Athersys

Innovative Medicines

Outstanding Science

Annual Report
2008

Highlights

Athersys is a clinical stage biopharmaceutical company with a growing pipeline of potential best-in-class therapeutics that are designed to treat significant and life-threatening diseases.

The Company's lead programs are in the areas of cardiovascular disease; bone marrow transplant support; neurological disease, including stroke; obesity, and central nervous system disorders, including those involving attention, cognition and wakefulness.

Athersys' strategic approach builds on internal and external knowledge to identify and develop highly differentiated products with best-in-class potential, as well as enable the Company to limit development risks and costs.

Continued enrollment in two MultiStem® Phase I clinical trials, for acute myocardial infarction, or AMI, and for reducing the risk and severity of graft-versus-host disease, or GVHD, in leukemia and lymphoma patients

Received FDA authorization to initiate a third Phase I clinical trial for MultiStem in ischemic stroke

MultiStem named by Frost & Sullivan as the 2008 North American Product Innovation of the Year in the stem cell and regenerative medicine field

Revenues of $3.1 million and a net loss of $18.0 million for the year ended December 31, 2008

Year-end capital position of $31.6 million in cash, cash equivalents and available-for-sale securities expected to support planned operations through 2011.

Dear Shareholders,

In 2008, we continued on our mission to develop therapeutic product candidates designed to extend and enhance the quality of human life. Our goal remains unchanged – to develop "best-in-class" products in areas of significant unmet clinical need across a range of therapeutic categories, including cardiovascular disease, cancer treatment support, stroke, obesity and others. We reached a number of major milestones in 2008 including: initiation of two Phase I clinical trials and authorization from the Food and Drug Administration (FDA) to initiate a third Phase I clinical trial for MultiStem, and the completion or advancement of additional studies in other areas that demonstrate the potential of our programs and technologies. We ended the year with a strong balance sheet, including approximately $32 million in cash, cash equivalents and available-for-sale securities, driving the capacity to advance our lead clinical development programs. Given our current business and operational plans and assuming no new financings, we believe our cash resources will be sufficient to fund our operations through 2011.

Our goal remains unchanged – to develop "best-in-class" products in areas of significant unmet clinical need across a range of therapeutic categories

Our current portfolio includes MultiStem, a patented and proprietary stem cell product that we are developing as a treatment for multiple disease indications. In addition, we are developing novel pharmaceuticals to treat indications such as obesity and certain neurological conditions that affect attention, cognition or wakefulness, such as narcolepsy, excessive daytime sleepiness, and chronic fatigue associated with Parkinson's disease or other conditions.

Our lead clinical program involves MultiStem, where we have made considerable progress since last year. Notably, MultiStem was awarded the 2008 North American product innovation of the year award by Frost & Sullivan. This award is given annually to the company in its industry for demonstrated excellence in new products and technologies, and MultiStem was selected over a broad range of other stem cell technologies.

MultiStem is an innovative biologic product that is manufactured from human stem cells obtained from adult bone marrow or other non-embryonic tissue sources. The product consists of a special class of human stem cells that have the ability to express a range of therapeutically relevant molecules, as well as form multiple cell types. As a result, we believe that MultiStem has the potential to deliver a therapeutic benefit in several ways, such as the reduction of inflammation, protection of damaged or injured tissue, and the formation of new blood vessels in response to ischemic injury. MultiStem achieves these benefits primarily through production of multiple factors that act to regulate the immune system, protect damaged or injured cells, and promote tissue repair and healing in other ways. In contrast to traditional cell therapy, which aims to achieve wholesale direct replacement of damaged tissue, MultiStem exhibits a more drug-like profile, in which cells may exert a benefit in multiple ways and then are cleared from the body over time.

…MultiStem represents a highly distinctive profile, combining true scalability with off-the-shelf utility, and multiple therapeutic mechanisms of benefit with a drug-like profile.

During several years of preclinical work we have conducted with outside independent collaborators and contract research organizations, MultiStem has demonstrated the potential to address the fundamental limitations exhibited by traditional bone marrow or hematopoietic stem cell transplants. These limitations include the historical requirement for tissue matching between donor and patient, 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, and a range of other potential safety issues. Unlike other cell types, after cells are isolated from a qualified donor, MultiStem may be expanded on a large scale for future clinical use and stored in frozen form until needed. Cells obtained from a single donor may be used to produce banks yielding hundreds of thousands to millions of doses of MultiStem – a yield far greater than that achievable with other stem cell types. Just as importantly, based on evidence to date, MultiStem may be administered without tissue matching or administration of drugs that suppress the immune system, in effect, creating the stem cell equivalent of a universal donor, or type O blood. With such a combination of characteristics, MultiStem represents a highly distinctive profile, combining true scalability with off-the-shelf utility, and multiple therapeutic mechanisms of benefit with a drug-like profile.

During 2008, we advanced two MultiStem programs into clinical development, initiating Phase I safety studies in cardiovascular disease for treating patients that have suffered an acute myocardial infarction (AMI), and in oncology treatment support, administering MultiStem to leukemia or lymphoma patients who are at risk of incurring graft versus host disease (GVHD) after receiving a traditional bone marrow or hematopoietic stem cell transplant. Both of these Phase I studies were initiated based on extensive preclinical work in which MultiStem displayed a strong safety profile and efficacy in relevant animal models.

Despite advances in cardiovascular medicine over the past few years, AMI remains a leading cause of death and disability, with more than 8 million Americans having suffered a heart attack according to the 2008 American Heart Association statistical summary, and more than 16 million Americans suffering from coronary heart disease. Importantly, many patients that suffer a heart attack are at significant risk for progressing to congestive heart failure, and there is a substantial need for new and more effective treatments. Many believe that stem cell therapy might provide an important benefit to patients that have suffered an AMI, or that are experiencing other forms of cardiovascular disease.

In October 2008, we announced the successful initiation of patient enrollment in the AMI Phase I study. As of the first quarter of 2009, we had seven clinical sites screening and enrolling patients. These sites include leading cardiovascular treatment centers such as The Cleveland Clinic, Henry Ford, University of Michigan, and Care Group. As of the first quarter of 2009, we were approximately one-third of the way through patient

enrollment for the AMI study. We may add additional sites to the study in the near future and hope to complete enrollment for the study by the end of 2009, announcing top line results shortly thereafter.

Another area of clinical need is for cancer treatment support, especially for patients at risk from complications due to radiation and chemotherapy. In 2008, we began a Phase I study involving administration of MultiStem to cancer patients at risk for complications from a traditional bone marrow or hematopoietic stem cell transplant. We now have three participating clinical centers and expect to add additional centers in the future. While initial patient enrollment has been slower than we had hoped, we are exploring several options to accelerate the progress in this area, such as increasing the number of sites, implementing protocol amendments to increase the number of eligible patients, and possibly implementing a GVHD treatment arm in the study.

In addition to these current studies, in December 2008, we were granted authorization by the FDA to initiate a third clinical study, administering MultiStem to patients for the treatment of ischemic stroke. According to recent American Heart Association estimates, over 700,000 patients suffered an ischemic stroke in the United States in 2008, and it remains one of the most significant unmet medical needs facing our healthcare system. The estimated direct and indirect costs of stroke in 2008 were more than $65 billion.

In preclinical studies, a single dose of MultiStem administered intravenously has demonstrated the potential to safely deliver a substantial and durable therapeutic benefit, even when administered several days after an ischemic stroke has occurred.

Current drug therapy for treating an ischemic stroke is limited to administration of the clot-dissolving drug tPA. In accordance with current clinical guidelines, tPA must be administered to stroke patients within three hours after the occurrence of the ischemic stroke in order to remove the clot and to minimize potential risks, such as bleeding into the brain. However, many strokes occur at night or at a place or time during which immediate diagnosis or medical treatment is simply not available. As a result, only a very small percentage of ischemic stroke patients are treated with tPA.

In preclinical studies, a single dose of MultiStem administered intravenously has demonstrated the potential to safely deliver a substantial and durable therapeutic benefit, even when administered several days after an ischemic stroke has occurred. Based on results from multiple studies, 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.

The Phase I safety study authorized by the FDA is a double-blind, placebo-controlled study that allows for administration of MultiStem to patients between 48 and 60 hours after an ischemic stroke has occurred. This treatment window would represent a meaningful increase over currently available treatment options. Furthermore, authorization of this Investigational New Drug Application, or IND, represents the first clinical study in ischemic stroke patients using an off the shelf stem cell therapy –

one that can be produced at scale. If MultiStem is demonstrated to be both safe and effective in appropriately designed and well controlled studies, we believe that it would have a substantial effect on the standard of care for ischemic stroke and could improve the quality of life for many patients in need, while also creating substantial value for our shareholders.

Working with partners and collaborators, we intend to explore the potential utility of MultiStem for treating a range of other conditions, including autoimmune diseases, other conditions that involve the immune system, and certain neurological conditions, especially those in which inflammation plays a role.

Recognizing that we are not in a position to pursue each opportunity by relying solely on our current resources or internal operational capabilities, we are doing two key things. First, we are engaged in a network of collaborations with outstanding investigators across various disciplines and disease areas in work that is being conducted at leading institutions both here in the United States and Europe. We are excited by the progress being made in many of these collaborations, and look forward to publications and presentations that highlight the progress.

We are encouraged by the growing evidence of interest in and commitment to this area among companies that possess complementary capabilities, significant resources, and a dedication to developing therapies with best-in-class potential.

Additionally, we are actively evaluating possible partnering opportunities with companies that understand the potential of stem cell therapy and its possible long-term impact across multiple clinical areas. We are encouraged by the growing evidence of interest in and commitment to this area among companies that possess complementary capabilities, significant resources and a dedication to developing therapies with best-in-class potential.

In addition to our MultiStem programs, we are developing pharmaceuticals for the treatment of obesity and other conditions, particularly those that affect the central nervous system. In the obesity area, we are developing compounds that selectively stimulate the 5HT2c serotonin receptor in the brain, which is known to play an important role in regulating appetite. These compounds, known as 5HT2c agonists, are designed to reduce appetite and food intake in order to achieve substantial weight loss over time. In our view, the “ideal compound” or “combination product” for obesity is yet to be developed. Further, we believe our compounds have demonstrated best-in-class selectivity of the 5HT2c receptor versus other receptors that are important for safety, tolerability and ultimately maximizing effectiveness and convenience. Although we suspended our development program of ATHX-105, we remain focused on developing a potent, selective 5HT2c agonist with improved characteristics, best-in-class efficacy, safety and tolerability, while we explore potential partnering opportunities.

We are also independently developing novel, orally-active pharmaceutical products for the treatment of certain central nervous system disorders, including disorders affecting attention, cognition or wakefulness. This includes a range of indications, such as narcolepsy, excessive daytime sleepiness, or chronic fatigue associated with Parkinson’s or other disease conditions. It also includes potential indications such as attention deficit

hyperactivity disorder and cognitive disorders such as schizophrenia or certain diseases affecting memory. These programs are focused on the development of potent, selective histamine H3 receptor antagonist or inverse agonist compounds that act by elevating levels of neurotransmitters in the sleep and cognitive centers of the brain and stimulating neurological tone. This offers the potential to enhance wakefulness and cognition without causing hyperactivity, excessive "rebound" sleepiness or addiction.

Specifically, we have been committed to developing compounds that exhibit outstanding potency and selectivity, half lives suitable for once-per-day dosing, and a strong safety profile that is free of toxicological properties that could be problematic for competing programs established at other companies. We are confident that we are well positioned to achieve that objective and have established a portfolio of compounds that we believe have an outstanding competitive profile. As with our other programs, we are currently evaluating potential partnering opportunities around this program and look forward to updating our shareholders as appropriate.

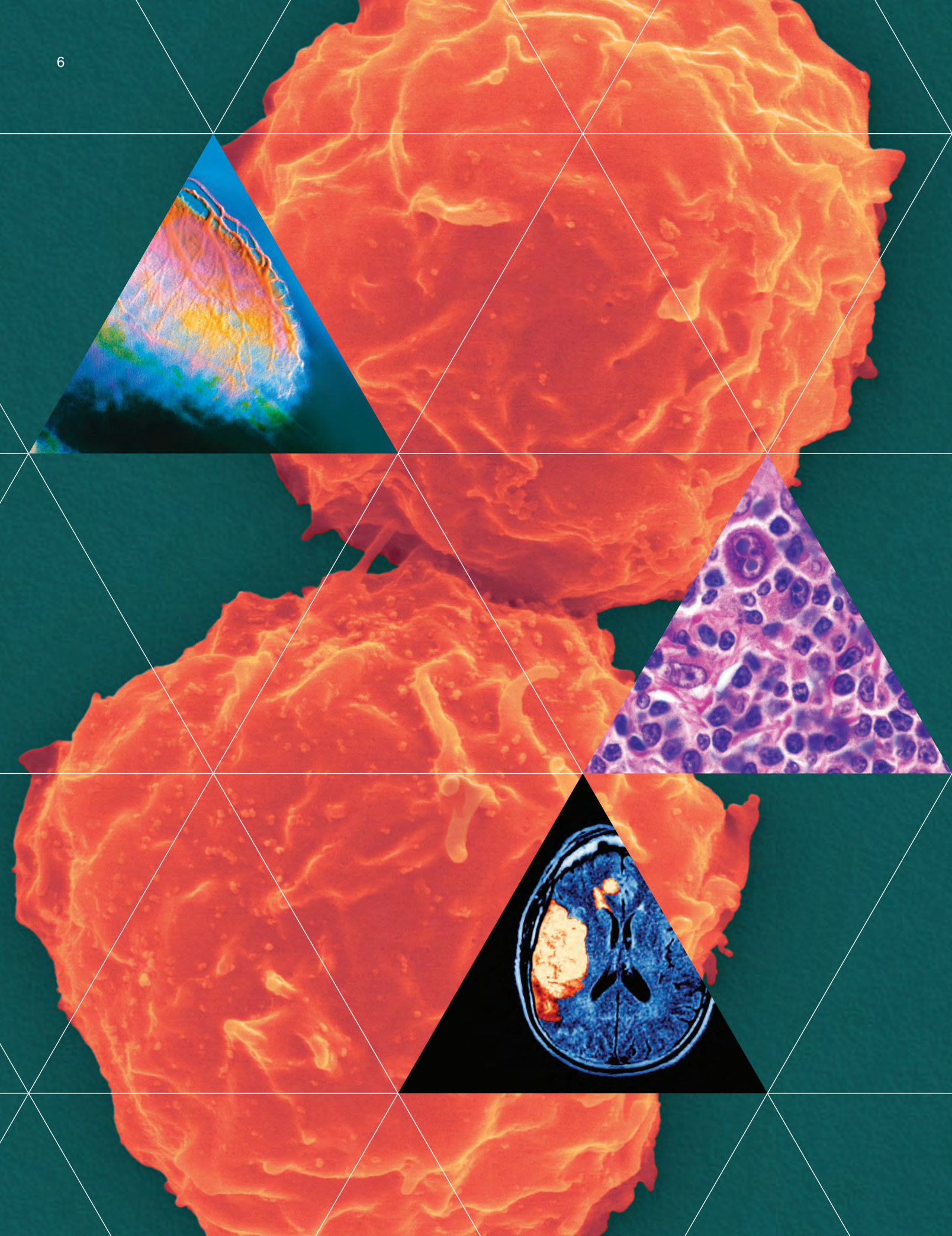
At Athersys, we believe that each program we are pursuing offers the opportunity to develop best-in-class therapeutic products with the potential to establish safer and more effective therapies to treat patients suffering from a broad range of diseases.

At Athersys, we believe that each program we are pursuing offers the opportunity to develop best-in-class therapeutic products with the potential to establish safer and more effective therapies to treat patients suffering from a broad range of diseases. We are committed to achieving that goal, and believe that in doing so we will be able to create substantial value for our shareholders.

We appreciate our shareholders' continued support and confidence as we pursue our goals. We especially want to thank our employees, whose irrepressible enthusiasm and commitment are gratefully acknowledged.

Sincerely,

Gil Van Bokkelen
Chairman and Chief Executive Officer



MultiStem and Other Programs in Development

During 2008, we made considerable progress in the development of MultiStem, our proprietary cell therapy platform. Two MultiStem programs were advanced into clinical development in the areas of treating acute myocardial infarction and for cancer treatment related transplant support. In addition, at the end of the year, Athersys received a third FDA authorization to initiate a phase I clinical trial evaluating MultiStem for the treatment of ischemic stroke.

Heart Attack

Myocardial infarction, one of the leading causes of death and disability in the United States, is caused by the blockage of one or more arteries that supply oxygenated blood to the heart. In many instances, this is caused by the rupture of an athero-sclerotic plaque deposit that subsequently lodges in an artery, blocking blood flow in the heart. Myocardial infarction is associated with a variety of risk factors including age, high blood pressure, smoking, sedentary lifestyle and genetics. Preclinical studies have demonstrated that the administration of allogeneic MultiStem following a surgically induced myocardial infarction resulted in significant functional improvement in cardiac output and other functional parameters. Furthermore, administration of immunosuppressive drugs was not required. Athersys has initiated a multi-center phase I clinical trial and is working with leading cardiovascular treatment clinical sites and experts to complete the trial.

Opposite page: (Background) Scanning electron micrograph of hematopoietic stem cells isolated from human bone marrow. (Inset, from top to bottom) Coronary angiogram showing multiple stenoses (narrowings) of the left coronary artery, which could lead to a heart attack; Photomicrograph of Hodgkin's disease (lymphoma); MRI of the brain showing an ischemic cerebrovascular accident (stroke) in the right superficial sylvian territory.

HSC Transplant Support

For many types of cancer, such as leukemia or other blood-borne cancers, treatment typically involves radiation therapy or chemotherapy, alone or in combination, which can substantially deplete the cells of the patient's blood and immune system. Other tissues may also be affected, such as cells in the digestive tract and in the pulmonary system, resulting in severe anemia, immunodeficiency, significant reduction in digestive capacity, or other problems that may result in significant disability or death. One possible treatment is a peripheral blood stem cell transplant or a bone marrow transplant. However, finding a closely matched donor is often difficult or even impossible, and even when such a donor is found, immunological complications, such as GVHD, may result in serious disability or death.

