development candidate or a cell therapy product have not been demonstrated; (2) applicable regulatory requirements for cells, a clinical development candidate or a cell therapy product in one or more major markets shall have a material adverse impact on the ability to obtain regulatory approval for a cell therapy product in such markets; (4) our data regarding cells, a clinical development candidate or a cell therapy product were obtained, in whole or in part, through scientific fraud; or (5) a cell therapy product is not (or is not expected to be) commercially viable or profitable in at least one major market.

In January 2011, Angiotech announced its plans to pursue a recapitalization transaction through its voluntary filing under the Companies' Creditors Arrangement Act in Canada. In the event that Angiotech elects not to continue with our collaboration, Angiotech would return all rights to us and we would have an outstanding claim related to Angiotech's reimbursement of our fourth quarter 2010 collaboration costs and the costs through January 28, 2011, which was Angiotech's petition date. In the event that Angiotech fails to fund its obligations under the terms of our collaboration agreement, our net costs for subsequent AMI clinical trials would increase or alternative funding would be required for such clinical trials.

#### ***RTI Biologics, Inc.***

In September 2010, we entered into an agreement with RTI Biologics, Inc., or RTI, to develop and commercialize MAPC technology-based biologic implants for certain orthopedic applications in the bone graft substitutes market. The agreement provides for a \$5.0 million license fee, potential milestone payments and tiered royalties on worldwide commercial sales of implants using our technologies. We are currently working with RTI to develop products for these applications.

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

In December 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 is now 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 September 2008, Bristol-Myers Squibb successfully advanced into Phase II clinical development a drug candidate discovered using a target provided by us, thereby triggering a clinical development milestone payment to us.

Since the beginning of the collaboration, we have provided 27 cell lines to Bristol-Myers Squibb under the collaboration. Additionally, as of December 31, 2010, we have received an aggregate amount of \$1.7 million in milestone payments and \$8.0 million in license fees from Bristol-Myers Squibb under the collaboration.

We are preparing and delivering the final validated drug target for use by Bristol-Myers Squibb in its drug discovery efforts under the collaboration and do not expect any significant demand for new targets. We will remain entitled to receive license fees for targets delivered to Bristol-Myers Squibb, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology.

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

### **Competition**

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

Osiris is currently engaged in multiple Phase II and Phase III clinical trials involving Prochymal, an allogeneic stem cell product based on mesenchymal stem cells, or MSCs, that are obtained from healthy consenting donors, and are administered without tissue matching. However, in contrast to MultiStem, MSCs display limited expansion potential and more limited biological plasticity. In November 2008, Osiris announced a partnership in which Genzyme acquired development rights to Prochymal for certain markets outside the United States and Canada in exchange for \$130 million in license fees, up to \$1.25 billion in clinical and sales milestones, and royalties. Osiris retains commercial development rights to Prochymal for the United States and Canada.

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 more limited biological plasticity. In December 2010, Mesoblast announced a partnership with Cephalon, in which Cephalon paid an upfront license fee of \$130 million, and agreed to invest an additional \$220 million in equity for a 19.9% stake in the company. 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, acute myocardial infarction, Parkinson's disease, and Alzheimer's disease.

Other public companies are developing stem-related therapies, including Geron, Aastrom Biosciences, Stem Cells Inc., Johnson & Johnson, Celgene, Advanced Cell Technology, CRYO-CELL International, Pluristem and Cytori Therapeutics. In addition, private companies, such as Cognate Therapeutics, Gamida Cell, Plureon, Cellerix 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. There is currently one approved therapeutic product on the market for obesity, Xenical (also known as Alli), which is marketed by 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 recently 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 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, Roche, Sanofi-Aventis, GlaxoSmithKline, Eli Lilly and others. There are also a variety of biotechnology companies developing treatments for obesity, including Arena Pharmaceuticals, Orexigen, Vivus, Neurosearch, Amgen, Regeneron, Natestch Pharmaceutical Company, Alizyme, Amylin Pharmaceuticals, Neurocrine Biosciences, Shionogi, Metabolic Pharmaceuticals, Kyorin Pharmaceutical, 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.

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

### **Intellectual Property**

We rely on a combination of patent applications, patents, trademarks, and contractual provisions to protect our proprietary rights. We believe that to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. Currently, we require our officers, employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, and other advisors to execute confidentiality agreements in connection with their employment, consulting, or advisory relationships with us, where appropriate. We also require our employees, consultants, and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, developed using our property, or which relate to our business. We currently have an aggregate of 65 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 acquired ownership of part of our stem cell technology and intellectual property as a result of our 2003 acquisition of a holding company, which held the rights to the technology originally discovered at the University of Minnesota. We also have an exclusive license to additional MAPC-related inventions (or in other words, improvements) developed by the University of Minnesota through May 2009, and under a collaborative research agreement with the Katholieke Universiteit Leuven, or KUL, we have an exclusive license to MAPC-related inventions developed at KUL using the MAPC technology or intellectual property or that result from sponsored research funded by us. We also own and license additional intellectual property developed by us and others. We have 21 issued patents (seven U.S. patents and fourteen international patents) and more than 150 patent applications related to our stem cell technologies that currently provide patent coverage through as late as 2025. Of the 21 patents related to our stem cell technologies, four U.S. patents and nine non-U.S. patents apply to MAPC-based and related products. Additional patent applications are pending that, if issued, could extend beyond this date. Furthermore, in certain jurisdictions (such as the United States) a patent term may be extended to reflect the length of time a product is under regulatory review, and/or an extended period of market exclusivity may apply for certain products (e.g. exclusivity periods for orphan drug designation or biologics).

We have established a broad intellectual property portfolio related to our functional genomics technologies and small molecule product candidates. We have a broad patent estate with claims directed to compositions, methods of making, and methods of using our small molecule drug candidates. We have three U.S. patents and four patent applications with broad claims directed to selective 5HT<sub>2c</sub> agonists discovered at Athersys that currently provide patent coverage through as late as 2029. From our Histamine H<sub>3</sub> program, we have four U.S. patents and two patent applications with broad claims directed to compounds discovered at Athersys from two distinct chemical series that currently provide patent coverage through as late as 2028. In addition, we currently have 35 issued patents (sixteen U.S. patents and nineteen international patents) and six patent applications relating to compositions and methods for the RAGE technology that currently provide patent coverage through as late as 2017, and two U.S. patents and nine patent applications relating to human proteins and candidate drug targets that we identified through the application of RAGE and our other technologies that currently provide patent coverage through as late as 2022. The RAGE technology was developed by Dr. John Harrington and other Athersys scientists internally in the mid-1990s.

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

### **Research and Development**

Our research and development costs, which consist primarily of costs associated with external clinical trial costs, preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property application processes, and laboratory supply and reagent costs, were \$14.8 million in 2010, \$11.9 million in 2009 and \$16.5 million in 2008.

### **Government Regulation**

Any products we may develop and our research and development activities are subject to stringent government regulation in the United States by the FDA and, in many instances, by corresponding foreign and state regulatory agencies. The European Union, or EU, has vested centralized authority in the European Medicines Evaluation Agency and Committee on Proprietary Medicinal Products to standardize review and approval across EU member nations.

These regulatory agencies enforce comprehensive statutes, regulations, and guidelines governing the drug development process. This process involves several steps. Initially, the company must generate preclinical data to show safety before human testing may be initiated. In the United States, the 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 CTA is the European equivalent of the U.S. IND. CTA requirements are issued by each competent authority within the European Union and are enacted by local laws and Directives.

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

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

- preclinical tests in animals that demonstrate a reasonable likelihood of safety and effectiveness in human patients;
- submission to the FDA of an IND, which must become effective before clinical trials in humans can commence. If Phase I clinical trials are to be conducted initially outside the United States, a different regulatory filing is required, depending on the location of the trial;
- adequate and well controlled human clinical trials to establish the safety and efficacy of the drug or biologic in the intended disease indication;

- for drugs, submission of a New Drug Application, or NDA, or a Biologic License Application, or BLA, with the FDA; and
- FDA approval of the NDA or BLA before any commercial sale or shipment of the drug.

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

In addition to obtaining FDA approval for each product, each drug manufacturing facility must be inspected and approved by the FDA. All manufacturing establishments are subject to inspections by the FDA and by other federal, state, and local agencies, and must comply with 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.

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, 2010, we employed 44 full time equivalent employees, 20 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**

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge on our website, [www.athersys.com](http://www.athersys.com), as soon as reasonably practicable after they are filed with, or furnished to, the SEC.

## **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 and the trading price of our equity securities could 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.

### **Risks Related To Our Business and Our Industry**

***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 have incurred net losses of \$18 million in 2008, \$15 million in 2009 and \$11 million in 2010. As of December 31, 2010, we had an accumulated deficit of \$205 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 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 yet 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 \$16 million in 2008, \$5 million in 2009 and \$11 million in 2010. We expect to have available cash to fund our operations through 2011 based on our current business and operational plans and assuming no new financings or collaborations. Our future capital requirements will depend on many factors, including:

- 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;
- 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.

We cannot assure you that we will not need additional capital sooner than currently anticipated. We will need to raise substantial additional capital to fund our future operations. We cannot be certain that additional financing 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, 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, and if we encounter delays or difficulties in the development of this product candidate, our business would be harmed.***

We are heavily dependent upon the successful development of MultiStem 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;
- 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.



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

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

- test short-term safety and tolerability;
- study the absorption, distribution, metabolism and elimination of the product candidate;
- study the biochemical and physiological effects of the product candidate and the mechanisms of the drug action and the relationship between drug levels and effect; and
- understand the product candidate's side effects at various doses and schedules.

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

***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.***

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.

Currently, our material collaborations and licensing arrangements are our collaboration with Pfizer to develop and commercialize MultiStem for the treatment of IBD, our product co-development collaboration with Angiotech to jointly develop and ultimately market MultiStem for the treatment of damage caused by myocardial infarction and peripheral vascular disease, our collaboration agreement with Bristol-Myers Squibb pursuant to which we provide cell lines produced using our RAGE technology, our collaboration with RTI to develop and commercialize MAPC technology-based biologic implants for certain orthopedic applications in the bone graft substitutes market, and our license with the University of Minnesota pursuant to which we license certain aspects of the MultiStem technology. These arrangements do not have specific termination dates; rather, each arrangement terminates upon the occurrence of certain events.

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

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

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

Under the terms of our collaboration agreement with Angiotech, either party may choose, following the completion of Phase I trials, to opt-out of its obligation to fund further product development on a product-by-product basis, provided no clinical trials concerning such product candidate are currently ongoing. If Angiotech should decide to opt-out of funding the development of any of the product candidates for the covered indications, for any reason, we may be unable to fund the development on our own and could be forced to halt one or more MultiStem development programs. In January 2011, Angiotech announced its plans to pursue a recapitalization transaction through its voluntary filing under the Companies' Creditors Arrangement Act in Canada. In the event that Angiotech elects not to continue with our collaboration, Angiotech would return all rights to us and we would have an outstanding claim related to Angiotech's reimbursement of our fourth quarter 2010 collaboration costs and the costs through January 28, 2011, which was Angiotech's petition date. In the event that Angiotech fails to fund its obligations under the terms of our collaboration agreement, our net costs for subsequent AMI clinical trials would increase or alternative funding would be required for such clinical trials.

