

ATHERSYS, INC / NEW  
Form 10-K  
March 14, 2008

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

**Form 10-K**

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

(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, 2007
- 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 0-52108**

**Athersys, Inc.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**20-4864095**

*(I.R.S. Employer  
Identification No.)*

**3201 Carnegie Avenue, Cleveland, Ohio**

*(Address of principal executive offices)*

**44115-2634**

*(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 definitions of "large accelerated filer", "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   
(Do not check if a 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 29, 2007, 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 \$7.75 of such stock as quoted on the OTC Bulletin Board on such date) held by non-affiliates of the registrant was approximately \$106 million.

The registrant had 18,927,988 shares of common stock outstanding on March 13, 2008.

#### **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 2008 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 diseases. In 2007, we advanced our lead program for treating obesity into clinical development. We also advanced two additional programs in 2007, receiving authorization for Investigational New Drug applications, or INDs, for treatment of acute myocardial infarction, or AMI, and the complications (e.g., graft versus host disease) associated with hematopoietic stem cell/bone marrow transplantation for certain hematologic malignancies. We have additional programs in discovery and preclinical development for the treatment of ischemic stroke and certain cognitive or attention disorders. Our ability to advance these programs will depend on the success of our ongoing discovery and development efforts, obtaining necessary regulatory approvals and available capital resources.

Our lead product candidate is ATHX-105, which is a treatment for obesity that acts by stimulating the 5HT<sub>2c</sub> receptor, a key neurotransmitter receptor in the brain that regulates appetite. ATHX-105 is administered orally and has been shown in preclinical testing in animal models to reduce food intake and body weight by suppressing appetite without appearing to cause the adverse side effects that have been observed with other weight loss drugs. Results from clinical trials we conduct in humans may differ from our preclinical results.

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 studies 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. The maximum tolerated dose for ATHX-105 was determined to be 100 mg. ATHX-105 was generally well-tolerated at dose levels below 100 mg. The drug was well-absorbed, resulting in good drug exposures following oral administration. 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. Following a detailed analysis of the results of the clinical trial, the completion of certain required non-clinical studies and regulatory approval, we intend to initiate a Phase II clinical trial in the United States that will examine safety and effectiveness in clinically overweight or obese patients. In addition to ATHX-105, we have a portfolio of other compounds that we are developing as potential treatments for obesity.

We are also independently developing novel orally active pharmaceutical products for the treatment of central nervous system disorders, including sleep disorders such as narcolepsy or excessive daytime sleepiness, and other potential indications such as attention deficit hyperactivity disorder and other cognitive disorders. These programs are focused on the development of histamine H<sub>3</sub> receptor antagonist compounds that act by elevating levels of neurotransmitters in the sleep and cognitive centers of the brain and stimulating neurological tone, resulting in an enhanced state of wakefulness and cognition, without causing hyperactivity or addiction.

In addition to our pharmaceutical development programs, we are developing MultiStem<sup>®</sup>, a proprietary stem cell product for the treatment of multiple disease indications. MultiStem is a biologic product that is manufactured from human stem cells obtained from adult bone marrow or other nonembryonic tissue sources. After cells are isolated from a qualified donor, the MultiStem product may be produced on a large scale for future clinical use and stored in frozen form until needed. We believe that MultiStem may potentially be used to treat a range of disease indications, with each indication representing a distinct product development program requiring separate clinical trials. In May

2006, we entered into a product co-development collaboration with Angiotech Pharmaceuticals, Inc., or Angiotech, to jointly develop and ultimately market MultiStem for the treatment of damage caused by myocardial infarction and peripheral vascular disease. We are also independently developing MultiStem for hematopoietic stem cell, or HSC transplant support, ischemic stroke

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and potentially other disease indications. We retain the commercial rights to these programs and other potential applications of MultiStem.

In addition to our current product development programs, we developed our patented RAGE technology that provides us with the ability to produce human cell lines that express specific, biologically well validated drug targets without relying upon cloned and isolated gene sequences. While our RAGE technology is not a product, it is a commercial technology that we are successfully applying 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 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, 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 our leading product candidates (e.g., ATHX-105 and MultiStem) using a fast follower approach, thereby mitigating risk and reducing costs. This approach allows us to leverage others' prior clinical efforts and validation in the 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 United States Food and Drug Administration, or FDA.

*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 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. In order to enhance the value of our product candidates in these potential licensing or collaboration arrangements, we plan to internally develop our product candidates through at least Phase II clinical trials whenever possible. 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

strategic equity investments, license fees, milestone payments, and profit sharing or royalties.



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*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 enable us to file patent applications that cover new applications of our existing technologies or product candidates, including MultiStem.

*Out-license non-core applications of our technologies.* Certain elements of our technologies, 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, 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 core technologies and capabilities, we have established drug development programs in the areas of obesity and central nervous system disorders. In addition, 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 program into clinical development in 2007 and intend to advance two or more additional programs into clinical development in 2008.

### ***Pharmaceutical Programs***

#### ***ATHX-105 for Obesity***

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. The percentage of individuals who are defined as clinically obese has risen dramatically over the past several decades. According to the United States Centers for Disease Control and Prevention, or 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. This increase is not limited to adults. The percentage of young people who are overweight has more than tripled since 1980. Among children and teens aged six to 19 years, 16% (over nine million young people) are considered overweight. There has been a similar dramatic rise in the rate of obesity in Europe and Asia. Furthermore, the cost of this epidemic is significant. The FDA estimates that the total economic cost of obesity is currently about \$117 billion per year in the United States, including more than \$50 billion in avoidable medical costs. 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. Our most advanced drug development candidate is ATHX-105, a compound we discovered internally and have extensively analyzed and validated in preclinical studies. In July 2007, we initiated a Phase I clinical trial for ATHX-105 in the United Kingdom. The Phase I clinical trial had a standard design evaluating safety and tolerability of single dose administration, dose escalation, and maximum tolerated dose, followed by a study examining the effect of once-daily administration of ATHX-105 to healthy overweight or obese individuals for a period of one week. Participants in the study had a target body mass index of 25 to 35, and included groups at several different dose levels or placebo. Safety monitoring included the assessment of various cardiovascular parameters. The primary objective of the Phase I clinical trial was to assess the short-term safety and tolerability of ATHX-105 and to establish an appropriate dose range for subsequent clinical studies 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. The maximum tolerated dose for ATHX-105 was determined to be 100 mg, and the results from the clinical trial indicate that ATHX-105 was generally well-tolerated at dose levels below 100 mg. The drug

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appeared to be well-absorbed, resulting in good drug exposures following oral administration. 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. Following a detailed analysis of the results of the clinical trial, the completion of certain required non-clinical studies and regulatory approval, we intend to initiate a Phase II clinical trial in the United States that will examine safety and effectiveness in clinically obese patients.

As a result of the work that we have completed to date, we believe that ATHX-105 represents a potential best-in-class obesity drug based on its well validated mechanism of action, as well as the potency and overall safety profile we have observed in preclinical studies and our recently completed phase I clinical trial. We are developing ATHX-105 as an orally administered pill to regulate appetite and reduce food intake in clinically obese individuals, defined as those individuals with a body mass index greater than 30. In addition to ATHX-105, we are developing a diverse portfolio of back-up compounds that act by the same mechanism as ATHX-105, as well as complementary obesity programs that act according to different biological mechanisms of action.

ATHX-105 is designed to act by stimulating a key receptor in the brain that regulates appetite and food intake the 5HT<sub>2c</sub> receptor. The role of this receptor in regulating food intake is well understood in both animal models and humans. In 1996, Wyeth Pharmaceuticals launched the anti-obesity drug Redux<sup>®</sup> (dexfenfluramine), a non-specific serotonin receptor agonist that was used with the stimulant phentermine in a combination commonly known as fen-phen. This diet drug combination gained rapid and widespread acceptance in the clinical marketplace, and was shown to be highly effective at regulating appetite, reducing food intake, and causing weight loss. Unfortunately, in addition to stimulating the 5HT<sub>2c</sub> receptor, Redux also stimulated the 5HT<sub>2b</sub> receptor that is found in the heart. The activation of 5HT<sub>2b</sub> by Redux is believed to have caused significant cardiovascular problems in a number of patients and, as a result, Redux<sup>®</sup> 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 5HT<sub>2b</sub> receptor as the underlying cause of the cardiovascular problems. These findings suggest that highly selective compounds that stimulate the 5HT<sub>2c</sub> receptor, but that do not appreciably stimulate the 5HT<sub>2b</sub> receptor, could be developed that maintain the desired appetite suppressive effects without the cardiovascular toxicity. Recently, Arena Pharmaceuticals developed a selective 5HT<sub>2c</sub> agonist, Lorcaserin, which exhibits significant selectivity for the 5HT<sub>2c</sub> receptor relative to the 5HT<sub>2b</sub> 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 5HT<sub>2c</sub> receptor relative to another serotonin receptor expressed in the brain, the 5HT<sub>2a</sub> 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 5HT<sub>2c</sub> receptor, but that avoid the 5HT<sub>2b</sub> receptor and other receptors, such as 5HT<sub>2a</sub>. Our specific goal is to develop an orally administered pill that reduces appetite by stimulating the 5HT<sub>2c</sub> receptor, but that does not stimulate the 5HT<sub>2b</sub> receptor, the 5HT<sub>2a</sub> receptor, or other receptors that could cause adverse side effects. Based on extensive preclinical studies that we have conducted with ATHX-105, it has been shown to be a highly potent and selective compound. We believe that the superior selectivity displayed by ATHX-105 for the 5HT<sub>2c</sub> receptor relative to both

the 5HT2b receptor and the 5HT2a receptor will result in a cleaner safety profile in clinical studies, which appears to be supported by the results of our recently

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completed phase I clinical trial, and may allow us to achieve better efficacy, as well as a more convenient dosing schedule than other 5HT<sub>2C</sub> agonist programs.

In preclinical testing in rodents, obese animals that received once-daily doses of ATHX-105 exhibited a 57% reduction in daily food intake as compared to animals receiving placebo alone. In addition, after receiving once-daily doses of ATHX-105 for two weeks, these animals weighed 10% less than the animals that were treated with placebo alone. The effect was dose proportional, and animals that received increasing doses of ATHX-105 showed progressively greater weight loss.