In multiple animal models, MultiStem has been shown to be non-immunogenic, even without the typical genetic matching required for conventional bone marrow or stem cell transplantation. Furthermore, MultiStem suppresses the T-cell mediated immune response believed to be responsible for causing GVHD. Based on work in relevant preclinical models, administration of MultiStem may have the potential to reduce the incidence or severity of complications associated with traditional bone marrow or hematopoietic stem cell transplants, and may also enhance gastrointestinal function. In 2008, Athersys initiated a phase I clinical trial as an open label, multicenter trial, involving leading experts in the field of bone marrow transplantation.

Stroke

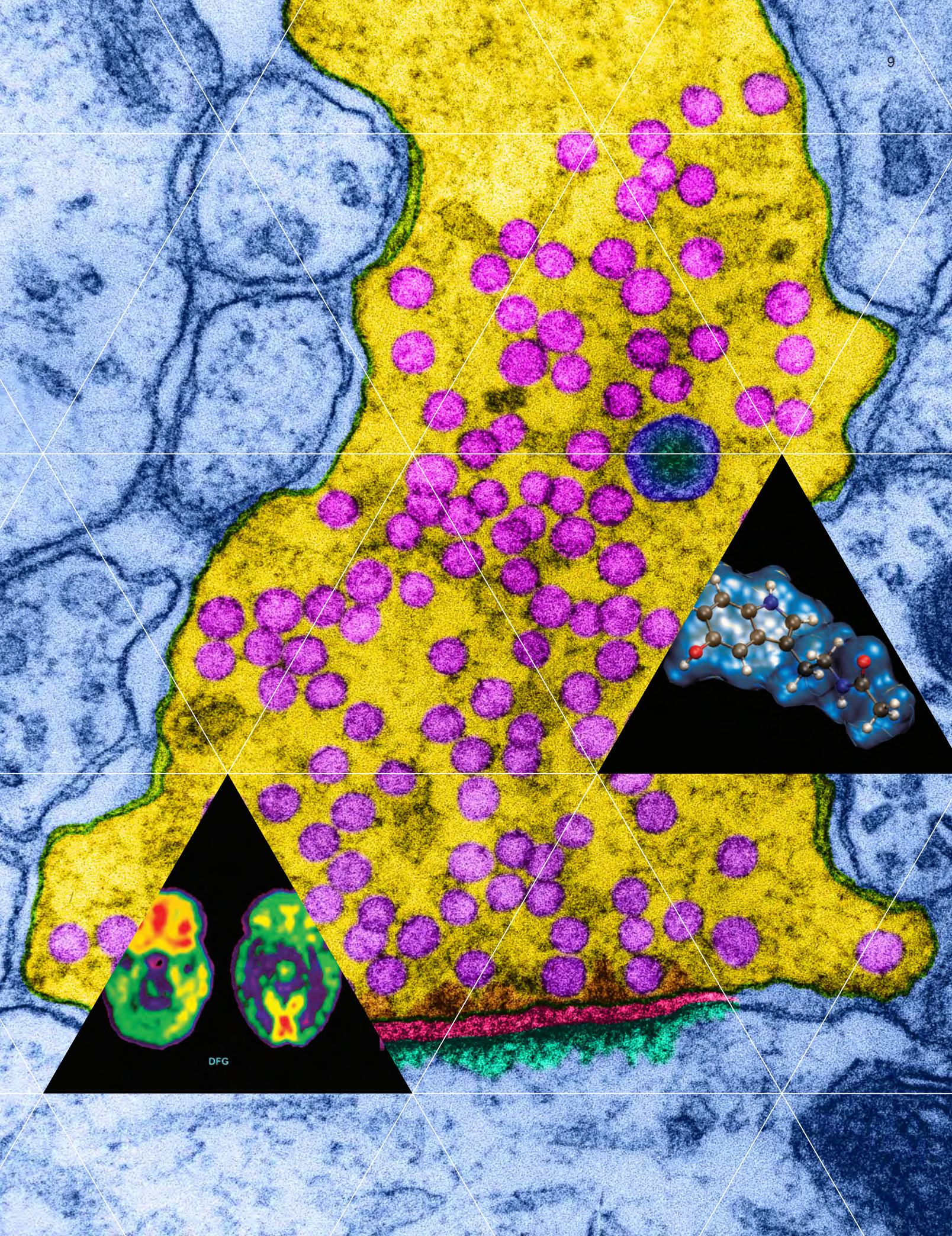
A third focus of Athersys' regenerative medicine program is the use of MultiStem for the treatment of neurological injury as a result of ischemic stroke, which accounts for approximately 85% of all strokes and is one of the leading causes of death and disability in the United States. In 2008, more than 700,000 patients suffered from an ischemic stroke in the U.S., and total direct and indirect costs were estimated at $65 billion. Despite the magnitude of the burden on the healthcare system, there has been little progress toward the development of treatments that improve the prognosis for stroke victims. The only FDA-approved drug currently available is the anti-clogging factor, tPA, which must be administered to the patient within three hours of the stroke's onset to avoid potential complications. As a result of this limited treatment window, only a small percentage of patients receive tPA following an ischemic stroke.

Results from preclinical studies conducted over two years and then subsequently presented at the annual American Academy of Neurology meeting indicated that the administration of MultiStem, even one week after a surgically induced stroke, results in substantial long-term therapeutic benefit and is well tolerated. We completed additional preclinical safety studies and received an IND authorization by the FDA in December 2008. The IND allows for the administration of MultiStem to eligible patients that have suffered an ischemic stroke within 48 to 60 hours following the original event.

Opposite page: (Background) Electron micrograph of an excitatory synapse from the central nervous system. (Inset, left to right) PET scans of the brain comparing a healthy patient and a schizophrenic patient of identical age; Molecular model of serotonin, a neurotransmitter affecting mood, memory, appetite, and sleep.

Obesity

Athersys continues to focus on the development of safe and effective new medicines to combat obesity, a substantial contributing factor to a range of diseases that represent the major causes of death and disability in the developed world today, including cardiovascular disease, stroke, certain types of cancer, and diabetes. In order to achieve this goal, we have focused on the development of a portfolio of potent, selective 5HT2c agonists for potential development as novel therapies for the treatment of obesity. Stimulation of the 5HT2c serotonin receptor is believed to be one of the most effective mechanisms for achieving appetite suppression and subsequent weight loss. As we continue our development efforts, we are also exploring potential partnerships for this program.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H3 Antagonists for the Treatment of Sleep and Certain Other Cognitive Disorders

We are developing multiple classes of highly potent and selective compounds designed to block the H3 receptor, which regulates levels of histamine and other neurotransmitters in certain areas of the brain that play a direct role in regulating sleep and cognitive function. These non-stimulant, non-addictive, orally-administered compounds represent a new class of drugs that could have an improved efficacy and safety profile relative to existing drugs used for the treatment of narcolepsy and related sleep disorders, such as amphetamines and related stimulants with substantial side-effects. Individuals suffering from these and other conditions may experience persistent tiredness and lack of energy, or chronic fatigue from Parkinson's or cancer treatment.

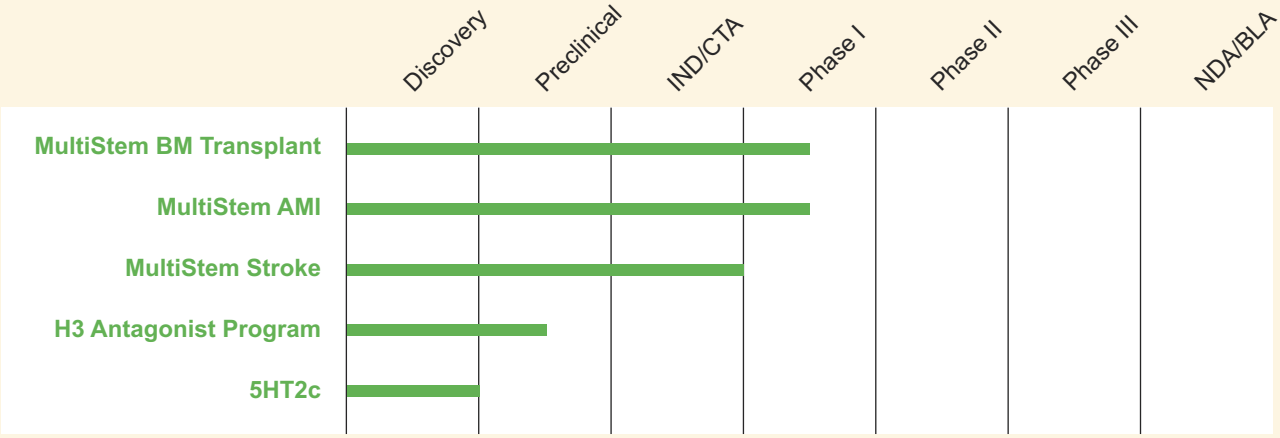
Individuals with attention or cognitive disorders may suffer from an inability to focus, solve problems, process information, communicate, and may have memory impairment. These disorders include ADHD (Attention Deficit Hyperactivity Disorder), schizophrenia, Alzheimer's disease and other forms of dementia. Currently available treatments cause side effects and do not adequately address the clinical need.

In preclinical studies, some of our more advanced compounds significantly enhanced wakefulness without causing hyperactivity. Certain compounds appeared far more potent than currently available therapies, achieving a comparable or better effect on wakefulness at substantially lower doses. In addition, these compounds did not appear to cause the excessive rebound sleepiness that is a characteristic of other agents used to promote wakefulness. We intend to continue the study of H3 antagonist compounds with additional pharmacology and safety testing and are exploring partnering opportunities.

Other Key Technologies

In addition to our product development programs, we have developed RAGE, a patented 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 that express the target of interest. With the broad freedom to work with drug targets that may be inaccessible to other companies as a result of intellectual property restrictions, we have produced cell lines that express targets that have potential relevance across a range of disease areas. Many of these were produced in collaboration for drug development programs at major pharmaceutical companies, and some have been produced for the internal drug development programs at Athersys. ▲

Development Status of Key Programs



During 2008, we advanced two Phase I clinical trials for MultiStem in cardiovascular disease for treating patients that have suffered an AMI, and in oncology treatment support, administering MultiStem to leukemia or lymphoma patients who are at risk of incurring GVHD after receiving a traditional bone marrow or hematopoietic stem cell transplant. We also received authorization from the FDA to initiate a third Phase I clinical trial for the treatment of ischemic stroke.

In addition to our MultiStem programs, we are developing pharmaceuticals for the treatment of obesity and certain neurological conditions affecting attention, cognition and wakefulness. In the obesity area, we are focusing on compounds that selectively stimulate the 5HT2c serotonin receptor in the brain, which is known to play an important role in regulating appetite. In the neurological arena, we are independently developing novel orally active pharmaceutical products designed to block the H3 receptor for the treatment of obesity or certain central nervous system disorders, including sleep disorders such as narcolepsy or excessive daytime sleepiness, and other potential indications such as ADHD. Through the application of our proprietary technologies, we have established a pipeline of highly differentiated, potential "best-in-class" therapeutic candidates. This chart presents a snapshot, as of the first quarter 2009, of drug development programs at Athersys. We will continue to identify opportunities to develop drug therapies that we believe are innovative and offer significant benefit to patients, as well as create value for our shareholders.

Directors and Corporate Officers

Management

Gil Van Bokkelen, Ph.D.
Chairman and CEO

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

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

Robert Deans, Ph.D.
Senior Vice President,
Regenerative Medicine

Laura Campbell, C.P.A.
Vice President, Finance

Board of Directors

Gil Van Bokkelen, Ph.D.
Chairman & CEO

John Harrington
Executive Vice President and
Chief Scientific Officer

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.

William Mulligan
Managing Partner,
Primus Venture Partners

Michael Sheffery, Ph.D.
General Partner,
OrbiMed Advisors

Jordan Davis
Managing Partner,
Radius Ventures

Floyd D. Loop, M.D.
Retired, former CEO and
Chairman of the Board
of Govenors of the Cleveland
Clinic Foundation

Lorin J. Randall
Financial Consultant

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, 2008

OR

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

For the transition period from _____ to _____

Commission file number 001-33876

Athersys, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $.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 Act. 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 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, 2008, 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 $2.45 of such stock as quoted on the NASDAQ Capital Market on such date) held by non-affiliates of the registrant was approximately $32.3 million.

The registrant had 18,927,988 shares of common stock outstanding on March 12, 2009.

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 2009 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 is currently being evaluated in two ongoing clinical trials. In addition, we are developing novel pharmaceuticals to treat indications such as obesity, certain cognitive and attention disorders, narcolepsy or other forms of excessive daytime sleepiness.

MultiStem is a biologic product that is manufactured from human stem cells obtained from adult bone marrow or other nonembryonic tissue sources. 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, protection of damaged or injured tissue, and the formation of new blood vessels in regions of ischemic injury. These cells exhibit a drug-like profile in that they act primarily through the production of factors that regulate the immune system, protect damaged or injured cells, promote tissue repair and healing and most or all of the cells are cleared from the body over time.

During several years of preclinical work, MultiStem has demonstrated the potential to address each of the fundamental limitations observed with traditional bone marrow or hematopoietic stem cell transplants. These limitations include the historical requirement for tissue matching between donor and patient, 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, and a range of other potential safety issues. Unlike other cell types, MultiStem cells, after isolation from a qualified donor, may be expanded on a large scale for future clinical use and stored in frozen form until needed. Cells obtained from a single donor require no genetic modification and may be used to produce banks yielding hundreds of thousands to millions of doses of MultiStem — an amount far greater than other stem cell types.

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: (1) it may be produced on an industrial scale, in a well validated and reproducible manner; (2) it may be administered without tissue matching or the need for immune suppressive drugs, making it analogous to type O blood; (3) it exhibits a consistent safety profile; and (4) it appears capable of delivering a therapeutic benefit through more than one mechanism of action. Factors expressed by MultiStem are believed to reduce inflammation and regulate immune system function, protect damaged or injured cells and tissue, promote formation of new blood vessels, and augment tissue repair and healing in other ways. 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 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.

Working with independent investigators, we have conducted preclinical studies in relevant animal models designed to evaluate safety and potential therapeutic benefit in various disease indications. Based on the results of these and other studies, we advanced two MultiStem programs into clinical development in 2008, initiating phase I clinical trials in cardiovascular disease (treating patients that have suffered an acute myocardial infarction) and in oncology treatment support (administering MultiStem to leukemia or lymphoma patients who are receiving a traditional bone marrow or hematopoietic stem cell, or HSC, transplant to reduce the risk or severity of graft versus host disease, or GVHD). We are conducting the acute myocardial infarction clinical trial with our partner Angiotech Pharmaceuticals, Inc., or Angiotech. In May 2006, we entered into a 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. 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 will receive nearly half of the net profits from the sale of any jointly developed, approved products. In addition, we retain the exclusive commercial rights to the development of MultiStem for other indication areas, including oncology treatment support, neurological indications, autoimmune disease, and other areas.

In December 2008, we were granted authorization by the United States Food and Drug Administration, or FDA, to initiate a third clinical trial, administering MultiStem for the treatment of ischemic stroke. According to recent American Heart Association estimates, over 700,000 patients suffered an ischemic stroke in the United States in 2008. Current drug therapy for treating an ischemic stroke is limited to administration of the clot dissolving drug tPA. According to current clinical guidelines, tPA must be administered to stroke patients within three hours after the occurrence of the ischemic stroke in order to remove the clot while minimizing potential risks, such as bleeding into the brain. However, many strokes occur at night or during a time where immediate diagnosis and medical treatment is not available, and as a result, only a very small percentage of ischemic stroke patients are treated with tPA.

In preclinical studies conducted by Athersys and its collaborators, a single dose of MultiStem administered intravenously has demonstrated the potential to safely deliver a significant therapeutic benefit even when administered several days after an ischemic stroke has occurred. 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. 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.

Working with partners and collaborators, and as resources permit, we intend to explore the potential utility of MultiStem for treating a range of other conditions, including autoimmune diseases, other conditions that involve the immune system, and certain neurological conditions, especially those in which inflammation plays a role. We believe that MultiStem could have utility in treating multiple diseases, and as a result, has the potential to create significant value for our Company and our stockholders.

In addition to our MultiStem programs, we are developing pharmaceuticals for the treatment of obesity and certain neurological conditions associated with cognition, attention and wakefulness. In the obesity area, we are developing compounds that selectively stimulate the 5HT2c serotonin receptor in the brain, which is known to play an important role in regulating appetite. These compounds, known as 5HT2c agonists, are designed to reduce appetite and food intake, in order to achieve substantial weight loss over time.

We have completed several clinical trials involving ATHX-105, a potent and selective 5HT2c receptor agonist that was being developed for the treatment of obesity. In July 2007, we initiated a phase I clinical trial for ATHX-105 in the United Kingdom. The primary objective of the phase I clinical trial was to assess the short-term safety of ATHX-105 and to establish an appropriate dose range for subsequent clinical trials that will be conducted in order to assess safety and effectiveness. The phase I clinical trial, which included 107 subjects, was completed in January 2008, and top line results were announced shortly after completion of the study.

The results of the study demonstrated that ATHX-105 was well-absorbed, resulting in good drug exposures following oral administration, and was generally well tolerated up to a maximum tolerated dose of 100 mg. There were no severe or serious adverse events observed in the clinical trial, no negative effects on cardiovascular, hematology or other clinical parameters, and no discontinuations due to adverse events. In addition to this study, we completed two phase I clinical trials in the United Kingdom to further assess safety and tolerability of ATHX-105 administered at various dose levels, as well as examine regional absorption of the drug in the gastrointestinal tract for the purpose of developing a formulated product.

Based upon the results of these and other studies, we applied to the FDA in the summer of 2008 to initiate a double blind, placebo controlled phase II clinical trial involving administration of ATHX-105 to patients in the United States. In September 2008, following the FDA's review of our investigational new drug application, or IND, the proposed trial was placed on partial clinical hold pending the receipt of additional information and resolution of several issues relating to ATHX-105's preclinical package and the proposed phase II study design.

At the suggestion of the FDA, we conducted two additional studies to provide further data about ATHX-105's potential toxicological profile, one repeating a prior study under different conditions and another study that we had not previously conducted and that is not typically included in preclinical evaluation. While the first study confirmed our prior negative findings, meaning the absence of a relevant toxicological effect, the second study produced data that suggests a rat specific toxicological effect. We met with the FDA to discuss the issues and reached resolution regarding all of the study design issues related to the partial clinical hold. However, based on the results of the additional test and discussions with the FDA, we believe that the apparent rodent specific effect could require additional non-clinical studies and greatly complicate long-term toxicology testing and thereby increase substantially the development time, risks and costs associated with subsequent development of ATHX-105. Furthermore, these increased risks of development could make it substantially more difficult or impractical for us to establish an attractive, third-party collaboration for the further development and commercialization of ATHX-105.