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

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

- health concerns, whether actual or perceived, or unfavorable publicity regarding our obesity drugs, stem cell products or those of our competitors;
- the timing of market entry as compared to competitive products;
- the rate of adoption of products by our collaborators and other companies in the industry;
- any product labeling that may be required by the FDA or other United States or foreign regulatory agencies for our products or competing or comparable products;
- convenience and ease of administration;
- pricing;
- perceived efficacy and side effects;
- marketing;
- availability of alternative treatments;
- levels of reimbursement and insurance coverage; and
- activities by our competitors.

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

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

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

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

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.

***If our pharmaceutical product candidates do not successfully complete the clinical trial process, we will not be able to partner or market them. Even successful clinical trials may not result in a partnering transaction or a marketable product and may not be entirely indicative of a product's safety or efficacy.***

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. Even successful clinical trials may not result in a marketable product or be indicative of the efficacy or safety of a product. Many factors or variables could affect the results of clinical trials and cause them to appear more promising than they may otherwise be. Product candidates that successfully complete clinical trials could ultimately be found to be unsafe or ineffective.

In addition, our ability to complete clinical trials depends on many factors, including obtaining adequate clinical supplies and having a sufficient rate of patient recruitment. For example, patient recruitment is a function of many factors, including:

- the size of the patient population;
- the proximity of patients to clinical sites;
- the eligibility criteria for the trial;
- the perceptions of investigators and patients regarding safety; and
- the availability of other treatment options.

***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.

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

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

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

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

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

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

***If we are unable to 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.

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

We are highly dependent on our executive officers Gil Van Bokkelen, Ph.D., our Chief Executive Officer, as well as other executive and scientific officers, including William Lehmann, J.D., M.B.A., President and Chief Operating Officer, John Harrington, Ph.D., Chief Scientific Officer and Executive Vice President, Robert Deans, Ph.D., Senior 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.

***Our ability to compete in the biopharmaceutical market may decline if we do not adequately protect our proprietary technologies.***

Our success depends in part on our ability to obtain and maintain intellectual property that protects our technologies and our pharmaceutical 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 small molecule programs. In addition, we are prosecuting numerous distinct patent families directed to composition, methods of production, and methods of use of MultiStem and related technologies. If we are unsuccessful in obtaining and maintaining these patents related to products and technologies, we may ultimately be unable to commercialize products that we are developing or may elect to develop in the future.

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

- we were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies or product candidates upon which we rely;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- others did not publicly disclose our claimed technology before we conceived the subject matter included in any of our patent applications;
- any of our pending or future patent applications will result in issued patents;

- any of our patent applications will not result in interferences or disputes with third parties regarding priority of invention;
- any patents that may be issued to us, our collaborators or our licensors will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our ability to do business; or
- new proprietary technologies from third parties, including existing licensors, will be available for licensing to us on reasonable commercial terms, if at all.

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

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

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.

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

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

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

We are not currently a party to any litigation, interference, opposition, protest, reexamination or any other potentially adverse governmental, ex parte or inter-party proceeding with regard to our patent or trademark positions. However, the life sciences and other technology industries are characterized by extensive litigation regarding patents and other intellectual property rights. Many life sciences and other technology companies have employed intellectual property litigation as a way to gain a competitive advantage. If we become involved in litigation, interference proceedings, oppositions, reexamination, protest or other potentially adverse intellectual property proceedings as a result of alleged infringement by us of the rights of others or as a result of priority of invention disputes with third parties, we might have to spend significant amounts of money, time and effort defending our position and we may not be successful. In addition, any claims relating to the infringement of third-party proprietary rights or proprietary determinations, even if not meritorious, could result in costly litigation, lengthy governmental proceedings, divert management's attention and resources, or require us to enter into royalty or license agreements that are not advantageous to us. If we do not have the financial resources to support such litigation or appeals, we may forfeit or lose certain commercial rights. Even if we have the financial resources to continue such litigation or appeals, we may lose. In the event that we lose, we may be forced to pay very substantial damages; we may have to obtain costly license rights, which may not be available to us on acceptable terms, if at all; or we may be prohibited from selling products that are found to infringe the patent rights of others.

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.



***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 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, Bristol-Myers Squibb, Merck, Roche, Johnson & Johnson, Sanofi-Aventis and GlaxoSmithKline as well as smaller biotechnology or biopharmaceutical companies such as Arena Pharmaceuticals, Orexigen, Celgene, Vivus, Osiris, Geron, Aastrom, Stem Cells Inc., and Cytori Therapeutics. Most of our current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources, and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally.

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

Universities and public and private research institutions are also potential competitors. While these organizations primarily have educational objectives, they may develop proprietary technologies related to stem cells or secure patent protection that we may need for the development of our technologies and products. We may attempt to license these proprietary technologies, but these licenses may not be available to us on acceptable terms, if at all.

Our competitors, either alone or with their collaborative partners, may succeed in developing technologies or products that are more effective, safer, more affordable or more easily commercialized than ours, and our competitors may obtain intellectual property protection or commercialize products sooner than we do. Developments by others may render our product candidates or our technologies obsolete.

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

***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.

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

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

- we may have to issue convertible debt or equity securities to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock;
- an acquisition may negatively impact our results of operations because it may require us to incur large one-time charges to earnings, amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or it may cause adverse tax consequences, substantial depreciation or deferred compensation charges;
- we may encounter difficulties in assimilating and integrating the business, technologies, products, personnel or operations of companies that we acquire;
- certain acquisitions may disrupt our relationship with existing collaborators who are competitive to the acquired business;
- acquisitions may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient revenue to offset acquisition costs;
- an acquisition may disrupt our ongoing business, divert resources, increase our expenses and distract our management;
- acquisitions may involve the entry into a geographic or business market in which we have little or no prior experience; and
- key personnel of an acquired company may decide not to work for us.

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

***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.

***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.

***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, as well as liability insurance for conducting 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.

***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.

## **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 currently expires in March 2012, and we have an option to extend the lease in annual increments through March 2013 at our current rent of \$267,000 per year. Also, we currently lease office and laboratory space for our Belgian subsidiary. The lease currently expires in January 2012, and we have an option to renew annually through December 2014. The annual rent in Belgium is subject to adjustments based on an inflationary index.

## **ITEM 3. LEGAL PROCEEDINGS**

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

## **ITEM 3A. EXECUTIVE OFFICERS OF THE REGISTRANT**

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

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

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

### Gil Van Bokkelen, Ph.D.

Age: 50

*Dr. Van Bokkelen* has served as our Chief Executive Officer and Chairman since August 2000. Dr. Van Bokkelen co-founded Athersys in October 1995 and served as Chief Executive Officer and Director since Athersys' founding. Prior to May 2006, he also served as Athersys' President. Dr. Van Bokkelen is the current Chairman of the Alliance for Regenerative Medicine, a Washington D.C. based consortium of companies, patient advocacy groups, disease foundations, and clinical and research institutions that are committed to the advancement of the field of regenerative medicine. 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) and the Kent State University Board of Trustees from 2001 to 2004. He received his Ph.D. in Genetics from Stanford University, his B.A. in Economics from the University of California at Berkeley, and his B.A. in Molecular Biology from the University of California at Berkeley.

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

Age: 45

*Mr. Lehmann* has served as our President and Chief Operating Officer since June 2006. Mr. Lehmann joined Athersys in September 2001 and was Athersys' Executive Vice President of Corporate Development and Finance from August 2002 until June 2006, when he became Athersys' President and Chief Operating Officer. From 1994 to 2001, Mr. Lehmann was with McKinsey & Company, Inc., an international management consulting firm, where he worked extensively with new technology and service-based businesses in the firm's Business Building practice. Prior to joining McKinsey, he worked at Wilson, Sonsini, Goodrich & Rosati, a Silicon Valley law firm, and worked with First Chicago Corporation, a financial institution. Mr. Lehmann received his J.D. from Stanford University, his M.B.A. from the University of Chicago, and his B.A. from the University of Notre Dame.

John J. Harrington, Ph.D.

Age: 43

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

Robert J. Deans, Ph.D.

Age: 59

*Dr. Deans* has served as our Senior Vice President, Regenerative Medicine since June 2006. Dr. Deans has led Athersys' regenerative medicine research and development activities since February 2003 and has served as Vice President of Regenerative Medicine since October 2003, until he was named Senior Vice President of Regenerative Medicine in June 2006. Dr. Deans is highly regarded as an expert in stem cell therapeutics, with over fifteen 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 Therapeutics, Inc., a biotechnology company, from 1998 to 2001 and Director of Research and Development with the Immunotherapy Division of Baxter International, Inc., a global healthcare company, from 1992 to 1998. Dr. Deans was also previously on faculty at USC Medical School in Los Angeles, between 1981 and 1998, in the departments of Microbiology and Neurology at the Norris Comprehensive Cancer Center. Dr. Deans was an undergraduate at MIT, received his Ph.D. at the University of Michigan, and did his post-doctoral work at UCLA in Los Angeles.

Laura K. Campbell, CPA

Age: 47

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

**ITEM 4. RESERVED**

## 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.

	<u>High</u>	<u>Low</u>
<b>Year ended December 31, 2010:</b>		
First Quarter.....	\$ 4.40	\$ 2.32
Second Quarter.....	\$ 3.63	\$ 2.56
Third Quarter.....	\$ 3.55	\$ 2.34
Fourth Quarter.....	\$ 3.19	\$ 2.42
<b>Year ended December 31, 2009:</b>		
First Quarter.....	\$ 1.28	\$ 0.45
Second Quarter.....	\$ 1.04	\$ 0.75
Third Quarter.....	\$ 1.35	\$ 0.78
Fourth Quarter.....	\$ 6.40	\$ 0.97

#### **Holders**

As of February 28, 2011, the number of holders of record was approximately 694 of which one is Cede & Co., a nominee for The Depository Trust Company, or DTC. Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co., as one stockholder.

#### **Dividend Policy**

We would have to rely upon dividends and other payments from our wholly-owned subsidiary, ABT Holding Company, to generate the funds necessary to make dividend payments, if any, on our common stock. ABT Holding Company, however, is legally distinct from us and has no obligation to pay amounts to us. The ability of ABT Holding Company to make dividend and other payments to us is subject to, among other things, the availability of funds and applicable state laws. However, there are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us. We did not pay cash dividends on our common stock during the past two 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.