In dogs, oral administration of a low dose (0.1mg/kg) of ATHX-105 resulted in a short-term reduction of food intake of approximately 50%, while animals receiving a 10-fold higher dose (1.0 mg/kg) of ATHX-105 exhibited a complete cessation of short-term food intake that resolved over time as the drug cleared. Based upon these results, and the results of other studies that we have conducted, we calculate the effective dose range in dogs to be approximately 0.1 to 0.2 mg/kg.

In extensive preclinical testing in both dogs and monkeys, ATHX-105 appeared to be safe and well tolerated, even when administered at doses substantially higher than those that caused a significant reduction in food intake. In dogs, the maximum tolerated dose was established at 36 mg/kg, a dose level approximately 180 to 360 times higher than the effective dose range observed in short-term food intake studies. We also studied the safety profile of ATHX-105 in cynomolgous monkeys, administering doses for two weeks that are 40 to 50 times greater than the expected effective dose levels in humans, which were well tolerated with no signs of adverse effects.

In addition, we are developing other compounds that are designed to stimulate the 5HT<sub>2c</sub> receptor with greater potency and/or specificity than ATHX-105. Some of these compounds have demonstrated significant reductions in food intake in rodent models. We plan to subject these compounds to further safety and efficacy testing in animals while we continue to develop ATHX-105. Furthermore, we have created cell lines that express obesity targets that are distinct from 5HT<sub>2c</sub> by utilizing our other technologies and have screened for compounds using our compound library that are designed to significantly reduce food intake by acting against these targets. Although these compounds are at earlier stages of preclinical development, we believe they represent promising opportunities for future development.

### *H<sub>3</sub> Antagonists for the Treatment of Sleep Disorders and Certain Other Cognitive Disorders*

In addition to our obesity program, we are developing a class of pharmaceuticals that are designed to enhance wakefulness and promote cognitive abilities. Individuals that suffer from narcolepsy or other conditions that result in excessive daytime sleepiness, or EDS, may experience persistent tiredness and lack of energy. 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 U.S. 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 Modafinil include anxiety, depression, rash, and rare occurrences of serious and potentially life threatening reactions including Stevens Johnson Syndrome, Toxic Epidermal Necrolysis, and multi-organ hypersensitivity. Sales of Provigil in 2006 were reported to be over \$700 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 ADHD, and the company subsequently abandoned efforts in this market.

Similarly, 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, 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) that 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

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\$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 U.S. 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 a preclinical study recently conducted at an independent lab, we have tested one of our more advanced compounds in a well validated rodent sleep model. During the study, this compound significantly enhanced wakefulness without causing apparent adverse events. In comparison to modafinil or caffeine, this compound was far more potent, achieving a comparable or better effect on wakefulness at substantially lower doses. In addition, this compound 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 this and other H3 antagonist compounds we are developing for potential applications in treating narcolepsy, excessive daytime sleepiness, certain attention or cognitive disorders, and other conditions. In addition, we intend to conduct additional pharmacology and safety testing. If these studies are successful, and depending on the availability of capital resources, we would consider filing an IND for the initiation of clinical trials. Recently, pharmaceutical companies such as Glaxo-SmithKline and Johnson & Johnson have advanced H3 antagonists into clinical trials for the treatment of conditions such as narcolepsy and dementia, respectively.

## ***Regenerative Medicine Programs***

### ***MultiStem A Novel Approach to Regenerative Medicine***

In addition to our pharmaceutical programs, 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 such as in the treatment of heart attack, the side effects associated with HSC/bone marrow transplantation for certain hematopoietic malignancies such as graft versus host disease, or GVHD, stroke, and potentially other areas. We have received FDA authorization to initiate clinical trials in the areas of AMI and HSC transplant support. We believe that MultiStem represents a significant advancement in the field of stem cell therapy.

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, for several reasons, 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. While the field of stem cell therapy is very promising, it is also highly controversial and fraught with challenges.

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 areas that utilize stem cell therapy or other

forms of regenerative medicine. In 2002, Dr. Catherine Verfaillie and her team published research first describing 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. In their



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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 multiple 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 more of individual doses.

*Off-the-shelf utility.* Unlike traditional bone marrow or hematopoietic stem cell transplants, which require extensive genetic matching between donor and recipient, MultiStem cells do not appear, based on preclinical testing in animals, to require extensive tissue matching prior to administration. MultiStem treatment may be allogeneic, meaning that these cells would not need to be 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, 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. 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.

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 reuse, in regulatory filings, data and information from certain preclinical safety studies to support the development of MultiStem for treating multiple distinct diseases. As a result, we expect to be able to efficiently add additional 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.

### *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, and the University of Oregon Health Sciences Center, we have studied MultiStem in a range of 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 initially plan, subject to the availability of adequate resources, to advance MultiStem into clinical development in three areas: treatment of damage caused by myocardial infarction; support in the hematologic

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malignancy setting to reduce certain complications associated with HSC transplantation; and treatment for stroke caused by a blockage of blood flow in the brain. For these areas, we intend to use one MultiStem cell product, produced and validated using a single manufacturing platform.

### **Heart Attack**

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 potentially 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. Upon obtaining the results of these and other studies, we filed an IND for the use of MultiStem for the treatment of acute myocardial infarction, and in December 2007, we announced the authorization by the FDA of our IND for this indication. We intend to initiate a multicenter Phase I clinical trial in this indication in 2008. We intend to work with leading experts in the area of cardiovascular disease to complete the 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 of our regenerative medicine program 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 of the bone marrow, blood, and immune system. However, 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, which 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

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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 death or serious disability.

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 other important functions.

In November 2007, we announced authorization by the FDA of our IND for the application of MultiStem in support of bone marrow transplantation for the treatment of certain cancers of the blood and immune system. We intend to initiate a Phase I clinical trial in 2008 examining the safety and tolerability of MultiStem in patients receiving a bone marrow transplant related to their treatment for hematologic malignancy. The trial will be an open label, multicenter trial. Participating clinicians will include 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 80% of all strokes. Recent progress toward the development of safer and more effective treatments for ischemic stroke has been disappointing. Despite the fact that 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 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.

Upon completion of remaining preclinical safety studies, we intend to submit an IND for this application in 2008. The subsequent initiation of a clinical trial will depend on obtaining FDA authorization of this IND, and 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.

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**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 purchased \$10.0 million in aggregate principal amount of subordinated convertible promissory notes, the principal amount of which was automatically converted along with accrued interest into our common stock upon the closing of our financing in June 2007. 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 plan to jointly fund clinical development activity, whereby preclinical costs will be borne solely by Athersys, costs for phase I and phase II studies will be 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. We will 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.

In December 2007, we achieved a clinical development milestone upon the authorization of our IND by the FDA. This milestone event required Angiotech to either purchase \$5.0 million of our common stock or forego the purchase and allow us to select from two pre-defined milestone replacements. Angiotech opted to forego the purchase, and we elected to increase our share of the net profits from the future sale of approved products as the replacement milestone.

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

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, which is expected to be August 5, 2019 based on currently issued patents, and (2) the 15-year anniversary.

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



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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 study 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 we will achieve any milestones or receive any payments. Through December 31, 2007, we have received an aggregate of approximately \$6.0 million in license fees and milestone payments from Bristol-Myers Squibb.

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

### **Competition**

We face significant competition with respect to the various dimensions of our business. With regards to our efforts to develop ATHX-105 or other compounds for the treatment of obesity, there are already approved therapeutic products on the market, such as Xenical, which is marketed by Roche, and Meridia, which is marketed by Abbott Pharmaceuticals. However, both of these drugs can have side effects that we believe have limited their adoption by patients and clinicians. For example, potential side effects associated with taking Xenical 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 heart beat, or a history of stroke are cautioned not to take Meridia.

In addition to these products, other companies are actively developing therapeutic products for the treatment of obesity, including Sanofi-Aventis, which is developing the drug Rimonabant, which acts by suppressing appetite by blocking the CB1 receptor, also known as the marijuana receptor for its recognized role as the site of action of the cannabinoids found in marijuana that can stimulate appetite. Rimonabant has been approved for use in Europe in treating obesity, but is not approved for use in the United States. In Phase III clinical trials, patients taking Rimonabant exhibited statistically significant weight loss. Notable adverse events among some patients taking the

drug included respiratory infection, dizziness, nausea, anxiety, and depression, which were observed at higher frequency among patients taking the drug relative to those taking placebo in the control group. In June 2007, an FDA advisory panel voted unanimously against the

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approval of Rimonabant, citing safety concerns potentially associated with this drug class and its biological mechanism of action, and Sanofi withdrew its NDA application shortly thereafter. However, Rimonabant is still approved for use in Europe. Other pharmaceutical companies including Merck and Pfizer are also developing CB1 antagonists.

Other companies are also attempting to develop novel 5HT<sub>2c</sub> agonists. One company, Arena Pharmaceuticals, completed a Phase II clinical trial with its novel product candidate APD356, also referred to as Lorcaserin. Clinically obese patients taking 10 mg of the drug twice per day exhibited statistically significant weight loss over the three-month study period, exhibiting an average loss of 7.9 lbs, compared to those taking the placebo, who lost an average of 0.7 lbs. All patients on the study underwent cardiovascular safety monitoring both during and after the study, and there were no reported adverse events with respect to cardiovascular safety according to the company. Potential side effects observed among patients taking the drug at 10 mg dose twice per day included headache (26.7% vs. 17.8% in the placebo group), dizziness (7.8% vs. 0% in the placebo group), nausea (11.2% vs. 3.4% in the placebo group), and vomiting (5.2% vs. 0.8% in the placebo group).

In February 2007, Arena Pharmaceuticals announced that it had completed enrollment of 3,182 patients in a double blind, randomized and placebo controlled Phase III clinical trial of Lorcaserin designed to evaluate safety and efficacy of twice daily 10 mg doses of Lorcaserin administered for one year. The primary efficacy endpoint is the percentage of patients exhibiting greater than 5% weight loss over baseline at 52 weeks. An independent Data Safety Monitoring Board will evaluate cardiovascular safety in all patients at 6 and 12 months after initiation of the trial. The results of the initial six-month review were announced in the third quarter of 2007 and indicated no significant cardiovascular safety issues. The results of the twelve-month cardiovascular safety review are expected in the first quarter of 2008. Arena Pharmaceuticals has initiated two additional Phase III clinical trials of Lorcaserin to further evaluate the drug, including in the Type 2 diabetes population.

