

ATHERSYS, INC / NEW  
Form 424B3  
January 18, 2012  
Table of Contents

Filed Pursuant to Rule 424(b)(3)  
Registration No. 333-178418

PROSPECTUS

**8,000,000 Shares**

**Athersys, Inc.**

**Common Stock**

This prospectus relates to a common stock purchase agreement that we entered into with Aspire Capital Fund, LLC (referred to in this prospectus as *Aspire Capital* or the *selling stockholder* ) and the potential sale of up to 8,000,000 shares of our common stock by Aspire Capital, consisting of 7,066,666 shares that we may issue at our option to Aspire Capital in the future pursuant to the terms of that purchase agreement, 666,667 shares that we previously sold to Aspire Capital pursuant to that purchase agreement, and 266,667 shares that we previously issued to Aspire Capital as consideration for entering into that purchase agreement. The prices at which Aspire Capital may sell the shares pursuant to this prospectus will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of our shares by Aspire Capital. However, we may receive proceeds of up to an additional \$19.0 million from the sale of our common stock to Aspire Capital pursuant to that purchase agreement we entered into with Aspire Capital, once the registration statement, of which this prospectus is a part, is declared effective.

Aspire Capital is an *underwriter* within the meaning of the Securities Act of 1933, as amended.

Our common stock is listed on The NASDAQ Capital Market under the symbol *ATHX*. The last sale price of our common stock on January 13, 2012, as reported by The NASDAQ Capital Market, was \$2.11 per share.

**Investing in our common stock involves risk. Please read carefully the section entitled Risk Factors beginning on page 6 of this prospectus.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Prospectus dated January 17, 2012.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	6
<u>Cautionary Note Regarding Forward-Looking Statements</u>	22
<u>Use of Proceeds</u>	23
<u>Common Stock Price Range</u>	24
<u>Dividend Policy</u>	24
<u>Dilution</u>	25
<u>Selected Consolidated Financial Data</u>	26
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	27
<u>Business</u>	41
<u>Management</u>	56
<u>Certain Relationships and Related-Party Transactions</u>	73
<u>Beneficial Ownership of Common Stock</u>	74
<u>Selling Stockholder</u>	77
<u>The Aspire Capital Transaction</u>	78
<u>Description of Capital Stock</u>	82
<u>Material U.S. Federal Income Tax Consequences to Non-U.S. Holders</u>	83
<u>Plan of Distribution</u>	86
<u>Legal Matters</u>	88
<u>Experts</u>	88
<u>Where You Can Find More Information</u>	88
<u>Index to Financial Statements</u>	F-1

**We have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized any other person to provide you with different information. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we, nor the selling stockholder, are making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, operating results and prospects may have changed since that date.**

## **Table of Contents**

### **PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections entitled Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations, and our historical consolidated financial statements and related notes included elsewhere in this prospectus. In this prospectus, unless the context requires otherwise, references to Athersys, we, our or us refer to Athersys, Inc. and its consolidated subsidiaries.*

#### **Company Overview**

We are an international biopharmaceutical company that is focused in the field of regenerative medicine. We are committed to the discovery and development of best-in-class therapies designed to extend and enhance the quality of human life and have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. We are developing our lead platform product, MultiStem<sup>®</sup>, a patented and proprietary allogeneic stem cell product that has been evaluated in two fully-enrolled Phase I clinical trials and is currently being evaluated in ongoing Phase II clinical trials. Our current clinical development programs are focused on treating cardiovascular disease, neurological conditions, inflammatory & immune disorders, and other conditions. These represent major areas of clinical need, as well as substantial commercial opportunities.

We believe MultiStem represents a breakthrough in the field of regenerative medicine and stem cell therapy. MultiStem is a patented and proprietary product that has demonstrated the ability to enhance tissue repair and healing in multiple ways, and could be used to treat a range of disease indications. In contrast to traditional pharmaceutical products or biologics that are capable of acting through a single biological mechanism of action, the MultiStem product can enhance healing and tissue repair through multiple distinct mechanisms in parallel, by producing multiple therapeutic factors and dynamically responding to the needs of the body resulting in a more effective therapeutic response.

The MultiStem product is unique because, unlike other approaches to regenerative medicine, it can be manufactured on a large scale, it may be administered in an off-the-shelf manner with minimal processing, can augment healing in multiple ways (and in ways that other cell therapy approaches do not appear to be capable of), and has demonstrated a consistent safety profile in both preclinical and clinical studies. Like drugs and biologics, the product is cleared from the body over time, enhancing product safety relative to other types of stem cell therapy. Even so, the therapeutic effects of treatment with MultiStem cells appear to be durable.

We believe the therapeutic and commercial potential for MultiStem is very broad, applying to multiple areas of significant unmet medical need. We are pursuing many opportunities that represent potential multi-billion dollar markets. While traditional pharmaceuticals or biologic therapies typically may be used to treat only a single disease or narrowly defined set of related conditions, MultiStem appears to have far broader potential and could be developed efficiently to treat a range of disease indications.

Working with an international network of leading investigators and prominent research and clinical institutions, we have evaluated the use of MultiStem as a potential treatment for a range of disease indications. Working collaboratively, and through our own internal efforts, we have explored the potential for MultiStem to be used in various therapeutic areas, including acute and chronic forms of cardiovascular disease, neurological conditions, inflammatory & immune disease, certain pulmonary conditions, and other areas.

To date, we have successfully advanced MultiStem product candidates into four clinical stage programs, each of which addresses a significant area of medical need, and represents a large commercial market

## **Table of Contents**

opportunity. MultiStem is being evaluated in two fully-enrolled clinical trials, one exploring the potential to treat patients that have suffered a heart attack and another evaluating the potential to provide supportive care and reduce treatment side effects, such as graft versus host disease, or GvHD, for patients being treated for leukemia or related conditions. MultiStem is also being evaluated in two additional ongoing clinical programs in the neurological, inflammatory & immune disease areas. In one study, which is being conducted with our partner Pfizer Inc., or Pfizer, MultiStem is being administered to patients with inflammatory bowel disease, or IBD. In another ongoing study, we are evaluating the potential to treat patients that have suffered neurological damage from a stroke.

In addition to our MultiStem programs, we are applying our pharmaceutical discovery capabilities to identify and develop novel pharmaceuticals to treat obesity, related metabolic conditions such as diabetes, and certain neurological indications, and small molecule compounds that may be used to enhance the production or therapeutic effectiveness of MultiStem or related products, increase the product's biological potency for certain indications and lead to second or third generation products in the regenerative medicine area.