**ITEM 6. SELECTED FINANCIAL DATA**

(in thousands, except per share data)

	<b>Year Ended December 31,</b>				
	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Consolidated Statement of Operations Data:</b>					
<b>Revenues:</b>					
Contract revenue .....	\$ 6,685	\$ 1,079	\$ 1,880	\$ 1,433	\$ 1,908
Grant revenue .....	2,254	1,080	1,225	1,827	1,817
Total revenues .....	8,939	2,159	3,105	3,260	3,725
<b>Costs and expenses:</b>					
Research and development .....	14,779	11,920	16,500	15,817	9,741
General and administrative .....	5,387	5,621	5,479	7,975	3,347
Depreciation .....	284	233	218	283	528
Loss from operations .....	(11,511)	(15,615)	(19,092)	(20,815)	(9,891)
<b>Other (expense) income:</b>					
Other (expense) income, net .....	(69)	(126)	48	2,017	208
Interest income .....	203	375	1,146	1,591	119
Interest expense .....	—	—	(94)	(1,263)	(1,047)
Accretion of premium on convertible debt .....	—	—	—	(456)	(260)
Loss before cumulative effect of change in accounting principle .....	(11,377)	(15,366)	(17,992)	(18,926)	(10,871)
Cumulative effect of change in accounting principle .....	—	—	—	—	306
<b>Net loss</b> .....	<b>\$ (11,377)</b>	<b>\$ (15,366)</b>	<b>\$ (17,992)</b>	<b>\$ (18,926)</b>	<b>\$ (10,565)</b>
Preferred stock dividends .....	—	—	—	(659)	(1,408)
Deemed dividend resulting from induced conversion of convertible preferred stock .....	—	—	—	(4,800)	—
<b>Net loss attributable to common stockholders</b> .....	<b>\$ (11,377)</b>	<b>\$ (15,366)</b>	<b>\$ (17,992)</b>	<b>\$ (24,385)</b>	<b>\$ (11,973)</b>
<b>Basic and diluted net loss per common share attributable to common stockholders:</b>					
Loss before cumulative effect of change in accounting principle .....	\$ (0.60)	\$ (0.81)	\$ (0.95)	\$ (2.26)	\$ (41.89)
Cumulative effect of change in accounting principle .....	—	—	—	—	1.05
<b>Net loss per share</b> .....	<b>\$ (0.60)</b>	<b>\$ (0.81)</b>	<b>\$ (0.95)</b>	<b>\$ (2.26)</b>	<b>\$ (40.84)</b>
Weighted average shares outstanding, basic and diluted .....	18,929,749	18,928,379	18,927,988	10,811,119	293,142
<b>December 31,</b>					
	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents .....	\$ 2,105	\$ 11,167	\$ 12,552	\$ 13,248	\$ 1,528
Available-for-sale securities, short-term .....	13,076	10,135	15,460	22,477	—
Working capital (deficit) .....	9,106	16,291	26,789	32,849	(3,206)
Available-for-sale securities, long-term .....	—	5,080	3,601	13,850	—
Total assets .....	19,106	28,331	33,877	52,225	4,266
Long-term obligations, less current portion .....	—	—	—	—	9,310
Accrued dividends .....	—	—	—	—	8,882
Total stockholders' equity (deficit) .....	9,005	18,957	31,563	47,631	(20,007)



## **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 and Recent Developments**

We are a biopharmaceutical company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human life. Through the application of our proprietary technologies, we have established a pipeline of therapeutic product development programs in multiple disease areas. Our current product development portfolio includes MultiStem, a patented and proprietary stem cell product that we are developing as a treatment for multiple disease indications, and is currently being evaluated in clinical trials. In addition, we are developing novel pharmaceuticals to treat indications such as obesity and related metabolic conditions such as diabetes.

#### *Current Programs*

By applying our proprietary cell therapy platform, MultiStem, we have established therapeutic product development programs in the areas of treating cardiovascular disease, neurological disease, and immune system disorders. To date, we have advanced four programs to clinical development stage, including:

- An ongoing Phase II clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, the most common form of IBD. This study was authorized by the FDA in November 2010, and is being conducted with our partner Pfizer. This trial began enrolling patients in the study in February 2011;
- A Phase I clinical study involving administration of MultiStem to patients that have suffered an AMI, more commonly referred to as a heart attack. We successfully completed patient enrollment for this study in February 2010 and announced initial results in July 2010, demonstrating a consistent safety profile and encouraging signs of improvement in heart function among patients that had received treatment. We intend to initiate a Phase II study with our partner, Angiotech, to evaluate the safety and efficacy of MultiStem administration to AMI patients in 2011;
- An ongoing Phase I clinical study involving administration of MultiStem to patients suffering from leukemia or certain other blood-borne cancers, in which patients undergo radiation therapy and then receive a HSC transplant. Such patients are at risk for serious complications, including GVHD, which is an imbalance of immune system function caused by transplanted immune cells that attack various tissues and organs in the patient. In January 2011, we announced that we had successfully completed enrollment for the single ascending dose portion of this clinical trial and expect to announce preliminary results in the second quarter of 2011. In addition, the multiple ascending dose portion of this study is ongoing.
- An FDA authorized Phase I clinical study to evaluate administration of MultiStem to patients that have suffered an ischemic stroke. We are currently working with our clinical advisors to modify the proposed study design, including increasing the size of the study so that we can evaluate safety and efficacy.

In addition to our current and anticipated clinical development activities, we are also engaged in preclinical development and evaluation of MultiStem in other disease indications in the cardiovascular, neurological and immune disorder areas. 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 U.S. and in Europe.

We are also engaged in the development of novel small molecule therapies to treat obesity and related metabolic conditions, including diabetes, as well as other conditions. Currently we are focused on the development of potent, highly selective compounds that act through stimulation of a specific receptor in the brain that controls appetite — the 5HT<sub>2c</sub> serotonin receptor. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit outstanding selectivity, and intend to select a clinical development candidate for this program in 2011.

In September 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. The agreement provides for a \$5.0 million license fee paid in installments, of which \$3.0 million is guaranteed and \$2.0 million is contingent, potential milestone payments and tiered royalties on worldwide commercial sales of implants using our technologies. We are currently working with RTI to develop products for these applications.

*Financial*

In February 2011, we completed a registered direct offering generating 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 have incurred losses since inception of operations in December 1995 and had an accumulated deficit of \$205 million at December 31, 2010. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We have used the financing proceeds from private and public equity and debt offerings and other sources of capital to develop our technologies, to discover and develop therapeutic product candidates and to acquire certain technologies and assets. We have also built drug development capabilities that have enabled us to advance product candidates into clinical trials. We have established strategic collaborations that have provided revenues and capabilities to help further advance our product candidates, and we have also built a substantial portfolio of intellectual property.

**Results of Operations**

Since our inception, our revenues have consisted of contract revenues and milestone payments from our collaborators, and grant proceeds primarily from federal and state grants. We have derived no revenue from therapeutic products to date. Research and development expenses consist primarily of external clinical and preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property prosecution processes, facility costs, and laboratory supply and reagent costs. We expense research and development costs as they are incurred. We expect to continue to make significant investments in research and development to enhance our technologies, advance clinical trials of our product candidates, expand our regulatory affairs and product development capabilities, conduct preclinical studies of our product and manufacture our product candidates. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees and other corporate expenses. We expect to continue to incur substantial losses through at least the next several years.

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

**Revenues**

	<b>Year ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Contract revenue.....	\$ 6,685	\$ 1,079	\$ 1,880
Grant revenue .....	2,254	1,080	1,225
	<u>\$ 8,939</u>	<u>\$ 2,159</u>	<u>\$ 3,105</u>

## Research and development expenses

<i>Type of expense</i>	Year ended December 31,		
	2010	2009	2008
Personnel costs .....	\$ 4,124	\$ 3,607	\$ 2,924
Research supplies .....	1,218	907	849
Facilities .....	870	826	817
Clinical and preclinical development costs.....	4,394	1,904	7,878
Sponsored research.....	1,149	878	393
Patent legal fees.....	1,477	1,351	1,481
Other.....	1,002	1,151	1,431
Stock-based compensation.....	545	1,296	727
	<u>\$ 14,779</u>	<u>\$ 11,920</u>	<u>\$ 16,500</u>

## General and administrative expenses

<i>Type of expense</i>	Year ended December 31,		
	2010	2009	2008
Personnel costs .....	\$ 1,897	\$ 1,975	\$ 1,726
Facilities .....	279	299	342
Legal and professional fees .....	1,007	916	1,032
Other.....	1,283	919	1,250
Stock-based compensation.....	921	1,512	1,129
	<u>\$ 5,387</u>	<u>\$ 5,621</u>	<u>\$ 5,479</u>

### Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

*Revenues.* Revenues increased to \$8.9 million for the year ended December 31, 2010 from \$2.2 million for 2009. Contract revenue increased \$5.6 million for the year ended December 31, 2010 compared to the year ended December 31, 2009 primarily as a result of our collaboration with Pfizer that we entered into in December 2009 and our collaboration with RTI that we entered into in September 2010. Contract revenues for the year ended December 31, 2010 primarily consist of the recognition of revenue from these multi-element arrangements. We expect our contract revenues related to the Pfizer collaboration in 2011 and 2012 to reflect the amortization of the \$6.0 million non-refundable up-front license fee, research and development funding, and the performance of manufacturing services over the estimated performance period, and expect our contract revenues related to the RTI collaboration to reflect the amortization of the \$3.0 million license fee over the next several quarters aligned with the estimated performance period. Grant revenue increased \$1.2 million for the year ended December 31, 2010 compared to the year ended December 31, 2009 primarily due a grant received in October 2010 from the Internal Revenue Service under section 48D of the Internal Revenue Code aggregating \$733,000 for qualifying therapeutic discovery investments, as well as additional new grants that began late in 2009 and in 2010. Our grant revenues could fluctuate from period to period based on the timing of grant-related activities and the award of new grants.

*Research and Development Expenses.* Research and development expenses increased to \$14.8 million for the year ended December 31, 2010 from \$11.9 million in 2009. The increase of approximately \$2.9 million related primarily to an increase in clinical and preclinical development costs of \$2.5 million, an increase in personnel costs of \$517,000, an increase in research supply costs of \$311,000 and an increase in sponsored research costs of \$271,000 for the year ended December 31, 2010 compared to 2009. These increases were partially offset by a decrease in stock-based compensation expense of \$751,000, which declined as a result of a significant number of options becoming fully vested mid-2010. The increase in clinical and preclinical development costs for the year ended December 31, 2010 related primarily to increased manufacturing and process development costs, and costs associated with our MultiStem clinical trials. Our clinical costs for the year ended December 31, 2010 and 2009 are reflected net of Angiotech's cost-sharing amount of \$628,000 and \$847,000, respectively. The increase in personnel costs and research supplies related to the addition of personnel in support of our preclinical and clinical programs and regulatory affairs. Sponsored research costs increased primarily due to grant-funded programs that require collaboration with certain academic research institutions. We expect our research and development expenses to increase in 2011, primarily due to increased MultiStem clinical trial and clinical manufacturing expenses. 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 \$5.4 million in 2010 from \$5.6 million in 2009. The \$234,000 decrease was due primarily to a decrease in stock-based compensation expense of \$591,000, partially offset by an increase in other expenses of \$364,000 in 2010 compared to 2009. The decrease in stock-based compensation expense related to a significant number of options becoming fully vested mid-2010. The increase in other expenses for 2010 was primarily a result of increased investor and public relations costs and travel costs. We expect our general and administrative expenses to continue at similar levels in 2011.

*Depreciation.* Depreciation expense increased to \$284,000 in 2010 from \$233,000 in 2009. The increase in depreciation expense was due to depreciation on capital purchases made in 2010.

*Other Expense.* Included in other expense are impairment losses of \$46,000 and \$115,000 in 2010 and 2009, respectively, related to an investment in a privately-held company.

*Interest Income.* Interest income decreased to \$203,000 in 2010 from \$375,000 in 2009. The change in interest income was due to the decline in cash and investment balances during the period. We expect our 2011 interest income to continue at similar levels in 2011, taking into consideration the expected increase in our clinical development costs in 2011 and the investment of the proceeds from the February 2011 equity offering.