Consequently, we have decided to suspend further development of ATHX-105 and withdraw our IND application, and are currently focusing on the advancement of next generation compounds that exhibit improved characteristics. While the potential significance of this toxicological effect to humans remains unclear, it appears to be a compound-specific effect that is not representative of the class of next generation compounds that we are continuing to develop while we explore potential partnerships for the program.

We are also independently developing novel, orally-active pharmaceutical products for the treatment of certain central nervous system disorders, including disorders such as narcolepsy, excessive daytime sleepiness, and chronic fatigue associated with Parkinson's disease or other conditions, as well as other potential indications such as attention deficit hyperactivity disorder and other cognitive disorders such as schizophrenia. These programs are focused on the development of potent, selective histamine H3 receptor antagonist compounds that act by elevating levels of neurotransmitters in the sleep and cognitive centers of the brain and stimulating neurological tone. This elevation results in an enhanced state of wakefulness and cognition, without causing hyperactivity, excessive "rebound" sleepiness or addiction. The histamine H3 receptor antagonists being developed at Athersys represent a new class of drugs that could have an improved efficacy and safety profile relative to existing drugs used for the treatment of a range of conditions that affect cognitive ability, attention or wakefulness.

In addition to our current product development programs, we developed our patented random activation of gene expression, or 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 our ongoing collaboration with Bristol-Myers Squibb, and some have been produced for our internal drug development programs.

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 will continue to develop certain product candidates using a "fast follower" approach, thereby mitigating risk and reducing costs. This approach allows us to leverage others' prior clinical efforts and validation while we focus on development of best-in-class product candidates with differentiated profiles. Our intention is to develop our products for ultimate commercialization by us, our partners or licensees after they have received approval from the FDA and/or other regulatory agencies.

- *Apply our proprietary technologies toward the rapid 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 RAGE and MultiStem, provide us with a competitive advantage in drug discovery and product development by allowing us to move products quickly from the discovery phase into clinical trials. We will select candidates for internal development based on several factors, including the required regulatory approval pathway and the potential market into which the product may be sold, and our ability to feasibly fund development activities through commercialization and marketing of the approved product.

- *Enter into licensing or co-development arrangements for certain product candidates.* We intend to license certain of our product candidates to, or co-develop them with, qualified collaborators to broaden and accelerate our product development and commercialization efforts. We anticipate that this strategy will help us to enhance our return on product candidates for which we enter into collaborations through the receipt of a mix of license fees, milestone payments, and profit sharing or royalties. Certain partnerships may include strategic equity investments.

- *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 an ongoing research and development effort, both through internal activities and through collaborative research activities with others, which aims to develop new intellectual property and enables 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, such as their application toward the development of novel diagnostics or their use for the analysis, characterization or production of certain types of therapeutic product candidates such as biogenerics or biosimilars, may not be relevant to the key elements of our corporate strategy. We believe these applications may have significant potential value, however, and can 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 cardiovascular disease, HSC transplant support and ischemic stroke. We advanced our first two MultiStem programs into clinical development in 2008. In addition, by applying our core technologies and capabilities, we have established drug development programs in the areas of obesity, which was advanced through multiple phase I clinical trials in 2007 and 2008, and central nervous system disorders involving cognition, attention and wakefulness.

Regenerative Medicine Programs

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

We are developing a proprietary nonembryonic 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. Potential applications of MultiStem include the treatment of cardiovascular disease, cancer treatment related transplant support, certain neurological conditions, autoimmune disease and other conditions. We initiated phase I clinical trials in the areas of acute myocardial infarction, or AMI, and HSC transplant support in 2008 and received FDA authorization in late 2008 to initiate a phase I clinical trial in the area of ischemic stroke. We believe that MultiStem represents a significant advancement in the field of stem cell therapy and could have broad clinical application.

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 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 consisting of a rare and 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. In their potential product form, we refer to these cells as MultiStem.

These cells exhibit several important biological properties, including:

- *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 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 tumors or ectopic tissue. 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.

At each step of the MultiStem production process, cells are analyzed and qualified 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 produce clinical grade material. In March 2007, we and our manufacturing partner, Lonza Walkersville, Inc., announced the successful establishment of a Master Cell Bank produced under Good Manufacturing Practices, or GMP, and the production of clinical grade material for our initial clinical trials. 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.

MultiStem allows us to pursue multiple high value commercial opportunities from a single product platform, since we believe it has potential application in a range of disease states and therapeutic areas. For example, based on numerous preclinical discussions with the FDA, we believe that we will be able to apply data and information from certain preclinical safety studies to support the development of MultiStem for treating multiple distinct diseases and in multiple regulatory filings. As a result, we expect to be able to efficiently add clinical indications as we further expand the scope of potential applications for MultiStem, enabling us to reduce costs and shorten development timelines in comparison to traditional single-use preclinical studies. From the fourth quarter of 2007 through 2008, we submitted and the FDA authorized, three INDs involving administration of MultiStem in phase I clinical trials in treating distinct disease conditions.

MultiStem for Heart Attack, HSC Transplant Support in Treatment of Hematologic Malignancies & Stroke

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 animal models that reflect various types of human disease or injury, such as myocardial infarction, stroke, brain damage due to restricted blood flow in newborns, vascular disease, and bone marrow transplant support/GVHD. In addition, we are exploring, or intend to explore, the potential application of MultiStem in the treatment of a range of other conditions such as certain blood or immune deficiencies and various autoimmune diseases.

As stated above, we have consistently observed that MultiStem is safe and effective in animal models. As a result, we intend, subject to the availability of adequate resources, to advance MultiStem in clinical development in three areas: 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 may expand to other clinical indication areas as results warrant and resources permit.

Heart Attack

In our current phase I clinical trial, we are 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 2007 Statistical Update, there were approximately 865,000 cases of myocardial infarction that occurred in the United States in 2004 and approximately 7.9 million individuals living in the United States that had previously suffered a heart attack. In addition, there were more than 452,000 deaths that occurred from various forms of ischemic heart disease, and 156,000 deaths due directly to myocardial infarction in 2004. 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 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 qualified contract research organization, we completed additional preclinical studies in established pig models of acute myocardial infarction 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 phase I clinical trial in this indication. We are working with leading cardiovascular treatment clinical sites and experts in the area of cardiovascular disease to complete this phase I clinical trial.

We are developing MultiStem for this indication in conjunction with our partner, Angiotech. We entered into a product co-development collaboration with Angiotech in May 2006, for the potential application of MultiStem in multiple cardiovascular indications including myocardial infarction, peripheral vascular disease and certain other indications.

HSC Transplant Support in Hematologic Malignancy

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, significant 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.

Stroke

A third focus of our regenerative medicine program is the use of MultiStem for the treatment of neurological injury as a result of ischemic stroke, which 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, which must be administered to the patient within roughly three hours of the onset of the stroke. 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 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. Through research conducted by collaborators at the Medical College of Georgia and presented at the annual American Academy of Neurology meeting in April 2006, we observed 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. These results have been confirmed in subsequent studies that demonstrate MultiStem treatment is well tolerated, does not require immunosuppression, and results in a robust and durable therapeutic benefit even when administered one week after the initial stroke event.

In 2008, we completed additional preclinical safety studies and submitted an IND for this application, which was authorized by the FDA in December 2008. The subsequent initiation of a clinical trial will depend on the availability of capital resources to complete the study.

We believe that MultiStem could have broad potential to treat a range of conditions. In addition to the above programs, we are collaborating or intend to collaborate with other highly qualified investigators to evaluate the potential benefits of MultiStem in other disease indications, such as various blood and immune deficiencies, certain autoimmune diseases and other potential indications.

Pharmaceutical Programs

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. These compounds are 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® (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 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 that implicates 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. Recently, Arena Pharmaceuticals developed a selective 5HT2c agonist, Lorcaserin, which exhibits significant selectivity for the 5HT2c receptor relative to the 5HT2b receptor. In a phase II clinical trial conducted by Arena Pharmaceuticals, Lorcaserin was demonstrated to reduce appetite and cause statistically significant weight loss in patients that were administered the drug for a period of three months, without causing any apparent cardiovascular effects. However, at higher doses the drug has been shown to cause dizziness, nausea and headaches, which may be a consequence of its apparently more limited selectivity for the 5HT2c receptor relative to another serotonin receptor expressed in the brain, the 5HT2a receptor. Currently, Lorcaserin is undergoing a large scale, two-year phase III clinical trial that is designed to evaluate safety, including cardiovascular safety, and effectiveness at causing weight loss in patients that are administered Lorcaserin for a period of one year. Lorcaserin is being administered twice per day at a dosage level that is half the level previously observed to cause unacceptable levels of dizziness, nausea and headaches in prior clinical studies.

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 is 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 ATHX-105 and other compounds, we have demonstrated the ability to develop highly potent and selective compounds. We believe that the potency and selectivity profile displayed by compounds we develop for the 5HT2c receptor relative to both the 5HT2b receptor and the 5HT2a receptor 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 programs.

We have completed several clinical trials involving ATHX-105, a potent and selective 5HT2c receptor agonist that was being developed for the treatment of obesity. In July 2007, we initiated a phase I clinical trial for ATHX-105 in the United Kingdom. The primary objective of the phase I clinical trial was to assess the short-term safety of ATHX-105 and to establish an appropriate dose range for subsequent clinical trials that will be conducted in order to assess safety and effectiveness. The phase I clinical trial, which included 107 subjects, was completed in January 2008, and top line results were announced shortly after completion of the study.

The results of the study demonstrated that ATHX-105 was well-absorbed, resulting in good drug exposures following oral administration, and was generally well tolerated up to a maximum tolerated dose of 100 mg. There were no severe or serious adverse events observed in the clinical trial, no negative effects on cardiovascular, hematology or other clinical parameters, and no discontinuations due to adverse events. In addition to this study, we completed two phase I clinical trials in the United Kingdom to further assess safety and tolerability of ATHX-105 administered at various dose levels, as well as examine regional absorption of the drug in the gastrointestinal tract for the purpose of developing a formulated product.

Based upon the results of these and other studies, we applied to the FDA in the summer of 2008 to initiate a double blind, placebo controlled phase II clinical trial involving administration of ATHX-105 to patients in the United States. In September 2008, following the FDA's review of our investigational new drug application, or IND, the proposed trial was placed on partial clinical hold pending the receipt of additional information and resolution of several issues relating to ATHX-105's preclinical package and the proposed phase II study design.

At the suggestion of the FDA, we conducted two additional studies to provide further data about ATHX-105's potential toxicological profile, one repeating a prior study under different conditions and another study that we had not previously conducted and that is not typically included in preclinical evaluation. While the first study confirmed our prior negative findings, meaning the absence of a relevant toxicological effect, the second study produced data that suggests a rat specific toxicological effect. We met with the FDA to discuss the issues and reached resolution regarding all of the study design issues related to the partial clinical hold. However, based on the results of the additional test and discussions with the FDA, we believe that the apparent rodent specific effect could require additional non-clinical studies and greatly complicate long-term toxicology testing and thereby increase substantially the development time, risks and costs associated with subsequent development of ATHX-105. Furthermore, these increased risks of development could make it substantially more difficult or impractical for us to establish an attractive, third-party collaboration for the further development and commercialization of ATHX-105.

Consequently, we have decided to suspend further development of ATHX-105 and withdraw our IND application, and are currently focusing on the advancement of next generation compounds that exhibit improved characteristics. While the potential significance of this toxicological effect to humans remains unclear, it appears to be a compound-specific effect that is not representative of the class of next generation compounds that we are continuing to develop while we explore potential partnerships for the program.

H_3 Antagonists for the Treatment of Sleep Disorders and Certain Other Cognitive Disorders

In addition to our other programs, we are developing pharmaceuticals that are designed to enhance wakefulness and promote cognitive abilities in patients that experience attention or cognitive deficits. Individuals that suffer from narcolepsy or other conditions that result in excessive daytime sleepiness, or EDS, may experience persistent tiredness and lack of energy. Chronic fatigue may be experienced by patients with other disease conditions such as Parkinson's or those undergoing treatment for cancer. As a result, such individuals may experience significant difficulty in performing certain tasks and may suffer an impaired quality of life. More than 100,000 individuals in the United States suffer from narcolepsy or EDS. Historically, narcoleptics were treated with amphetamines and related stimulants that had substantial side-effects, but more recently have been prescribed Provigil (Modafinil). This compound works by an unknown mechanism, but appears to be relatively free of the stimulant side-effects of amphetamines. In addition to its use for narcolepsy, Provigil is also approved for the treatment of shift work sleep disorder, or SWSD, and sleep apnea. Known side effects experienced by patients taking Provigil include anxiety, depression, rash, and rare occurrences of serious and potentially life threatening reactions including Stevens Johnson Syndrome, Toxic Epidermal Necrolysis, Erythema Multiforme, and multi-organ hypersensitivity. Sales of Provigil in 2007 within the United States were reported to be over $800 million. Although Provigil appears to be an improvement over previous narcolepsy drugs, certain safety concerns were raised by the FDA when Cephalon, Inc. attempted to gain approval of modafinil for attention deficit-hyperactivity disorder, or ADHD, and the company subsequently abandoned efforts in this market.

Individuals with attention or cognitive disorders may suffer from an inability to focus, solve problems, process information, communicate, and may have memory impairment. Attention and cognitive disorders include ADHD, Schizophrenia, Alzheimer's disease and other forms of dementia. Datamonitor estimates that 23 million children in the seven major pharmaceutical markets (United States, France, Germany, Italy, Spain, United Kingdom and Japan) suffer from ADHD. Research also shows that 60% of children with ADHD maintain the disorder into adulthood. Despite the low rate of diagnosis, ADHD drug revenues reached $2.5 billion in 2004, 97% of which was generated within the United States. Currently available treatments cause side effects and do not adequately address the clinical need. Ritalin® (methylphenidate) is the most widely prescribed ADHD therapy. As a stimulant with abuse potential, it has been classified as a controlled substance by the FDA and the United States Drug Enforcement Agency. We believe there exists a significant market opportunity for safer and more effective treatments.

We are developing multiple classes of highly selective and potent compounds designed to block the H3 receptor and have established a program to develop non-stimulant, non-addictive, orally administered drugs for the treatment of narcolepsy or other conditions related to excessive daytime sleepiness. Our histamine H3 receptor antagonists represent a new class of drugs that could have an improved efficacy and safety profile relative to existing drugs used for the treatment of narcolepsy and related sleep disorders. The H3 receptor regulates levels of histamine and other neurotransmitters in certain areas of the brain that play a direct role in regulating sleep and cognitive function. In animal models, H3 receptor antagonists have been shown to increase histamine release in the brain and improve wakefulness, attention and learning. In preclinical studies conducted at independent labs, we have tested some of our more advanced compounds in well validated rodent sleep models. During these studies, compounds significantly enhanced wakefulness without causing hyperactivity. In comparison to modafinil or caffeine, certain compounds appeared far more potent, achieving a comparable or better effect on wakefulness at substantially lower doses. In addition, these compounds did not appear to cause the excessive rebound sleepiness that is a characteristic of other agents used to promote wakefulness, such as amphetamines.

We intend to continue the study of H3 antagonist compounds we are developing for potential applications in treating narcolepsy, excessive daytime sleepiness, chronic fatigue associated with certain disease conditions such as Parkinson's, certain attention or cognitive disorders, and other conditions. In addition, we intend to conduct additional pharmacology and safety testing of certain compounds we are developing, and are exploring potential partnering opportunities around this and other programs.

Other Key Technologies

In addition to our product development programs, we have developed RAGE, a patented 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. This technology platform provides us with broad freedom to work with drug targets that may be inaccessible to most other companies 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, and some have been produced for our internal drug development programs.

Collaborations and Partnerships

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.

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 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, 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.

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 plan has not been met; (2) the clinical efficacy and/or safety with respect to a clinical development candidate or a cell therapy product have not been demonstrated; (3) 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.

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. 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. Through December 31, 2008, we have received an aggregate of approximately $7.8 million in license fees and milestone payments from Bristol-Myers Squibb, of which $1.9 million was earned in 2008.

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. Our collaboration agreement with Bristol-Myers Squibb, which was initially established in 2001, is now in its final phase. We intend to continue to prepare and deliver validated drug targets for use by Bristol-Myers Squibb in its drug discovery efforts until the collaboration objectives have been fulfilled. 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. During 2009, our revenues may fluctuate compared to 2008 based on the timing of Bristol-Myers Squibb's demand for targets and the timing of our work and based on the achievement and timing of Bristol-Myers Squibb milestone achievements, if any. Beyond 2009, we anticipate that Bristol-Myers Squibb's demand for new targets will be reduced.

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.

Other public companies are developing stem-related therapies, including Geron, Aastrom Biosciences, Stem Cells Inc., Viacell, Celgene, Advanced Cell Technology, CRYO-CELL International, Mesoblast Limited and Cytori Therapeutics. In addition, private companies, such as Cognate Therapeutics, Gamida Cell, Arteriocyte, Plureon 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 are already approved therapeutic products on the market, such as Xenical (also known as Alli), which is marketed by Roche, and Meridia, which is marketed by Abbott Pharmaceuticals. However, both of these drugs have reported side effects that we believe have limited their adoption by patients and clinicians. For example, potential side effects associated with taking Xenical / Alli include cramping, intestinal discomfort, flatulence, diarrhea, and leakage of oily stool. Potential side effects associated with taking Meridia include increased blood pressure and heart rate, headache, dry mouth, constipation, and insomnia. Individuals with high blood pressure, heart disease, irregular heartbeat, or a history of stroke are also cautioned not to take Meridia.

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, Nastech 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 5HT2c agonist as a safe and effective treatment for obesity, it is likely that other companies will attempt to develop safer and more effective compounds in the same class, or will attempt to combine therapies in an effort to establish a safer and more effective therapeutic product.

Finally, we face competition with respect to our ability to produce drug targets for our drug development programs. There are many companies with established intellectual property that seek to restrict or protect the use of specific drug targets, including Incyte, Millennium Pharmaceuticals, Human Genome Sciences, Lexicon Genetics, CuraGen, Exelixis, Myriad Genetics, Sangamo BioSciences, and others.