## **Risks Related to Our Business**

Investing in our common stock involves substantial risk. You should carefully consider all of the information in this prospectus prior to investing in our common stock. There are numerous risk factors related to our business that are described under "Risk Factors" and elsewhere in this prospectus. Among these important risks are the following:

our clinical trials may not be successful, and clinical results may not reflect results seen in previously conducted preclinical studies;

we do not have adequate funding to complete development in some areas, and may not be able to access additional capital on reasonable terms or at all to complete development;

our current or future partners may not be able to adequately support development in designated areas, or they may elect to change their strategic or business priorities, and these changes may have an adverse impact on us, our development plans, or our business;

we may encounter unexpected regulatory changes that delay or impede our development and commercialization efforts;

there may be unexpected changes in intellectual property law;

product reimbursement challenges;

we may encounter manufacturing and distribution challenges; and

we may not be able to recruit or retain well qualified personnel that are necessary for us to conduct our business.

## **Corporate Information**

We were incorporated in Delaware in 1995 and our headquarters are located at 3201 Carnegie Avenue, Cleveland, Ohio 44115. Our telephone number is (216) 431-9900. Our website is <http://www.athersys.com>. The information contained on or accessible through our website is not part of this prospectus.



**Table of Contents**

**The Offering**

Common stock being offered by the selling stockholder	8,000,000 shares
Common stock outstanding	24,487,260 shares (as of December 31, 2011)
Use of proceeds	The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to an additional \$19.0 million in proceeds from the sale of our common stock to the selling stockholder under the common stock purchase agreement described below, which we currently intend to use for working capital and general corporate purposes. See Use of Proceeds.
Risk factors	See Risk Factors beginning on page 6 and other information included in this prospectus for a discussion of factors you should carefully consider before deciding whether to invest in our common stock.
NASDAQ symbol	Our common stock is listed on The NASDAQ Capital Market, or NASDAQ, under the symbol ATHX.
Unless otherwise indicated, all information in this prospectus reflects or assumes:	

the exclusion of 4,537,826 shares of common stock authorized and reserved for future issuance under outstanding awards under our equity incentive plans;

the exclusion of 962,174 shares of common stock authorized and reserved for future issuance under our equity incentive plans;

the exclusion of 1,075 shares of common stock issuable upon exercise of additional outstanding stock options;

the exclusion of 6,435,496 shares of common stock issuable upon exercise of outstanding warrants; and

the exclusion of any additional milestone payments to our former lenders, whether in the form of cash or shares of common stock. On November 11, 2011, we entered into a common stock purchase agreement (the agreement, as amended, is referred to in this prospectus as the Purchase Agreement), with Aspire Capital Fund, LLC, an Illinois limited liability company (referred to in this prospectus as Aspire Capital or the selling stockholder), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over the approximately 24-month term of the Purchase Agreement, should we elect to sell shares to Aspire Capital. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 266,667 shares of our common stock, which we refer to as the Commitment Shares, as a commitment fee. Upon execution of the Purchase Agreement, we sold to Aspire Capital 666,667 shares of common stock, which we refer to as the Initial Purchase Shares, for an aggregate purchase price of \$1,000,000. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, which we refer to as the Registration Rights Agreement, pursuant to which we agreed to file one or more registration statements, including the registration statement of which this prospectus

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

## Table of Contents

As of December 31, 2011, there were 24,487,260 shares of our common stock outstanding. The 8,000,000 shares of our common stock offered hereby represent approximately 32.7% of the total number of shares of our common stock outstanding as of December 31, 2011. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering under the Securities Act 8,000,000 shares of our common stock, which includes the Commitment Shares and the Initial Purchase Shares that have already been issued to Aspire Capital and an additional 7,066,666 shares of common stock that we may issue to Aspire Capital after the registration statement of which this prospectus is a part is declared effective under the Securities Act. All 8,000,000 shares of common stock are being offered pursuant to this prospectus.

After the SEC has declared effective the registration statement of which this prospectus is a part, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a Purchase Notice ), directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed \$500,000 per trading day, up to an additional \$19.0 million of our common stock in the aggregate at a per share price (the Purchase Price ) calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 100,000 shares, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a VWAP Purchase Notice ) directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on The NASDAQ Capital Market on the next trading day (the VWAP Purchase Date ), subject to a maximum number of shares we may determine (the VWAP Purchase Share Volume Maximum ) and a minimum trading price (the VWAP Minimum Price Threshold ) (as more specifically described below). The purchase price per Purchase Share pursuant to such VWAP Purchase Notice (the VWAP Purchase Price ) is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that in no event will any shares of common stock be sold at a Purchase Price less than \$1.45, or the Floor Price, unless and until such time as the stockholders of the Company approve the transaction contemplated by the Purchase Agreement. This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. Additionally, the Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement if such shares proposed to be issued and sold, when aggregated with all other shares of the Company's common stock that Aspire Capital and its affiliates beneficially own, would result in Aspire Capital and its affiliates beneficially owning more than 19.99% of the Company's then issued and outstanding common stock.

There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.



**Table of Contents****Summary Consolidated Financial Data**

The following is a summary of our financial position. The summary consolidated financial data set forth below should be read in conjunction with Selected Consolidated Financial Data, Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and the notes thereto included elsewhere in this prospectus.

	Year Ended December 31,			Nine Months Ended September 30,	
	2008	2009	2010	2010	2011
(in thousands, except per share data)					
<b>Consolidated Statement of Operations Data:</b>					
Contract and grant revenues	\$ 3,105	\$ 2,159	\$ 8,939	\$ 5,607	\$ 7,779
Operating expenses	22,197	17,774	20,450	15,034	17,283
Loss from operations	(19,092)	(15,615)	(11,511)	(9,427)	(9,504)
Other income, net	1,100	249	134	101	10
Net loss	\$ (17,992)	\$ (15,366)	\$ (11,377)	\$ (9,326)	\$ (9,494)
Basic and diluted net loss per common share	\$ (0.95)	\$ (0.81)	\$ (0.60)	\$ (0.49)	\$ (0.41)

Weighted average shares used in computing basic and diluted net loss

per common share	18,928	18,928	18,930	18,929	22,966
------------------	--------	--------	--------	--------	--------

Please see Note A to our consolidated financial statements contained elsewhere in this prospectus for an explanation of the method used to calculate net loss attributable to common stockholders, basic and diluted net loss per common share, and the number of shares used in the computation of per share amounts.