#### ***Year Ended December 31, 2009 Compared to Year Ended December 31, 2008***

*Revenues.* Revenues decreased to \$2.2 million for the year ended December 31, 2009 from \$3.1 million for 2008. Contract revenues for the year ended December 31, 2009 included \$171,000 of revenues from Pfizer in connection with our collaboration agreement entered into in December 2009. Also included in contract revenues are license fees and milestone payments from our collaboration with Bristol-Myers Squibb, which decreased in 2009 as a result of a decline in activity and as a result of a clinical development milestone achieved in September 2008. We intend to continue to prepare and deliver validated drug targets as needed by Bristol-Myers Squibb for use in its drug discovery efforts, and will remain entitled to receive license fees, milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology. Grant revenue decreased \$145,000 primarily due to the completion of a state grant in 2008 and due to the timing of expenditures that are reimbursed with grant proceeds.

*Research and Development Expenses.* Research and development expenses decreased to \$11.9 million in 2009 from \$16.5 million in 2008. The decrease of \$4.6 million related primarily to a decrease in clinical and preclinical development costs of \$6.0 million, a decrease in other research and development expenses of \$280,000 and a decrease in patent legal fee expense of \$130,000 in 2009 compared to 2008. These decreases were partially offset by an increase in personnel costs of \$683,000, an increase in stock-based compensation expense of \$569,000, an increase in sponsored research of \$485,000, and an increase in research supplies and facilities expenses of \$67,000 in 2009 compared to 2008. Of the \$6.0 million decrease in clinical and preclinical development costs, \$5.3 million related to costs associated with the completion of an ATHX-105 Phase I clinical trial in the first half of 2008 and preparations for a Phase II clinical trial of ATHX-105 in 2008, which included several preclinical studies and manufacturing costs. ATHX-105 development was suspended early in 2009 and there will be no future costs incurred for this product candidate. The remaining \$700,000 decrease in clinical and preclinical development costs related primarily to a \$235,000 credit from a renegotiated contract with a contract research organization in June 2009, reduced manufacturing costs associated with our MultiStem clinical trials, and reduced external costs for regulatory consulting and preclinical studies. Our clinical costs in 2009 and 2008 are reflected net of Angiotech's cost-sharing reimbursements related to our MultiStem acute myocardial infarction collaboration in the amount of \$847,000 and \$943,000, respectively. Patent legal fee expense for 2009 decreased compared to 2008, but continued to be significant as a result of further development and maintaining our portfolio of patent applications. The increase in personnel costs related to the addition of personnel in support of our clinical programs and regulatory affairs, a 2009 company-wide performance bonus, salary increases and increased benefit costs. The increase in stock-based compensation expense related to a change in our estimated forfeiture rate, increased expense related to options held by certain consultants that are computed using variable accounting, and the issuance of stock option awards in 2009. Sponsored research costs increased primarily due to grant-funded programs that require collaboration with certain 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 increased to \$5.6 million in 2009 from \$5.5 million in 2008. The \$100,000 increase was due primarily to an increase in stock-based compensation expense of \$383,000 and an increase in personnel costs of \$249,000, partially offset by a decrease in other expenses of \$331,000, a decrease in legal and professional fees of \$116,000 and a decrease in facilities expense of \$43,000 in 2009 compared to 2008. The increase in stock-based compensation expense related to a change in our estimated forfeiture rate and the issuance of stock option awards in 2009. The increase in personnel costs related to a 2009 company-wide performance bonus, salary increases and increased benefit costs. The decrease in other expenses for 2009 was primarily a result of reduced temporary help and outsourced accounting services in 2009. The decrease in legal and professional fees in 2009 was primarily a result of reduced legal fees incurred in connection with SEC filings and transactional work.

*Depreciation.* Depreciation expense increased to \$233,000 in 2009 from \$218,000. The increase in depreciation expense was due to depreciation on capital purchases made in 2009.

*Other Expense.* Included in other expense for 2009 is an impairment loss of \$115,000 related to an investment in a privately-held company.

*Interest Income.* Interest income decreased to \$375,000 in 2009 from \$1.1 million in 2008. The change in interest income was due to the decline in cash and investment balances during the period. While we received \$6.0 million in fees from Pfizer in 2009, this payment had limited impact on interest income given its receipt in late December 2009.

*Interest Expense.* Interest expense decreased to \$0 in 2009 from \$94,000 in 2008 due to the repayment of our senior loan in June 2008.

## **Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and available-for-sale securities. At December 31, 2010, we had \$2.1 million in cash and cash equivalents and \$13.1 million in available-for-sale securities. We have primarily financed our operations through private equity and debt 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 February 2011, we completed a registered direct offering generating 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.

Our former lenders retain a right to receive a milestone payment of \$2.25 million upon the occurrence of certain events as follows: (1) the entire amount upon (a) the merger with or into another entity where our stockholders do not hold at least a majority of the voting power of the surviving entity, (b) the sale of all or substantially all of our assets, or (c) our liquidation or dissolution; or (2) a portion of the amount from proceeds of equity financings not tied to specific research and development activities that are part of a research or development collaboration, in which case, the lenders will receive an amount equal to 10% of proceeds above \$5.0 million in cumulative gross proceeds until the milestone amount is paid in full. The milestone payment is payable in cash, except that if the milestone event is (2) above, we may elect to pay 75% of the milestone in shares of common stock at the per-share offering price. No amounts have been recorded for the milestone in December 31, 2010, 2009 or 2008. In connection with the offering in February 2011, the lenders were entitled to a milestone payment under this obligation in the amount of \$810,000, of which \$202,500 was paid in cash in February 2011 and \$607,500 was paid through the issuance of our common stock to the former lenders at \$2.96 per share. The senior lenders also received warrants to purchase 149,026 shares of common stock with an exercise price of \$5.00 upon the closing of our equity offering in June 2007. The exercise of such warrants could provide us with cash proceeds. No warrants were exercised at December 31, 2010.

In December 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem for the treatment of IBD for the worldwide market. Under the terms of the agreement, we received a non-refundable up-front cash payment of \$6 million from Pfizer and will also receive research funding and support. 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 any milestones. Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase III clinical development.

In connection with our MultiStem collaboration with Angiotech, upon the successful achievement of specified clinical development and commercialization milestones, we may also receive up to \$63.75 million of aggregate cash payments and \$3.75 million from an additional equity investment, though there can be no assurance that we will achieve any milestones. Under the terms of the collaboration, the parties are jointly funding clinical development activity, whereby preclinical costs are borne solely by us, costs for Phase I and Phase II clinical trials are borne 50% by us and 50% by Angiotech, costs for the first Phase III clinical trial will be borne 33% by us and 67% by Angiotech, and costs for any subsequent Phase III clinical trial will be borne 25% by us and 75% by Angiotech. We have lead responsibility for preclinical and early clinical development and manufacturing of the MultiStem product, and Angiotech has lead responsibility for later clinical trials and commercialization. Upon product commercialization, we will receive nearly half of the net profits from the sale of any jointly developed, approved products. In January 2011, Angiotech announced its plans to pursue a recapitalization transaction through its voluntary filing under the Companies' Creditors Arrangement Act in Canada. In the event that Angiotech elects not to continue with our collaboration, Angiotech would return all rights to us and we would have an outstanding claim related to Angiotech's reimbursement of our fourth quarter 2010 collaboration costs and the costs through January 28, 2011, which was Angiotech's petition date. In the event that Angiotech fails to fund its obligations under the terms of our collaboration agreement, our net costs for subsequent AMI clinical trials would increase or alternative funding would be required for such clinical trials.

In September 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 the agreement, we are entitled to a \$5.0 million license fee paid in installments, of which \$3.0 million is guaranteed and \$2.0 million is contingent, of which \$2.0 million has been received by December 31, 2010. We are also eligible to receive an additional \$35.5 million in cash payments upon the successful achievement of certain development and commercial milestones, though there can be no assurance that we will achieve any milestones. In addition, we will receive tiered royalties on worldwide commercial sales of implants using our technologies.

Our collaboration agreement with Bristol-Myers Squibb, which was initially established in 2001, is now in its final phase since the requirement for Bristol-Myers Squibb to nominate new targets ended in 2009. We are preparing and delivering the final validated drug target for use by Bristol-Myers Squibb in its drug discovery efforts under the collaboration and do not expect any significant demand for new targets. We will remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb over the course of the 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 milestones or royalties.

In October 2010, we were awarded grants from the Internal Revenue Service under section 48D of the Internal Revenue Code aggregating \$733,000 for qualifying therapeutic discovery investments that have been incurred.

Our available-for-sale securities typically include U.S. government obligations and corporate debt securities. As of December 31, 2010, approximately 85% of our investments were in U.S. government obligations, including government-backed agencies. We have been investing conservatively due to 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. Also, although these 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 testing and clinical trials of our product candidates. We expect to have available cash to fund our operations through 2011 based on our current business and operational plans and assuming no new financings or collaborations. Our capital requirements beyond that will depend on a number of factors, including scientific progress in our research and development programs, additional personnel costs, progress in preclinical testing and clinical trials, and the costs in filing and prosecuting patent applications and enforcing patent claims. Further, these requirements may change at any time due to technological advances or competition from other companies. We will continue to explore and consider new opportunities for funding our operations and activities through grants and business partnerships involving our technologies and product candidates, as well as selling equity securities and possibly borrowings from financial institutions. We cannot assure you that adequate funding will be available to us or, if available, that it will be available on acceptable terms. Any shortfall in funding could result in our having to curtail research and development efforts.

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, obtaining regulatory approval or clearances for, and commercializing our technologies and products resulting from these technologies.

Net cash used in operating activities was \$10.6 million, \$4.6 million and \$15.7 million in 2010, 2009 and 2008, respectively, and represented the use of cash in funding clinical and preclinical product development activities. We expect that net cash used in operating activities will increase in 2011 in connection with increased research and development expenses of our MultiStem clinical trials and our Pfizer and Angiotech collaborations.

Net cash provided by investing activities was \$1.5 million in 2010, \$3.2 million in 2009 and \$16.8 million in 2008. The fluctuations from period to period are due to the timing of purchases and maturity dates of investments and the purchase of equipment. Purchases of equipment were \$390,000, \$381,000 and \$532,000 in 2010, 2009 and 2008, respectively. We expect that our capital equipment expenditures will continue at similar levels in 2011 compared to 2010.

Financing activities neither used nor provided cash in 2010 and 2009, and used cash of \$1.8 million in 2008 related to repayment of our senior loan in 2008.

Investors in our equity offering in June 2007 received five-year warrants to purchase an aggregate of 3,250,000 shares of common stock with an exercise price of \$6.00 per share. The lead investor in the June offering, Radius Venture Partners, invested \$10.0 million and received additional five-year warrants to purchase an aggregate of 500,000 shares of common stock with a cash or cashless exercise price of \$6.00 per share. The placement agents for the June 2007 offering received five-year warrants to purchase an aggregate of 1,093,525 shares of common stock with a cash or cashless exercise price of \$6.00 per share. Also, bridge investors received in the June 2007 offering five-year warrants to purchase an aggregate of 132,945 shares of common stock with an exercise price of \$6.00 per share. The exercise of such warrants could provide us with cash proceeds. No warrants have been exercised at December 31, 2010.