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 Pfizer, 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 Orexigen, Vivus, Neurosearch, Amgen, Regeneron, Natestch Pharmaceutical Company, Alizyme, Amylin Pharmaceuticals, Neurocrine Biosciences, Shionogi, Metabolic Pharmaceuticals, Kyorin Pharmaceutical, and others. It is likely that, given the magnitude of the market opportunity, many companies will continue to focus on the obesity area, and that competition will remain high. If we are successful at developing ATHX-105 or another compound as a safe and effective treatment for obesity, it is likely that other companies will attempt to develop safer and more effective 5HT<sub>2c</sub> agonists, or will attempt to combine therapies in an effort to establish a safer and more effective therapeutic product.

We also face significant competition with respect 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. These include both public companies, such as Osiris, Genzyme, Geron, Aastrom Biosciences, Stem Cells Inc., Cell Genesys, Viacell, Celgene, Advanced Cell Technology, CRYO-CELL International, Mesoblast Limited and Cytori Therapeutics, and private companies, such as Cognate Therapeutics, Neuronyx, Gamida Cell, Arterioocyte, Plureon and others. Given the magnitude of the potential opportunity for stem cell therapy, we expect competition in this area to intensify in the coming years.

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

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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 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 5HT<sub>2c</sub> 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 H<sub>3</sub> 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 U.S. 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 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 have one issued U.S. patent related to this technology, and three U.S. patent applications, as well as many corresponding international patent applications. In addition, there are six pending applications for additional MAPC-related inventions from research conducted by us alone or with our collaborators.

We also have an exclusive license to additional MAPC-related inventions (or in other words, improvements) developed by the University of Minnesota, which includes 13 pending patent applications, and covers inventions made at the University of Minnesota through May 2009. We pay all patent prosecution costs for the inventions that we elect to license. This license agreement terminates when the last patent licensed to us expires (currently, no U.S. patents have been granted for inventions subject to the license agreement). 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 MAPC technology. The University of Minnesota is entitled to a royalty on net sales of products developed from the MAPC technology.

In addition, under a collaborative research agreement with the Katholieke Universiteit Leuven (KUL), we have an exclusive license to MAPC-related inventions, which include one pending application developed at KUL using the MAPC technology or intellectual property or that result from sponsored research funded by us. KUL is entitled to milestone payments related to the continued operation of the research agreement and would receive a royalty on net

sales of products developed using MAPC-related inventions. The research agreement may be terminated after two years or upon material breach by either party. KUL may terminate the license if we fail to pay royalties when due or upon material breach of the license terms.

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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 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, were \$15.8 million in 2007, \$9.7 million in 2006 and \$12.6 million in 2005.

## **Government Regulation**

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

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

A CTA is the European equivalent of the U.S. IND. CTA requirements are issued by 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 U.S. 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 study;

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



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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 ATHX-105 and MultiStem for any clinical studies 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 science, 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 and executives with significant experience in the biotechnology and pharmaceutical industries.

As of December 31, 2007, we employed 31 individuals, of whom 14 hold Ph.D. degrees. In addition to our employees, we also use the service and support of several outside consultants and advisors. None of our employees is represented by a union, and we believe relationships with our employees are good.

**Available Information**

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

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### **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 \$14.6 million in 2005, \$10.6 million in 2006 and \$18.9 million in 2007. As of December 31, 2007, we had an accumulated deficit of \$160.5 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 tested yet in humans. 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 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 \$12.1 million in 2005, \$8.4 million in 2006 and \$12.1 million in 2007. We anticipate using \$23 million to \$25 million to fund our activities in 2008, which is an increase in cash expenditures reflecting the impact of the ATHX-105 Phase II clinical trial. With the anticipated completion of the ATHX-105 Phase II clinical trial, we expect lower clinical development costs in 2009, and as a result, expect to have available cash to fund our operations into 2010 based on our current business and operating 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;

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our ability, or our partners ability and willingness, to advance partnered products or programs;

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

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

the time and cost involved in obtaining regulatory approvals;

the cost of manufacturing our product candidates;

expenses related to complying with GMP of therapeutic product candidates;

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

competing technological and market developments;

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

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

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

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

the level of our sales and marketing expenses; and

our ability to introduce and sell new products.

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

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

***We are heavily dependent on the successful development and commercialization of our two key product candidates, ATHX-105 and MultiStem, and if we encounter delays or difficulties in the development of either or both candidates, our business would be harmed.***

We are developing multiple therapeutic product candidates, but we are heavily dependent upon the successful development of two particular product candidates: ATHX-105 for the treatment of obesity and MultiStem initially for the treatment of damage caused by certain cardiovascular disorders and for the treatment of bone marrow transplant support and GVHD. Our business would be materially harmed if we encounter difficulties in the development of either of these product candidates, such as:

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

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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 either 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 ATHX-105 and MultiStem, in animals, but we may not see positive results when ATHX-105, MultiStem or any of 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 concentration 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 products 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 developed or 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.



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***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 pharmaceutical 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 study 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.



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***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 studies, to opt-out of its obligation to fund further product development on a product-by-product basis, provided no clinical studies 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;

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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 pharmaceutical formulations 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, including 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, including ATHX-105 and MultiStem, 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

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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 ATHX-105, 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 ATHX-105 for 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.





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***We will 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 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 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

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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 four patent applications that seek to protect the composition of matter and method of use related to ATHX-105, as well as other compounds that we have identified in the same class. In addition, we are prosecuting more than 20 distinct patent applications directed to composition, methods of production, and methods of use of MultiStem and related technologies. We have also filed four patent applications with claims directed to compounds from our histamine H3 program. If we are unsuccessful in obtaining these patents, we may ultimately be unable to commercialize ATHX-105 or MultiStem or other 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;

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- 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 U.S. 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

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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.



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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.***

Many companies are engaged in the pursuit of safe and effective obesity drugs. 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, such as ATHX-105, 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

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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;

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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 U.S. 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 U.S. 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.

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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.





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**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

Our principal offices are located at 3201 Carnegie Avenue in Cleveland, Ohio. We currently lease approximately 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 \$45,000, subject to annual adjustments based on an inflationary index. The lease includes an option to renew for four additional years through December 31, 2014.

**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 2007.

**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: 47

*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 the Kent State University Board of Trustees from 2001 to 2004, and has served as an advisor to 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: 42

*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

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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: 40

*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 U.S. 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: 56

*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: 44

*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.

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

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:

	<b>High</b>	<b>Low</b>
<b>Year ending December 31, 2007:</b>		
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.

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 period indicated.

	<b>High</b>	<b>Low</b>
<b>Year ending December 31, 2007:</b>		
Fourth Quarter (from December 12, 2007 through December 31, 2007)	\$ 5.01	\$ 3.51

 **Holders**

As of February 29, 2008, the number of holders of record was approximately 938, 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.

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

	<b>2003</b>	<b>Year Ended December 31,</b>			<b>2007</b>
		<b>2004</b>	<b>2005</b>	<b>2006</b>	
		<b>(In thousands, except per share data)</b>			
<b>Consolidated Statement of Operations</b>					
<b>Data:</b>					
Revenues:					
License fees	\$ 1,393	\$ 820	\$ 763	\$ 1,908	\$ 1,433
Grants	759	2,318	2,833	1,817	1,827
Total revenues	2,152	3,138	3,596	3,725	3,260
Costs and expenses:					
Research and development	13,675	12,415	12,578	9,741	15,817
Purchased in-process R&D	9,500				
General and administrative	10,882	4,717	3,755	3,347	7,975
Depreciation	1,803	1,297	982	528	283
Restructuring costs	1,076	107	251		
Loss from operations	(34,784)	(15,398)	(13,970)	(9,891)	(20,815)
Other income (expense):					
Other income and equity in earnings of unconsolidated affiliate	1,114		18	208	2,017
Interest income	644	317	317	119	1,591
Interest expense	(135)	(73)	(964)	(1,047)	(1,263)
Accretion of premium on convertible debt				(260)	(456)
Loss before cumulative effect of change in accounting principle	\$ (33,161)	\$ (15,154)	\$ (14,599)	\$ (10,871)	\$ (18,926)
Cumulative effect of change in accounting principle				306	
Net loss	(33,161)	(15,154)	(14,599)	(10,565)	(18,926)
Preferred stock dividends	(2,164)	(2,325)	(2,253)	(1,408)	(659)
Deemed dividend resulting from induced conversion of convertible preferred stock					(4,800)
<b>Net loss attributable to common stockholders</b>	<b>\$ (35,325)</b>	<b>\$ (17,479)</b>	<b>\$ (16,852)</b>	<b>\$ (11,973)</b>	<b>\$ (24,385)</b>
<b>Basic and diluted net loss per common share attributable to common stockholders:</b>					
Loss before cumulative effect of change in accounting principle	\$ (130.90)	\$ (59.82)	\$ (57.79)	\$ (41.89)	\$ (2.26)
				1.05	

Cumulative effect of change in  
accounting principle

Net loss	\$ (130.90)	\$ (59.82)	\$ (57.79)	\$ (40.84)	\$ (2.26)
Weighted average shares outstanding, basic and diluted	269,861	292,173	291,612	293,142	10,811,119

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	2003	2004	December 31, 2005	2006	2007
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 4,580	\$ 3,303	\$ 1,080	\$ 1,528	\$ 13,248
Restricted cash	670				
Available-for-sale securities (short-term)	18,909	13,976	3,481		22,477
Working capital (deficit)	18,514	17,018	1,828	(3,206)	32,849
Available-for-sale securities (long-term)	1,833				13,850
Total assets	30,503	20,894	7,309	4,266	52,225
Long-term obligations, less current portion	578	7,215	4,684	9,310	
Accrued dividends	8,911	11,236	7,473	8,882	
Total stockholders' equity (deficit)	14,951	1,151	(8,584)	(20,007)	47,631

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

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

**Overview**

We are 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 diseases. In July 2007, we initiated a Phase I clinical trial in the United Kingdom with our lead candidate in clinical development (ATHX-105 for the treatment of obesity), and completed this trial in January 2008. In the fourth quarter of 2007, we received FDA authorization to advance two MultiStem product development programs into clinical trials, in the areas of HSC transplant support, and for treatment of damage from myocardial infarction. The application of MultiStem for certain cardiovascular applications, including myocardial infarction and peripheral vascular disease, is being developed with our partner, Angiotech. We intend to initiate both of these trials in 2008, and file an additional IND for treatment of ischemic stroke in 2008. We are also developing pharmaceutical products for the treatment of certain conditions affecting the central nervous system, such as ADHD, narcolepsy and other cognitive or attention disorders. In addition to these drug development programs, we are also developing MultiStem for certain other disease indications.