	December 31, 2010	September 30, 2011
(in thousands)		
<b>Consolidated Balance Sheet Data:</b>		
Cash, cash equivalents and available-for-sale securities	\$ 15,181	\$ 16,542
Working capital	9,106	10,333
Total assets	19,106	18,861
Warrant liability		1,100
Total stockholders' equity	9,005	10,579

---

**Table of Contents**

**RISK FACTORS**

*An investment in our common stock involves a high degree of risk. Accordingly, you should carefully consider the following risk factors, together with all of the other information contained in this prospectus, including our consolidated financial statements and related notes, before making an investment in our common stock. If any of the following risks actually occurs, we may not be able to conduct our business as currently planned, and our business, operating results and financial condition could be harmed. In that case, the market price of our common stock could decline, and you could lose all or a part of your investment.*

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

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

Since our inception in 1995, we have incurred significant losses and negative cash flows from operations. We incurred net losses of \$18 million in 2008, \$15 million in 2009 and \$11 million in 2010. As of September 30, 2011, we had an accumulated deficit of \$215 million, and anticipate incurring additional losses for at least the next several years. We expect to spend significant resources over the next several years to enhance our technologies and to fund research and development of our pipeline of potential products. To date, substantially all of Athersys' revenue has been derived from corporate collaborations, license agreements and government grants. In order to achieve profitability, we must develop products and technologies that can be commercialized by us or through future collaborations. Our ability to generate revenues and become profitable will depend on our ability, alone or with potential collaborators, to timely, efficiently and successfully complete the development of our product candidates. We have never earned revenue from selling a product and we may never do so, as none of our product candidates have been approved for sale, since they are currently being tested yet in humans and animal studies. We cannot assure you that we will ever earn revenue or that we will ever become profitable. If we sustain losses over an extended period of time, we may be unable to continue our business.

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

The development of our product candidates will require a commitment of substantial funds to conduct the costly and time-consuming research, which may include preclinical and clinical testing, necessary to obtain regulatory approvals and bring our products to market. Net cash used in our operations was \$16 million in 2008, \$5 million in 2009 and \$11 million in 2010 and \$10 million for the nine months ended September 30, 2011.

At September 30, 2011, we had \$16.5 million of cash, cash equivalents and investments, and we will need substantially more to advance our product candidates through development. Furthermore, we will need to add additional capital to fund our operations through the completion of our current clinical trials. Our future capital requirements will depend on many factors, including:

our ability to raise capital to fund our operations;

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

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

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

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;

**Table of Contents**

expenses related to complying with good manufacturing practices, or 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.

The extent to which we utilize the Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the agreement is limited. See *The Aspire Capital Transaction* section of this prospectus for additional information. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement during the continuance of an event of default or at a purchase price of less than \$1.45. Even if we are able to access the full \$20.0 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

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

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

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

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

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

## Table of Contents

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

an inability to follow our current development strategy for obtaining regulatory approval from the FDA because of changes in the regulatory approval process;

less than desired or complete lack of efficacy or safety in preclinical studies or clinical trials; and

intellectual property constraints that prevent us from making, using, or commercializing the product candidate.

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

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

test short-term safety and tolerability;

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

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

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

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

***Our product candidates are in an early stage of development and we currently have no therapeutic products approved for sale. If we are unable to develop, obtain regulatory approval or market any of our product candidates, our financial condition will be negatively affected, and we may have to curtail or cease our operations.***

We are in the early stage of product development, and we are dependent on the application of our technologies to discover or develop therapeutic product candidates. We currently do not sell any approved therapeutic products and do not expect to have any products commercially available for several years, if at all. You must evaluate us in light of the uncertainties and complexities affecting an early stage biotechnology company. Our product candidates require additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals or clearances before marketing. To date, no one to our knowledge has commercialized any therapeutic products using our technologies and we might never commercialize any product using our technologies and strategy. In addition, we may not succeed in developing new product candidates as an alternative to our existing portfolio of product candidates. If our current product candidates are delayed or fail, or we fail to successfully develop and commercialize new product candidates, our financial condition may be negatively affected, and we may have to curtail or cease our operations.



---

**Table of Contents**

***We may not successfully maintain our existing collaborative and licensing arrangements, or establish new ones, which could adversely affect our ability to develop and commercialize our product candidates.***

A key element of our business strategy is to commercialize some of our product candidates through collaborations with other companies. Our strategy includes establishing collaborations and licensing agreements with one or more pharmaceutical, biotechnology or device companies, preferably after we have advanced product candidates through the initial stages of clinical development. However, we may not be able to establish or maintain such licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

Our agreements with our collaborators and licensees may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply, or commercialization of certain product candidates, or could require or result in litigation or arbitration. Moreover, disagreements could arise with our collaborators over rights to intellectual property or our rights to share in any of the future revenues of products developed by our collaborators. These kinds of disagreements could result in costly and time-consuming litigation. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators.

Currently, our material collaborations and licensing arrangements are our collaboration with Pfizer to develop and commercialize MultiStem for the treatment of IBD, our collaboration agreement with Bristol-Myers Squibb pursuant to which we provide cell lines produced using our Random Activation of Gene Expression, or RAGE, technology, our collaboration with RTI Biologics, or RTI, to develop and commercialize Multipotent Adult Progenitor Cell, or MAPC, technology-based biologic implants for certain orthopedic applications in the bone graft substitutes market, and our license with the University of Minnesota pursuant to which we license certain aspects of the MultiStem technology. These arrangements do not have specific termination dates; rather, each arrangement terminates upon the occurrence of certain events.

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

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

Additionally, our current or future corporate collaborators will retain the ability to pursue other research, product development or commercial opportunities that may be directly competitive with our programs. If these collaborators elect to prioritize or pursue other programs in lieu of ours, we may not be able to advance product



## **Table of Contents**

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.

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

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

health concerns, whether actual or perceived, or unfavorable publicity regarding our obesity drugs, stem cell products or those of our competitors;

the timing of market entry as compared to competitive products;

the rate of adoption of products by our collaborators and other companies in the industry;

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

convenience and ease of administration;

pricing;

perceived efficacy and side effects;

marketing;

availability of alternative treatments;

levels of reimbursement and insurance coverage; and

activities by our competitors.

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

In addition to the regulatory requirements for our pharmaceutical programs, we will also require regulatory approvals for each distinct application of our stem cell product. In each case, we will be required to conduct clinical trials to demonstrate safety and efficacy of MultiStem,

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

or various products that incorporate or use MultiStem. For product candidates that advance to clinical testing, we cannot be certain that we or a collaborator will successfully complete the clinical trials necessary to receive regulatory product approvals. This process is lengthy and expensive.

We intend to seek approval for our product candidates through the FDA approval process. To obtain regulatory approvals, we must, among other requirements, complete clinical trials showing that our products are safe and effective for a particular indication. Under the approval process, we must submit clinical and non-clinical data to demonstrate the medication is safe and effective. For example, we must be able to provide

## **Table of Contents**

data and information, which may include extended pharmacology, toxicology, reproductive toxicology, bioavailability and genotoxicity studies to establish suitability for Phase II or large scale Phase III clinical trials.

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

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

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

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

Many factors, known and unknown, can adversely affect clinical trials and the ability to evaluate a product's efficacy. During the course of treatment, patients can die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Even if unrelated to our product, certain events can nevertheless adversely impact our clinical trials. As a result, our ability to ultimately develop and market the products and obtain revenues would suffer.