Our contractual payment obligations as of December 31, 2010 are as follows:

**Payment due by Period**

<u>Contractual Obligations</u>	<u>Total</u>	<u>Less than 1 Year</u>	<u>1 – 3 Years</u>	<u>3 – 5 Years</u>	<u>More than 5 Years</u>
Operating leases for facilities and equipment lease.....	\$ 487,000	\$ 390,000	\$ 97,000	\$ —	\$ —
Research funding .....	465,000	327,000	138,000	—	—
Total.....	<u>\$ 952,000</u>	<u>\$ 717,000</u>	<u>\$ 235,000</u>	<u>\$ —</u>	<u>\$ —</u>

We lease office and laboratory space under an operating lease and have options to renew the lease in annual increments through March 2013 at the initial rental rate, and we executed options to renew through March 2012. Also, we lease office and laboratory space for our Belgian subsidiary that includes options to renew annually through December 2014 and the annual rent is subject to adjustments based on an inflationary index. We executed an option to renew this lease through January 2012.

The research funding in the table above represents our current funding commitment for a research program that began in 2007. We approved the funding for the final stage of the collaboration that will continue through August 2012.

We filed a resale registration statement with the SEC for 18,508,251 shares of common stock, which includes all shares of common stock issued in the equity offering in June 2007 and shares of common stock issuable upon exercise of the warrants issued in the offering (as well as the 531,781 shares of common stock issued to the bridge investors and the 132,945 shares underlying their warrants). The resale registration statement was declared effective by the SEC on October 18, 2007. Under the registration rights agreement entered into in connection with the offering, subject to certain exceptions, if the resale registration statement ceases to remain effective, a 1% cash penalty will be assessed for each 30-day period until the registration statement becomes effective again, capped at 10% of the aggregate gross proceeds we received from the equity offering. Because the penalty is based on the number of unregistered shares of common stock held by investors in the offering, our maximum penalty exposure will decline over time as investors sell their shares of common stock that were included in the registration statement.

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

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

***Revenue Recognition***

Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, manufacturing revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under Accounting Standards Codification, or ASC, 605-25, Multiple-Element Arrangements, (which originated primarily from the guidance in EITF 00-21) 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 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 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 consolidated financial statements included in this annual report on Form 10-K.

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 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.

#### ***Clinical Trial Costs***

Clinical trial costs are accrued based on work performed by outside contractors who manage and perform the trials. We obtain initial estimates of total costs based on enrollment of subjects, project management estimates and other activities. Actual costs are typically charged to us and recognized as the tasks are completed by the contractor. 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. Since such actual costs are typically invoiced as incurred or based on contractual amounts for services rendered, the amounts are generally not susceptible to significant changes in estimates.

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

We determine the appropriate classification of investment securities at the time of purchase and re-evaluate such designation as of each balance sheet date. Our investments typically consist primarily of United States government obligations and corporate debt securities, which are classified as available-for-sale and are valued based on quoted prices in active markets for identical assets (Level 1). Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported as a component of accumulated other comprehensive income. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization or accretion is included in interest income. Realized gains and losses on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method.

Interest earned on securities classified as available-for-sale is included in interest income. Since the elements related to accounting for these investments are reflected on monthly statements, the amounts are not based on estimates that are susceptible to change. None of our financial assets are in markets that are not active.

### ***Stock-Based Compensation***

We recognize stock-based compensation expense on the straight-line method and use a Black-Scholes option-pricing model to estimate the grant-date fair value of share-based awards. The expected term of options granted represent the period of time that option grants are expected to be outstanding. We use the "simplified" method to calculate the expected life of option grants given our limited history and beginning in 2010, determine volatility by using our historical stock volatility. Prior to 2010, we determined volatility by using the historical stock volatility of other companies with similar characteristics since we did not have meaningful historical volatility of our own stock at that time. 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.

### **Recently Issued Accounting Standards**

In September 2009, ASC 605-25, *Multiple-Element Arrangements*, was updated (Accounting Standards Update, or ASU, No. 2009-13) related to revenue recognition for arrangements with multiple elements. The revised guidance provides for two significant changes to the existing guidance, the first relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting, which will likely result in the requirement to separate more deliverables within an arrangement leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Together, these changes are likely to result in earlier recognition of revenue for multiple-element arrangements than under previous guidance. The new guidance also significantly expands the disclosures required for multiple-element revenue arrangements. The new guidance is effective for the Company for new arrangements entered into on or after January 1, 2011. The future adoption of this new guidance may have the potential effect of less revenue deferral for new collaborations than we have historically experienced.

In March 2010, ASC 605-28, *Milestone Method of Revenue Recognition*, was amended (ASU No. 2010-17) related to the ratification of the application of the proportional performance model of revenue recognition when applied to milestones in research and development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The new guidance is effective for the Company for new arrangements entered into on or after January 1, 2011. This new guidance will not have a material effect on our financial statements upon adoption, since we have been historically recognizing milestone revenue consistent with this guidance.

## 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,” “will,” or other similar 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:

- the possibility of delays in, adverse results of and excessive costs of the development process;
- our ability to successfully initiate and complete clinical trials;
- changes in external market factors;
- changes in our industry’s overall performance;
- changes in our business strategy;
- our ability to protect our intellectual property portfolio;
- our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;
- our ability to meet milestones under our collaboration agreements;
- our collaborators’ ability to continue to fulfill their obligations under the terms of our collaboration agreements;
- 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 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.

## **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, if any. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Due in part to these factors, our future investment income may fall short of expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates. We invest our excess cash primarily in debt instruments of the U.S. government and its agencies and corporate debt securities. As of December 31, 2010, approximately 85% of our investments were in U.S. government obligations, including government-backed agencies. We have been investing conservatively due to the current economic conditions, including the current credit crisis, 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, 2010, we had no borrowings outstanding.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

### CONSOLIDATED FINANCIAL STATEMENTS

Athersys, Inc.  
Years Ended December 31, 2010, 2009 and 2008

Athersys, Inc.

Consolidated Financial Statements

Years Ended December 31, 2010, 2009 and 2008

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
Athersys, Inc.

We have audited the accompanying consolidated balance sheets of Athersys, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Athersys, Inc. at December 31, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U. S. generally accepted accounting principles.

Cleveland, Ohio  
March 25, 2011

/s/ ERNST & YOUNG LLP

Athersys, Inc.

Consolidated Balance Sheets

(In Thousands, Except Share and Per Share Amounts)

	<u>December 31,</u>	
	<u>2010</u>	<u>2009</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents .....	\$ 2,105	\$ 11,167
Available-for-sale securities .....	13,076	10,135
Accounts receivable.....	2,328	352
Receivable from Angiotech .....	106	229
Investment interest receivable .....	71	93
Prepaid expenses and other.....	258	173
Total current assets .....	<u>17,944</u>	<u>22,149</u>
Available-for-sale securities .....	—	5,080
Deposits and other .....	38	38
Equipment, net.....	955	849
Equity investments .....	169	215
Total assets .....	<u>\$ 19,106</u>	<u>\$ 28,331</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable.....	\$ 1,498	\$ 1,128
Accrued compensation and related benefits.....	580	667
Accrued clinical trial costs.....	207	83
Accrued expenses .....	1,012	857
Deferred revenue .....	5,541	3,123
Total current liabilities.....	<u>8,838</u>	<u>5,858</u>
Deferred revenue .....	1,263	3,516
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at December 31, 2010 and December 31, 2009.....	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized, 18,930,678 and 18,929,333 shares issued and outstanding at December 31, 2010 and December 31, 2009, respectively .....	19	19
Additional paid-in capital .....	214,174	212,704
Accumulated other comprehensive income .....	26	71
Accumulated deficit.....	(205,214)	(193,837)
Total stockholders' equity .....	<u>9,005</u>	<u>18,957</u>
Total liabilities and stockholders' equity .....	<u>\$ 19,106</u>	<u>\$ 28,331</u>

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Operations

(In Thousands, Except Share and Per Share Amounts)

	<u>Year Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
<b>Revenues</b>			
Contract revenue.....	\$ 6,685	\$ 1,079	\$ 1,880
Grant revenue .....	<u>2,254</u>	<u>1,080</u>	<u>1,225</u>
Total revenues.....	<b>8,939</b>	<b>2,159</b>	<b>3,105</b>
<b>Costs and expenses</b>			
Research and development (including stock compensation expense of \$545, \$1,296 and \$727 in 2010, 2009 and 2008, respectively) .....	14,779	11,920	16,500
General and administrative (including stock compensation expense of \$921, \$1,512 and \$1,129 in 2010, 2009 and 2008, respectively) .....	5,387	5,621	5,479
Depreciation .....	<u>284</u>	<u>233</u>	<u>218</u>
Total costs and expenses.....	<u>20,450</u>	<u>17,774</u>	<u>22,197</u>
Loss from operations .....	(11,511)	(15,615)	(19,092)
Other (expense) income, net.....	(69)	(126)	48
Interest income .....	203	375	1,146
Interest expense .....	—	—	(94)
Net loss .....	<u>\$ (11,377)</u>	<u>\$ (15,366)</u>	<u>\$ (17,992)</u>
<b>Basic and diluted net loss per common share.....</b>	<b>\$ (0.60)</b>	<b>\$ (0.81)</b>	<b>\$ (0.95)</b>
<b>Weighted average shares outstanding, basic and diluted.....</b>	<b>18,929,749</b>	<b>18,928,379</b>	<b>18,927,988</b>

See accompanying notes.



Athersys, Inc.

Consolidated Statements of Stockholders' Equity

(In Thousands, Except Share Amounts)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Stated Value	Number of Shares	Par Value				
Balance at January 1, 2008.....	—	\$ —	18,927,988	\$ 19	\$ 208,039	\$ 52	\$ (160,479)	\$ 47,631
Stock based compensation.....	—	—	—	—	1,856	—	—	1,856
Comprehensive loss:								
Net loss .....	—	—	—	—	—	—	(17,992)	(17,992)
Unrealized gain on available-for-sale securities .....	—	—	—	—	—	68	—	68
Total comprehensive loss.....	—	—	—	—	—	—	—	(17,924)
<b>Balance at December 31, 2008</b>	—	—	<b>18,927,988</b>	<b>19</b>	<b>209,895</b>	<b>120</b>	<b>(178,471)</b>	<b>31,563</b>
Stock based compensation.....	—	—	—	—	2,808	—	—	2,808
Issuance of common stock.....	—	—	1,345	—	1	—	—	1
Comprehensive loss:								
Net loss .....	—	—	—	—	—	—	(15,366)	(15,366)
Unrealized loss on available-for-sale securities .....	—	—	—	—	—	(49)	—	(49)
Total comprehensive loss.....	—	—	—	—	—	—	—	(15,415)
<b>Balance at December 31, 2009</b>	—	—	<b>18,929,333</b>	<b>19</b>	<b>212,704</b>	<b>71</b>	<b>(193,837)</b>	<b>18,957</b>
Stock based compensation.....	—	—	—	—	1,466	—	—	1,466
Issuance of common stock.....	—	—	1,345	—	4	—	—	4
Comprehensive loss:								
Net loss .....	—	—	—	—	—	—	(11,377)	(11,377)
Unrealized loss on available-for-sale securities .....	—	—	—	—	—	(45)	—	(45)
Total comprehensive loss.....	—	—	—	—	—	—	—	(11,422)
<b>Balance at December 31, 2010</b>	—	\$ —	<b>18,930,678</b>	<b>\$ 19</b>	<b>\$ 214,174</b>	<b>\$ 26</b>	<b>\$ (205,214)</b>	<b>\$ 9,005</b>