We have incurred losses since inception of operations in December 1995 and had an accumulated deficit of \$160.5 million at December 31, 2007. 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 its operations. Athersys has used the financing proceeds from private equity and debt offerings and other sources of capital to develop its technologies, such as RAGE, and to acquire its stem cell technology. We have also built drug development capabilities that have enabled us to advance product candidates into clinical trials. We have established strategic collaborations that provide revenues and capabilities to help to further advance our product candidates, and we have also built a substantial portfolio of intellectual property.

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

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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.

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.

BTHC VI's acquisition of Athersys effected a change in control and was accounted for as a reverse acquisition whereby Athersys is the accounting acquirer for financial statement purposes. Accordingly, the financial statements presented reflect the historical results of Athersys and do not include the historical financial results of BTHC VI prior to the consummation of the merger. 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.

On June 8, 2007, we completed the offering of 13,000,000 shares of our common stock and received gross proceeds of \$65.0 million. Investors in the June offering 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 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 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. The placement agents also 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. 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. For the year ended December 31, 2007, stock compensation expense was approximately \$5.1 million, of which \$2.5 million was recorded as research and development expense and \$2.6 million was recorded as general and administrative expense. At December 31, 2007, total unrecognized compensation cost related to unvested stock options was approximately \$5.0 million, which is expected to be recognized by December 31, 2011 using the straight-line method.

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

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 studies that will be conducted in order to assess safety and

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effectiveness. The Phase I clinical trial, which included 107 subjects, was completed in January 2008. 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. Following a detailed analysis of the results of the clinical trial, the completion of certain required non-clinical studies and regulatory approval, we intend to initiate a Phase II clinical trial in the United States that will examine safety and effectiveness in clinically obese patients.

In addition, applying our MultiStem platform, we have established therapeutic product development programs in the areas of cardiovascular disease, HSC transplant support and ischemic stroke. We intend to advance two or more MultiStem programs into clinical development in 2008.

**Results of Operations**

Since Athersys inception, its revenues have consisted of license fees from its collaborators and grant proceeds from federal and state grants. Athersys has 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. Athersys expenses 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. Our expenses are expected to increase as we expand our business development activities and support our operating activities. To date, Athersys has financed its 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 Athersys revenues and expenses for the periods indicated. The following tables are stated in thousands.

**Revenues**

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
License fees	\$ 1,433	\$ 1,908	\$ 763
Grant revenue	1,827	1,817	2,833
	<b>\$ 3,260</b>	<b>\$ 3,725</b>	<b>\$ 3,596</b>

**Research and development expenses**

	<b>Year Ended December 31,</b>		
<b>Type of Expense</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
Personnel costs	\$ 2,813	\$ 2,721	\$ 4,587
Research supplies	679	1,208	2,286
Facilities	762	879	1,127

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Clinical and preclinical development costs	5,723	2,702	966
Sponsored research	465	579	1,129
Patent legal fees	1,086	595	714
Other	1,821	781	968
Stock-based compensation	2,468	276	801
	\$ 15,817	\$ 9,741	\$ 12,578

**Table of Contents*****General and administrative expenses***

<b>Type of Expense</b>	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Personnel costs	\$ 1,987	\$ 1,891	\$ 1,858
Facilities	330	291	286
Legal and professional fees	1,165	590	446
Other	1,822	392	508
Stock-based compensation	2,671	183	657
	\$ 7,975	\$ 3,347	\$ 3,755

***Year Ended December 31, 2007 Compared to Years 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. We expect our revenues from license fees and grants to continue at similar levels in 2008.

**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 clinical trial, performance of ATHX-105 non-clinical studies, and increases in MultiStem preclinical and clinical costs and manufacturing expenses. We expect these expenses to continue to increase in 2008 as we expect to initiate our ATHX-105 Phase II clinical trial and two or more MultiStem clinical trials. 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. We anticipate consistent levels of patent legal expense in 2008. 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

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fees incurred in connection with SEC filings, accounting and auditing fees incurred in connection with SEC filings and fees for our board of directors. We expect our general and administrative expenses to continue at similar levels in 2008.

*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. Due to declining interest rates and lower cash balances as a result of our ongoing and planned clinical and preclinical development, we expect our 2008 interest income to be less than 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. We expect our interest expense to decrease for 2008 compared to 2007 as a result of the conversion of these promissory notes and our repayment of our Senior Loan in June 2008, unless we issue new debt.

*Accretion of Premium on Convertible Debt.* The accretion of premium on convertible debt increased to \$0.5 million in 2007 from \$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. 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 into common stock upon the closing of the equity offering in June 2007.

***Year Ended December 31, 2006 Compared to Year Ended December 31, 2005***

*Revenues.* Revenues increased to \$3.7 million for the year ended December 31, 2006 from \$3.6 million for the comparable period in 2005. License fee revenues increased \$1.1 million over this period as a result of the nature and timing of target acceptances under Athersys' collaboration agreement with Bristol-Myers Squibb. Grant revenue decreased \$1.0 million for the year ended December 31, 2006 compared to the year ended December 31, 2005. In July 2003, Athersys was awarded a \$5.0 million state grant that spanned three years and was completed in February 2006. This grant was renewed in May 2006 for approximately \$3.5 million that will also span three years. The decrease in grant revenue for the year ended December 31, 2006 is principally the result of recognizing eight months of revenue under this state grant in 2006 versus twelve months of revenue in 2005. In addition, Athersys had fewer active NIH grant awards in 2006 as compared to 2005.



*Research and Development Expenses.* Research and development expenses decreased to \$9.7 million in 2006 from \$12.6 million in 2005. The decrease of approximately \$2.9 million in research and development expenses relates primarily to a decrease in personnel costs of \$1.9 million, a decrease in research supplies expenses of \$1.1 million, a decrease in sponsored research of \$550,000 and a decrease in facilities and other

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costs of \$435,000 related to the restructuring and reduction in force that occurred late in 2005. In addition, patent legal fees decreased \$119,000 and stock compensation expense decreased \$525,000 in 2006 compared to 2005. These decreases were partially offset by an increase in preclinical and clinical expenses of \$1.7 million in 2006 compared to 2005. As Athersys has evolved from a research-oriented company to a product-oriented company, its staffing needs have evolved, resulting in the reductions in personnel and related costs. Athersys has been optimizing the mix of its internal capabilities with the capabilities of its outside collaborators, academic institutions, and third-party contract research organizations resulting in an increase in these costs.

*General and Administrative Expenses.* General and administrative expenses decreased to \$3.3 million in 2006 from approximately \$3.8 million in 2005. The decrease in general and administrative expenses was due primarily to a decrease in stock compensation expense of \$474,000 and a decrease in other expenses of \$116,000. These decreases were offset by an increase in legal and professional fees of \$144,000, which was a result of legal costs associated with potential financing and strategic transactions.

*Depreciation.* Depreciation expense decreased to \$528,000 in 2006 from \$982,000 in 2005. The decrease in depreciation expense was due to more laboratory equipment, computer equipment, furniture, and leasehold improvements becoming fully depreciated, combined with fewer purchases of new equipment.

*Restructuring Costs.* Restructuring costs for the year ended December 31, 2005 were a result of the restructuring and reduction in force, which occurred late in 2005.

*Other Income and Equity in Earnings of Unconsolidated Affiliate.* 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 on the statement of operations.

*Interest Income.* Interest income decreased to \$119,000 for the year ended December 31, 2006 from \$317,000 in 2005. Changes in interest income were due to changes in Athersys' average cash balances and available-for-sale securities during those years.

*Interest Expense.* Interest expense on Athersys' debt outstanding under its senior loan and its subordinated convertible promissory notes increased to \$1,047,000 for the year ended December 31, 2006 from \$964,000 for the comparable period in 2005. The increase in interest expense is due to the subordinated convertible promissory notes issued by Athersys in May 2006 and October 2006.

*Accretion of Premium on Convertible Debt.* The accretion of premium on convertible debt for the year ended December 31, 2006 was a result of the \$2.5 million in aggregate principal amount of subordinated secured convertible promissory notes issued in October 2006. The notes, if not converted, were repayable with accrued interest at maturity, plus a repayment fee of 200% of the outstanding principal. Athersys has computed a premium on the debt in the amount of \$5.25 million due upon redemption, which is being accreted over the term of the notes using the effective interest method. This accretion was reversed and recorded in additional paid-in-capital in June 2007 when the notes were converted into common stock upon the closing of the equity offering 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.

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### **Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and available-for-sale securities. At December 31, 2007, we had \$13.2 million in cash and cash equivalents, and \$36.3 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, which includes the gross proceeds of \$65.0 million received in the June 2007 offering.

We will require substantial additional funding in order to continue our research and product development programs, including preclinical testing and clinical trials of our product candidates. We anticipate using \$23 million to \$25 million in 2008, which is an increase in cash expenditures reflecting the impact of the ATHX-105 Phase II clinical trial. With the anticipated completion of the ATHX-105 Phase II clinical trial, we expect lower clinical development costs in 2009, and as a result, expect to have available cash to fund our operations into 2010 based on our current business and operating 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. 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 \$12.1 million, \$8.4 million and \$12.1 million in 2007, 2006 and 2005, respectively, and represented the use of cash in funding technology development and product development initiatives. We expect that net cash used in operating activities will increase as we increase our clinical trial activity for ATHX-105 and MultiStem and as we continue to advance our various research and product development activities.

Net cash used in investing activities was \$36.4 million in 2007. Net cash provided by investing activities was \$3.4 million and \$10.3 million in 2006 and 2005, respectively. 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 \$161,000, \$83,000 and \$239,000 in 2007, 2006 and 2005, respectively. We expect that our capital equipment expenditures to continue at similar levels in 2008.

Financing activities provided cash of \$60.2 million in 2007 and \$5.4 million in 2006, and used cash of \$446,000 in 2005. 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.

Our Senior Loan will be repaid in full in June 2008, which had a balance of \$1.8 million at December 31, 2007. The Senior Lenders have the 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 Senior Loan 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, and (c) our

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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 this 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. 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 the June offering.