Even promising results in preclinical studies and initial clinical trials do not ensure successful results in later clinical trials, which test broader human use of our products. Many companies in our industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials. Even successful clinical trials may not result in a marketable product or be indicative of the efficacy or safety of a product. Many factors or variables could affect the results of clinical trials and cause them to appear more promising than they may otherwise be. Product candidates that successfully complete clinical trials could ultimately be found to be unsafe or ineffective. In addition, our ability to complete clinical trials depends on many factors, including obtaining adequate clinical supplies and having a sufficient rate of patient recruitment. For example, patient recruitment is a function of many factors, including:

the size of the patient population;

the proximity of patients to clinical sites;

the eligibility criteria for the trial;

the perceptions of investigators and patients regarding safety; and

the availability of other treatment options.



## **Table of Contents**

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

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

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

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

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

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

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

Our failure or the failure of our potential collaborators or third party manufacturers to comply with applicable FDA or other regulatory requirements including manufacturing, quality control, labeling, safety

## **Table of Contents**

surveillance, promoting and reporting may result in criminal prosecution, civil penalties, recall or seizure of our products, total or partial suspension of production or an injunction, as well as other regulatory action against our product candidates or us. Discovery of previously unknown problems with a product, supplier, manufacturer or facility may result in restrictions on the sale of our products, including a withdrawal of such products from the market. The occurrence of any of these events would negatively impact our business and results of operations.

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

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

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

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

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

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

***Our ability to compete in the biopharmaceutical market may decline if we are not successful in adequately protecting 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

## Table of Contents

complex legal and factual questions, including the ability to establish patentability of compounds and methods for using them for which we seek patent protection. We cannot predict the breadth of claims that will ultimately be allowed in our patent applications, if any, including those we have in-licensed or the extent to which we may enforce these claims against our competitors. We have filed multiple patent applications that seek to protect the composition of matter and method of use related to our small molecule programs. In addition, we are prosecuting numerous distinct patent families directed to composition, methods of production, and methods of use of MultiStem and related technologies. If we are unsuccessful in obtaining and maintaining these patents related to products and technologies, we may ultimately be unable to commercialize products that we are developing or may elect to develop in the future.

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

we were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies or product candidates upon which we rely;

others will not independently develop similar or alternative technologies or duplicate any of our technologies;

others did not publicly disclose our claimed technology before we conceived the subject matter included in any of our patent applications;

any of our pending or future patent applications will result in issued patents;

any of our patent applications will not result in interferences or disputes with third parties regarding priority of invention;

any patents that may be issued to us, our collaborators or our licensors will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;

we will develop additional proprietary technologies that are patentable;

the patents of others will not have an adverse effect on our ability to do business; or

new proprietary technologies from third parties, including existing licensors, will be available for licensing to us on reasonable commercial terms, if at all.

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

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

our loss of some of the rights that enable us to utilize this technology, and our ability to develop products based on MultiStem could be seriously hampered.



## **Table of Contents**

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

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

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

***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

## Table of Contents

into royalty or license agreements that are not advantageous to us. If we do not have the financial resources to support such litigation or appeals, we may forfeit or lose certain commercial rights. Even if we have the financial resources to continue such litigation or appeals, we may lose. In the event that we lose, we may be forced to pay very substantial damages; we may have to obtain costly license rights, which may not be available to us on acceptable terms, if at all; or we may be prohibited from selling products that are found to infringe the patent rights of others.

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

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

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

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

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

## **Table of Contents**

successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally.

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

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

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

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

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

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

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

we may have to issue convertible debt or equity securities to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock;

an acquisition may negatively impact our results of operations because it may require us to incur large one-time charges to earnings, amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or it may cause adverse tax consequences, substantial depreciation or deferred compensation charges;

**Table of Contents**

we may encounter difficulties in assimilating and integrating the business, technologies, products, personnel or operations of companies that we acquire;

certain acquisitions may disrupt our relationship with existing collaborators who are competitive to the acquired business;

acquisitions may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient revenue to offset acquisition costs;

an acquisition may disrupt our ongoing business, divert resources, increase our expenses and distract our management;

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

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

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

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

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

changes and limits in import and export controls;

increases in custom duties and tariffs;

changes in currency exchange rates;

economic and political instability;

changes in government regulations and laws;

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

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

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

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

Frequently foreign governments impose strict price controls on newly approved therapeutic products. If we obtain regulatory approval to sell products in foreign countries, we may be unable to obtain a price that provides an adequate financial return on our investment. Furthermore, legislation in the United States may permit re-importation of drugs from foreign countries into the United States, including re-importation from foreign countries where the drugs are sold at lower prices than in the United States due to foreign government-mandated

---

**Table of Contents**

price controls. Such a practice, especially if it is conducted on a widespread basis, may significantly reduce our potential United States revenues from any drugs that we are able to develop.

***If we elect not to sell our products in foreign countries that impose government mandated price controls because we decide it is uneconomical to do so, a foreign government or patent office may attempt to terminate our intellectual property rights in that country, enabling competitors to make and sell our products.***

In some cases we may choose not to sell a product in a foreign country because it is uneconomical to do so under a system of government-imposed price controls, or because it could severely limit our profitability in the United States or other markets. In such cases, a foreign government or patent office may terminate any intellectual property rights we may obtain with respect to that product. Such a termination could enable competitors to produce and sell our product in that market. Furthermore, such products may be exported into the United States through legislation that authorizes the importation of drugs from outside the United States. In such an event, we may have to reduce our prices, or we may be unable to compete with low-cost providers of our drugs, and we could be financially harmed as a result.

***We may encounter difficulties managing our growth, which could adversely affect our business.***

At various times we have experienced periods of rapid growth in our employee numbers as a result of a dramatic increase in activity in technology programs, genomics programs, collaborative research programs, discovery programs, and scope of operations. At other times, we have had to reduce staff in order to bring our expenses in line with our financial resources. Our success will also depend on the ability of our officers and key employees to continue to improve our operational capabilities and our management information and financial control systems, and to expand, train and manage our work force.

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

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

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

***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

## **Table of Contents**

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.

### **Risks Related to this Offering and our Common Stock**

*The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.*

We are registering for sale the Commitment Shares that we have issued, the Initial Purchase Shares previously sold to Aspire Capital and an additional 7,066,666 shares that we may sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered in this offering will be sold by Aspire Capital over a period of up to approximately 24 months from the date of this prospectus. The number of shares of common stock that we may sell under the Purchase Agreement may exceed 8,000,000 shares, depending on the sales price, which can be no less than the Floor Price. If we elect to sell more than the 8,000,000 shares of common stock offered hereby, we must first register under the Securities Act the sale by Aspire Capital of any additional shares we may elect to sell to Aspire Capital before we can put such additional shares to Aspire Capital under the Purchase Agreement. Additionally, the number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase

**Table of Contents**

Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Purchase Agreement may cause the trading price of our common stock to decline.