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Operating activities</b>			
Net loss .....	\$ (11,377)	\$ (15,366)	\$ (17,992)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation .....	284	233	218
Gain on sale of equipment .....	—	(21)	(24)
Provision on notes receivable .....	—	—	74
Stock-based compensation .....	1,466	2,808	1,856
Amortization of premium on available-for-sale securities and other .....	225	305	28
Changes in operating assets and liabilities:			
Accounts receivable .....	(1,976)	(92)	618
Receivable from Angiotech .....	123	5	(171)
Prepaid expenses and other assets .....	(63)	449	178
Accounts payable and accrued expenses .....	562	479	(467)
Deferred revenue .....	165	6,581	(29)
Net cash used in operating activities .....	<b>(10,591)</b>	<b>(4,619)</b>	<b>(15,711)</b>
<b>Investing activities</b>			
Purchase of available-for-sale securities .....	(8,834)	(11,692)	(26,594)
Proceeds from maturities of available-for-sale securities .....	10,753	15,300	43,917
Investment in privately-held company .....	—	(14)	—
Proceeds from sale of equipment .....	—	21	24
Purchases of equipment .....	(390)	(381)	(532)
Net cash provided by investing activities .....	<b>1,529</b>	<b>3,234</b>	<b>16,815</b>
<b>Financing activities</b>			
Principal payments on debt .....	—	—	(1,800)
Net cash used in financing activities .....	—	—	(1,800)
Decrease in cash and cash equivalents .....	(9,062)	(1,385)	(696)
Cash and cash equivalents at beginning of year .....	11,167	12,552	13,248
Cash and cash equivalents at end of year .....	<b>\$ 2,105</b>	<b>\$ 11,167</b>	<b>\$ 12,552</b>

See accompanying notes.

*Athersys, Inc.*

*Notes to Consolidated Financial Statements*

**A. Background**

We are a biopharmaceutical company engaged in the discovery and development of therapeutic products in one business segment. 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.

**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*, (which originated primarily from the guidance in EITF 00-21) 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 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.

**B. Accounting Policies, continued**

**Revenue Recognition, continued**

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. Included in 2010 grant revenues is a grant of \$733,000 received from the Internal Revenue Service under section 48D of the Internal Revenue Code for qualifying therapeutic discovery investments that have been incurred.

**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.

*Notes to Consolidated Financial Statements, (continued)*

**B. Accounting Policies, continued**

**Research and Development**

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

**Collaborative Arrangements**

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

**Clinical Trial Costs**

Clinical trial costs are accrued based on work performed by outside contractors, who manage and perform the trials. We obtain initial estimates of total costs based on enrollment of subjects, project management estimates and other activities. Actual costs are typically charged to us and recognized as the tasks are completed by the contractor. 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 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, 2010.

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

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

**Long-Lived Assets**

Equipment is stated at acquired cost less accumulated depreciation. Laboratory and office equipment are depreciated on the straight-line basis over the estimated useful lives (three to seven years).

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.

*Notes to Consolidated Financial Statements, (continued)*

**B. Accounting Policies, continued**

In connection primarily with a milestone that was achieved in 2006, we and an affiliate own preferred stock in a privately-held company with an aggregate value of approximately \$300,000. We evaluated this cost-method investment and deemed the investment to be other-than-temporarily impaired at March 31, 2010 and December 31, 2009, recognizing \$46,000 and \$115,000 of impairment loss in 2010 and 2009, respectively. No impairment losses were recorded in 2008.

**Patent Costs and Rights**

Costs of prosecuting and maintaining patents and patent rights are expensed as incurred. As of December 31, 2010, we have filed for broad intellectual property protection on our proprietary technologies. We currently have numerous U.S. patent applications and corresponding international patent applications related to our technologies, as well as many issued U.S. and international patents.

**Comprehensive Income (Loss)**

Unrealized gains and losses on our available-for-sale securities are the only components of accumulated other comprehensive income (loss). Total comprehensive income or loss is disclosed in the consolidated statement of stockholders' equity.

**Concentration of Credit Risk**

Accounts receivable are subject to concentration of credit risk due to the absence of a large number of customers. At December 31, 2010, three customers accounted for 83% of accounts receivable. We do not require collateral from our customers.

**Use of Estimates**

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

**Stock-Based Compensation**

We recognize stock-based compensation expense on the straight-line method and use a Black-Scholes option-pricing model to estimate the 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 beginning in 2010, determine volatility by using our historical stock volatility. Prior to 2010, we determined volatility by using the historical stock volatility of other companies with similar characteristics since we did not have meaningful historical volatility of our own stock at that time. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

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

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

*Athersys, Inc.*

*Notes to Consolidated Financial Statements, (continued)*

**B. Accounting Policies, continued**

The following weighted-average input assumptions were used in determining the fair value:

	<b>December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Volatility.....	<b>119.5%</b>	89.5%	69.6%
Risk-free interest rate.....	<b>1.0%</b>	2.4%	3.0%
Expected life of option .....	<b>4.09 years</b>	5.01 years	5.09 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, 2010 and 2009. 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:

- Outstanding stock options to purchase 4,308,013, 4,001,149 and 3,738,473 shares of common stock for the years ended December 31, 2010, 2009 and 2008, respectively; and
- Warrants to purchase 5,125,496 shares of common stock for each of the years ended December 31, 2010, 2009 and 2008.

**Recently Issued Accounting Standards**

In September 2009, ASC 605-25, *Multiple-Element Arrangements*, was updated (Accounting Standards Update (“ASU”) No. 2009-13) related to revenue recognition for arrangements with multiple elements. The revised guidance provides for two significant changes to the existing guidance, the first relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting, which will likely result in the requirement to separate more deliverables within an arrangement leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Together, these changes are likely to result in earlier recognition of revenue for multiple-element arrangements than under previous guidance. The new guidance also significantly expands the disclosures required for multiple-element revenue arrangements. The new guidance is effective for the Company for new arrangements entered into on or after January 1, 2011. The future adoption of this new guidance may have the potential effect of less revenue deferral for new collaborations than we have historically experienced.

Notes to Consolidated Financial Statements, (continued)

**B. Accounting Policies, continued**

In March 2010, ASC 605-28, *Milestone Method of Revenue Recognition*, was amended (ASU No. 2010-17) related to the ratification of the application of the proportional performance model of revenue recognition when applied to milestones in research and development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The new guidance is effective for the Company for new arrangements entered into on or after January 1, 2011. This new guidance will not have a material effect on our financial statements upon adoption, since we have been historically recognizing milestone revenue consistent with this guidance.

**Reclassifications**

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

**C. Equipment**

Equipment consists of (in thousands):	December 31,	
	2010	2009
Laboratory equipment.....	\$ 5,915	\$ 6,262
Office equipment and leasehold improvements.....	3,731	3,639
	9,646	9,901
Accumulated depreciation .....	(8,691)	(9,052)
	<u>\$ 955</u>	<u>\$ 849</u>

**D. Financial Instruments**

*Investments in Available-for-Sale Securities*

Our available-for-sale securities typically include U.S. government obligations and corporate debt securities. As of December 31, 2010, approximately 85% of our investments were in U.S. government obligations, including government-backed agencies.

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 of December 31, 2010 (in thousands):

Description	Balance as of December 31, 2010	Fair Value Measurements at December 31, 2010 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities .....	\$ 13,076	\$ 13,076	\$ —	\$ —

Fair value is based upon quoted market prices in active markets. We had no Level 2 or Level 3 assets at December 31, 2010. 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 to a fair value measurement may result in a reclassification between hierarchy levels. There have been no such reclassifications.

*Athersys, Inc.*

*Notes to Consolidated Financial Statements, (continued)*

**D. Financial Instruments, continued**

The following is a summary of available-for-sale securities (in thousands) at December 31, 2010 and 2009, respectively:

	<u>Amortized Cost</u>	<u>Gross Unrealized Losses</u>	<u>Gross Unrealized Gains</u>	<u>Estimated Fair Value</u>
December 31, 2010:				
U.S. government obligations, including government-backed agencies .....	\$ 11,034	\$ —	\$ 23	\$ 11,057
Corporate debt securities .....	<u>2,016</u>	<u>—</u>	<u>3</u>	<u>2,019</u>
	<b><u>\$ 13,050</u></b>	<b><u>\$ —</u></b>	<b><u>\$ 26</u></b>	<b><u>\$ 13,076</u></b>
December 31, 2009:				
U.S. government obligations, including government-backed agencies .....	\$ 12,613	\$ (12)	\$ 52	\$ 12,653
Corporate debt securities .....	<u>2,531</u>	<u>—</u>	<u>31</u>	<u>2,562</u>
	<b><u>\$ 15,144</u></b>	<b><u>\$ (12)</u></b>	<b><u>\$ 83</u></b>	<b><u>\$ 15,215</u></b>

We had no realized gains or losses on the sale of available-for-sale securities for any of the periods presented. Unrealized gains and losses on our available-for-sale securities are excluded from earnings and are reported as a separate component of stockholders' equity within accumulated other comprehensive income until realized. When available-for-sale securities are sold in the future, the cost of the securities will be specifically identified and used to determine any realized gain or loss. The net unrealized gain on available-for-sale securities was \$26,000 and \$71,000 as of December 31, 2010 and 2009, respectively.

The amortized cost of and estimated fair value of available-for-sale securities at December 31, 2010 by contractual maturity are shown below (in thousands). Actual maturities may differ from contractual maturities because the issuers of the securities may have the right to repay the obligations without prepayment penalties.

	<u>December 31, 2010</u>	
	<u>Amortized Cost</u>	<u>Estimated Fair Value</u>
Due in one year or less .....	\$ 13,050	\$ 13,076
Due after one year through two years .....	<u>—</u>	<u>—</u>
	<b><u>\$ 13,050</u></b>	<b><u>\$ 13,076</u></b>

*Financing Arrangements*

We lease office and laboratory space under an operating lease and have options to renew the lease in annual increments through March 2013 at the initial rental rate, and we executed options to renew through March 2012. Also, we entered into a lease agreement for office and laboratory space for our Belgian subsidiary, which includes options to renew annually through December 2014, subject to adjustments based on an inflationary index, and the lease included an option to expand that was exercised in 2009. We executed an option to renew this lease through January 2012.

Aggregate rent expense was approximately \$387,000, \$337,000, and \$314,000 in 2010, 2009 and 2008, respectively. The future annual minimum lease commitments at December 31, 2010 are approximately \$390,000 for 2011, \$93,000 for 2012 and \$4,000 for 2013.



*Notes to Consolidated Financial Statements, (continued)*

**D. Financial Instruments, continued**

Our former lenders retain a right to receive a milestone payment of \$2.25 million upon the occurrence of certain events as follows: (1) the entire amount upon (a) the merger with or into another entity where our stockholders do not hold at least a majority of the voting power of the surviving entity, (b) the sale of all or substantially all of our assets, or (c) our liquidation or dissolution; or (2) a portion of the amount from proceeds of equity financings not tied to specific research and development activities that are part of a research or development collaboration, in which case, the lenders will receive an amount equal to 10% of proceeds above \$5.0 million in cumulative gross proceeds until the milestone amount is paid in full. The milestone payment is payable in cash, except that if the milestone event is (2) above, we may elect to pay 75% of the milestone in shares of common stock at the per-share offering price. No amounts have been recorded for the milestone in December 31, 2010, 2009 or 2008. In connection with our February 2011 equity offering, the lenders were entitled to a milestone payment under this obligation in the amount of \$810,000, of which \$202,500 was paid in cash in February 2011 and \$607,500 was paid through the issuance of our common stock to the former lenders at \$2.96 per share. We paid no interest during the years ended December 31, 2010 and 2009, and \$76,000 during the year ended December 31, 2008.