In connection with developing MultiStem for the treatment of the cardiovascular disorders of myocardial infarction and peripheral vascular disease as part of a commercial collaboration with Angiotech that was entered into in May 2006, in support of the collaboration, 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 the June offering. 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 plan to jointly fund clinical development activity, whereby preclinical costs will be borne solely by Athersys, costs for phase I and phase II studies will be 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. We will 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, of which \$63,000 was due from Angiotech at December 31, 2007. 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 December 2007, we achieved a clinical development milestone upon the authorization of our IND by the FDA. This milestone event required Angiotech to either purchase \$5.0 million of our common stock, or forego the purchase and allow us to select from two pre-defined milestone replacements. Angiotech opted to forego the purchase, and we elected to increase our share of the net profits from the sale of approved products as the replacement milestone.

Our contractual payment obligations as of December 31, 2007 are as follows:

<b>Contractual Obligations</b>	<b>Total</b>	<b>Less Than</b>		<b>More</b>
		<b>1 Year</b>	<b>1-3 Years</b>	<b>Than</b>
				<b>3-5</b>
				<b>Years</b>
				<b>5 Years</b>
Operating lease for facilities	\$ 741,000	\$ 309,000	\$ 432,000	
Long-term debt (principal)	\$ 1,800,000	\$ 1,800,000		
Long-term debt (interest)	\$ 75,000	\$ 75,000		
Research funding	\$ 1,327,000	\$ 336,000	\$ 991,000	
<b>Total</b>	<b>\$ 3,943,000</b>	<b>\$ 2,520,000</b>	<b>\$ 1,423,000</b>	

The amount of long-term debt on the balance sheet at December 31, 2007 is reflected net of a discount. 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 \$45,000, 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 funding commitment for research programs conducted at KUL. Our agreement provides KUL with four years of research funding commencing in September 2007 and requires our approval on annual research programs and budgets. We approved the first year's research program, but have included in the table above the minimum funding for the subsequent years,

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which is denominated in Euros and has been converted into U.S. dollars using the December 31, 2007 exchange rate. KUL is entitled to an annual milestone payment related to the continued operation of the research agreement, which is included in the table above, and may receive royalties on future net sales of products developed using MAPC-related inventions. The research agreement may be terminated after two years or upon material breach by either party. KUL may terminate the license if we fail to pay royalties when due or upon material breach of the license terms.

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. 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.

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 U.S. 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.

Our critical accounting policies include:

### ***Revenue Recognition***

Our revenue recognition policies are in accordance with the SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force 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 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 us is recognized when performance is complete and when collectability is reasonably assured. 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). Upon acceptance by the collaborator of a cell line for use in its own product development efforts, we have no further performance obligations with respect to the cell line or products developed using the cell line. In addition, we receive specified payments upon the collaborator's achievement of certain developmental milestones (e.g., clinical trial phases), which is recognized when the milestone is achieved by our collaborator.



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

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***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.

***Clinical Trial Costs***

Clinical trial costs are accrued based on work performed by outside contractors who manage and perform the trials. We obtain estimates of total costs based on enrollment of subjects, completion of studies and other events. Accrued clinical trial costs are subject to revisions as clinical trials progress, and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

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

We determine the appropriate classification of investment securities at the time of purchase and re-evaluate such designation as of each balance sheet date. Our investments typically consist primarily of 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 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.

***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. 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), we recognized compensation expense on the accelerated method using graded vesting. For awards granted subsequent to adoption of SFAS No. 123(R), 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 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. Prior to the adoption of SFAS No. 123(R), we were permitted to recognize forfeitures as an expense reduction upon occurrence. The adjustment to apply estimated forfeitures to previously recognized

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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.

### **Recently Issued Accounting Standards**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157, which creates a framework for measuring fair value, clarifies the definition of fair value and expands the disclosures regarding fair value measurements. SFAS No. 157 does not require any new fair value measurements and is effective for fiscal years beginning after November 15, 2007, thus January 1, 2008. We adopted the new standard as of the effective date and currently do not believe the adoption will have a material impact on our financial position or future results as we are already performing our investment valuation calculations and estimating the fair value of our financial instruments using methodology which is principally consistent with SFAS No. 157. We will continue to study the impact that SFAS No. 157 will have on future disclosures of the fair values of our nonfinancial assets and liabilities.

### **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 words. 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 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;

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

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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 U.S. government and its agencies, corporate debt securities, floating-rate notes and A1+/P1 commercial paper.

We enter into loan arrangements with financial institutions when needed. At December 31, 2007, we had borrowings of approximately \$1.8 million million outstanding under our Senior Loan, which bears interest at a fixed rate of approximately 13%.

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

**Athersys, Inc.**

**Consolidated Financial Statements**

**Years Ended December 31, 2007, 2006 and 2005**

**Contents**

<u>Reports of Independent Registered Public Accounting Firm</u>	50
<u>Consolidated Balance Sheets as of December 31, 2007 and 2006</u>	52
<u>Consolidated Statements of Operations for each of the years ended December 31, 2007, 2006 and 2005</u>	53
<u>Consolidated Statements of Stockholders' Equity (Deficit) for each of the years ended December 31, 2007, 2006 and 2005</u>	54
<u>Consolidated Statements of Cash Flows for each of the years ended December 31, 2007, 2006 and 2005</u>	55
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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Athersys, Inc.

We have audited the accompanying consolidated balance sheets of Athersys, Inc. as of December 31, 2007 and 2006, 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, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Athersys, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2008 expressed an unqualified opinion thereon.

Cleveland, Ohio  
March 14, 2008



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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Athersys, Inc.

We have audited Athersys, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Athersys, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting, which is included in Item 9A. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Athersys, Inc. maintained, in all material aspects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Athersys, Inc. as of December 31, 2007 and 2006 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, 2007 and our report dated March 14, 2008 expressed an unqualified opinion thereon.

Cleveland, Ohio  
March 14, 2008



**Table of Contents****Athersys, Inc.****Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except share and per share amounts)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 13,248	\$ 1,528
Available-for-sale securities	22,477	
Accounts receivable	836	872
Receivable from Angiotech	63	
Investment interest receivable	262	
Deposit	163	
Prepaid expenses and other	394	261
Total current assets	37,443	2,661
Available-for-sale securities	13,850	
Deposit	100	100
Notes receivable, net	86	562
Equipment, net	387	509
Accounts receivable, net	42	117
Equity investments	317	317
Total assets	\$ 52,225	\$ 4,266
<b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,011	\$ 898
Accrued compensation and related benefits	71	423
Accrued clinical trial costs	735	
Accrued expenses and other	993	1,214
Current portion of long-term debt, net	1,784	3,332
Total current liabilities	4,594	5,867
Long-term debt		1,800
Convertible promissory notes, net		7,510
Accrued interest		214
Accrued dividends		8,882
Stockholders' equity (deficit):		
Convertible preferred stock, at stated value; no shares authorized at December 31, 2007; 481,540 shares authorized, 364,524 shares issued and outstanding with an aggregate		68,301

liquidation preference of \$68,187 at December 31, 2006;

Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at December 31, 2007 and December 31, 2006

Common stock, \$0.001 par value; 100,000,000 shares authorized, 18,927,988 shares issued and outstanding at December 31, 2007; 1,433,972 shares authorized, 293,770 shares issued and outstanding at December 31, 2006;

	<b>19</b>	
Additional paid-in capital	<b>208,039</b>	53,495
Treasury stock, at cost		(250)
Accumulated other comprehensive income	<b>52</b>	
Accumulated deficit	<b>(160,479)</b>	(141,553)
Total stockholders' equity (deficit)	<b>47,631</b>	(20,007)
Total liabilities and stockholders' equity (deficit)	<b>\$ 52,225</b>	\$ 4,266

See accompanying notes.

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## Athersys, Inc.

## Consolidated Statements of Operations

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except share and per share amounts)</b>		
<b>Revenues</b>			
License fees	\$ 1,433	\$ 1,908	\$ 763
Grant revenue	1,827	1,817	2,833
Total revenues	<b>3,260</b>	3,725	3,596
<b>Costs and expenses</b>			
Research and development (including stock compensation expense of \$2,468, \$276 and \$801 in 2007, 2006 and 2005, respectively)	<b>15,817</b>	9,741	12,578
General and administrative (including stock compensation expense of \$2,671, \$183 and \$657 in 2007, 2006 and 2005, respectively)	<b>7,975</b>	3,347	3,755
Depreciation	<b>283</b>	528	982
Restructuring costs (including stock compensation income of \$128)			251
Total costs and expenses	<b>24,075</b>	13,616	17,566
Loss from operations	<b>(20,815)</b>	(9,891)	(13,970)
Other income	<b>2,017</b>	91	18
Equity in earnings of unconsolidated affiliate		117	
Interest income	<b>1,591</b>	119	317
Interest expense	<b>(1,263)</b>	(1,047)	(964)
Accretion of premium on convertible debt	<b>(456)</b>	(260)	
<b>Loss before cumulative effect of change in accounting principle</b>	<b>(18,926)</b>	(10,871)	(14,599)
Cumulative effect of change in accounting principle		306	
<b>Net loss</b>	<b>\$ (18,926)</b>	\$ (10,565)	\$ (14,599)
<b>Preferred stock dividends</b>	<b>(659)</b>	(1,408)	(2,253)
<b>Deemed dividend resulting from induced conversion of convertible preferred stock</b>	<b>(4,800)</b>		
<b>Net loss attributable to common stockholders</b>	<b>\$ (24,385)</b>	\$ (11,973)	\$ (16,852)
<b>Basic and diluted net loss per common share attributable to common stockholders</b>			
Loss before cumulative effect of change in accounting principle	<b>\$ (2.26)</b>	\$ (41.89)	\$ (57.79)
Cumulative effect of change in accounting principle		1.05	
<b>Net loss</b>	<b>\$ (2.26)</b>	\$ (40.84)	\$ (57.79)

<b>Weighted average shares outstanding, basic and diluted</b>	<b>10,811,119</b>	293,142	291,612
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See accompanying notes.