In addition to the Initial Purchase Shares, Aspire Capital may ultimately purchase all, some or none of the remaining \$19.0 million of common stock that, together with the Commitment Shares, is the subject of this prospectus. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement under the registration statement, of which this prospectus is a part, may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital in this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

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

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



**Table of Contents**

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus, including the sections entitled Prospectus Summary, Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business, contains forward-looking statements that represent our beliefs, projections and predictions about future events or our future performance. You can identify forward-looking statements by terminology such as may, will, would, could, should, expect, intend, plan, anticipate, believe, estimate, predict, potential, continue or the negative of these terms or other similar terms or phrases. These forward-looking statements are necessarily subjective and involve known and unknown risks, uncertainties and other important factors that could cause our actual results, performance or achievements or industry results to differ materially from any future results, performance or achievement described in or implied by such statements.

Factors that may cause actual results to differ materially from expected results described in forward-looking statements include, but are not limited to:

uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem for the treatment of IBD, acute myocardial infarction, or AMI, stroke and other disease indications, and the prevention of graft-versus-host disease, or GvHD;

our ability to raise capital to fund our operations;

final results from our MultiStem clinical trials;

the possibility of delays in, adverse results of and excessive costs of the development process;

our ability to successfully initiate and complete clinical trials;

changes in external market factors;

changes in our industry's overall performance;

changes in our business strategy;

our ability to protect our intellectual property portfolio;

our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;

our ability to meet milestones under our collaboration agreements;

our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreement;

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

changes in productivity and reliability of suppliers; and

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

See **Risk Factors** for a more complete discussion of these risks and uncertainties and for other risks and uncertainties. Any forward-looking statement you read in this prospectus reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, operating results, growth strategy and liquidity. You should not place undue reliance on these forward-looking statements because such statements speak only as to the date when made. We assume no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future, except as otherwise required by applicable law.

This prospectus also contains statistical data and estimates we obtained from industry publications and reports generated by third parties. Although we believe that the publications and reports are reliable, we have not independently verified their data.

**Table of Contents**

**USE OF PROCEEDS**

The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to an additional \$19.0 million in proceeds from the sale of our common stock to the selling stockholder under the Purchase Agreement, for a total of \$20.0 million in proceeds. We will bear all reasonable expenses incident to the registration of the shares of our common stock under federal and state securities laws other than expenses incident to the delivery of the shares to be sold by Aspire Capital. Any transfer taxes payable on these shares and any commissions and discounts payable to underwriters, agents, brokers or dealers will be paid by Aspire Capital.

Assuming the sale by us of all of an additional \$19.0 million of shares of our common stock to Aspire Capital and estimated expenses of \$0.2 million, the total net proceeds to us, giving effect to our initial sale of \$1.0 million of common stock to Aspire Capital, would be \$19.8 million, which we currently intend to use for working capital and general corporate purposes.

This anticipated use of net proceeds from the sale of our common stock to Aspire Capital under the Purchase Agreement represents our intentions based upon our current plans and business conditions. As a result, our management will retain broad discretion over the allocation of the net proceeds from the sale of our common stock to Aspire Capital under the Purchase Agreement.

**Table of Contents****COMMON STOCK PRICE RANGE**

Our common stock is listed on The NASDAQ Capital Market under the symbol ATHX. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on The NASDAQ Capital Market.

	<b>High</b>	<b>Low</b>
<b>Year ending December 31, 2012</b>		
First Quarter (through January 13, 2012)	\$ 2.26	\$ 1.75
<b>Year ended December 31, 2011</b>		
Fourth Quarter	\$ 2.42	\$ 1.13
Third Quarter	\$ 2.86	\$ 1.00
Second Quarter	\$ 3.10	\$ 2.50
First Quarter	\$ 3.08	\$ 2.35
<b>Year ended December 31, 2010</b>		
Fourth Quarter	\$ 3.19	\$ 2.42
Third Quarter	\$ 3.55	\$ 2.34
Second Quarter	\$ 3.63	\$ 2.56
First Quarter	\$ 4.40	\$ 2.32

The last reported sales price for our common stock on January 13, 2012 is set forth on the cover page of this prospectus. As of December 31, 2011, there were approximately 656 holders of record of our common stock.

**DIVIDEND POLICY**

We would have to rely upon dividends and other payments from our wholly-owned subsidiary, ABT Holding Company, to generate the funds necessary to make dividend payments, if any, on our common stock. ABT Holding Company, however, is legally distinct from us and has no obligation to pay amounts to us. The ability of ABT Holding Company to make dividend and other payments to us is subject to, among other things, the availability of funds and applicable state laws. However, there are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us. We did not pay cash dividends on our common stock during the past three years ended December 31, 2011. 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****DILUTION**

If you acquire shares of our common stock from the selling stockholder in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this offering. Our historical net tangible book value of common stock as of September 30, 2011 was \$10.6 million, or \$0.45 per share of common stock. Historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding.

After giving effect to (i) the issuance of the 266,667 Commitment Shares, (ii) the sale of the 666,667 Initial Purchase Shares, at a price of \$1.50 per share for an aggregate amount of \$1.0 million, (iii) the issuance of 50,000 shares of common stock to our former lenders and (iv) the sale of an additional 7,066,666 shares of common stock at \$1.45 per share, and after deducting estimated offering expenses payable by us, our pro forma net tangible book value as of September 30, 2011 would have been \$21.6 million, or \$0.68 per share of common stock. This represents an immediate increase in pro forma net tangible book value of \$0.23 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of \$0.77 per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share	\$ 1.45
Historical net tangible book value per share as of September 30, 2011	\$ 0.45
Increase in net tangible book value per share attributable to this offering	0.23
Pro forma net tangible book value per share after this offering	0.68
Dilution per share to investors participating in this offering	\$ 0.77

The shares sold in this offering, if any, in addition to the Commitment Shares and the Initial Purchase Shares may be sold from time to time at various prices.

Each \$0.25 increase in the per share price at which we sell shares to Aspire Capital under the Purchase Agreement from the assumed offering price of \$1.45 per share would increase our pro forma net tangible book value by \$1.7 million, our pro forma net tangible book value per share by \$0.05 and dilution per share to new investors purchasing shares of common stock in this offering by \$0.20, assuming that the number of shares of common stock offered, as set forth on the cover page of this prospectus, remains the same and after deducting estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only.

The table and calculations set forth above are based on the number of shares of common stock outstanding as of September 30, 2011 and assumes no exercise of any outstanding options or warrants. To the extent that options or warrants are exercised, there will be further dilution to new investors.

The above information excludes:

4,528,826 shares of common stock authorized and reserved for future issuance under outstanding awards under our equity incentive plans;

971,174 shares of common stock authorized and reserved for future issuance under our equity incentive plans;

1,075 shares of common stock issuable upon exercise of additional outstanding stock options;

6,435,496 shares of common stock issuable upon exercise of outstanding warrants; and

any additional milestone payments to our former lenders, whether in the form of cash or shares of common stock.



**Table of Contents****SELECTED CONSOLIDATED FINANCIAL DATA**

The selected consolidated financial data set forth below should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and the notes thereto included elsewhere in this prospectus.