**E. Collaborations and Revenue Recognition**

*Pfizer*

In December 2009, we entered into a collaboration with Pfizer to develop and commercialize MultiStem to treat inflammatory bowel disease ("IBD") for the worldwide market. Under the terms of the agreement, we received a non-refundable up-front license and technology access payment of \$6.0 million from Pfizer and receive research funding and support. In addition, we are also 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. No revenue for milestones was recognized in 2010 or 2009.

Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at phase III clinical development.

We evaluated the facts and circumstances of the agreement and determined the Pfizer agreement had obligations constituting deliverables and concluded that it had multiple deliverables, including deliverables relating to the grant of a license and access to our technology, performance of research and development services, and performance of certain manufacturing services, and concluded that these deliverables should be combined into a single unit of accounting, and further concluded that our participation on a joint steering committee was primarily for governance—type activities and did not represent a substantive obligation or deliverable. We are recognizing the license and technology access fee and research and development funding ratably on a straight-line basis over the estimated performance period, which began in December 2009 and is estimated to be completed in 2012, and are recognizing manufacturing revenue beginning upon the culmination of the earnings process and amortizing it over the remainder of the performance period of the bundled unit of accounting. Prepaid license and technology access fee and prepaid research and development funding are recorded as deferred revenue and is amortized on a straight-line basis over the performance period.

*Angiotech*

In our co-development collaboration with Angiotech, we bear all preclinical costs and the parties jointly fund clinical development activity. We have primary responsibility for preclinical and early clinical development and clinical manufacturing, and Angiotech will take the lead on pivotal and later clinical trials and commercialization. The parties will share net profits from the future sale of approved products and we may receive cash payments and an equity investment and based on the successful achievement of specified clinical development and commercialization milestones.

We continue to jointly fund clinical development activities with Angiotech in accordance with our co-development collaboration. Our clinical costs are recorded net of Angiotech's cost-share, which amounted to \$628,000, \$847,000 and \$943,000 in 2010, 2009 and 2008, respectively. The amount due from Angiotech was \$106,000 and \$229,000 at December 31, 2010 and 2009, respectively, and is disclosed separately on the balance sheet.

Notes to Consolidated Financial Statements, (continued)

**E. Collaborations and Revenue Recognition, continued**

*RTI Biologics, Inc.*

In September 2010, we entered into an agreement with RTI, a provider of orthopedic and other biologic implants, under which we provided RTI a license to our Multipotent Adult Progenitor Cell (“MAPC”) technologies to enable RTI to develop and commercialize MAPC technology-based biologic implants exclusively for certain orthopedic applications in the bone graft substitutes market. Under the terms of the agreement, we will receive a \$5 million license fee in installments, of which \$3.0 million is guaranteed and \$2.0 million is contingent on future milestone events. The first \$1.0 million of guaranteed fees was received at inception, with the remaining \$2.0 million to be received in \$1.0 million installments in each of December 2010 and March 2011. The December 2010 installment was received timely, and the final \$1.0 million to be received in March 2011 is reflected in receivables on the balance sheet at December 2010. We are also eligible to receive milestone payments upon the successful achievement of certain development and commercial milestones. Included in these milestones are two \$1.0 million license fee payments that are contingent on certain events. 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 the 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 was recognized in 2010.

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 recognize the license fee ratably on a straight-line basis over the estimated performance period, which began in September 2010 and is estimated to be completed in the fourth quarter of 2011.

**F. Capitalization**

At December 31, 2010, we had 100.0 million shares of common stock and 10.0 million shares of undesignated preferred stock authorized. No shares of preferred stock have been issued as of December 31, 2010.

We may issue shares of common stock to our former lenders and to Angiotech in connection with future milestones. Also, we entered into a license and sponsored research agreement in 2007 with an academic institution whereby, in addition to annual research funding, the institution may receive 1,345 shares of common stock on each of four anniversary dates.

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

	<u>December 31</u>	
	<u>2010</u>	<u>2009</u>
Stock option plans .....	4,500	4,500
Warrants to purchase common stock — 2007 offering .....	4,976	4,976
Warrants to purchase common stock — Lenders .....	149	149
	<u>9,625</u>	<u>9,625</u>

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.

*Athersys, Inc.*

*Notes to Consolidated Financial Statements, (continued)*

**G. Stock-Based Compensation**

We have two incentive plans that authorized an aggregate of 4,500,000 shares of common stock for awards to employees, directors and consultants. These equity incentive plans authorize the issuance of equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units, and other stock-based awards to qualified employees, directors and consultants.

As of December 31, 2010, a total of 193,063 shares were available for issuance under our equity compensation plans and options to purchase 4,308,013 shares of common stock were outstanding (including certain assumed options from 2007 covering 1,075 shares). We recognized \$1,466,000, \$2,808,000 and \$1,856,000 of stock compensation expense in 2010, 2009 and 2008, respectively, which included approximately \$264,000 in 2009 related to a change in estimate of our forfeiture rate. At December 31, 2010, total unrecognized estimated compensation cost related to unvested stock options was approximately \$798,000, which is expected to be recognized by the end of 2014 using the straight-line method.

The weighted average fair value of option shares granted in 2010, 2009 and 2008 was \$2.22, \$2.04 and \$2.00 per share, respectively. The total fair value of option shares vested in 2010, 2009 and 2008 was \$1,835,000, \$2,257,000 and \$2,337,000, respectively. There is no aggregate intrinsic value of fully vested option shares and option shares expected to vest as of December 31, 2010 since the market value was less than the exercise price of the options at the end of the year.

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

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding January 1, 2008 .....	3,679,884	\$ 5.24
Granted .....	218,000	3.36
Exercised .....	—	—
Forfeited / Terminated / Expired .....	<u>(159,411)</u>	<u>6.64</u>
Outstanding December 31, 2008 .....	3,738,473	5.07
Granted .....	272,000	3.17
Exercised .....	—	—
Forfeited / Expired .....	<u>(9,324)</u>	<u>8.26</u>
Outstanding December 31, 2009 .....	4,001,149	4.94
Granted .....	390,437	2.96
Exercised .....	—	—
Forfeited / Expired .....	<u>(83,573)</u>	<u>6.39</u>
Outstanding December 31, 2010 .....	<u>4,308,013</u>	<u>\$ 4.73</u>
Vested during 2010 .....	680,570	\$ 4.46
Vested and exercisable at December 31, 2010 .....	3,921,601	\$ 5.05

<b>Exercise Price</b>	<b>December 31, 2010</b>					
	<b>Options Outstanding</b>			<b>Options Vested and Exercisable</b>		
	<b>Number of Options</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Weighted Average Exercise Price</b>	<b>Number of Options</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Weighted Average Exercise Price</b>
\$1.35 – 3.20 .....	584,938	5.28	\$ 2.59	234,317	4.62	\$ 2.40
\$4.00 – 4.99 .....	137,000	6.89	\$ 4.32	101,209	6.83	\$ 4.34
\$5.00 – 7.80 .....	3,585,000	5.63	\$ 5.07	3,585,000	5.63	\$ 5.07
\$90.66 .....	<u>1,075</u>	2.39	\$ 90.66	<u>1,075</u>	2.39	\$ 90.66
	<u>4,308,013</u>			<u>3,921,601</u>		

The weighted average contractual life of unvested options at December 31, 2010 was 5.84 years.

*Athersys, Inc.*

*Notes to Consolidated Financial Statements, (continued)*

**H. Income Taxes**

At December 31, 2010, we had net operating loss and research and development tax credit carryforwards of approximately \$40,526,000 and \$2,990,000, respectively, for income tax purposes. Such losses and credits may be used to reduce future taxable income and tax liabilities and will expire in 2030.

We have net operating loss carryforwards of approximately \$7,626,000 ("Pre-Merger NOL") that are limited for use under Section 382 of the Internal Revenue Code to an annual net operating loss carryforward of \$464,000. The Pre-Merger NOL may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2012 and 2026.

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

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Net operating loss carryforwards.....	\$ 13,779	\$ 9,892
Net operating loss carryforwards — Pre-Merger NOL .....	2,593	2,751
Research and development credit carryforwards.....	2,990	2,070
License fee.....	1,195	2,011
Compensation expense .....	2,715	2,432
Other.....	636	506
Total deferred tax assets .....	23,908	19,662
Valuation allowance for deferred tax assets .....	(23,908)	(19,662)
Net deferred tax assets.....	\$ —	\$ —

Because of our cumulative losses, the deferred tax assets have been fully offset by a valuation allowance. We have not paid income taxes for the three-year period ended December 31, 2010.

**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 made no contributions to this plan for the three-year period ended December 31, 2010.

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

The following table presents quarterly data for the years ended December 31, 2010 and 2009, in thousands, except per share data:

	<b>2010</b>				
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Full Year</b>
Revenues.....	\$ 1,740	\$ 1,871	\$ 1,996	\$ 3,332	\$ 8,939
Net loss.....	\$ (2,561)	\$ (3,077)	\$ (3,688)	\$ (2,051)	\$ (11,377)
<b>Basic and diluted net loss per common share .....</b>	<b>\$ (0.14)</b>	<b>\$ (0.16)</b>	<b>\$ (0.19)</b>	<b>\$ (0.11)</b>	<b>\$ (0.60)</b>
	<b>2009</b>				
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Full Year</b>
Revenues.....	\$ 370	\$ 436	\$ 484	\$ 869	\$ 2,159
Net loss.....	\$ (3,625)	\$ (3,347)	\$ (3,380)	\$ (5,014)	\$ (15,366)
Basic and diluted net loss per common share.....	\$ (0.19)	\$ (0.18)	\$ (0.18)	\$ (0.26)	\$ (0.81)

**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. Based on that evaluation, these officers have concluded that as of December 31, 2010, our disclosure controls and procedures are effective.

**Management’s report on internal control over financial reporting:** Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation under the framework in Internal Control — Integrated Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2010.

**Changes in internal control:** During the fourth quarter of 2010, 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 March 25, 2011, 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, 2011 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, 2011 through December 31, 2011. 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, executing against the established operating plan and capital acquisition objectives, and advancement of strategic partnership and program activities. There is no formally adopted plan document for the Plan.

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

A summary of the plan is attached to this annual report on Form 10-K as Exhibit 10.41 and is hereby incorporated herein by reference thereto.

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information regarding Athersys' directors, including the identification of the audit committee and the audit committee financial expert, is incorporated by reference to the information contained in Athersys' Proxy Statement with respect to the 2011 Annual Meeting of Stockholders, or the 2011 Proxy Statement, under the headings "Election of Directors" and "The Board of Directors and its Committees". Information concerning executive officers is contained in Item 3A of Part I of this annual report on Form 10-K under the heading "Executive Officers of the Registrant."

The information regarding Section 16(a) beneficial ownership reporting compliance is incorporated by reference to the material under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" in the 2011 Proxy Statement.