We believe our most significant competitors are fully integrated pharmaceutical companies and more established 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 have a broad patent estate with claims directed to compositions, methods of production, and methods of use of MAPCs 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 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 develop by us and others. We have eleven issued patents and approximately 110 patent applications related to our stem cell technologies.

We have established a broad intellectual property portfolio related to our key functional genomics technologies and 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. In our 5HT2c program, we have filed four patent applications with broad claims directed to ATHX-105, related compounds in the same chemical series from which ATHX-105 was derived, and back-up and second generation compounds from distinct chemical series. In our Histamine H3 program, we have filed four patent applications with broad claims directed to compounds from two distinct chemical series. All compounds described in these patent applications were discovered at Athersys. In addition, we currently have twelve issued United States patents and various issued international patents relating to compositions and methods for the RAGE technology. These patents will expire in 2017. There are also several patent applications relating to human proteins and candidate drug targets that we have identified through the application of RAGE and our other technologies. 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 $16.5 million in 2008, $15.8 million in 2007 and $9.7 million in 2006.

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 United States IND. CTA requirements are issued by the Medicines and Healthcare Products Regulatory Agency, the United Kingdom's health authority and were enacted through the U.K. Medicines for Human Use (Clinical Trials) Regulations 2004, which implemented the EU Clinical Trials Directive in the United Kingdom.

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. Once clinical trials are initiated, they generally take five to seven years, or longer, to complete. After completion of clinical trials of 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, 2008, we employed 35 full time equivalent employees, 13 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 14(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge on our website, www.athersys.com, as soon as reasonably practicable after they are filed with, or furnished to, the SEC.

Merger and Name Change

On June 8, 2007, Athersys, Inc., a Delaware corporation, merged with a wholly owned subsidiary of BTHC VI, Inc., a Delaware corporation. On August 31, 2007, Athersys, Inc. changed its name to ABT Holding Company, and BTHC VI, Inc. changed its name to Athersys, Inc. In this annual report, unless otherwise indicated or the context otherwise requires, all references to "we" or "us" are to Athersys, Inc., the Delaware corporation formerly known as BTHC VI, Inc., together with its wholly owned subsidiary, ABT Holding Company, the Delaware corporation formerly known as Athersys, Inc. Specific discussions or comments relating only to BTHC VI, Inc. prior to the merger described above reference "BTHC VI," while those relating only to our subsidiary Athersys, Inc. prior to the merger reference "Athersys."

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

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

Since Athersys' inception in 1995, it has incurred significant losses and negative cash flows from operations. Athersys has incurred net losses of $11 million in 2006, $19 million in 2007 and $18 million in 2008. As of December 31, 2008, we had an accumulated deficit of $178 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 Athersys' operations was $8 million in 2006, $12 million in 2007 and $16 million in 2008. Based on current plans, we anticipate using $11 million to $13 million of our cash (net of cash inflows) to fund our activities in 2009, which includes clinical trial costs to advance our MultiStem programs and reflects a reduction in costs from 2008 as a result of the suspension of the ATHX-105 clinical program early in 2009. 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. 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, particularly in light of the current credit crisis. 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 canditates 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 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, 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.

The Angiotech collaboration terminates upon the earliest to occur of (a) 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 trial or later, or (b) the later of (1) the expiration date of the last-to-expire patent licensed to Angiotech or (2) the 15-year anniversary. Neither we nor Angiotech may terminate the collaboration at will, but either party may elect at certain points to not move forward with individual product development programs. However, Angiotech has the right to terminate the collaboration if, among other things, Angiotech, in its reasonable judgment, determines that a primary endpoint in a clinical trial within a clinical development plan has not been fulfilled or met, or if the clinical efficacy and/or safety with respect to cells, or a clinical development candidate or a cell therapy product have not been demonstrated.

The Bristol-Myers Squibb collaboration terminates 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 a product utilizing our cell line or ten years after commercial sales of that product began.

The University of Minnesota license agreement terminates when the last patent licensed to us expires. We may terminate the license agreement at any time. The University of Minnesota may terminate the license if we fail to pay royalties when due or fail to perform the material terms of the license, such as our obligation to use commercially reasonable efforts to commercialize the MultiStem technology.

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.

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 pharmaceutical product candidates and our MultiStem product candidate. There can be no guarantee that we can obtain sufficient and acceptable quantities of our pharmaceutical product candidates or of our MultiStem product candidate on acceptable terms, which may delay or impair our ability to develop, test and market such products.

Our current business strategy relies on third parties to manufacture and produce our pharmaceutical product candidates and MultiStem product candidate in accordance with good manufacturing practices established by the FDA, or similar regulations in other countries. Our pharmaceutical product candidates or MultiStem product candidate may be in competition with other products or companies for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority than our product candidates. These third parties may not deliver sufficient quantities of our pharmaceutical or MultiStem product candidates, manufacture our pharmaceutical and 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 pharmaceutical product candidates or 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 pharmaceutical product candidates or 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 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 our contract manufacturers are not satisfying our needs and we decide not to establish our own manufacturing capabilities, it could be difficult and very expensive to change suppliers. Any change in the location of manufacturing would require FDA inspection and approval, which could interrupt the supply of products and may be time-consuming and expensive to obtain. If we are unable to identify alternative contract manufacturers that are qualified to produce our products, we may have to temporarily suspend the production of products, and would be unable to generate revenue from the sale of 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 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.

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 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 more than 25 distinct patent applications directed to composition, methods of production, and methods of use of MultiStem and related technologies. If we are unsuccessful in obtaining these patents, 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. As a result of this license, we have agreed to use commercially reasonable efforts to develop and commercialize this technology. If we fail to comply with those obligations, we may lose 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, umbilical cord 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, Sanofi-Aventis and GlaxoSmithKline as well as smaller biotechnology or biopharmaceutical companies such as Arena Pharmaceuticals, Orexigen, Vivus, Osiris, Geron, Aastrom, Stem Cells Inc., Viacell 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:

- 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 the 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 53,000 square feet of space for our corporate offices and laboratories, with about 40,000 square feet of state-of-the-art laboratory space. The lease currently expires in March 2010, and we have an option to extend the lease in annual increments through March 2013 at our current rent of $267,000 per year. In 2008, we entered into a three-year lease agreement for office and laboratory space for our Belgian subsidiary, with an annual rent of approximately $42,000, subject to annual adjustments based on an inflationary index. The lease includes an option to expand, which, if exercised, would result in annual rent of approximately $80,000. The lease includes an option to renew for four additional years through December 31, 2014.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of security holders during the fourth quarter of 2008.

ITEM 4A. 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: 48

Dr. Van Bokkelen has served as our Chief Executive Officer and Chairman since June 2007. 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. He has served as Chairman of Athersys' board of directors since August 2000. Dr. Van Bokkelen is the current Chairman of the Center for Stem Cells and 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 in 2008, and the Kent State University Board of Trustees from 2001 to 2004, and has served as an advisor to a number of early stage and venture-backed companies, venture capital firms and non-profit organizations. 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: 43

Mr. Lehmann has served as our President and Chief Operating Officer since June 2007. Mr. Lehmann joined Athersys in September 2001 and was Athersys' Executive Vice President of Corporate Development and Finance from August 2002 until May 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: 41

Dr. Harrington has served as our Chief Scientific Officer, Executive Vice President and Director since June 2007. Dr. Harrington co-founded Athersys in October 1995 and has served as Athersys' Executive Vice President and Chief Scientific Officer and as Director since Athersys' founding. Dr. Harrington led the development of the RAGE technology as well as its application for gene discovery, drug discovery and commercial protein production applications. He is a listed inventor on 20 issued or pending United States patents, has authored 20 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 Ph.D. in Cancer Biology from Stanford University and his B.A. in Biochemistry and Cell Biology from the University of California at San Diego.

Robert J. Deans, Ph.D.
Age: 57

Dr. Deans has served as our Senior Vice President, Regenerative Medicine since June 2007. 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. 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: 45

Ms. Campbell has served as our Vice President, Finance since June 2007. Ms. Campbell joined Athersys in January 1998 as Controller and has served as Vice President of Finance since May 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.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Since December 12, 2007, our common stock has been traded on the NASDAQ Capital Market under the symbol "ATHX." Set forth below are the high and low sale prices for our common stock on the NASDAQ Capital Market for the periods indicated.

	High	Low
Year ended December 31, 2008:		
First Quarter	$ 5.00	$ 3.00
Second Quarter	$ 4.23	$ 1.55
Third Quarter	$ 4.00	$ 1.17
Fourth Quarter	$ 1.88	$ 0.15

	High	Low
Year ended December 31, 2007:		
Fourth Quarter (from December 12, 2007 through December 31, 2007)	$ 5.01	$ 3.51

Prior to the merger with BTHC VI, Inc., BTHC VI was a shell company with no operations and no or nominal assets. BTHC VI's common stock was eligible for trading on the OTC Bulletin Board, although no trading took place prior to the merger because none of BTHC VI's then-outstanding shares were able to be transferred under the terms of BTHC VI's bankruptcy plan until the merger was consummated. From June 8, 2007 to December 11, 2007, our common stock was quoted on the OTC Bulletin Board under the symbol "AHYS" at the following prices:

	High	Low
Year ended December 31, 2007:		
Second Quarter	$ 10.00	$ 5.25
Third Quarter	$ 8.75	$ 7.00
Fourth Quarter (through December 11, 2007)	$ 8.00	$ 4.40

These over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Holders

As of February 28, 2009, the number of holders of record was approximately 789, one of which 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 by record by Cede & Co., as one stockholder.

Dividend Policy

All of our assets consist of the capital stock of ABT Holding Company. We would have to rely upon dividends and other payments from 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, the terms of our indebtedness and applicable state laws. 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)

	Year Ended December 31,				
	2008	2007	2006	2005	2004
Consolidated Statement of Operations Data:					
Revenues:					
License fees	$ 1,880	$ 1,433	$ 1,908	$ 763	$ 820
Grants	1,225	1,827	1,817	2,833	2,318
Total revenues	3,105	3,260	3,725	3,596	3,138
Costs and expenses:					
Research and development	16,500	15,817	9,741	12,578	12,415
General and administrative	5,479	7,975	3,347	3,755	4,717
Depreciation	218	283	528	982	1,297
Restructuring costs	—	—	—	251	107
Loss from operations	(19,092)	(20,815)	(9,891)	(13,970)	(15,398)
Other income (expense):					
Other income and equity in earnings of unconsolidated affiliate	48	2,017	208	18	—
Interest income	1,146	1,591	119	317	317
Interest expense and other	(94)	(1,263)	(1,047)	(964)	(73)
Accretion of premium on convertible debt	—	(456)	(260)	—	—
Loss before cumulative effect of change in accounting principle	$ (17,992)	$ (18,926)	$ (10,871)	$ (14,599)	$ (15,154)
Cumulative effect of change in accounting principle	—	—	306	—	—
Net loss	(17,992)	(18,926)	(10,565)	(14,599)	(15,154)
Preferred stock dividends	—	(659)	(1,408)	(2,253)	(2,325)
Deemed dividend resulting from induced conversion of convertible preferred stock	—	(4,800)	—	—	—
Net loss attributable to common stockholders	$ (17,992)	$ (24,385)	$ (11,973)	$ (16,852)	$ (17,479)
Basic and diluted net loss per common share attributable to common stockholders:					
Loss before cumulative effect of change in accounting principle	$ (0.95)	$ (2.26)	$ (41.89)	$ (57.79)	$ (59.82)
Cumulative effect of change in accounting principle	—	—	1.05	—	—
Net loss	$ (0.95)	$ (2.26)	$ (40.84)	$ (57.79)	$ (59.82)
Weighted average shares outstanding, basic and diluted	18,927,988	10,811,119	293,142	291,612	292,173

	December 31,				
	2008	2007	2006	2005	2004
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 12,552	$ 13,248	$ 1,528	$ 1,080	$ 3,303
Available-for-sale securities (short-tem)	15,460	22,477	—	3,481	13,976
Working capital (deficit)	26,789	32,849	(3,206)	1,828	17,018
Available-for-sale securities (long-tem)	3,601	13,850	—	—	—
Total assets	33,877	52,225	4,266	7,309	20,894
Long-term obligations, less current portion	—	—	9,310	4,684	7,215
Accrued dividends	—	—	8,882	7,473	11,236
Total stockholders' equity (deficit)	31,563	47,631	(20,007)	(8,584)	1,151

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 consists of MultiStem, a patented and proprietary stem cell product that we are developing as a treatment for multiple disease indications, and that is currently being evaluated in two ongoing clinical trials. In addition, we are developing novel pharmaceuticals to treat indications such as obesity, certain cognitive and attention disorders, as well as narcolepsy, other forms of excessive daytime sleepiness and chronic fatigue associated with certain disease indications.

Current Programs

In 2008, we advanced two MultiStem programs into clinical development, initiating phase I studies in cardiovascular disease (treating patients that have suffered an acute myocardial infarction) and in oncology treatment support (administering MultiStem to leukemia or lymphoma patients who are receiving a traditional bone marrow or HSC transplant to reduce the risk or severity of GVHD). We are conducting the acute myocardial infarction clinical trial with our partner Angiotech. In May 2006, we entered into a 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. We retain the exclusive commercial rights to the development of MultiStem for other indication areas, including oncology treatment support, neurological indications, autoimmune disease, and other areas.

In September 2008, Angiotech announced certain reorganization initiatives to reduce its costs, citing the potential need for an amendment and reduction in cash outlays related to our collaboration on a list of possible actions. At this time, no such amendment or reduction has been requested or made to our collaboration, and Angiotech continues to fund its share of phase I costs on a timely basis. In the event that Angiotech fails to fund its obligations under the terms of our contract, our net costs for the phase I clinical trial would increase or the clinical trial may be curtailed.

We applied to the FDA in the summer of 2008 to initiate a double blind, placebo controlled phase II clinical trial involving administration of ATHX-105 to patients in the United States. In September 2008, following the FDA's review of our investigational new drug application, or IND, the proposed trial was placed on partial clinical hold pending the receipt of additional information and resolution of several issues relating to ATHX-105's preclinical package and the proposed phase II study design.

At the suggestion of the FDA, we conducted two additional studies to provide further data about ATHX-105's potential toxicological profile, one repeating a prior study under different conditions and another study that we had not previously conducted and that is not typically included in preclinical evaluation. While the first study confirmed our prior negative findings, meaning the absence of a relevant toxicological effect, the second study produced data that suggests a rat specific toxicological effect. We met with the FDA to discuss the issues and reached resolution regarding all of the study design issues related to the partial clinical hold. However, based on the results of the additional test and discussions with the FDA, we believe that the apparent rodent specific effect could require additional non-clinical studies and greatly complicate long-term toxicology testing and thereby increase substantially the development time, risks and costs associated with subsequent development of ATHX-105. Furthermore, these increased risks of development could make it substantially more difficult or impractical for us to establish an attractive, third-party collaboration for the further development and commercialization of ATHX-105.

Consequently, we have decided to suspend further development of ATHX-105 and withdraw our IND application, and are currently focusing on the advancement of next generation compounds that exhibit improved characteristics. While the potential significance of this toxicological effect to humans remains unclear, it appears to be a compound-specific effect that is not representative of the class of next generation compounds that we are continuing to develop while we explore potential partnerships for the program.

We are also independently developing novel orally active pharmaceutical products for the treatment of certain central nervous system disorders, including disorders such as narcolepsy, excessive daytime sleepiness, and chronic fatigue, as well as other potential indications such as attention deficit hyperactivity disorder and other cognitive disorders such as schizophrenia.

Financial

In June 2007, we completed a merger with BTHC VI, Inc. and its wholly-owned subsidiary that was formed for the purpose of completing the merger. BTHC VI was a public shell corporation with substantially no assets, liabilities or operations. We continued as the surviving entity in the merger and our business became the sole operations of BTHC VI after the merger. BTHC VI's acquisition of us effected a change in control and was accounted for as a reverse acquisition whereby we were the accounting acquirer for financial statement purposes. Accordingly, our financial statements present our historical results and do not include the historical financial results of BTHC VI prior to the merger. At the time the merger was effective, each share of common stock of Athersys was exchanged into 0.0358493 shares of BTHC VI common stock, par value $0.001 per share. Prior to the merger, BTHC VI effected a 1-for-1.67 reverse stock split of its shares of common stock and increased the number of authorized shares of common stock to 100,000,000. Athersys' authorized and issued shares of common and preferred stock have been retroactively restated for all periods presented to reflect the merger exchange ratio of 0.0358493. Basic and diluted net loss per share attributable to common stockholders have been computed using the retroactively restated common stock.

In connection with the merger in June 2007, Athersys negotiated with holders of its convertible preferred stock a planned restructuring of its capital stock, which included the conversion of the preferred stock into shares of its common stock, the termination of warrants issued to the former holders of Class C Convertible Preferred Stock, and the elimination of accrued dividends payable to the former holders of Class C Convertible Preferred Stock. As a result, immediately prior to the consummation of the merger with BTHC VI, all convertible preferred stock (including termination of warrants and elimination of accrued dividends) was converted into 53,341,747 shares of common stock. The change to the conversion ratios of the convertible preferred stock was deemed to be an induced conversion, which resulted in a $4.8 million deemed dividend and an increase to the net loss attributable to common stockholders in June 2007. Upon the closing of the merger, the 53,341,747 shares of common stock were exchanged for 1,912,356 shares of BTHC VI common stock using the merger exchange ratio. Athersys also retired all shares of stock held in treasury.

Immediately after the merger, we completed an offering of 13,000,000 shares of common stock for aggregate gross proceeds of $65.0 million in June 2007, which included the issuance of warrants to purchase 3,250,000 shares of common stock to the investors. We also issued warrants to purchase 500,000 shares of common stock to the lead investor and warrants to purchase 1,093,525 shares of common stock to the placement agents. The placement agents also received cash fees in an amount equal to approximately $5.5 million, which was based on 8.5% of the gross proceeds, excluding proceeds from existing investors. In consideration for certain advisory services, we paid an affiliate of BTHC VI's then-largest stockholder a one-time fee of $350,000 in cash upon consummation of the merger.