**Table of Contents****Athersys, Inc.****Consolidated Statements of Stockholders Equity (Deficit)**

	Convertible Preferred Stock		Common Stock		Additional	Accumulated Other Comprehensive Income	Unearned Compensation Common Stock	Accumulated Deficit	Stock
	Number of Shares	Stated Value	Number of Shares	Par Value	Paid-in Capital	Treasury Stock	Options	Deficit	(Loss)
January 1, 2005	422,468	\$ 68,301	292,257	\$	\$ 51,831	\$	\$ (35)	\$ (2,557)	\$ (116,389)
of common stock,			72		3				
of common stock	(57,944)		(1,388)			(250)			
of unearned compensation							1,330		
of common stock					(418)			418	
Dividends Class C					(1,306)				
Dividends Class E					(947)				
of Class E preferred									
					6,016				
Comprehensive Loss:									(14,599)
Gain on sale securities							18		
Comprehensive loss									
December 31,	364,524	68,301	290,941		55,179	(250)	(17)	(809)	(130,988)
of common stock			2,829		130				
of common stock					250				
of Class C					(809)			809	
of Class C					153				
Dividends Class C					(1,408)				
Comprehensive Loss:									(10,565)
Gain on sale securities							17		

Comprehensive loss

December 31,

and compensation  
 dividends Class C  
 of cumulative  
 dividends Class C  
 of preferred  
 common stock  
 of common stock  
 that exercises  
 of treasury

364,524	68,301	293,770		53,495	(250)	(141,553)
				5,139		
				(659)		
				9,541		
(364,524)	(68,301)	1,912,356	2	68,299		
		1,003,190	1	9		
				(250)	250	

Common stock  
 with BTHC VI,

of common stock,  
 shares  
 of common stock

299,622					
13,001,379	13	58,479			
		492			

of common stock  
 of  
 notes  
 Comprehensive Loss:

2,417,671	3	13,494			
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(18,926)

gain on  
 of sale securities

52

Comprehensive loss

December 31,

\$	18,927,988	\$ 19	\$ 208,039	\$	\$ 52	\$	\$ (160,479)	\$
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See accompanying notes.



**Table of Contents****Athersys, Inc.****Consolidated Statements of Cash Flows**

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands)</b>		
<b>Operating activities</b>			
Net loss	\$ (18,926)	\$ (10,565)	\$ (14,599)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	283	528	982
Fixed asset impairment			87
Gain on sale of equipment			(18)
Equity in earnings of unconsolidated affiliate		(117)	
Accretion of premium on convertible debt	456	260	
Provision/forgiveness of notes receivable	193	122	
Earned milestone applied to note receivable	283		
Stock-based compensation	5,139	459	1,330
Expense related to warrants issued to lenders	476		
Income from cumulative effect of change in accounting principle		(306)	
Amortization of premium (discount) on available for sale securities and other	(52)	15	(44)
Changes in operating assets and liabilities:			
Accounts receivable	111	(361)	22
Receivable from Angiotech	(63)		
Prepaid expenses and other assets	(558)	21	10
Accounts payable and accrued expenses	592	1,546	112
Net cash used in operating activities	(12,066)	(8,398)	(12,118)
<b>Investing activities</b>			
Purchase of available for sale securities	(46,316)	(3,426)	(5,006)
Proceeds from maturities of available for sale securities	10,100	6,932	15,563
Proceeds from sale of equipment			23
Purchases of equipment	(161)	(83)	(239)
Net cash (used in) provided by investing activities	(36,377)	3,423	10,341
<b>Financing activities</b>			
Principal payments on debt	(3,332)	(2,083)	(199)
Proceeds from convertible promissory notes	5,000	7,500	
Repurchase of common and preferred stock held in treasury			(250)
Proceeds from issuance of common stock, net	58,495	6	3
Net cash provided by (used in) financing activities	60,163	5,423	(446)
Increase (decrease) in cash and cash equivalents	11,720	448	(2,223)

Cash and cash equivalents at beginning of year	<b>1,528</b>	1,080	3,303
Cash and cash equivalents at end of year	<b>\$ 13,248</b>	\$ 1,528	\$ 1,080

See accompanying notes.

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**Athersys, Inc.**

**Notes to Consolidated Financial Statements**

**A. Background, Recent 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.

Upon the closing of the Offering, the \$10.0 million of convertible notes issued to Angiotech Pharmaceuticals, Inc. ( Angiotech ) (see Note F) were converted along with accrued interest into 1,885,890 shares of

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**Athersys, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**A. Background, Recent Merger and Offering (Continued)**

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. 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.

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 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

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**Athersys, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**B. Accounting Policies (Continued)**

upon the collaborator's achievement of certain developmental milestones (e.g., clinical trial phases), which are recognized when the milestones are achieved by our collaborator.

Revenue from grants consists primarily of funding under cost reimbursement programs 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 estimates of total costs based on enrollment of subjects, completion of studies and other events. Accrued clinical trial costs are 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 remit royalty payments based on product sales to certain parties under license agreements. The Company did not pay any royalties during the three-year period ended December 31, 2007.

**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



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**Athersys, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**B. Accounting Policies (Continued)**

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.

**Long-Lived Assets**

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

Long-lived assets are evaluated for impairment when events or changes in circumstances indicate that the carrying amount of the asset or related group of assets may not be recoverable. If the expected future undiscounted cash flows are less than the carrying amount of the asset, an impairment loss is recognized at that time. Measurement of impairment may be based upon appraisal, market value of similar assets or discounted cash flows. No impairment losses were recorded in 2007 or 2006. In connection with a restructuring in 2005, the Company reduced the carrying value of certain laboratory equipment to its realizable value, resulting in an impairment loss of \$87,000.

**Patent Costs and Rights**

Costs of prosecuting and maintaining patents and patent rights are expensed as incurred. As of December 31, 2007, 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, 2007 and 2006, one customer accounted for 51% and 78% 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**

Prior to the Company's adoption of Statement of Financial Accounting Standard ( SFAS ) No. 123(Revised 2004), *Share-Based Payment* ( SFAS No. 123(R) ), the Company accounted for its stock-based compensation in accordance with the intrinsic value method as described in the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, as permitted by SFAS No. 123, *Accounting for Stock Based Compensation* ( SFAS No. 123 ).

**Table of Contents****Athersys, Inc.****Notes to Consolidated Financial Statements (Continued)****B. Accounting Policies (Continued)**

As such, in 2005, compensation was measured on the date of issuance or grant as the excess of the current estimated market value of the underlying stock over the exercise price of the stock option. Any unearned compensation was recognized over the respective vesting periods of the equity instruments, if any, using the graded vesting method as prescribed by Financial Accounting Standards Board ( FASB ) Interpretation No. 28.

Effective January 1, 2006, the Company adopted the fair value recognition provisions of 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.

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 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 table illustrates the effect on net loss in 2005 if the Company had applied the fair value recognition provisions of SFAS No. 123 to options granted under the Company's stock option plans prior to the adoption of SFAS No. 123(R). For purposes of this pro forma disclosure, the value of the options was estimated using a Black-Scholes option-pricing formula and amortized to expense over the options' vesting periods (in thousands, except per share):

	<b>Year Ended December 31, 2005</b>
Net loss attributable to common stockholders:	
As reported	\$ (16,852)
Total stock compensation expense included in net loss, as reported	1,260

Total stock compensation expense under the fair value method for all awards		(2,312)
Pro forma net loss attributable to common stockholders	\$	(17,904)
Net loss per common share attributable to common stockholders:		
Basic and diluted as reported	\$	(57.79)
Basic and diluted pro forma	\$	(61.40)

**Table of Contents****Athersys, Inc.****Notes to Consolidated Financial Statements (Continued)****B. Accounting Policies (Continued)**

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

	<b>2007</b>	<b>December 31, 2006</b>	<b>2005</b>
Volatility	<b>73.4%</b>	53.6%	49.8%
Risk-free interest rate	<b>5.3%</b>	4.8%	3.7%
Expected life of option	<b>5.36 years</b>	4.0 years	4.0 years
Expected dividend yield	<b>0.0%</b>	0.0%	0.0%

**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*, for all periods presented. 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.

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 3,679,884, 116,083, and 138,795 shares of common stock for the years ended December 31, 2007, 2006 and 2005, respectively;

Warrants to purchase 5,125,496, 25,639, and 25,639 shares of common stock for the years ended December 31, 2007, 2006 and 2005, respectively;

Shares of common stock issuable upon conversion of convertible preferred stock in the amount of 160,041 for the year ended December 31, 2007 and 364,524 for both the years ended December 31, 2006 and 2005; and

Shares of common stock issuable upon the conversion of the convertible promissory notes in the amount of 112,098 and 72,995 for the years ended December 31, 2007 and 2006.

**Reclassification**

Certain prior year deposits have been reclassified from current assets to long-term assets to conform with the current year presentation.

**Recently Issued Accounting Standard**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, ( SFAS No. 157 ), which creates a framework for measuring fair value, clarifies the definition of fair value and expands the disclosures regarding fair value measurements. SFAS No. 157 does not require any new fair value measurements and is effective for fiscal years beginning after November 15, 2007, thus January 1, 2008. The Company adopted the new standard as of the effective date and currently does not believe the adoption will have a material impact

**Table of Contents****Athersys, Inc.****Notes to Consolidated Financial Statements (Continued)****B. Accounting Policies (Continued)**

on its financial position or future results as it is already performing its investment valuation calculations and estimating the fair value of its financial instruments using methodology that is principally consistent with SFAS No. 157. The Company will continue to study the impact that SFAS No. 157 will have on future disclosures of the fair values of our nonfinancial assets and liabilities.

**C. Equipment**

Equipment consists of (in thousands):

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Laboratory equipment	\$ 5,839	\$ 5,825
Office equipment and leasehold improvements	3,481	3,334
	<b>9,320</b>	9,159
Accumulated depreciation	<b>(8,933)</b>	(8,650)
	<b>\$ 387</b>	\$ 509

**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 and Note Receivable***

In 2003, the Company acquired MCL LLC ( MCL ) through a merger with one of its subsidiaries. The Company acquired its adult stem cell technology 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. Under the terms of the note, interest accrued on the unpaid principal at approximately 5% per annum for the first two years, and the further accrual of interest would cease until one year after the Company's common stock became publicly-traded. In November 2005, interest on the note ceased to accrue, but will resume accruing in June 2008 as a result of the Company's Merger.