	Year Ended December 31,					Nine Months Ended	
	2006	2007	2008	2009	2010	September 30,	2011
	(in thousands, except share and per share data)						
<b>Consolidated Statement of Operations Data:</b>							
Revenues:							
Contract revenue	\$ 1,908	\$ 1,433	\$ 1,880	\$ 1,079	\$ 6,685	\$ 4,515	\$ 6,712
Grant revenue	1,817	1,827	1,225	1,080	2,254	1,092	1,067
<b>Total revenues</b>	<b>3,725</b>	<b>3,260</b>	<b>3,105</b>	<b>2,159</b>	<b>8,939</b>	<b>5,607</b>	<b>7,779</b>
Costs and expenses:							
Research and development	9,741	15,817	16,500	11,920	14,779	10,569	13,360
General and administrative	3,347	7,975	5,479	5,621	5,387	4,249	3,721
Depreciation	528	283	218	233	284	216	202
<b>Loss from operations</b>	<b>(9,891)</b>	<b>(20,815)</b>	<b>(19,092)</b>	<b>(15,615)</b>	<b>(11,511)</b>	<b>(9,427)</b>	<b>(9,504)</b>
Other (expense) income:							
Other income (expense), net	208	2,017	48	(126)	(69)	(64)	(65)
Interest income	119	1,591	1,146	375	203	165	75
Interest expense	(1,047)	(1,263)	(94)				
Accretion of premium on convertible debt	(260)	(456)					
<b>Loss before cumulative effect of change in accounting principle</b>	<b>(10,871)</b>	<b>(18,926)</b>	<b>(17,992)</b>	<b>(15,366)</b>	<b>(11,377)</b>	<b>(9,326)</b>	<b>(9,494)</b>
Cumulative effect of change in accounting principle	306						
<b>Net loss</b>	<b>\$ (10,565)</b>	<b>\$ (18,926)</b>	<b>\$ (17,992)</b>	<b>\$ (15,366)</b>	<b>\$ (11,377)</b>	<b>\$ (9,326)</b>	<b>\$ (9,494)</b>
Preferred stock dividends	(1,408)	(659)					
Deemed dividend resulting from induced conversion of convertible preferred stock		(4,800)					
<b>Net loss attributable to common stockholders</b>	<b>\$ (11,973)</b>	<b>\$ (24,385)</b>	<b>\$ (17,992)</b>	<b>\$ (15,366)</b>	<b>\$ (11,377)</b>	<b>\$ (9,326)</b>	<b>\$ (9,494)</b>
<b>Basic and diluted net loss per common share attributable to common stockholders:</b>							
Loss before cumulative effect of change in accounting principle	\$ (41.89)	\$ (2.26)	\$ (0.95)	\$ (0.81)	\$ (0.60)	\$ (0.49)	\$ (0.41)
Cumulative effect of change in accounting principle	1.05						
<b>Net loss per share</b>	<b>\$ (40.84)</b>	<b>\$ (2.26)</b>	<b>\$ (0.95)</b>	<b>\$ (0.81)</b>	<b>\$ (0.60)</b>	<b>\$ (0.49)</b>	<b>\$ (0.41)</b>
Weighted average shares outstanding, basic and diluted	293,142	10,811,119	18,927,988	18,928,379	18,929,749	18,929,436	22,966,047

Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

	2006	2007	December 31, 2008	2009	2010	September 30, 2010	September 30, 2011
<b>Consolidated Balance Sheet Data:</b>							
Cash and cash equivalents	\$ 1,528	\$ 13,248	\$ 12,552	\$ 11,167	\$ 2,105	\$ 2,210	\$ 8,539
Available-for-sale securities, short-term		22,477	15,460	10,135	13,076	13,615	8,003
Working capital (deficit)	(3,206)	32,849	26,789	16,291	9,106	9,871	10,333
Available-for-sale securities, long-term		13,850	3,601	5,080		2,015	
Total assets	4,266	52,225	33,877	28,331	19,106	22,181	18,861
Long-term obligations, less current portion	9,310						
Warrant liability							1,100
Accrued dividends	8,882						
Total stockholders' equity (deficit)	(20,007)	47,631	31,563	18,957	9,005	10,857	10,579



---

**Table of Contents**

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

*The following discussion and analysis should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this prospectus. The following discussion and analysis contains forward-looking statements that reflect our plans, estimates and beliefs and involves risks and uncertainties. Our actual results could differ materially from those discussed in these forward-looking statements as a result of various factors, including those discussed below, under the headings "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" and in other parts of this prospectus.*

**Overview and Recent Developments**

We are an international biopharmaceutical company that is focused in the field of regenerative medicine. We have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple areas. Our current clinical development programs are focused on treating cardiovascular disease, neurological conditions, inflammatory & immune disorders, and other conditions. We are developing our lead platform product, MultiStem, a patented and proprietary allogeneic stem cell product that has been evaluated in two fully-enrolled Phase I clinical trials and is currently being evaluated in ongoing Phase II clinical trials. We are also applying our pharmaceutical discovery capabilities to identify and develop small molecule compounds with potential applications in indications such as obesity, related metabolic conditions and certain neurological conditions, and for the modulation of stem cells or related applications in the regenerative medicine area.

*Current Programs*

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

**Inflammatory Bowel Disease:** MultiStem is being evaluated in an ongoing Phase II clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, the most common form of IBD. This study was authorized by the FDA in November 2010 and is being conducted with our partner, Pfizer. This trial began enrolling patients in the study in February 2011 and is expected to enroll approximately 130 patients. Enrollment of this trial is expected to be completed in 2012.

**Ischemic Stroke:** We recently initiated a Phase II clinical study to evaluate the administration of MultiStem to patients that have suffered an ischemic stroke, an area of significant unmet clinical need. In preclinical studies, administration of a single dose of MultiStem, even several days after a stroke, resulted in significant and durable improvements. We will evaluate the potential clinical benefits of MultiStem in this ongoing double blind, placebo controlled trial being conducted at leading stroke centers across the United States. The study is expected to include approximately 140 patients, and patient enrollment was initiated in the fall of 2011.

**Acute Myocardial Infarction:** We have evaluated the administration of MultiStem to patients that have suffered an AMI, more commonly referred to as a heart attack in a Phase I clinical study. In July 2010, we announced interim results for this study, demonstrating a consistent safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment and who received treatment after experiencing a heart attack. One year follow-up data suggested that the benefit observed was sustained over time. We are currently preparing for a Phase II study. In light of the recent termination of our license and collaboration agreement with Angiotech Pharmaceuticals, Inc., or Angiotech, we expect to review the study design, objectives and expected timelines to streamline the study where possible and to ensure optimal alignment with our ongoing clinical development, business development and financial objectives. This is expected to delay our Phase II study initiation into 2012.