Upon the closing of the June offering, the $10.0 million aggregate principal amount of convertible notes issued to Angiotech were converted along with accrued interest into 1,885,890 shares of common stock at a conversion price of $5.50 per share, which was 110% of the price per share in the June offering, in accordance with the terms of the notes.

Upon the closing of the June offering, the notes issued to bridge investors were converted along with accrued interest into 531,781 shares of common stock at a conversion price of $5.00 per share, which was the price per share in the June offering. The bridge investors also exercised their $0.01 warrants upon the conversion of the convertible preferred stock in connection with the merger for 999,977 shares of common stock at an aggregate exercise price of $10,000. Upon the conversion of the bridge notes, the bridge investors also received five-year warrants to purchase 132,945 shares of common stock at $6.00 per share, which terms were consistent with the warrants issued to new investors in the June offering.

In May 2007, Athersys terminated the majority of stock option awards to its officers, employees, directors and consultants. Only a nominal number of option awards (5,052 option shares) held by former employees and consultants were assumed by us. Upon closing the merger, options for 3,625,000 shares of common stock were issued under our equity incentive plans to employees, directors and consultants with an exercise price of $5.00 per share, resulting in stock compensation expense of $5.1 million in 2007.

Also in May 2007, Athersys sold certain non-core technology related to its asthma discovery program to Wyeth Pharmaceuticals for $2.0 million.

We have incurred losses since inception of operations in December 1995 and had an accumulated deficit of $178 million at December 31, 2008. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We have used the financing proceeds from private equity and debt offerings and other sources of capital to develop our technologies, to discover and develop therapeutic product candidates 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 license fees and milestone payments from our collaborators and grant proceeds primarily from federal and state grants. We have derived no revenue on the sale of FDA-approved products to date. Research and development expenses 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. 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 products and manufacture our products. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees and other corporate expenses. To date, we have financed our operations through private equity and debt financing and investments by strategic collaborators. We expect to continue to incur substantial losses through at least the next several years.

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

Revenues	Year ended December 31, 2008	2007	2006
License fees	$ 1,880	$ 1,433	$ 1,908
Grant revenue	1,225	1,827	1,817
	$ 3,105	$ 3,260	$ 3,725

Research and development expenses *Type of expense*	Year ended December 31, 2008	2007	2006
Personnel costs	$ 2,924	$ 2,813	$ 2,721
Research supplies	849	679	1,208
Facilities	817	762	879
Clinical and preclinical development costs	7,878	5,723	2,702
Sponsored research	393	465	579
Patent legal fees	1,481	1,086	595
Other	1,431	1,821	781
Stock-based compensation	727	2,468	276
	$ 16,500	$ 15,817	$ 9,741

General and administrative expenses *Type of expense*	Year ended December 31, 2008	2007	2006
Personnel costs	$ 1,726	$ 1,987	$ 1,891
Facilities	342	330	291
Legal and professional fees	1,032	1,165	590
Other	1,250	1,822	392
Stock-based compensation	1,129	2,671	183
	$ 5,479	$ 7,975	$ 3,347

Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

Revenues. Revenues decreased to $3.1 million for the year ended December 31, 2008 from $3.3 million for 2007. Grant revenue decreased $0.6 million primarily due to the completion of a 2006 state grant in October 2008 as well as the timing of expenditures that are reimbursed with grant proceeds. License fee revenues increased $0.4 million as a result of the nature and timing of target acceptances under our collaboration agreement with Bristol-Myers Squibb and the achievement of a clinical development milestone in September 2008. During 2009, our revenues may fluctuate compared to 2008 based on the timing of Bristol-Myers Squibb's demand for targets and the timing of our work and based on the achievement and timing of Bristol-Myers Squibb milestones, if any. Beyond 2009, we anticipate that Bristol-Myers Squibb's demand for new targets will be reduced. Additionally, our grant revenues could fluctuate during any year based on the timing of grant-related activities and the award of new grants.

Research and Development Expenses. Research and development expenses increased to $16.5 million in 2008 from $15.8 million in 2007. The increase of approximately $0.7 million related primarily to an increase in clinical and preclinical development costs of $2.2 million, an increase in patent legal fees of $395,000, an increase in research supplies expenses of $170,000 and an increase in personnel costs of $111,000 in 2008 compared to 2007. These increases were partially offset by a decrease in stock compensation expense of $1.7 million, a decrease in other expenses of $390,000 and a decrease in sponsored research of $72,000 in 2008 compared to 2007. The $2.2 million increase in preclinical and clinical costs is a result of the completion of the ATHX-105 phase I clinical trial, preparations for the ATHX-105 phase II clinical trial, completion of two additional phase I trials in the United Kingdom, performance of ATHX-105 non-clinical studies, and increases in MultiStem preclinical and clinical costs and manufacturing expenses. Our clinical costs in 2008 and 2007 are reflected net of Angiotech's cost-sharing amount related to our MultiStem acute myocardial infarction collaboration in the amount of $943,000 and $63,000, respectively. The increase in patent legal fees for 2008 was a result of maintaining our growing and maturing portfolio of patent applications, including prosecution costs for several cases that entered the national phase in 2008. Personnel costs increased due to the addition of personnel in support of our clinical programs, annual salary increases and increased benefit costs, which was partially offset by the absence of bonus payments in 2008. The

decrease in other expenses was primarily a result of a milestone payment in 2007 in the amount of $1.0 million associated with a stem cell collaboration milestone and a stem cell IND milestone and was paid to the former owners of the technology. This decrease was partially offset by an increase in outsourced research and development expenses. We expect our research and development expenses to decrease in 2009, primarily as a result of the decision to suspend further development of ATHX-105, partially offset by expected increases in clinical development costs associated with our MultiStem programs. 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 $5.5 million in 2008 from $8.0 million in 2007. The $2.5 million decrease was due primarily to a decrease in stock compensation expense of $1.5 million, decrease in other expenses of $572,000, decrease in personnel costs of $261,000 , and a decrease in legal and professional fees of $133,000. The decrease in other expenses for 2008 was primarily as result of a one-time advisory fee of $350,000 in 2007 related to the merger. Personnel costs decreased due to the absence of bonus payments in 2008, which was partially offset by the addition of administrative support personnel, annual salary increases and increased benefit costs. The decrease in legal and professional fees in 2008 was primarily a result of reduced legal fees incurred in connection with SEC filings and transactional work. We expect our general and administrative expenses to continue at similar levels in 2009.

Depreciation. Depreciation expense decreased to $218,000 in 2008 from $283,000 in 2007. The decrease in depreciation expense was due to more laboratory equipment, computer equipment, furniture and leasehold improvements becoming fully depreciated.

Other Income. In May 2007, Athersys sold certain non-core technology related to its asthma discovery program to Wyeth Pharmaceuticals for $2.0 million.

Interest Income. Interest income decreased to $1.1 million in 2008 from $1.6 million in 2007. The change in interest income was due to the receipt and investment of the proceeds from the equity offering in June 2007, the proceeds of which have been declining as they are used to fund operations. Due to declining interest rates and lower cash balances as a result of our ongoing and planned clinical and preclinical development, we expect our 2009 interest income to be less than 2008.

Interest Expense. Interest expense on Athersys' debt outstanding under its senior loan and its subordinated convertible promissory notes decreased to $94,000 in 2008 from $1.3 million in 2007. The decrease in interest expense was due to the repayment of the senior loan in June 2008, conversion in June 2007 of $2.5 million in aggregate principal amount of subordinated convertible promissory notes issued to bridge investors, and conversion in June 2007 of $10 million in aggregate principal amount of subordinated convertible promissory notes issued to Angiotech. We do not expect any significant interest expense in 2009 unless we incur new debt.

Accretion of Premium on Convertible Debt. The accretion of premium on convertible debt of $0.5 million in 2007 relates to the $2.5 million in aggregate principal amount of subordinated secured convertible promissory notes issued to bridge investors in 2006 that were converted into common stock upon the closing of the equity offering in June 2007. The notes, if not converted, were repayable with accrued interest at maturity, plus a repayment fee of 200% of the outstanding principal. Athersys computed a premium on the debt in the amount of $5.25 million due upon redemption, which was being accreted over the term of the notes using the effective interest method. The unamortized premium was reversed and recorded in additional paid-in-capital when the notes were converted in June 2007.

Year Ended December 31, 2007 Compared to Year Ended December 31, 2006

Revenues. Revenues decreased to $3.3 million for the year ended December 31, 2007 from $3.7 million for 2006. License fee revenues decreased $0.5 million as a result of the nature and timing of target acceptances under our collaboration agreement with Bristol-Myers Squibb and Pfizer. Grant revenue remained consistent at $1.8 million for each of 2007 and 2006.

Research and Development Expenses. Research and development expenses increased to $15.8 million in 2007 from $9.7 million in 2006. The increase of approximately $6.1 million related primarily to an increase in clinical and preclinical development costs of $3.0 million, an increase in stock compensation expense of $2.2 million, an increase in other expenses of $1.0 million and an increase in patent legal fees of $0.5 million in 2007 compared to 2006. These increases were partially offset by a decrease in research supplies expenses of $529,000, a decrease in sponsored research of $114,000 and a decrease in facilities costs of $117,000 in 2007 compared to 2006. The $3.0 million increase in preclinical and clinical costs is a result of the initiation of the ATHX-105 phase I clinical trial, performance of ATHX-105 non-clinical studies, and increases in MultiStem preclinical and clinical costs and manufacturing expenses. Included in other expenses for 2007 were two milestone payments totaling $1.0 million in cash and stock associated with a collaboration milestone and an IND milestone related to our stem cell technology paid to the former owners of the technology. In 2006, other expenses included a milestone payment of $125,000 paid in stock related to a patent milestone covering the stem cell technology. These were the final milestone payments to be made by us under the agreement governing the acquisition of the stem cell technology. The increase in patent legal fees for 2007 was a result of maintaining our growing and maturing portfolio of patent applications and the performance of patent legal work related to the May 2007 asthma asset sale. Included in personnel costs for 2007 and 2006 was approximately $447,000 and $121,000, respectively, of bonus payments related to the achievement of certain milestones. 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 $8.0 million in 2007 from $3.3 million in 2006. The increase was due primarily to an increase in stock compensation expense of $2.5 million, an increase in other expenses of $1.4 million, an increase in legal and professional fees of $575,000 and an increase in personnel and facilities costs of $135,000. Included in other expenses for 2007 was a one-time advisory fee of $350,000 related to the merger, an allowance against a loan receivable in the amount of $193,000, and $1.3 million of other general and administrative costs such as printing costs for SEC filings, Nasdaq listing fees, directors' and officers' insurance costs, investor and public relations costs, recruiting costs and costs related to compliance with Section 404 of the Sarbanes-Oxley Act of 2002. Included in personnel costs for 2007 and 2006 was approximately $475,000 and $89,000, respectively, of bonus payments related to the achievement of certain milestones. Also included in personnel costs in May 2006 was approximately $122,000 ($146,000 including tax) in connection with the forgiveness of a 2002 loan made to our Chief Executive Officer. The increase in legal and professional fees in 2007 was primarily a result of legal fees incurred in connection with SEC filings, accounting and auditing fees incurred in connection with SEC filings and fees for our board of directors.

Depreciation. Depreciation expense decreased to $283,000 in 2007 from $528,000 in 2006. The decrease in depreciation expense was due to more laboratory equipment, computer equipment, furniture and leasehold improvements becoming fully depreciated.

Other Income and Equity in Earnings of Unconsolidated Affiliate. In May 2007, Athersys sold certain non-core technology related to its asthma discovery program to Wyeth Pharmaceuticals for $2.0 million. In January 2006, a milestone was achieved related to Athersys' joint venture with Oculus. As a result, Athersys received $100,000 of stock-based proceeds from Oculus, which was recorded in other income. Similarly, Oculus also received stock-based proceeds in another company in the amount of $260,000. Athersys recorded its share of Oculus' net income (after recapturing past net losses) of $117,000 in equity in earnings of unconsolidated affiliate in 2006.

Interest Income. Interest income increased to $1.6 million in 2007 from $119,000 in 2006. The change in interest income was due to the receipt and investment of the proceeds from the equity offering in June 2007.

Interest Expense. Interest expense on Athersys' debt outstanding under its senior loan and its subordinated convertible promissory notes increased to $1.3 million for 2007 from $1.0 million in 2006. The increase in interest expense was due to the $2.5 million in aggregate principal amount of subordinated convertible promissory notes issued by Athersys to its bridge investors in October 2006, and the $10 million in aggregate principal amount of subordinated convertible promissory notes issued to Angiotech in 2006 and 2007. These convertible promissory notes were converted in the equity offering in June 2007.

Accretion of Premium on Convertible Debt. The accretion of premium on convertible debt was $0.5 million in 2007 and $0.3 million in 2006. The accretion relates to the $2.5 million in aggregate principal amount of subordinated secured convertible promissory notes issued to bridge investors in October 2006 that were converted into common stock upon the closing of the equity offering in June 2007. The notes, if not converted, were repayable with accrued interest at maturity, plus a repayment fee of 200% of the outstanding principal. Athersys computed a premium on the debt in the amount of $5.25 million due upon redemption, which was being accreted over the term of the notes using the effective interest method. The unamortized premium was reversed and recorded in additional paid-in-capital when the notes were converted in June 2007.

Cumulative Effect of Change in Accounting Principle. Effective January 1, 2006, Athersys adopted the fair value recognition provisions of SFAS No. 123(R) using the modified-prospective-transition method. SFAS No. 123(R) requires Athersys to estimate forfeitures in calculating the expense relating to share-based compensation, while previously Athersys was permitted to recognize forfeitures as an expense reduction upon occurrence. The adjustment to apply estimated forfeitures to previously recognized share-based compensation was accounted for as a cumulative effect of a change in accounting principle at January 1, 2006 and reduced net loss by $306,000 for the year ended December 31, 2006.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and available-for-sale securities. At December 31, 2008, we had $12.6 million in cash and cash equivalents and $19.1 million in available-for-sale securities. Athersys has primarily financed its operations through private equity and debt financings that have resulted in aggregate cumulative proceeds of approximately $200 million.

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. Our collaboration agreement with Bristol-Myers Squibb, which was initially established in 2001, is now in its final phase. We intend to continue to prepare and deliver validated drug targets for use by Bristol-Myers Squibb in its drug discovery efforts until the collaboration objectives have been fulfilled. 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.

Our available-for-sale securities typically include United States government obligations, corporate debt securities, floating rate notes and commercial paper. As of December 31, 2008, approximately 72% of our investments were in United States government obligations. 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 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. Based on current plans, we anticipate using $11 million to $13 million of our cash (net of cash inflows) to fund our activities in 2009, which includes clinical trial costs to advance our MultiStem programs and reflects a reduction in costs from 2008 as a result of the suspension of the ATHX-105 clinical program early in 2009. 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. Our funding requirements may change at any time due to technological advances or competition from other companies. Our future capital requirements will also depend on numerous other factors, including scientific progress in our research and development programs, additional personnel costs, progress in preclinical testing and clinical trials, the time and cost related to proposed regulatory approvals, if any, and the costs in filing and prosecuting patent applications and enforcing patent claims. We cannot assure you that adequate funding will be available to us or, if available, that it will be available on acceptable terms, particularly in light of the current credit crisis. Any shortfall in funding could result in our having to curtail our 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, commercializing and obtaining regulatory approval or clearances for our technologies and products resulting from these technologies.

Net cash used in operating activities was $15.7 million, $12.1 million and $8.4 million in 2008, 2007 and 2006, 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 decrease in 2009 primarily as a result of the decision to suspend further development of ATHX-105, which will be partially offset by expected increases in clinical development costs associated with our MultiStem programs.

Net cash provided by investing activities was $16.8 million in 2008 and $3.4 million in 2006. Net cash used in investing activities was $36.4 million in 2007. 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 $532,000, $161,000 and $83,000 in 2008, 2007 and 2006, respectively. We expect that our capital equipment expenditures will continue at similar levels in 2009 compared to 2008.

Financing activities used cash of $1.8 million in 2008 and provided cash of $60.2 million in 2007 and $5.4 million in 2006. These fluctuations relate primarily to proceeds from the equity offering in June 2007, the issuance of convertible promissory notes in 2007 and 2006 to Angiotech and the bridge investors in 2006, and repayments of our senior loan.

Investors in the equity offering in June 2007 also 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 in the June offering 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 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. The exercise of such warrants could provide us with cash proceeds. No warrants have been exercised at December 31, 2008.

Our senior loan was repaid in full in June 2008. The senior 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 senior 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 milestone events have occurred as of December 31, 2008. 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, 2008.

In connection with our 2006 MultiStem collaboration with Angiotech, Angiotech purchased subordinated convertible promissory notes in the aggregate principal amount of $10.0 million, which were converted along with accrued interest into common stock upon the closing of our equity offering in June 2007. Upon the successful achievement of specified clinical development and commercialization milestones, we may also receive up to $3.75 million of additional equity investments and $63.75 million of aggregate cash payments, 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 phase III clinical trials subsequent to the first 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 will take the lead on pivotal and later clinical trials and commercialization. Late in 2007, the parties began to share costs for phase I clinical development, which is reconciled quarterly. As of December 31, 2008, $234,000 was due from Angiotech representing its share of costs for the fourth quarter of 2008.

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, bone marrow transplantation and oncology support, blood and immune system disorders, autoimmune disease, and other indications that we may elect to pursue. In September 2008, Angiotech announced certain reorganization initiatives to reduce its costs, citing the need for a potential amendment and reduction in cash outlays related to our collaboration, among a list of several selected actions. At this time, no such amendment or reduction has been made to our collaboration, and Angiotech continues to fund its share of phase I costs on a timely basis. In the event that Angiotech fails to fund its obligations under the terms of our contract, our costs for the phase I clinical trial would increase or the clinical trial may be curtailed.

Our contractual payment obligations as of December 31, 2008 are as follows:

Contractual Obligations	Total	Less Than 1 Year	1 — 3 Years	3 — 5 Years	More Than 5 Years
Operating leases for facilities and equipment lease	$ 493,000	$ 335,000	$ 137,000	$ 21,000	—
Research funding	253,000	253,000	—	—	
Total	$ 746,000	$ 588,000	$ 137,000	$ 21,000	—

We have an operating lease for our office and laboratory space with options to renew through March 2013 at the existing rental rate. We exercised options to renew the lease through March 2010. In 2008, we entered into a three-year lease agreement for office and laboratory space for our Belgian subsidiary with an annual rent of approximately $42,000, subject to annual adjustments based on an inflationary index. The lease includes an option to renew for four additional years, through December 31, 2014.