Athersys has adopted a code of ethics that applies to its principal executive officer, principal financial officer and principal accounting officer. Athersys' code of ethics is posted under the Investors tab of its website at [www.athersys.com](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.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information regarding executive officer and director compensation is incorporated by reference to the information contained in the 2011 Proxy Statement under the heading "Executive Compensation".

The compensation committee report is incorporated by reference to the information contained in the 2011 Proxy Statement under the heading "Compensation Committee Report".

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

The information regarding security ownership of certain beneficial owners and management is incorporated by reference to the information contained in the 2011 Proxy Statement under the heading "Beneficial Ownership of Common Stock".

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

The information regarding certain relationships and related transactions and director independence is incorporated by reference to the information contained in the 2011 Proxy Statement under the heading "The Board of Directors and its Committees".

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

Information regarding fees paid to and services provided by our independent registered public accounting firm during the fiscal years ended December 31, 2010 and 2009 and the pre-approval policies and procedures of the audit committee is incorporated by reference to the information contained in the 2011 Proxy Statement under the heading "Ratification of the Appointment of Independent Auditors".

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

#### (a)(1) Financial Statements:

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2010 and 2009

Consolidated Statements of Operations for each of the years ended December 31, 2010, 2009 and 2008

Consolidated Statements of Stockholders' Equity for each of the years ended December 31, 2010, 2009 and 2008

Consolidated Statements of Cash Flow for each of the years ended December 31, 2010, 2009 and 2008

Notes to Consolidated Financial Statements

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

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

#### (a)(3) Exhibits.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
3.1	Certificate of Incorporation of Athersys, Inc., as amended as of August 31, 2007 (incorporated herein by reference to Exhibit 3.1 to the registrant's Registration Statement on Form S-3/A (Registration No. 333-144433) filed with the Commission on October 10, 2007)
3.2	Bylaws of Athersys, Inc., as amended as of October 30, 2007 (incorporated herein by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on October 31, 2007)
4.1	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on January 28, 2011)
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)

<u>Exhibit No.</u>	<u>Exhibit Description</u>
10.4	License Agreement, effective as of May 5, 2006, by and between Athersys, Inc. and Angiotech Pharmaceuticals, Inc. (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 Pharmaceuticals, Inc. (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)
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10.10†	Athersys, Inc. Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.10 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
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10.12	Loan and Security Agreement, and Supplement, dated as of November 2, 2004, by and among Athersys, Inc., Advanced Biotherapeutics, Inc., Venture Lending & Leasing IV, Inc., and Costella Kirsch IV, L.P. (incorporated herein by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on November 14, 2007)
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10.14	Amendment to Loan and Security Agreement, dated as of September 29, 2006, by and among Athersys, Inc., Advanced Biotherapeutics, Inc., Venture Lending & Leasing IV, Inc., and Costella Kirsch IV, L.P. (incorporated herein by reference to Exhibit 10.13 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.15†	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)
10.16†	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)
10.17†	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)
10.18†	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)
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10.20†	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)
10.21†	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)
10.22†	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)
10.23†	Employment Agreement, dated as of September 25, 2000, by and between Advanced Biotherapeutics, Inc. and Kurt Brunden (incorporated herein by reference to Exhibit 10.22 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. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Kurt Brunden (incorporated herein by reference to Exhibit 10.23 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)

<u>Exhibit No.</u>	<u>Exhibit Description</u>
10.25†	Non-Competition and Confidentiality Agreement, dated as of September 25, 2000, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and Kurt Brunden (incorporated herein by reference to Exhibit 10.24 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.26†	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)
10.27†	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)
10.28†	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)
10.29†	Employment Agreement, dated as of January 1, 2004, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.28 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.30†	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)
10.31†	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)
10.32†	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)
10.33†	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)
10.34	Securities Purchase Agreement, dated as of June 8, 2007, by and among Athersys, BTHC VI, Inc. and Investors (as defined therein) (incorporated herein by reference to Exhibit 10.33 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.35*	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)

Exhibit No.	Exhibit Description
10.36*	Strategic Alliance Agreement, by and between Athersys, Inc. and Angiotech Pharmaceuticals, Inc., dated as of May 5, 2006 (incorporated herein by reference to Exhibit 10.35 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on October 9, 2007)
10.37	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)
10.38†	Consulting Agreement, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and Dr. Kurt Brunden, dated as of July 23, 2007 (incorporated herein by reference to Exhibit 10.13 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on August 17, 2007)
10.39†	Form Indemnification Agreement for Directors, Officers and Directors and Officers (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on August 6, 2007)
10.41†	Summary of Athersys, Inc. 2011 Cash Bonus Incentive Plan
10.42*	Collaboration and License Agreement, dated as of December 18, 2009, by and between Athersys, Inc., ABT Holding Company, and Pfizer Inc. (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)
10.43*	Stand-by License Agreement, dated as of December 18, 2009, by and between Regents of the University of Minnesota, ABT Holding Company and Pfizer Inc. (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)
10.44	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)
10.45	Amendment No. 4 to Amended and Restated Registration <sup>®</sup> 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)
10.46*	License and Technical Assistance Agreement, dated as of September 10, 2010, between ABT Holding Company and RTI Biologics, Inc. (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)
10.47†	Form of Incentive Stock Option Agreement
10.48†	Form of Nonqualified Stock Option Agreement for Non-Employee Directors
21	List of Subsidiaries
23	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney

Exhibit No.	Exhibit Description
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 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.

\* Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission

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

## 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 25, 2011.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Gil Van Bokkelen</u> Gil Van Bokkelen	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 25, 2011
<u>/s/ Laura K. Campbell</u> Laura K. Campbell	Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)	March 25, 2011
* <u>John J. Harrington</u>	Executive Vice President, Chief Scientific Officer and Director	March 25, 2011
* <u>Lorin J. Randall</u>	Director	March 25, 2011
* <u>George M. Milne, Jr.</u>	Director	March 25, 2011
* <u>Jack L. Wyszomierski</u>	Director	March 25, 2011
* <u>Lee Babiss</u>	Director	March 25, 2011
* <u>Ismail Kola</u>	Director	March 25, 2011

\* 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

## EXHIBIT INDEX

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10.32†	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)
10.33†	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)
10.34	Securities Purchase Agreement, dated as of June 8, 2007, by and among Athersys, BTHC VI, Inc. and Investors (as defined therein) (incorporated herein by reference to Exhibit 10.33 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.35*	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)
10.36*	Strategic Alliance Agreement, by and between Athersys, Inc. and Angiotech Pharmaceuticals, Inc., dated as of May 5, 2006 (incorporated herein by reference to Exhibit 10.35 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on October 9, 2007)
10.37	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)
10.38†	Consulting Agreement, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and Dr. Kurt Brunden, dated as of July 23, 2007 (incorporated herein by reference to Exhibit 10.13 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on August 17, 2007)
10.39†	Form Indemnification Agreement for Directors, Officers and Directors and Officers (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on August 6, 2007)
10.41†	Summary of Athersys, Inc. 2011 Cash Bonus Incentive Plan
10.42*	Collaboration and License Agreement, dated as of December 18, 2009, by and between Athersys, Inc., ABT Holding Company, and Pfizer Inc. (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)
10.43*	Stand-by License Agreement, dated as of December 18, 2009, by and between Regents of the University of Minnesota, ABT Holding Company and Pfizer Inc. (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)

<u>Exhibit No.</u>	<u>Exhibit Description</u>
10.44	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)
10.45	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)
10.46*	License and Technical Assistance Agreement, dated as of September 10, 2010, between ABT Holding Company and RTI Biologics, Inc. (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)
10.47†	Form of Incentive Stock Option Agreement
10.48†	Form of Nonqualified Stock Option Agreement for Non-Employee Directors
21	List of Subsidiaries
23	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 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.
*	Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission
†	Indicates management contract or compensatory plan, contract or arrangement in which one or more directors or executive officers of the registrant may be participants

## CERTIFICATIONS

I, Gil Van Bokkelen, certify that:

1. I have reviewed this annual report on Form 10-K of Athersys, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 25, 2011

/s/ Gil Van Bokkelen

Gil Van Bokkelen  
Chief Executive Officer and  
Chairman of the Board of Directors

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## CERTIFICATIONS

I, Laura K. Campbell, certify that:

1. I have reviewed this annual report on Form 10-K of Athersys, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 25, 2011

/s/ Laura K. Campbell

Laura K. Campbell

Vice President of Finance

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Athersys, Inc. (the "Company") on Form 10-K for the year ended December 31, 2010, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: March 25, 2011

/s/ Gil Van Bokkelen  
Name: Gil Van Bokkelen  
Title: Chairman and Chief Executive Officer

/s/ Laura K. Campbell  
Name: Laura K. Campbell  
Title: Vice President of Finance

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

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## Directors and Executive Officers

## Stockholder Information

### Management

**Gil Van Bokkelen, Ph.D.**  
Chairman and CEO

**William (B.J.) Lehmann Jr., J.D.**  
President and  
Chief Operating Officer

**John J. Harrington, Ph.D.**  
Executive Vice President and  
Chief Scientific Officer

**Robert J. Deans, Ph.D.**  
Executive Vice President,  
Regenerative Medicine

**Laura K. Campbell, C.P.A.**  
Vice President of Finance

### Board of Directors

**Gil Van Bokkelen, Ph.D.**  
Chairman and CEO of Athersys, Inc.

**Lee E. Babiss, Ph.D.**  
Executive Vice President of Global  
Laboratory Services of PPD, Inc.,  
a contract research organization

**John J. Harrington, Ph.D.**  
Executive Vice President  
and Chief Scientific Officer of  
Athersys, Inc.

**Ismail Kola, Ph.D.**  
Executive Vice President of UCB  
S.A., a biopharmaceutical company

**George M. Milne, Ph.D.**  
Retired, former President of  
Worldwide Strategic and  
Operations Management  
and Executive Vice President  
of Global Research and  
Development of Pfizer Inc.,  
a pharmaceutical company

**Lorin J. Randall**  
Financial Consultant,  
former Chief Financial Officer of  
Eximias Pharmaceutical Corp.,  
i-STAT Corp. and  
CFM Technologies, Inc.

**Jack L. Wyszomierski**  
Financial Consultant,  
former Chief Financial Officer of  
VWR International, LLC  
and Schering-Plough Corp.

### Corporate Headquarters

Athersys, Inc.  
3201 Carnegie Ave.  
Cleveland, OH 44115-2634  
Phone: (216) 431-9900  
Fax: (216) 361-9495  
www.Athersys.com

### Stock Listing

The Company's common stock  
trades on the NASDAQ Capital  
Market under the symbol "ATHX"

### Transfer Agent & Registrar

Computershare  
250 Royall Street  
Canton, MA 02021

### Independent Auditors

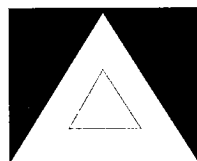
Ernst & Young  
Suite 1300  
925 Euclid Avenue  
Cleveland, OH 44115

### Legal Counsel

Jones Day  
North Point  
901 Lakeside Avenue  
Cleveland, OH 44114

### Investor Relations

Lisa Wilson  
President  
In-Site Communications  
211 E 70th St., 30G  
New York, NY 10021



**Athersys**  
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[ATHERSYS.COM](http://ATHERSYS.COM)

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Cleveland, Ohio 44115-2634