## Table of Contents

Hematopoietic Stem Cell Transplant / GvHD: We are engaged in a clinical study of the administration of MultiStem to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a hematopoietic stem cell, or HSC, transplant. Such patients are at risk for serious complications, including GvHD, an imbalance of immune system function caused by transplanted immune cells that attack various tissues and organs in the patient. In May 2011, we released preliminary data from the single dose arm of the study, which demonstrated the safety of MultiStem in this indication and suggested that MultiStem may have a beneficial effect in reducing incidence and severity of GvHD. We recently completed enrollment of the repeat dose arm and expect to release additional data by early 2012.

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

We are also working with our collaborator, RTI, to develop products for certain orthopedic applications in the bone graft substitutes market using our stem cell technologies.

We are also engaged in the development of novel small molecule therapies to treat obesity and other conditions. Currently, we are focused on the development of potent, highly selective compounds that act through stimulation of a specific receptor in the brain, the 5HT<sub>2c</sub> serotonin receptor. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit outstanding receptor selectivity and are working towards the selection of a clinical development candidate for this program.

### *Financial*

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of \$215 million at September 30, 2011. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We have used the financing proceeds from private equity and debt offerings and other sources of capital to develop our technologies, to discover and develop therapeutic product candidates, develop business collaborations and to acquire certain technologies and assets.

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

As of September 30, 2011, we had approximately \$16.5 million of cash, cash equivalents and investments available to fund continued operations, after expending approximately \$10.0 million to fund operations over the last nine months and reflecting the fundraising activity earlier in the year. To fund our continued operations and create shareholder value through the advancement of clinical programs and otherwise, we intend to enter into additional development partnerships, secure additional grant funding, and take advantage of complementary traditional and alternative fundraising approaches.

During 2011, we were awarded grants aggregating approximately \$800,000 for projects spanning over the next few years, including our alliance with Fast Forward, LLC, described herein. The sources of funding including federal, state, European and private organizations and are generally aimed at the advancement of our preclinical MultiStem programs and MultiStem process development.

**Table of Contents**

In November 2011, we entered into the Purchase Agreement, which provides that Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock through an equity purchase agreement over a two-year term, subject to our election to sell any such shares, and the terms and conditions set forth therein. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price. As part of the agreement, Aspire Capital made an initial investment of \$1.0 million in us through the purchase of 666,667 shares of our common stock at \$1.50 per share, and received 266,667 additional shares as compensation for its commitment. In connection with this initial investment, our former lenders were entitled to a milestone payment in the amount of \$100,000, of which \$25,000 was paid in cash and \$75,000 was paid through the issuance of our common stock to the former lenders at our election at \$1.50 per share in November 2011.

**Results of Operations**

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

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

**Revenues**

	Year Ended December 31,			Nine Months Ended September 30,	
	2008	2009	2010	2010	2011
Contract revenue	\$ 1,880	\$ 1,079	\$ 6,685	\$ 4,515	\$ 6,712
Grant revenue	1,225	1,080	2,254	1,092	1,067
	\$ 3,105	\$ 2,159	\$ 8,939	\$ 5,607	\$ 7,779

**Research and development expenses**

Type of expense	Year Ended December 31,			Nine Months Ended September 30,	
	2008	2009	2010	2010	2011
Personnel costs	\$ 2,924	\$ 3,607	\$ 4,124	\$ 2,996	\$ 3,503
Research supplies	849	907	1,218	912	983
Facilities	817	826	870	656	733
Clinical and preclinical development costs	7,878	1,904	4,394	3,043	4,559
Sponsored research	393	878	1,149	777	1,140
Patent legal fees	1,481	1,351	1,477	1,011	1,338
Other	1,431	1,151	1,002	700	952
Stock-based compensation	727	1,296	545	474	152
	\$ 16,500	\$ 11,920	\$ 14,779	\$ 10,569	\$ 13,360

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

Type of expense	Year Ended December 31,			Nine Months Ended September 30,	
	2008	2009	2010	2010	2011
Personnel costs	\$ 1,726	\$ 1,975	\$ 1,897	\$ 1,457	\$ 1,460
Facilities	342	299	279	213	207
Legal and professional fees	1,032	916	1,007	817	787
Other	1,250	919	1,283	990	1,018
Stock-based compensation	1,129	1,512	921	772	249
	\$ 5,479	\$ 5,621	\$ 5,387	\$ 4,249	\$ 3,721

**Nine Months Ended September 30, 2011 and 2010**

**Revenues.** Revenues increased to \$7.8 million for the nine months ended September 30, 2011 from \$5.6 million in the comparable period in 2010. Our contract revenues reflect the amortization of Pfizer payments, including a \$6.0 million non-refundable up-front license fee, research and development funding, and the performance of manufacturing services over the estimated performance period, and the amortization of a \$3.0 million guaranteed license fee over the estimated performance period from the RTI collaboration. Our contract revenues may also include license fees, milestone payments and royalties on compounds developed by Bristol-Myers Squibb using one of our technologies. Contract revenue increased \$2.2 million for this period primarily as a result of the impact of our arrangement with RTI to develop an orthopedic allograft product which was initiated in September 2010, and our arrangement with Pfizer. Grant revenue decreased \$25,000 for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 primarily due to the timing of expenditures that are reimbursed with grant proceeds. Our grant revenues may fluctuate from period to period based on the timing of grant-related activities and the award of new grants.

**Research and Development Expenses.** Research and development expenses increased to \$13.4 million for the nine months ended September 30, 2011 from \$10.6 million in the comparable period in 2010. The increase of approximately \$2.8 million related primarily to an increase in clinical and preclinical development costs of \$1.5 million, an increase in personnel costs of \$507,000, an increase in sponsored research costs of \$363,000, an increase in facilities and other research costs of \$329,000, an increase in patent legal fees of \$327,000 and an increase in research supply costs of \$71,000 for the nine months ended September 30, 2011 from the comparable period in 2010. These increases were partially offset by a decrease in stock compensation expense of \$322,000 for this period. The increase in clinical and preclinical development costs for the nine months ended September 30, 2011 from the comparable period in 2010 related primarily to costs associated with our MultiStem clinical trials, including increased manufacturing and process development costs. Our clinical costs for the nine months ended September 30, 2011 and 2010 are reflected net of Angiotech's cost-sharing amount of \$312,000 and \$521,000, respectively. The increase in personnel costs related to the addition over the past twelve months of personnel supporting our preclinical and clinical programs, combined with the impact of the accrual of a potential bonus in connection with our compensation plan. Sponsored research costs increased primarily due to an increase in grant-funded programs that require collaboration with certain academic research institutions. Patent legal fees increased related to international patent prosecution activities. We expect our research and development expenses for the remainder of 2011 to increase due to increased MultiStem clinical trial and clinical manufacturing activities.

**General and Administrative Expenses.** General and administrative expenses decreased to \$3.7 million for the nine months ended September 30, 2011 from \$4.2 million in the comparable period in 2010. The \$528,000 decrease was due primarily to a decrease in stock compensation expense of \$523,000 for this period. We expect our general and administrative expenses to continue at similar levels for the remainder of 2011.