The research funding in the table above represents our current funding commitment for a four-year research program that began in 2007. We approved the funding for the first two years of research programs; however, funding for the remaining two years is subject to our continuation of the program and approval of the annual research plans. If we approve funding for the remaining two years of the program, we will be obligated to contribute additional funding for the program.

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.

Athersys has never paid dividends on its capital stock, and all accrued cumulative dividends were eliminated in June 2007 in connection with the merger.

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 revenue recognition policies are in accordance with the SEC Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition, and Emerging Issues Task Force, or EITF, No. 00-21, Revenue Arrangements with Multiple Deliverables, which provide guidance on revenue recognition in financial statements and are based on the interpretations and practices developed by the SEC. Our license and collaboration agreements may contain multiple elements, including technology access and development fees, cost-sharing, milestones and royalties.

Our license fee revenue primarily consists of fees received from a collaborator, 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, revenue from grants 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.

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, the amounts are not based on estimates that are susceptible to change.

Investments in Available-for-Sale Securities

We adopted the provisions of Statement of Financial Accounting Standards, or SFAS, No. 157 related to our financial assets and liabilities on January 1, 2008, and accordingly, 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, corporate debt securities, floating rate notes and commercial paper, all of 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.

In October 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position, or FSP, FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, which clarifies the application of SFAS No. 157, *Fair Value Measurements*, in a market that is not active and illustrates key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP did not have an impact on our financial statements.

Stock-Based Compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123(R) using the modified-prospective-transition method. We recognize expense on the straight-line method.

We use a Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards under SFAS No. 123(R). The expected term of options granted represent the period of time that option grants are expected to be outstanding. We use the "simplified" method under SEC Staff Accounting Bulletin No. 110 to calculate the expected life of option grants in 2008 and 2007 given our limited history. We determine volatility by using the historical stock volatility of other companies with similar characteristics. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

SFAS No. 123(R) requires forfeitures to be 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 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 December 2007, the FASB ratified the consensus reached in EITF Issue No. 07-1, *Accounting for Collaborative Arrangements.* The effective date of EITF 07-1 is January 1, 2009 for calendar year companies with retrospective application required for all periods presented for collaborative arrangements existing as of the effective date. EITF 07-1 requires certain disclosures related to collaborative arrangements where parties are active participants and exposed to significant risks and rewards dependent on the commercial success of the activity. We do not expect its adoption to have a material impact on our financial statements.

In May 2008, the FASB issued FASB Staff Position APB 14-1, or FSP 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. FSP 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash on conversion to separately account for the liability and equity components in a manner that reflects the issuer's nonconvertible debt borrowing rate. We currently have no convertible debt instruments, but are evaluating the retrospective effect that FSP 14-1 may have on our financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*. This statement, which addresses the accounting for business acquisitions, is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited, and generally applies to business acquisitions completed after December 31, 2008. Among other things, the new standard requires that all acquisition-related costs be expensed as incurred, and that all restructuring costs related to acquired operations be expensed as incurred. This new standard also addresses the current and subsequent accounting for assets and liabilities arising from contingencies acquired or assumed. We do not expect its adoption to have a material impact on our financial statements. SFAS No. 141R could have a material impact on our financial statements in future periods if we complete a significant acquisition.

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:

- our ability to successfully initiate or complete clinical trials for our product candidates;
- the possibility of delays in, adverse results of and excessive costs of the development process;
- 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 enter into licensing or co-development arrangements for certain product candidates;
- our possible inability to execute our strategy due to changes in our industry or the economy generally, including the current economic crisis;
- our ability to obtain capital in difficult market conditions;
- changes in financial stability of collaborators;
- 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. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Due in part to these factors, our future investment income may fall short of expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates. We invest our excess cash primarily in debt instruments of the United States government and its agencies, corporate debt securities, floating-rate notes and A1+/P1 commercial paper. As of December 31, 2008, approximately 72% of our investments were in United States government obligations. 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, 2008, we had no borrowings outstanding.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CONSOLIDATED FINANCIAL STATEMENTS

Athersys, Inc.
Years Ended December 31, 2008, 2007 and 2006

Athersys, Inc.

Consolidated Financial Statements

Years Ended December 31, 2008, 2007 and 2006

Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Athersys, Inc.

We have audited the accompanying consolidated balance sheets of Athersys, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2008. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Athersys, Inc. at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U. S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note B to the consolidated financial statements, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, effective January 1, 2006.

/s/ ERNST & YOUNG LLP

Cleveland, Ohio
March 12, 2009

Athersys, Inc.

Consolidated Balance Sheets

(In Thousands, Except Share and Per Share Amounts)

	December 31, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	**$ 12,552**	$ 13,248
Available-for-sale securities	**15,460**	22,477
Accounts receivable	**260**	836
Receivable from Angiotech	**234**	63
Investment interest receivable	**189**	262
Deposits	**—**	163
Prepaid expenses and other	**408**	394
Total current assets	**29,103**	37,443
Available-for-sale securities	**3,601**	13,850
Deposits	**144**	100
Accounts receivable, net	**—**	42
Notes receivable, net	**12**	86
Equipment, net	**701**	387
Equity investments	**316**	317
Total assets	**$ 33,877**	$ 52,225
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 1,498**	$ 1,011
Accrued compensation and related benefits	**97**	71
Accrued clinical trial costs	**58**	735
Accrued expenses and other	**661**	993
Current portion of long-term debt, net	**—**	1,784
Total current liabilities	**2,314**	4,594
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at December 31, 2008 and December 31, 2007	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized, 18,927,988 shares issued and outstanding at December 31, 2008 and and December 31, 2007	**19**	19
Additional paid-in capital	**209,895**	208,039
Accumulated other comprehensive income	**120**	52
Accumulated deficit	**(178,471)**	(160,479)
Total stockholders' equity	**31,563**	47,631
Total liabilities and stockholders' equity	**$ 33,877**	$ 52,225

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Operations

(In Thousands, Except Share and Per Share Amounts)

	Year Ended December 31,		
	2008	**2007**	**2006**
Revenues			
License fees	**$ 1,880**	$ 1,433	$ 1,908
Grant revenue	**1,225**	1,827	1,817
Total revenues	**3,105**	3,260	3,725
Costs and expenses			
Research and development (including stock compensation expense of $727, $2,468 and $276 in 2008, 2007 and 2006, respectively)	**16,500**	15,817	9,741
General and administrative (including stock compensation expense of $1,129, $2,671 and $183 in 2008, 2007 and 2006, respectively)	**5,479**	7,975	3,347
Depreciation	**218**	283	528
Total costs and expenses	**22,197**	24,075	13,616
Loss from operations	**(19,092)**	(20,815)	(9,891)
Other income	**49**	2,017	91
Equity in earnings (loss) of unconsolidated affiliate	**(1)**	—	117
Interest income	**1,146**	1,591	119
Interest expense	**(94)**	(1,263)	(1,047)
Accretion of premium on convertible debt	**—**	(456)	(260)
Loss before cumulative effect of change in accounting principle	**(17,992)**	(18,926)	(10,871)
Cumulative effect of change in accounting principle	—	—	306
Net loss	**$ (17,992)**	$ (18,926)	$ (10,565)
Preferred stock dividends	**—**	(659)	(1,408)
Deemed dividend resulting from induced conversion of convertible preferred stock	**—**	(4,800)	—
Net loss attributable to common stockholders	**$ (17,992)**	$ (24,385)	$ (11,973)
Basic and diluted net loss per common share attributable to common stockholders			
Loss before cumulative effect of change in accounting principle	**$ (0.95)**	$ (2.26)	$ (41.89)
Cumulative effect of change in accounting principle	—	—	1.05
Net loss	**$ (0.95)**	$ (2.26)	$ (40.84)
Weighted average shares outstanding, basic and diluted	**18,927,988**	10,811,119	293,142

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Stockholders' Equity (Deficit)

(In Thousands, Except Share Amounts)

	Convertible Preferred Stock		Common Stock		Additional		Accumulated Other	Unearned Compensation-		Total Stockholders'
	Number of Shares	Stated Value	Number of Shares	Par Value	Paid-in Capital	Treasury Stock	Comprehensive Income (Loss)	Common Stock Options	Accumulated Deficit	Equity (Deficit)
Balance at January 1, 2006	364,524	$ 68,301	290,941	$ —	$ 55,179	$ (250)	$ (17)	$ (809)	$ (130,988)	$ (8,584)
Issuance of common stock	—	—	2,829	—	130	—	—	—	—	130
Issuance of common stock warrant	—	—	—	—	250	—	—	—	—	250
Adoption of SFAS No. 123(R)	—	—	—	—	(809)	—	—	809	—	—
Stock-based compensation	—	—	—	—	153	—	—	—	—	153
Accrued dividends — Class C	—	—	—	—	(1,408)	—	—	—	—	(1,408)
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	—	(10,565)	(10,565)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	17	—		17
Total comprehensive loss										(10,548)
Balance at December 31, 2006	364,524	68,301	293,770	—	53,495	(250)	—	—	(141,553)	(20,007)
Stock based compensation	—	—	—	—	5,139	—	—	—	—	5,139
Accrued dividends — Class C	—	—	—	—	(659)	—	—	—	—	(659)
Elimination of cumulative accrued dividends — Class C	—	—	—	—	9,541	—	—	—	—	9,541
Conversion of preferred stock to common stock	(364,524)	(68,301)	1,912,356	2	68,299	—	—	—	—	—
Issuance of common stock from warrant exercises	—	—	1,003,190	1	9	—	—	—	—	10
Retirement of treasury stock	—	—	—	—	(250)	250	—	—	—	—
Shares of common stock for merger with BTHC VI, Inc.	—	—	299,622	—		—	—	—	—	—
Issuance of common stock, net of expenses	—	—	13,001,379	13	58,479	—	—	—	—	58,492
Issuance of common stock warrants	—	—	—	—	492	—	—	—	—	492
Issuance of common stock for conversion of convertible notes	—	—	2,417,671	3	13,494	—	—	—	—	13,497
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	—	(18,926)	(18,926)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	52	—	—	52
Total comprehensive loss										(18,874)
Balance at December 31, 2007	—	—	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)**
Balance at December 31, 2008	**—**	**$ —**	**18,927,988**	**$ 19**	**$ 209,895**	**$ —**	**$ 120**	**$ —**	**$ (178,471)**	**$ 31,563**

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

	Year Ended December 31,		
	2008	**2007**	**2006**
Operating activities			
Net loss	**$ (17,992)**	$ (18,926)	$ (10,565)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	**218**	283	528
Gain on sale of equipment	**(24)**	—	—
Equity in (earnings) loss of unconsolidated affiliate	**1**	—	(117)
Accretion of premium on convertible debt	**—**	456	260
Provision/forgiveness of notes receivable	**74**	193	122
Earned milestone applied to note receivable	**—**	283	—
Stock-based compensation	**1,856**	5,139	459
Expense related to warrants issued to lenders	**16**	476	—
Income from cumulative effect of change in accounting principle	**—**	—	(306)
Amortization of premium (discount) on available-for-sale securities and other	**11**	(52)	15
Changes in operating assets and liabilities:			
Accounts receivable	**618**	111	(361)
Receivable from Angiotech	**(171)**	(63)	—
Prepaid expenses and other assets	**178**	(558)	21
Accounts payable and accrued expenses	**(496)**	592	1,546
Net cash used in operating activities	**(15,711)**	(12,066)	(8,398)
Investing activities			
Purchase of available-for-sale securities	**(26,594)**	(46,316)	(3,426)
Proceeds from maturities of available-for-sale securities	**43,917**	10,100	6,932
Proceeds from sale of equipment	**24**	—	—
Purchases of equipment	**(532)**	(161)	(83)
Net cash provided by (used in) investing activities	**16,815**	(36,377)	3,423
Financing activities			
Principal payments on debt	**(1,800)**	(3,332)	(2,083)
Proceeds from convertible promissory notes	**—**	5,000	7,500
Proceeds from issuance of common stock, net	**—**	58,495	6
Net cash (used in) provided by financing activities	**(1,800)**	60,163	5,423
(Decrease) increase in cash and cash equivalents	**(696)**	11,720	448
Cash and cash equivalents at beginning of year	**13,248**	1,528	1,080
Cash and cash equivalents at end of year	**$ 12,552**	$ 13,248	$ 1,528

See accompanying notes.

A. Background, Merger and Offering

Athersys, Inc. ("Athersys" or the "Company") is 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.

On June 8, 2007, Athersys' subsidiary, which was then named Athersys, Inc. ("Old Athersys"), effected a merger into a wholly-owned subsidiary of a public company (the "Merger"). The public company, BTHC VI, Inc. ("BTHC VI"), was a shell corporation with no assets, liabilities or operations as of the date of the Merger and had 299,622 shares of common stock outstanding. Upon completion of the Merger, the officers and directors of Old Athersys assumed control over the operations of BTHC VI, and Old Athersys' operations became the sole operations of BTHC VI on a consolidated basis. In August 2007, BTHC VI changed its name to Athersys, Inc.

Prior to the consummation of the Merger, Old Athersys negotiated with holders of its convertible preferred stock a planned restructuring of its capital stock, which included the conversion of its preferred stock into shares of Old Athersys' common stock, the termination of warrants issued to the former holders of Class C Convertible Preferred Stock, and the elimination of accrued dividends payable to the former holders of Class C Convertible Preferred Stock. As a result, immediately prior to the consummation of the Merger, all convertible preferred stock (including termination of warrants and elimination of accrued dividends) was converted into 53,341,747 shares of common stock. The change to the conversion ratios of the convertible preferred stock was deemed to be an induced conversion, which resulted in a $4.8 million deemed dividend and an increase to the net loss attributable to common stockholders in June 2007. Upon the closing of the Merger, the 53,341,747 shares of Old Athersys common stock were exchanged for 1,912,356 shares of BTHC VI common stock using the Merger exchange ratio. Old Athersys also retired all shares of stock held in treasury.

At the time the Merger was effective, each share of Old Athersys' common stock was exchanged into 0.0358493 shares of BTHC VI common stock, par value $0.001 per share. Prior to the Merger, BTHC VI effected a 1-for-1.67 reverse stock split of its shares of common stock and increased the number of authorized shares of common stock to 100,000,000.

BTHC VI's acquisition of Old Athersys effected a change in control and was accounted for as a reverse acquisition whereby Old Athersys is the accounting acquirer for financial statement purposes. Accordingly, the financial statements of the Company presented reflect the historical results of Old Athersys and do not include the historical financial results of BTHC VI prior to the consummation of the Merger. The Company's authorized and issued shares of common and preferred stock have been retroactively restated for all periods presented to reflect the Merger exchange rate of 0.0358493. Basic and diluted net loss per share attributable to common stockholders has been computed using the retroactively restated common stock.

Immediately after the Merger, the Company completed an offering of 13,000,000 shares of common stock for aggregate gross proceeds of $65,000,000 (the "Offering"). Offering costs in the amount of approximately $6.5 million were netted against the proceeds of the Offering, resulting in net proceeds from the Offering of approximately $58.5 million. The Offering included the issuance of warrants to purchase 3,250,000 shares of common stock to the investors with an exercise price of $6.00 and a five-year term. The Company also issued warrants to purchase 500,000 shares of common stock to the lead investor and warrants to purchase 1,093,525 shares of common stock to the placement agents, all with an exercise price of $6.00 and five-year terms. The placement agents also received a cash fee in an amount equal to 8.5% of the gross proceeds, less proceeds from existing investors in Old Athersys. In consideration for certain advisory services, Old Athersys paid an affiliate and largest stockholder of BTHC VI a one-time fee of $350,000 in cash upon consummation of the Merger.

A. Background, Merger and Offering, continued

Upon the closing of the Offering, the $10.0 million aggregate principal amount of convertible notes issued to Angiotech Pharmaceuticals, Inc. ("Angiotech") (see Note F) were converted along with accrued interest into 1,885,890 shares of common stock at a conversion price of $5.50 per share, which was 110% of the price per share in the Offering, in accordance with the terms of the notes.

Upon the closing of the Offering, the notes issued to bridge investors (see Note G) were converted along with accrued interest into 531,781 shares of common stock at a conversion price of $5.00 per share, which was the price per share in the Offering, in accordance with the terms of the bridge notes. The bridge investors also exercised their $0.01 warrants upon the conversion of the convertible preferred stock in connection with the Merger for 999,977 shares of common stock at an aggregate exercise price of $10,000. Upon the conversion of the bridge notes, the bridge investors also received five-year warrants to purchase 132,945 shares of common stock at $6.00 per share, which terms were consistent with the warrants issued to new investors in the Offering.

The Company 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 Offering 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 purchase 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 received in the Offering. Because the penalty is based on the number of unregistered shares of common stock held by investors in the Offering, the Company's maximum penalty exposure will decline over time as investors sell their shares of common stock that were included in the registration statement.

In 2007, Old Athersys sold certain non-core technology related to its asthma drug discovery program to a pharmaceutical company for $2.0 million, which was recognized as a gain on the sale in other income in 2007.

B. Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts and results of operations of the Company and its 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 the Company does not control the investee, but has the ability to exercise significant influence over the investee's operations and financial policies.

Revenue Recognition

The Company's revenue recognition policies are in accordance with the SEC Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition*, and Emerging Issues Task Force ("EITF") No. 00-21, *Revenue Arrangements with Multiple Deliverables*, which provide guidance on revenue recognition in financial statements and are based on the interpretations and practices developed by the SEC. The Company's license and collaboration agreements may contain multiple elements, including technology access and development fees, cost-sharing, milestones and royalties.

Revenue from transactions that do not require future performance obligations from the Company is recognized when performance is complete and when collectability is reasonably assured. The Company's license fee revenue primarily consists of fees received from a collaborator, which are specifically set forth in the license and collaboration agreement as amounts due to the Company based on its completion of certain tasks (e.g., delivery and acceptance of a cell line). Upon acceptance by the collaborator of a cell line for use in its own product development efforts, the Company has no further performance obligations with respect to the cell line or products developed using the cell line. In addition, the Company receives specified payments upon the collaborator's achievement of certain developmental milestones (e.g., clinical trial phases), which are recognized when the milestones are achieved by the Company's collaborator.