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, 2007), 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 \$192,568 in 2007 to reserve a portion of the note balance for which collectability is uncertain, leaving a net balance of \$86,000 at December 31, 2007. In the event that the proceeds from the sale of common stock by



**Table of Contents****Athersys, Inc.****Notes to Consolidated Financial Statements (Continued)****D. Notes Receivable; MCL Acquisition (Continued)**

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***

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

	<b>Amortized Cost</b>	<b>Gross Unrealized Losses</b>	<b>Gross Unrealized Gains</b>	<b>Estimated Fair Value</b>
Floating Rate Notes	\$ 6,000	\$	\$	\$ 6,000
Debt securities issued by U.S. Treasury	20,400		49	20,449
Corporate debt securities	3,336	(6)	9	3,339
Commercial paper	6,539			6,539
	<b>\$ 36,275</b>	<b>\$ (6)</b>	<b>\$ 58</b>	<b>\$ 36,327</b>

Estimated fair values are based on quoted market prices. 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 \$52,000 as of December 31, 2007.

The amortized cost of and estimated fair value of available-for-sale securities at December 31, 2007, 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, 2007 (in thousands).

	<b>December 31, 2007</b>	
	<b>Amortized Cost</b>	<b>Estimated Fair Value</b>
Due in one year or less	\$ 22,439	\$ 22,477
Due after one year through two years	13,836	13,850

\$ 36,275 \$ 36,327

***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. Rent expense for the facility was approximately \$267,000 in each of 2007, 2006 and 2005.

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 \$45,000, 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 \$85,000. The lease includes an option to renew for four additional years, through December 31, 2014.

Table of Contents**Athersys, Inc.****Notes to Consolidated Financial Statements (Continued)****E. Financial Instruments (Continued)**

The future annual minimum lease commitments at December 31, 2007 are approximately \$309,000 for 2008, \$315,000 for 2009, and \$117,000 for 2010.

**Long-Term Debt**

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

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Notes payable to lenders; issued November 2004; matures June 2008, including \$487,500 terminal payment; 13% interest rate; secured	<b>\$ 1,800</b>	\$ 5,132
Discount related to warrant issuance	<b>(16)</b>	
Total, net	<b>1,784</b>	5,132
Less current portion, net	<b>1,784</b>	3,332
Long-term debt	<b>\$</b>	<b>\$ 1,800</b>

In November 2004, the Company issued a \$7,500,000 note payable to lenders, the proceeds of which were unrestricted and used for general corporate purposes. The notes are payable in 30 monthly installments after the initial interest-only period that expired on December 1, 2005, with a fixed interest rate of 13% and a maturity date of June 1, 2008. A terminal payment of \$487,500 is due June 1, 2008. The debt has no financial covenants and is secured by substantially all of the Company's assets, excluding intellectual property, unless the Company's cash balance falls below a defined threshold. Deferred financing costs of \$44,000 were capitalized in 2004 in connection with the note, which were being amortized over the term of the note using the effective interest method and will be fully amortized in 2008.

The lenders have the 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, and (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 this 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, 2007.

The lenders also received warrants to purchase 149,026 shares of common stock with an exercise price of \$5.00 upon the closing of the Offering in June 2007. The value of the warrants was \$492,000 based on the Black-Scholes valuation of the underlying security, of which \$476,000 was recorded as interest expense in 2007 and the remaining \$16,000 of which will be expensed in 2008.

In September 2006, the agreement governing the note was amended to provide for a potential deferral of four monthly principal payments. Two such principal payments were deferred, and were subsequently repaid along with accumulated interest in January 2007. The amortization of the remaining loan balance was based on the original terms and was not adjusted as a result of the amendment. The scheduled maturity of long-term debt is \$1.8 million in 2008.

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**Athersys, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**E. Financial Instruments (Continued)**

Fair value of the Company's long-term debt at December 31, 2007 is not determinable due to lack of marketability of the fixed-rate debt. The Company paid interest of \$456,000, \$832,000 and \$964,000 during the years ended December 31, 2007, 2006 and 2005, respectively.

**F. Collaboration**

In 2006, the Company entered into a co-development collaboration with Angiotech. The Company issued a \$5 million convertible promissory note to Angiotech at the inception of the program, which was followed by the issuance of an additional convertible promissory note of \$5 million in January 2007 upon the achievement of certain milestones. The notes bore interest at 5% and had a six-year term. 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.

In December 2007, the Company achieved a clinical development milestone upon the authorization of an investigation new drug application by the U.S. Food and Drug Administration. This milestone event required Angiotech to either purchase \$5.0 million of common stock of Athersys, or forego the purchase and allow Athersys to select from two pre-defined milestone replacements. Angiotech opted to forego the purchase and Athersys elected to increase its share of the net profits from the future sale of approved products as the replacement milestone.

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 \$63,000 in 2007. The \$63,000 was due from Angiotech at December 31, 2007 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 to three members of management. The notes bore interest at 10% and had a three-year term. 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

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**Athersys, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**G. Convertible Bridge Notes (Continued)**

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.

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 eliminated and recorded as 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, 2007, 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, 2007.

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 the anniversary dates.

As described in Note A, all of Old Athersys pre-Merger convertible preferred stock, outstanding warrants, accrued dividends and treasury shares were terminated in connection with the Merger. The holders of the majority of Old Athersys pre-Merger shares of preferred stock retained certain registration rights. Prior to the Merger, Old Athersys had the following preferred stock outstanding:

Convertible Class A, B, C, D, F and G Preferred stock, which generally were entitled to voting rights, dividends when declared, liquidation rights, and conversion rights at the holders election on a 1:1 basis;

Convertible Class C and E Preferred Stock carried cumulative, accrued dividends; and

The Class E Preferred Stock had limited voting rights and liquidation rights. As of October 2005, the shares of Class E Preferred stock were no longer convertible into shares of common stock, and the accrued dividend was no longer payable.





**Table of Contents****Athersys, Inc.****Notes to Consolidated Financial Statements (Continued)****H. Capitalization (Continued)**

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

	<b>December 31</b>	
	<b>2007</b>	<b>2006</b>
Stock option plans	<b>4,500</b>	277
Conversion of Class A, B, C, D, F, and G preferred stock		365
Conversion of unissued blank check preferred stock		9
Conversion of convertible notes    Angiotech*		1,887
Conversion of convertible notes    Bridge investors*		532
Warrants to purchase common stock    Bridge investors*		1,000
Warrants to purchase common stock    Offering	<b>4,976</b>	
Warrants to purchase common stock    Lenders*	<b>149</b>	149
Warrant to purchase common stock    Miscellaneous		26
	<b>9,625</b>	4,245

\* Amounts were not determinable at December 31, 2006, but were determined in June 2007 in connection with the Offering

**I. Joint Venture**

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 2006, a milestone was achieved and Athersys received \$100,000 of stock-based proceeds in another company related to its investment in Oculus, which is included in other income on the Company's 2006 statement of operations.

Also in connection with the milestone achievement in 2006, Oculus received stock-based proceeds in another company in the amount of \$260,000. Athersys recognized approximately \$117,000 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, 2007 and 2006, Oculus had no significant assets, liabilities, stockholders equity or results of operations, other than the milestone proceeds in 2006 as described above.

**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

**Table of Contents****Athersys, Inc.****Notes to Consolidated Financial Statements (Continued)****J. Stock Option Plans (Continued)**

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, 2007, 4,634 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, 2007, a total of 824,750 shares are available for issuance under the Company's equity compensation plans and options covering 3,679,884 shares of common stock are outstanding (including the 4,634 assumed options described above). The Company recognized \$5,139,000, \$457,000 and \$1,459,000 of stock compensation expense in 2007, 2006 and 2005, respectively. At December 31, 2007, total unrecognized compensation expense related to unvested stock options was approximately \$5,017,000, which is expected to be recognized ratably by December 31, 2011 using the straight-line method. The weighted average fair value of option shares granted in 2007, 2006 and 2005 was \$2.82, \$0 and \$154.81 per share, respectively. The total fair value of option shares vested in 2007, 2006 and 2005 was \$4,742,000, \$428,000, and \$2,312,000, respectively. There is no aggregate intrinsic value of fully vested option shares and option shares expected to vest as of December 31, 2007 since the market value was less than the exercise price of the options at the end of the year.

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

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding January 1, 2005	149,017	\$ 92.61
Granted	1,470	362.63
Exercised	(63)	41.84
Forfeited	(11,628)	133.89
Outstanding December 31, 2005	138,796	92.05
Granted		
Exercised	(72)	83.68
Forfeited	(22,641)	150.91
Outstanding December 31, 2006	116,083	80.62
Granted	<b>3,738,000</b>	<b>5.06</b>
Exercised		

Forfeited/Terminated/Expired	<b>(174,199)</b>		<b>51.21</b>
Outstanding December 31, 2007	<b>3,679,884</b>	<b>\$</b>	<b>5.24</b>
Vested during 2007	<b>1,663,957</b>	<b>\$</b>	<b>5.02</b>
Vested and exercisable at December 31, 2007	<b>1,668,591</b>	<b>\$</b>	<b>5.42</b>

**Table of Contents****Athersys, Inc.****Notes to Consolidated Financial Statements (Continued)****J. Stock Option Plans (Continued)**

Exercise Price	Options Outstanding			Options Vested and Exercisable		
	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
\$ 4.99- 7.80	3,675,250	8.45	\$ 5.06	1,663,957	8.76	\$ 5.02
\$69.74-278.95	4,634	2.25	\$ 152.08	4,634	2.25	\$ 152.08
	3,679,884			1,668,591		

The weighted average contractual life of unvested options at December 31, 2007 was 8.2 years.

**K. Income Taxes**

At December 31, 2007, the Company had net operating loss and research and development tax credit carryforwards of approximately \$7,021,000 and \$438,000, respectively, for income tax purposes. Such losses and credits may be used to reduce future taxable income and tax liabilities and will expire in 2027.

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 \$9,018,000 ( 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 2010 and 2027.

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

	December 31,	
	2007	2006
Net operating loss carryforwards	\$ 2,387	\$
Net operating loss carryforwards Pre-Merger NOL	3,066	37,369
Research and development credit carryforwards	438	5,759
Compensation expense	1,221	4,275
Other	539	568
Total deferred tax assets	7,651	47,971

Valuation allowance for deferred tax assets	(7,651)	(47,971)
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, 2007.