B. Accounting Policies, continued

Revenue from grants consists of funding under cost reimbursement programs primarily from federal and state sources for qualified research and development activities performed by the Company. Revenue from grants is recorded when earned under the terms of the agreements.

Cash and Cash Equivalents

The Company considers 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 the Company's cash equivalents approximates fair value due to the short maturity of the investments.

Research and Development

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

Collaborative Arrangements

Collaborative arrangements that involve cost or revenue 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 the Company on a net basis in the statement of operations (e.g., total cost, less reimbursement from collaborator). If the Company is 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.

Clinical Trial Costs

Clinical trial costs are accrued based on work performed by outside contractors, who manage and perform the trials. The Company obtains initial estimates of total costs based on enrollment of subjects, project management estimates and other activities. Actual costs are typically charged to the Company 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

The Company may be required to make royalty payments to certain parties based on product sales under license agreements. The Company did not pay any royalties during the three-year period ended December 31, 2008.

Investments in Available-for-Sale Securities

Management determines the appropriate classification of investment securities at the time of purchase and re-evaluates such designation as of each balance sheet date. The Company's investments typically consist primarily of U.S. government obligations, corporate debt securities, floating rate notes and commercial paper, all of which are classified as available-for-sale. 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.

B. Accounting Policies, continued

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).

In accordance with the guidance in Statement of Financial Accounting Standard ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-lived Assets*, 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. No impairment losses were recorded in 2008, 2007 or 2006.

Patent Costs and Rights

Costs of prosecuting and maintaining patents and patent rights are expensed as incurred. As of December 31, 2008, the Company has filed for broad intellectual property protection on its proprietary technologies. The Company currently has numerous U.S. patent applications and corresponding international patent applications related to its technologies, as well as many issued U.S. and international patents.

Comprehensive Income (Loss)

Unrealized gains and losses on the Company's 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 (deficit).

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, 2008 and 2007, one customer accounted for 39% and 51% of accounts receivable, respectively. The Company does not require collateral from its 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

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment*, ("SFAS No. 123(R)"), using the modified-prospective-transition method. Under that transition method, compensation cost recognized since January 1, 2006 included: (a) compensation cost for all share-based payments granted prior to, but not yet vested, as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). For some of the awards granted prior to the adoption of SFAS No. 123(R), the Company recognized compensation expense using a grading vesting method. For awards granted subsequent to adoption of SFAS No. 123(R), the Company recognizes expense on the straight-line method.

B. Accounting Policies, continued

The Company uses a Black-Scholes option-pricing model to estimate the grant-date fair value of share-based awards under SFAS No. 123(R). The expected term of options granted represent the period of time that option grants are expected to be outstanding. The Company uses the "simplified" method under SAB No. 110 to calculate the expected life of option grants in 2008 and 2007 given its limited history. The Company determines volatility by using the historical stock volatility of other companies with similar characteristics.

SFAS No. 123(R) requires forfeitures to be 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, the Company will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest. Prior to the adoption of SFAS No. 123(R), the Company was permitted to recognize forfeitures as an expense reduction upon occurrence. The adjustment to apply estimated forfeitures to previously recognized share-based compensation was accounted for as a cumulative effect of a change in accounting principle at January 1, 2006, and reduced net loss by $305,587 for the year ended December 31, 2006.

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

	December 31,		
	2008	**2007**	**2006**
Volatility	**69.6%**	73.4%	53.6%
Risk-free interest rate	**3.0%**	5.3%	4.8%
Expected life of option	**5.09 years**	5.36 years	4.0 years
Expected dividend yield	**0.0%**	0.0%	0.0%

Income Taxes

Deferred tax liabilities and assets are determined based on the differences between the financial reporting and tax basis of assets and liabilities and are measured using the tax rate and laws currently in effect. In accordance with SFAS No. 109, *Accounting for Income Taxes,* ("SFAS No. 109"), the Company evaluates its 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.

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position reported or expected to be reported on a tax return as well as guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. Athersys adopted the provisions of FIN 48 on January 1, 2007. Upon adoption of FIN 48 and through December 31, 2008, Athersys determined that it had no liability for uncertain income taxes as prescribed by FIN 48. Athersys' 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 attributable to common stockholders is presented in conformity with SFAS No. 128, *Earnings Per Share*. In accordance with SFAS No. 128, basic and diluted net loss per share has been computed using the weighted-average number of common stock outstanding during the period.

The change to the conversion ratios of the convertible preferred stock in June 2007 represented an induced conversion, which resulted in a deemed dividend in the amount of $4.8 million that was included in determining the net loss attributable to common stockholders in 2007.

B. Accounting Policies, continued

The Company has outstanding options and warrants, and prior to June 8, 2007, had outstanding options, warrants, convertible debt and convertible preferred stock, which have not been used in the calculation of diluted net loss per share because, to do so would be anti-dilutive. As such, the numerator and the denominator used in computing both basic and diluted net loss per share are equal. The following instruments were excluded from the calculation of diluted net loss per share attributable to common stockholders because their effects were antidilutive:

- Outstanding stock options to purchase 3,738,473, 3,679,884 and 116,083, shares of common stock for the years ended December 31, 2008, 2007 and 2006, respectively;
- Warrants to purchase 5,125,496, 5,125,496 and 25,639, shares of common stock for the years ended December 31, 2008, 2007 and 2006, respectively;
- Shares of common stock issuable upon conversion of convertible preferred stock in the amount of 160,041 and 364,524 for the years ended December 31, 2007 and 2006, respectively; and
- Shares of common stock issuable upon the conversion of convertible promissory notes in the amount of 112,098 and 72,995 for the years ended December 31, 2007 and 2006, respectively.

Recently Issued Accounting Standards

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements. The FASB delayed the effective date of SFAS No. 157 for non-financial assets and liabilities to fiscal years beginning after November 15, 2008. The Company adopted the non-deferred provisions of SFAS No. 157 related to its financial assets and liabilities on January 1, 2008 and such adoption did not have a material impact of its financial position, results of operations or cash flows.

In October 2008, the FASB issued FASB Staff Position ("FSP"), FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, which clarifies the application of SFAS No. 157, *Fair Value Measurements*, in a market that is not active and illustrates key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP did not have an impact on the Company's financial statements.

In December 2007, the FASB ratified the consensus reached in EITF Issue No. 07-1, *Accounting for Collaborative Arrangements.* The effective date of EITF 07-1 is January 1, 2009 for calendar year companies with retrospective application required for all periods presented for collaborative arrangements existing as of the effective date. EITF 07-1 requires certain disclosures related to collaborative arrangements where parties are active participants and exposed to significant risks and rewards dependent on the commercial success of the activity. The Company does not expect the adoption of EITF 07-1 to have a material impact on its financial statements.

In May 2008, the FASB issued FASB Staff Position APB 14-1 ("FSP 14-1"), *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. FSP 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash on conversion to separately account for the liability and equity components in a manner that reflects the issuer's nonconvertible debt borrowing rate. The Company currently has no convertible debt instruments, but is evaluating the retrospective effect that FSP 14-1 may have on its financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised), *Business Combinations*. This statement, which addresses the accounting for business acquisitions, is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited, and generally applies to business acquisitions completed after December 31, 2008. Among other things, SFAS No. 141(R) requires that all acquisition-related costs be expensed as incurred, and that all restructuring costs related to acquired operations be expensed as incurred. SFAS No. 141(R) also addresses the current and subsequent accounting for assets and liabilities arising from contingencies acquired or assumed. The Company does not expect the adoption of SFAS No. 141(R) to have a material impact on its financial statements. SFAS No. 141(R) could have a material impact on its financial statements in future periods if the Company completes a significant acquisition in the future.

B. Accounting Policies, continued

C. Equipment

Equipment consists of (in thousands):	December 31, 2008	2007
Laboratory equipment	$ **6,045**	$ 5,839
Office equipment and leasehold improvements	**3,607**	3,481
	9,652	9,320
Accumulated depreciation	**(8,951)**	(8,933)
	$ **701**	$ 387

D. Notes Receivable; MCL Acquisition

Note Receivable from Officer

The Company had a note receivable from an officer with an unpaid principal and interest balance of $122,000 in connection with a loan made in 2002, which was forgiven in 2006.

MCL Acquisition

In 2003, the Company acquired MCL LLC ("MCL") through a merger with one of its subsidiaries. The Company acquired adult stem cell technologies through the merger. In addition to the purchase price for the merger, the Company was obligated to make three milestone payments. The first milestone, related to the issuance of a patent, was completed in 2006 resulting in the issuance of 2,758 shares of common stock to the former members of MCL. The value placed on the shares was approximately $125,000 using a fair value estimate at the time of the milestone achievement. In 2007, the Company achieved the final two milestones, which related to collaborative activities and the filing of an investigational new drug application with the U.S. Food and Drug Administration. The milestones resulted in the issuance of 1,379 shares of the Company's common stock and cash payments of $1,000,000 in 2007. The value of the shares was approximately $7,000 using a fair value estimate at the time of the milestone achievement.

In connection with the MCL merger, the Company received a $511,000 note issued by one of the former owners of MCL. Principal and accrued interest is repayable (i) out of a percentage of proceeds from the sale of shares of common stock held by the former owner (who owned 28,662 shares at December 31, 2008), and (ii) upon the achievement of the final cash milestone, $283,000 of the final cash milestone can be withheld by Athersys as partial repayment of the note. The Company achieved the final milestone in 2007 and therefore, withheld $283,000 of the milestone payment as partial repayment on the note. The Company recorded an allowance of approximately $74,000 and $193,000 in 2008 and 2007, respectively, to reserve a portion of the note balance for which collectability is uncertain, leaving a net balance of $12,000 at December 31, 2008. In the event that the proceeds from the sale of common stock by the former owner are insufficient to repay the principal and interest in full, any remaining balance due will be forgiven by Athersys at that time.

E. Financial Instruments

Investments in Available-for-Sale Securities

On January 1, 2008, the Company adopted SFAS No. 157 related to its financial assets and liabilities and the methods to measure fair value of assets and liabilities as set forth therein. Its available-for-sale securities typically include U.S. government obligations, corporate debt securities, floating rate notes and commercial paper. As of December 31, 2008, approximately 72% of its investments were in U.S. government obligations.

E. Financial Instruments, continued

SFAS No. 157 classifies 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, 2008 (in thousands):

		Fair Value Measurements at December 31, 2008 Using		
Description	Balance as of December 31, 2008	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	$ 19,061	$ 19,061	$ —	$ —

Fair value is based upon quoted market prices in active markets. We had no level 2 or level 3 assets at December 31, 2008. The Company reviews and reassesses 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.

The following is a summary of available-for-sale securities (in thousands) at December 31, 2008 and 2007, respectively:

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Estimated Fair Value
December 31, 2008:				
U.S. government obligations	$ 13,603	$ —	$ 125	$ 13,728
Corporate debt securities	5,338	(24)	19	5,333
	$ 18,941	**$ (24)**	**$ 144**	**$ 19,061**
December 31, 2007:				
Floating Rate Notes	$ 6,000	$ —	$ —	$ 6,000
U.S. government obligations	20,400	—	49	20,449
Corporate debt securities	3,336	(6)	9	3,339
Commercial paper	6,539	—	—	6,539
	$ 36,275	$ (6)	$ 58	$ 36,327

The Company 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 the Company's 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 $120,000 and $52,000 as of December 31, 2008 and 2007, respectively.

The amortized cost of and estimated fair value of available-for-sale securities at December 31, 2008, by contractual maturity, are shown below. Actual maturities may differ from contractual maturities because the issuers of the securities may have the right to repay the obligations without prepayment penalties. Although the investments are available-for-sale, it is the Company's intention to hold the investments classified as long-term for more than a year from December 31, 2008 (in thousands).

E. Financial Instruments, continued

	December 31, 2008	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 15,375	$ 15,460
Due after one year through two years	3,566	3,601
	$ 18,941	**$ 19,061**

Financing Arrangements

The Company leases office and laboratory space under an operating lease. The Company initially entered into the lease in 2000 and has options to renew the lease in annual increments through March 2013 at the initial rental rate. The Company executed options to renew through March 2010.

In February 2008, the Company entered into a three-year lease agreement for office and laboratory space for its Belgian subsidiary, with annual rent expense of approximately $42,000, subject to annual adjustments based on an inflationary index. The lease includes an option to expand, which, if exercised, would result in annual rent of approximately $80,000. The lease includes an option to renew for four additional years, through December 31, 2014.

Aggregate rent expense was approximately $314,000 in 2008 and $267,000 in each of 2007 and 2006. The future annual minimum lease commitments at December 31, 2008 are approximately $335,000 for 2009, $137,000 for 2010 and $21,000 for 2011.

Long-Term Debt

A summary of the Company's long-term debt outstanding is as follows (in thousands):

	December 31,	
	2008	2007
Notes payable to lenders; issued November 2004; matured June 2008 including $487,500 terminal payment; 13% interest rate; secured	$ —	$ 1,800
Discount related to warrant issuance	—	(16)
Total, net	—	1,784
Less — current portion, net	—	1,784
Long-term debt	$ —	$ —

In 2004, the Company issued $7.5 million aggregate principal amount of notes payable to lenders, the proceeds of which were unrestricted and used for general corporate purposes. The notes were payable in 30 monthly installments after an initial interest-only period with a fixed interest rate of 13%. The notes had a maturity date of June 1, 2008 and included a terminal payment of $487,500 due at maturity. Deferred financing costs were capitalized in connection with the note, which were amortized over the term of the note using the effective interest method.

The lenders retain a right to receive a milestone payment of $2.25 million upon the occurrence of certain events as clarified in the October 2007 amendment to the loan agreement as follows: (1) the entire amount upon (a) the merger with or into another entity where the Company's 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 the Company's assets, or (c) the Company's 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, the Company may elect to pay 75% of the milestone in shares of common stock at the per-share offering price. No amounts have been recorded in relation to the milestone as of December 31, 2008, 2007 or 2006.

E. Financial Instruments, continued

The lenders also received warrants to purchase 149,026 shares of common stock with an exercise price of $5.00 per share and a seven-year term upon the closing of the Offering in June 2007 in accordance with the loan agreement. The value of the warrants was $492,000 based on the Black-Scholes valuation of the underlying security, of which $16,000 and $476,000 was recorded as interest expense in 2008 and 2007, respectively.

Fair value of the Company's long-term debt at December 31, 2007 was not determinable due to lack of marketability of the fixed-rate debt. The Company paid interest of $76,000, $456,000 and $832,000 during the years ended December 31, 2008, 2007 and 2006, respectively.

F. Collaboration

In 2006, the Company entered into a co-development collaboration with Angiotech. The Company issued a convertible promissory note in the principal amount of $5.0 million to Angiotech at the inception of the program, which was followed by the issuance of an additional convertible promissory note in the principal amount of $5.0 million in January 2007 upon the achievement of certain milestones. The notes bore interest at 5% and had six-year terms. Upon the closing of the Offering, the convertible notes aggregating $10.0 million were converted along with accrued interest into 1,885,890 shares of common stock at a conversion price of $5.50 per share, which was 110% of the price per share in the Offering, in accordance with the terms of the notes.

The Company may receive equity investments and cash payments based on the successful achievement of specified clinical development and commercialization milestones. Under the terms of the collaboration, preclinical costs are borne solely by the Company and the parties jointly fund clinical development activity. The Company has 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 as further described below. The parties will share net profits from the future sale of approved products.

Under the terms of the collaboration, the parties jointly fund clinical development activity, whereby costs for phase I and II studies are borne 50% by Athersys and 50% by Angiotech, costs for the first phase III study will be borne 33% by Athersys and 67% by Angiotech, and costs for any phase III studies subsequent to the first phase III study will be borne 25% by Athersys and 75% by Angiotech. Late in 2007, the parties began to share costs for phase I clinical development. The Company considered the provisions of EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, and determined that neither party is a principal party for clinical development costs, since both the costs and responsibilities are shared and neither party is in the business of conducting clinical development services for others. Therefore, the Company recorded clinical development costs net of Angiotech's 50% cost-share, which amounted to $943,000 and $63,000 in 2008 and 2007, respectively. The amount due from Angiotech was $234,000 and $63,000 at December 31, 2008 and 2007, respectively, and is disclosed separately on the balance sheet.

G. Convertible Bridge Notes

In 2006, the Company completed a bridge financing of $2.5 million in the form of convertible promissory notes. The notes were issued primarily to existing stockholders of the Company, including $205,000 in the aggregate to three members of management. The notes bore interest at 10% and had three-year terms. The notes were only convertible into shares of stock of the same class as issued in the Company's next bona fide equity financing, at a conversion price equal to the price per share in the bona fide equity financing. The notes, if not converted, were repayable with accrued interest at maturity, plus a repayment fee of 200% of the outstanding principal.

The bridge investors also received warrants in connection with the bridge financing. The warrants were exercisable for shares of common stock only upon a restructuring of the Company's capital stock in connection with a bona fide financing. The number of shares that could be purchased under the warrants was based on a formula whereby the bridge investors would receive warrants valued at two times their investment divided by the pre-money value of the Company upon a restructuring and bona fide equity financing. The exercise price of the warrants was $0.01 per share.

G. Convertible Bridge Notes, continued

The Company allocated $250,000 of the purchase price of the debt to the warrants based on the relative fair value of the notes and the warrants. The Company computed a premium on the debt in the amount of $5,250,000 due upon redemption, which was being accreted over the term of the notes using the effective interest method.

Upon the closing of the Offering, the bridge notes were converted along with accrued interest into 531,781 shares of common stock at a conversion price of $5.00 per share. The unamortized premium and discount on the notes were reversed and recorded in additional paid-in capital. The bridge noteholders also exercised their warrants upon the closing of the Offering for 999,977 shares of common stock at an aggregate exercise price of $10,000. Upon the conversion of the bridge notes, the bridge noteholders also received five-year warrants to purchase 132,945 shares of common stock at $6.00 per share, which terms were consistent with the warrants issued to new investors in the Offering.

H. Capitalization

At December 31, 2008, the Company has 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, 2008.

The Company may issue shares of common stock to its lenders and to Angiotech in connection with future milestones (see Notes E and F). Also, the Company 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 five anniversary dates. The issuance of the shares is subject to Board approval and the continuation of sponsored research at the institution. If the Board does not approve the issuance of the shares, then the Company will remit $20,000 in cash plus the value of the shares, as defined, to the institution on each of the anniversary dates of the agreement.

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

	December 31	
	2008	**2007**
Stock option plans	**4,500**	4,500
Warrants to purchase common stock — Offering	**4,976**	4,976
Warrants to purchase common stock — Lenders	**149**	149
	9,625	9,625

I. Joint Venture and Investment in Equity Securities

Athersys owns 50.2% of Oculus Pharmaceuticals, Inc. (“Oculus”) related to a 2001 joint venture. Athersys accounts for its investment in Oculus under the equity method due to significant minority investor rights (i.e., “substantive participating rights,” as defined by EITF 96-16) retained by the other investors. In connection with a settlement that occurred in 2003 and a milestone that was achieved in 2006, Athersys received stock-based proceeds in another privately-held company in the amount of $200,000 in aggregate.

In connection with that same milestone in 2006, Oculus also received stock-based proceeds in the privately-held company in the amount of $260,000, in addition to $23,000 previously received. Athersys recognized approximately $117,000 in 2006 as its share of the Oculus net income, after recapturing prior losses in excess of the Company’s investment in and advances to the joint venture. Consistent with its wind-up strategy, Oculus will remain in existence as a dormant entity only as long as it is necessary to serve as a pass through of any further milestone-based consideration and final distribution to its remaining shareholders. As of December 31, 2008 and 2007, Oculus had no significant assets, liabilities, stockholders’ equity or results of operations.

I. Joint Venture and Investment in Equity Securities continued

Athersys evaluated its cost-method investment in the equity securities of the privately-held company that sells laboratory systems to the life sciences industry, and as a result of adverse changes in market conditions, the fair value of the equity securities is less than the carrying amount at December 31, 2008. The severity of the impairment (fair value is approximately 16% less than cost) and the duration of the impairment (less than 3 months) correlate with the weak market environment. Based on the Company's evaluation of the near-term prospects of the investee and its ability and intent to hold the investment for a reasonable period of time sufficient for a recovery of fair value, the Company does not consider the investment to be other-than-temporarily impaired at December 31, 2008.

(in thousands)	Carrying Amount	Unrealized Losses	Estimated Fair Value
December 31, 2008:			
Equity securities held by Athersys	$ 200	$ (32)	$ 168
Equity securities held by Oculus (50.2% Athersys portion)	142	(13)	129
	$ 342	**$ (45)**	**$ 297**

J. Stock Option Plans

In 2007, the Company adopted 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.

In May 2007, the majority of Old Athersys' pre-Merger outstanding options were terminated. The Company accounted for the termination of these awards as a settlement and all previously unrecognized compensation expense ($385,000) was recognized on the termination date in 2007. New option awards to purchase 3,625,000 shares of common stock with an exercise price of $5.00 per share were granted to employees, directors and consultants in June 2007 upon the closing of the Merger. The options that were granted to employees generally vested 40% on the date of grant and vest ratably over three years. The options granted to non-employees and board members generally vest at varying percentages over three years.

Prior to the Merger in 2007, Old Athersys maintained equity incentive plans in which 277,000 shares were available for issuance and 116,083 options were outstanding at December 31, 2006. Upon the closing of the Merger, BTHC VI assumed 5,052 of these options, which will be governed by Old Athersys' original equity plans until the awards expire. As of December 31, 2008, 2,473 of these assumed awards remain outstanding. All of the remaining outstanding option awards under Old Athersys' former equity incentive plans were terminated prior to the Merger.

As of December 31, 2008, a total of 764,000 shares are available for issuance under the Company's equity compensation plans and options to purchase 3,738,473 shares of common stock are outstanding (including the assumed options covering 2,473 shares described above). The Company recognized $1,856,000, $5,139,000 and $459,000 of stock compensation expense in 2008, 2007 and 2006, respectively. At December 31, 2008, total unrecognized estimated compensation cost related to unvested stock options was approximately $3,033,000, which is expected to be recognized by June 30, 2012 using the straight-line method.

The weighted average fair value of option shares granted in 2008, 2007 and 2006 was $2.00, $2.82 and $-0- per share, respectively. The total fair value of option shares vested in 2008, 2007 and 2006 was $2,337,000, $4,742,000 and $428,000, respectively. There is no aggregate intrinsic value of fully vested option shares and option shares expected to vest as of December 31, 2008 since the market value was less than the exercise price of the options at the end of the year.

J. Stock Option Plans, continued

A summary of the Company's stock option activity and related information is as follows:

	Number of Options	Weighted Average Exercise Price
Outstanding January 1, 2006	138,796	$ 92.05
Granted	—	—
Exercised	(72)	83.68
Forfeited	(22,641)	150.91
Outstanding December 31, 2006	116,083	80.62
Granted	3,738,000	5.06
Exercised	—	—
Forfeited / Terminated / Expired	(174,199)	51.21
Outstanding December 31, 2007	3,679,884	5.24
Granted	**218,000**	**3.36**
Exercised	—	—
Forfeited / Expired	**(159,411)**	**6.64**
Outstanding December 31, 2008	**3,738,473**	**$ 5.07**
Vested during 2008	**858,477**	**$ 5.05**
Vested and exercisable at December 31, 2008	**2,416,657**	**$ 5.20**

	December 31, 2008					
	Options Outstanding			Options Vested and Exercisable		
Exercise Price	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$1.88 – 2.96	115,000	5.60	$ 2.74	20,625	4.48	$ 2.90
$4.00 – 4.99	141,000	8.89	$ 4.31	19,250	8.62	$ 4.69
$5.00 – 7.80	3,480,000	7.52	$ 5.06	2,374,309	7.62	$ 5.05
$69.74 – 278.95	2,473	2.49	$ 174.97	2,473	2.49	$ 174.97
	3,738,473			**2,416,657**		

The weighted average contractual life of unvested options at December 31, 2008 was 7.3 years.

K. Income Taxes

At December 31, 2008, the Company had net operating loss and research and development tax credit carryforwards of approximately $22,810,000 and $1,404,000, respectively, for income tax purposes. Such losses and credits may be used to reduce future taxable income and tax liabilities and will expire in 2028.

As a result of the change in ownership related to the capital restructuring and Offering, the Company lost the use of a significant portion of Athersys' pre-Merger net operating loss carryforwards. The remaining pre-merger net operating loss carryforward of approximately $8,554,000 ("Pre-Merger NOL") is 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 2011 and 2026.

K. Income Taxes, continued

Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31, 2008	December 31, 2007
Net operating loss carryforwards	$ 7,755	$ 2,387
Net operating loss carryforwards — Pre-Merger NOL	2,908	3,066
Research and development credit carryforwards	1,404	438
Compensation expense	1,700	1,221
Other	468	539
Total deferred tax assets	14,235	7,651
Valuation allowance for deferred tax assets	(14,235)	(7,651)
Net deferred tax assets	$ —	$ —

Because of the Company's cumulative losses, the deferred tax assets have been fully offset by a valuation allowance. The Company has not paid income taxes for the three-year period ended December 31, 2008.

L. Profit Sharing Plan and 401(k) Plan

The Company has a profit sharing and 401(k) plan that covers substantially all employees. The Plan allows for discretionary contributions by the Company. The Company made no contributions to this plan for the three-year period ended December 31, 2008.

M. Quarterly Financial Data (unaudited)

The following table presents quarterly data for the years ended December 31, 2008 and 2007, in thousands, except per share data:

	2008				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Revenues	$ 792	$ 776	$ 1,278	$ 259	$ 3,105
Net loss	$ (4,664)	$ (4,122)	$ (4,493)	$ (4,713)	$ (17,992)
Preferred stock dividends	$ —	$ —	$ —	$ —	$ —
Deemed dividend resulting from induced conversion of convertible preferred stock	$ —	$ —	$ —	$ —	$ —
Net loss attributable to common stockholders	$ (4,664)	$ (4,122)	$ (4,493)	$ (4,713)	$ (17,992)
Basic and diluted net loss per common share attributable to common stockholders	**$ (0.25)**	**$ (0.22)**	**$ (0.24)**	**$ (0.25)**	**$ (0.95)**

	2007				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Revenues	$ 879	$ 723	$ 860	$ 798	$ 3,260
Net loss	$ (2,720)	$ (7,069)	$ (4,439)	$ (4,698)	$ (18,926)
Preferred stock dividends	$ (375)	$ (284)	$ —	$ —	$ (659)
Deemed dividend resulting from induced conversion of convertible preferred stock	$ —	$ (4,800)	$ —	$ —	$ (4,800)
Net loss attributable to common stockholders	$ (3,095)	$ (12,153)	$ (4,439)	$ (4,698)	$ (24,385)
Basic and diluted net loss per common share attributable to common stockholders	$ (10.54)	$ (2.53)	$ (0.23)	$ (0.25)	$ (2.26)

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

Not applicable.

ITEM 9A(T). 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, 2008, 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, 2008.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the SEC that permit Athersys to provide only management's report in this annual report.

Changes in internal control: During the fourth quarter of 2008, 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

None.

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 2009 Annual Meeting of Stockholders, or the 2009 Proxy Statement. Information concerning executive officers is contained in Item 4A 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 2009 Proxy Statement.

The information regarding any changes in procedures by which stockholders may recommend nominees to Athersys' Board of Directors is incorporated by reference to the information contained in the 2009 Proxy Statement.

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

ITEM 11. EXECUTIVE COMPENSATION

The information regarding executive officer and director compensation is incorporated by reference to the information contained in the 2009 Proxy Statement.

The information regarding compensation committee interlocks and insider participation and the compensation committee report is incorporated by reference to the information contained in the 2009 Proxy Statement.

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 2009 Proxy Statement.

Equity Compensation Plan Information. The following table sets forth certain information regarding the Company's equity compensation plans as of December 31, 2008, unless otherwise indicated.

Plan Category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plan approved by security holders	2,493,500	$ 4.86	541,500
Equity compensation plan not approved by security holders (1)	1,244,973	$ 5.38	222,500
Total	**3,738,473**		**764,000**

(1) Includes 2,473 of shares of common stock issuable upon exercise of stock options that were assumed by BTHC VI in the merger.

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 2009 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICESN

Information regarding fees paid to and services provided by our independent registered public accounting firm during the fiscal years ended December 31, 2008 and 2007 and the pre-approval policies and procedures of the audit committee is incorporated by reference to the information contained in the 2009 Proxy Statement.

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, 2008 and 2007

Consolidated Statements of Operations for each of the years ended December 31, 2008, 2007 and 2006

Consolidated Statements of Stockholders' Equity (Deficit) for each of the years ended December 31, 2008, 2007 and 2006

Consolidated Statements of Cash Flow for each of the years ended December 31, 2008, 2007 and 2006

Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedules:

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

Schedule II – Valuation and Qualifying Accounts

(In thousands)	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Year Ended December 31, 2008				
Deducted from asset accounts:				
Allowance for doubtful accounts	$ 193	$ 74(A)	$ —	$ 267
Tax valuation allowances	7,651	6,584	—	14,235
Total 2008	**$ 7,844**	**$ 6,658**	$ —	**$ 14,502**
Year Ended December 31, 2007				
Deducted from asset accounts:				
Allowance for doubtful accounts	$ —	$ 193(A)	$ —	$ 193
Tax valuation allowances	47,971	1,954	42,274(B)	7,651
Total 2007	**$ 47,971**	**$ 2,147**	**$ 42,274**	**$ 7,844**
Year Ended December 31, 2006				
Deducted from asset accounts:				
Tax valuation allowances	$ 43,974	$ 3,997	$ —	$ 47,971
Total 2006	**$ 43,974**	**$ 3,997**	**$ —**	**$ 47,971**

(A) – Reserve on note receivable.

(B) – Deferred tax assets are fully offset by valuation allowances. As a result of the June 2007 equity offering and merger, the Company lost the use of a significant portion of its pre-merger net operating loss carryforwards.

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

(a)(3) Exhibits.

Exhibit No.	Exhibit Description
2.1	Agreement and Plan of Merger, dated as of May 24, 2007, by and among Athersys, Inc., BTHC VI, Inc. and B-VI Acquisition Corp. (incorporated herein by reference to Exhibit 10.1 to registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on May 24, 2007)
2.2	First Amendment to Agreement and Plan of Merger, dated as of June 8, 2007, by and among Athersys, Inc., BTHC VI, Inc. and B-VI Acquisition Corp. (incorporated herein by reference to Exhibit 2.2 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
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)
10.1*	Research Collaboration and License Agreement, dated as of December 8, 2000, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.2*	Cell Line Collaboration and License Agreement, dated as of July 1, 2002, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007)
10.3*	Extended Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007)
10.4	License Agreement, effective as of May 5, 2006, by and between Athersys, Inc. and Angiotech 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)

Exhibit No.	Exhibit Description
10.9	Amendment No. 3 to Amended and Restated Registration Rights Agreement, dated as of May 15, 2007, by and among Athersys, Inc. and the Existing Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.9 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.10†	BTHC VI, 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)
10.11†	BTHC VI, Inc. Equity Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.11 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.12	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)
10.13	Second Amendment to Loan and Security Agreement, dated as of October 30, 2007, by and among ABT Holding Company, Advanced Biotherapeutics, Inc., Venture Lending and Leasing IV, Inc., and Costella Kirsch IV, L.P. (incorporated herein by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on November 14, 2007)
10.14	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)
10.19†	Amendment No. 1 to Amended and Restated Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and John Harrington (incorporated herein by reference to Exhibit 10.18 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.20†	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)

Exhibit No.	Exhibit Description
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)
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)

Exhibit No.	Exhibit Description
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)
10.40	Advisory Agreement, dated as of May 24, 2007, by and between Halter Financial Group, L.P. and Athersys, Inc. (incorporated herein by reference to Exhibit 10.40 to the registrant's Registration Statement on Form S-1/A (Registration No. 333-144433) filed with the Commission on September 12, 2007)
10.41†	Summary of Athersys, Inc. 2008 Cash Bonus Plan (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 May 8, 2008)
21	List of Subsidiaries
23	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24	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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Cleveland, State of Ohio, on March 12, 2009.

ATHERSYS, INC.

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

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

Signature	Title	Date
/s/ Gil Van Bokkelen Gil Van Bokkelen	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 12, 2009
/s/ Laura K. Campbell Laura K. Campbell	Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	March 12, 2009
* John J. Harrington	Executive Vice President, Chief Scientific Officer and Director	March 12, 2009
* William C. Mulligan	Director	March 12, 2009
* George M. Milne, Jr.	Director	March 12, 2009
* Jordan S. Davis	Director	March 12, 2009
* Floyd D. Loop	Director	March 12, 2009
* Michael Sheffery	Director	March 12, 2009
* Lorin J. Randall	Director	March 12, 2009

* 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 a Power of Attorney executed by such persons and filed with the Securities and Exchange Commission.

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

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EXHIBIT 31.1

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 12, 2009

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

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EXHIBIT 31.2

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 12, 2009

/s/ Laura K. Campbell
Laura K. Campbell
Vice President, Finance

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EXHIBIT 32.1

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, 2008, 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 12, 2009

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

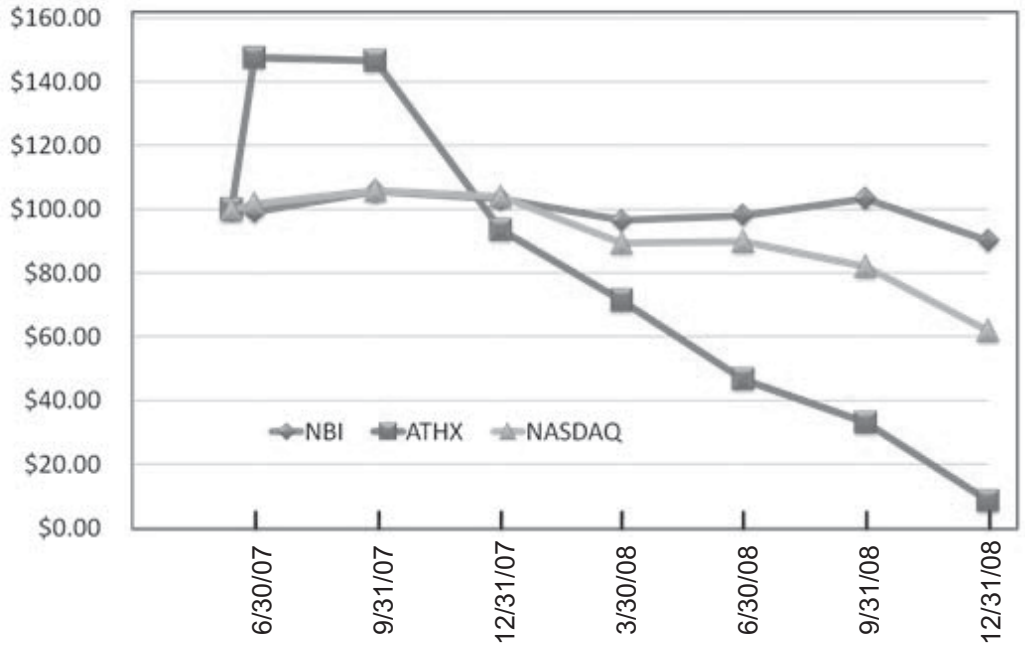
/s/ Laura K. Campbell
Name: Laura K. Campbell
Title: Vice President, Finance

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.

Stock Performance Graph

Notwithstanding any statement to the contrary in any of our previous of previous or future filings with the Securities and Exchange Commission, the following information relating to the price performance of our common stock shall not be deemed "filed" with the Commission or "soliciting material" under the Securities Exchange Act of 1934 and shall not be incorporated by reference into any such filings.

The following graph shows a comparison from June 12, 2007 (the date our common stock commenced trading after the merger) through December 31, 2008 of cumulative total return for the NASDAQ Composite Index (NASDAQ), our common stock (ATHX) and the NASDAQ Biotechnology Index (NBI). Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and the NASDAQ Biotechnology Index assumes reinvestment of dividends. We have never paid dividends on our common stock and have no present plans to do so.



Assumes $100 was invested on 6/12/07 in the NASDAQ composite index, NASDAQ biotech index or our common stock.

Shareholder Information

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
National City Bank
629 Euclid Avenue, Room 635
Cleveland, OH 44114

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
950 Third Avenue, 9th Floor
New York, NY 10022

3201 Carnegie Avenue
Cleveland, OH 44115-2634

Athersys.com