In July 2006, the FASB issued FASB Interpretation No. 48 ( FIN 48 ), *Accounting for Uncertainty in Income Taxes*, which is applicable for fiscal years beginning after December 15, 2006. 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, 2007, 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,

Table of Contents**Athersys, Inc.****Notes to Consolidated Financial Statements (Continued)****K. Income Taxes (Continued)**

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.

**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 in 2005, 2006 or 2007.

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

The following table presents quarterly data for the years ended December 31, 2007 and 2006, in thousands, except per share data:

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>2007 Third Quarter</b>	<b>Fourth Quarter</b>	<b>Full Year</b>
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)
<b>Basic and diluted net loss per common share attributable to common stockholders</b>	<b>\$ (10.54)</b>	<b>\$ (2.53)</b>	<b>\$ (0.23)</b>	<b>\$ (0.25)</b>	<b>\$ (2.26)</b>

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>2006 Third Quarter</b>	<b>Fourth Quarter</b>	<b>Full Year</b>
Revenues	\$ 629	\$ 490	\$ 1,126	\$ 1,480	\$ 3,725
Loss before cumulative effect of change in accounting principle	\$ (2,793)	\$ (3,295)	\$ (2,067)	\$ (2,716)	\$ (10,871)
Net loss	\$ (2,487)	\$ (3,295)	\$ (2,067)	\$ (2,716)	\$ (10,565)
Preferred stock dividends	\$ (348)	\$ (347)	\$ (347)	\$ (366)	\$ (1,408)
Net loss attributable to common stockholders	\$ (2,835)	\$ (3,642)	\$ (2,414)	\$ (3,082)	\$ (11,973)
<b>Basic and diluted net loss per common share attributable to common stockholders:</b>					
Loss before cumulative effect of change in accounting principle	\$ (10.78)	\$ (12.40)	\$ (8.22)	\$ (10.49)	\$ (41.89)

Cumulative effect of change in accounting principle	1.05				1.05
Net loss	\$ (9.73)	\$ (12.40)	\$ (8.22)	\$ (10.49)	\$ (40.84)



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

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of disclosure controls and procedures:* An evaluation was carried out under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this annual report. Based on that evaluation, these officers have concluded that as of December 31, 2007, 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, 2007. Our internal control over financial reporting as of December 31, 2007 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report, which is included in Item 8 of this annual report on Form 10-K and incorporated herein by reference.

*Changes in internal control:* During the fourth quarter of 2007, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

On March 13, 2008, our board of directors, based on the recommendation of the compensation committee, approved a cash bonus incentive plan for the year ended December 31, 2008 for our executive officers. Under the incentive plan, executive officers will be entitled to earn a bonus based upon the achievement of specified company goals, as well as specified individual goals. There is no formally adopted plan document for the incentive plan.

**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 2008 Annual Meeting of Stockholders, or the 2008 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 2008 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 2008 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

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website at [www.athersys.com](http://www.athersys.com). Athersys will post any amendments to, or waivers of, its code of ethics that apply to its principal executive officer, principal financial officer and principal accounting officer on its website.

**ITEM 11. EXECUTIVE COMPENSATION**

The information regarding executive officer and director compensation is incorporated by reference to the information contained in the 2008 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 2008 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 2008 Proxy Statement.

*Equity Compensation Plan Information.* The following table sets forth certain information regarding the Company's equity compensation plans as of December 31, 2007, unless otherwise indicated.

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options (a)</b>	<b>Weighted-Average Exercise Price of Outstanding Options (b)</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a)) (c)</b>
Equity compensation plan approved by security holders	2,442,750	\$ 5.00	592,250
Equity compensation plan not approved by security holders(1)	1,237,134	\$ 5.72	232,500
<b>Total</b>	<b>3,679,884</b>		<b>824,750</b>

(1) Includes 4,634 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 2008 Proxy Statement.

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

Information regarding fees paid to and services provided by our independent registered public accounting firm during the fiscal years ended December 31, 2007 and 2006 and the pre-approval policies and procedures of the audit committee is incorporated by reference to the information contained in the 2008 Proxy Statement.

**Table of Contents****PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES****(a)(1) *Financial Statements:***

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

Reports of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2007 and 2006

Consolidated Statements of Operations for each of the years ended December 31, 2007, 2006 and 2005

Consolidated Statements of Stockholders' Equity (Deficit) for each of the years ended December 31, 2007, 2006 and 2005

Consolidated Statements of Cash Flow for each of the years ended December 31, 2007, 2006 and 2005

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

	<b>Balance at Beginning of Year</b>	<b>Additions (In thousands)</b>	<b>Deductions</b>	<b>Balance at End of Year</b>
<b>Year Ended December 31, 2007</b>				
Deducted from asset accounts:				
Allowance for doubtful accounts	\$	\$	\$	\$
Tax valuation allowances	47,971	1,954	42,274(B)	7,651
<b>Total 2007</b>	<b>\$ 47,971</b>	<b>\$ 2,147</b>	<b>\$ 42,274</b>	<b>\$ 7,844</b>
<b>Year Ended December 31, 2006</b>				
Deducted from asset accounts:				
Tax valuation allowances	\$ 43,974	\$ 3,997	\$ (B)	\$ 47,971

<b>Total 2006</b>	<b>\$ 43,974</b>	<b>\$ 3,997</b>	<b>\$</b>	<b>\$ 47,971</b>
<b>Year Ended December 31, 2005</b>				
Deducted from asset accounts:				
Tax valuation allowances	\$ 38,861	\$ 5,113	\$ (B)	\$ 43,974
<b>Total 2005</b>	<b>\$ 38,861</b>	<b>\$ 5,113</b>	<b>\$</b>	<b>\$ 43,974</b>

(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.

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(a)(3) Exhibits.

<b>Exhibit No.</b>	<b>Exhibit Description</b>
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 10-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 of April 28, 2000, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.7 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.8	Amendment No. 2 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of November 19, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and

the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, as amended, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)



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<b>Exhibit No.</b>	<b>Exhibit Description</b>
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)

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<b>Exhibit No.</b>	<b>Exhibit Description</b>
10.21	Employment Agreement, dated as of May 22, 1998, by and between Athersys, Inc. and Laura K. Campbell (incorporated herein by reference to Exhibit 10.20 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.22	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Laura Campbell (incorporated herein by reference to Exhibit 10.21 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.23	Employment Agreement, dated as of September 25, 2000, by and between Advanced Biotherapeutics, Inc. and Kurt Brunden (incorporated herein by reference to Exhibit 10.22 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.24	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Kurt Brunden (incorporated herein by reference to Exhibit 10.23 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
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)

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<b>Exhibit No.</b>	<b>Exhibit Description</b>
10.34	Securities Purchase Agreement, dated as of June 8, 2007, by and among Athersys, BTHC VI, Inc. and Investors (as defined therein) (incorporated herein by reference to Exhibit 10.33 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.35*	Exclusive License Agreement, dated as of May 17, 2002, by and between Regents of the University of Minnesota and MCL LLC, assumed by ReGenesys, LLC through operation of merger on November 4, 2003 (incorporated herein by reference to Exhibit 10.34 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.36*	Strategic Alliance Agreement, by and between Athersys, Inc. and Angiotech Pharmaceuticals, Inc., dated as of May 5, 2006 (incorporated herein by reference to Exhibit 10.35 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on October 9, 2007)
10.37	Amendment No. 1 to Cell Line Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.36 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.38	Consulting Agreement, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and Dr. Kurt Brunden, dated as of July 23, 2007 (incorporated herein by reference to Exhibit 10.13 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on August 17, 2007)
10.39	Form Indemnification Agreement for Directors, Officers and Directors and Officers (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on August 6, 2007)
10.40	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).
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

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Cleveland, State of Ohio, on March 14, 2008.

ATHERSYS, INC.

By: /s/ Gil Van Bokkelen

Gil Van Bokkelen

Title: Chief Executive Officer

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Gil Van Bokkelen Gil Van Bokkelen	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 14, 2008
/s/ Laura K. Campbell Laura K. Campbell	Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	March 14, 2008
* John J. Harrington	Executive Vice President, Chief Scientific Officer and Director	March 14, 2008
* William C. Mulligan	Director	March 14, 2008
* George M. Milne, Jr.	Director	March 14, 2008
* Jordan S. Davis	Director	March 14, 2008
* Floyd D. Loop	Director	March 14, 2008

Michael Sheffery

\*

Director

March 14, 2008

Lorin J. Randall

- \* 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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**Table of Contents****EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Exhibit Description</b>
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 10-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 of April 28, 2000, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.7 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.8	Amendment No. 2 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of November 19, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and



the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, as amended, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)

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<b>Exhibit No.</b>	<b>Exhibit Description</b>
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)

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<b>Exhibit No.</b>	<b>Exhibit Description</b>
10.21	Employment Agreement, dated as of May 22, 1998, by and between Athersys, Inc. and Laura K. Campbell (incorporated herein by reference to Exhibit 10.20 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.22	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Laura Campbell (incorporated herein by reference to Exhibit 10.21 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.23	Employment Agreement, dated as of September 25, 2000, by and between Advanced Biotherapeutics, Inc. and Kurt Brunden (incorporated herein by reference to Exhibit 10.22 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.24	Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Kurt Brunden (incorporated herein by reference to Exhibit 10.23 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
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)

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<b>Exhibit No.</b>	<b>Exhibit Description</b>
10.34	Securities Purchase Agreement, dated as of June 8, 2007, by and among Athersys, BTHC VI, Inc. and Investors (as defined therein) (incorporated herein by reference to Exhibit 10.33 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.35*	Exclusive License Agreement, dated as of May 17, 2002, by and between Regents of the University of Minnesota and MCL LLC, assumed by ReGenesys, LLC through operation of merger on November 4, 2003 (incorporated herein by reference to Exhibit 10.34 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.36*	Strategic Alliance Agreement, by and between Athersys, Inc. and Angiotech Pharmaceuticals, Inc., dated as of May 5, 2006 (incorporated herein by reference to Exhibit 10.35 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on October 9, 2007)
10.37	Amendment No. 1 to Cell Line Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.36 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
10.38	Consulting Agreement, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and Dr. Kurt Brunden, dated as of July 23, 2007 (incorporated herein by reference to Exhibit 10.13 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on August 17, 2007)
10.39	Form Indemnification Agreement for Directors, Officers and Directors and Officers (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on August 6, 2007)
10.40	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).
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