**Table of Contents**

*Depreciation.* Depreciation expense decreased to \$202,000 for the nine months ended September 30, 2011 from \$216,000 in the comparable period in 2010, as more assets are becoming fully depreciated.

*Interest Income, net.* Interest income represents interest earned on our cash and available-for-sale securities. Net interest income decreased to \$75,000 for the nine months ended September 30, 2011 from \$165,000 for the comparable period in 2010 due to the decline in our investment balances as they are used to fund our operations. We expect our 2011 interest income to decline for the remainder of the year due to declining cash balances resulting from our ongoing and planned clinical and preclinical development, absent any new financings or business transactions.

*Other Income (Expense), net.* Other income (expense), net, includes foreign currency gains and losses related to our activities in Europe and any realized gains and losses on the sale of our assets. Included in other expense in 2011 is a milestone payment of \$810,000 to our former lenders that was paid in connection with our February 2011 registered direct offering, 75% of which was settled in shares of common stock. Also in February 2011, we issued warrants to purchase common stock that are classified as liabilities, with changes in market value reflected as either other income or expense. For the nine months ended September 30, 2011, net other income of \$695,000 was recorded related to the decrease in the warrant liability.

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

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

*Research and Development Expenses.* Research and development expenses increased to \$14.8 million for the year ended December 31, 2010 from \$11.9 million in 2009. The increase of approximately \$2.9 million related primarily to an increase in clinical and preclinical development costs of \$2.5 million, an increase in personnel costs of \$517,000, an increase in research supply costs of \$311,000 and an increase in sponsored research costs of \$271,000 for the year ended December 31, 2010 compared to 2009. These increases were partially offset by a decrease in stock-based compensation expense of \$751,000, which declined as a result of a significant number of options becoming fully vested mid-2010. The increase in clinical and preclinical development costs for the year ended December 31, 2010 related primarily to increased manufacturing and process development costs, and costs associated with our MultiStem clinical trials. Our clinical costs for the year ended December 31, 2010 and 2009 are reflected net of Angiotech's cost-sharing amount of \$628,000 and \$847,000, respectively. The increase in personnel costs and research supplies related to the addition of personnel in support of our preclinical and clinical programs and regulatory affairs. Sponsored research costs increased primarily due to grant-funded programs that require collaboration with certain academic research institutions. We expect our research and development expenses to increase in 2011, primarily due to increased MultiStem clinical trial and clinical manufacturing expenses. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

**Table of Contents**

*General and Administrative Expenses.* General and administrative expenses decreased to \$5.4 million in 2010 from \$5.6 million in 2009. The \$234,000 decrease was due primarily to a decrease in stock-based compensation expense of \$591,000, partially offset by an increase in other expenses of \$364,000 in 2010 compared to 2009. The decrease in stock-based compensation expense related to a significant number of options becoming fully vested mid-2010. The increase in other expenses for 2010 was primarily a result of increased investor and public relations costs and travel costs. We expect our general and administrative expenses to continue at similar levels in 2011.

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

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

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

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

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

*Research and Development Expenses.* Research and development expenses decreased to \$11.9 million in 2009 from \$16.5 million in 2008. The decrease of \$4.6 million related primarily to a decrease in clinical and preclinical development costs of \$6.0 million, a decrease in other research and development expenses of \$280,000 and a decrease in patent legal fee expense of \$130,000 in 2009 compared to 2008. These decreases were partially offset by an increase in personnel costs of \$683,000, an increase in stock-based compensation expense of \$569,000, an increase in sponsored research of \$485,000, and an increase in research supplies and facilities expenses of \$67,000 in 2009 compared to 2008. Of the \$6.0 million decrease in clinical and preclinical development costs, \$5.3 million related to costs associated with the completion of an ATHX-105 Phase I clinical trial in the first half of 2008 and preparations for a Phase II clinical trial of ATHX-105 in 2008, which included several preclinical studies and manufacturing costs. ATHX-105 development was suspended early in 2009 and there will be no future costs incurred for this product candidate. The remaining \$700,000 decrease in clinical and preclinical development costs related primarily to a \$235,000 credit from a renegotiated contract with a contract research organization in June 2009, reduced manufacturing costs associated with our MultiStem clinical trials, and reduced external costs for regulatory consulting and preclinical studies. Our clinical costs in 2009 and 2008 are reflected net of Angiotech's cost-sharing reimbursements related to our MultiStem AMI collaboration in the amount of \$847,000 and \$943,000, respectively. Patent legal fee expense for 2009 decreased compared to 2008, but continued to be significant as a result of further development and maintaining our portfolio of patent applications. The increase in personnel costs related to the addition of personnel in support of our clinical programs and regulatory affairs, a 2009 company-wide performance bonus, salary increases and increased benefit

---

**Table of Contents**

costs. The increase in stock-based compensation expense related to a change in our estimated forfeiture rate, increased expense related to options held by certain consultants that are computed using variable accounting, and the issuance of stock option awards in 2009. Sponsored research costs increased primarily due to grant-funded programs that require collaboration with certain academic research institutions. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

*General and Administrative Expenses.* General and administrative expenses increased to \$5.6 million in 2009 from \$5.5 million in 2008. The \$100,000 increase was due primarily to an increase in stock-based compensation expense of \$383,000 and an increase in personnel costs of \$249,000, partially offset by a decrease in other expenses of \$331,000, a decrease in legal and professional fees of \$116,000 and a decrease in facilities expense of \$43,000 in 2009 compared to 2008. The increase in stock-based compensation expense related to a change in our estimated forfeiture rate and the issuance of stock option awards in 2009. The increase in personnel costs related to a 2009 company-wide performance bonus, salary increases and increased benefit costs. The decrease in other expenses for 2009 was primarily a result of reduced temporary help and outsourced accounting services in 2009. The decrease in legal and professional fees in 2009 was primarily a result of reduced legal fees incurred in connection with SEC filings and transactional work.

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

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

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

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

**Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and available-for-sale securities. At September 30, 2011, we had \$8.5 million in cash and cash equivalents and \$8.0 million in available-for-sale securities. We have primarily financed our operations through equity and debt financings. We conduct all of our operations through our wholly-owned subsidiary, ABT Holding Company. Consequently, our ability to fund our operations depends on ABT Holding Company's financial condition and its ability to make dividend payments or other cash distributions to us. There are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us.

In November 2011, we entered into the Purchase Agreement, which provides that Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock through an equity purchase agreement over a two-year term, subject to our election to sell any such shares, and the terms and conditions set forth therein. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price. As part of the agreement, Aspire Capital made an initial investment of \$1.0 million in us through the purchase of 666,667 shares of our common stock at \$1.50 per share, and received 266,667 additional shares as compensation for its commitment. In connection with this initial investment, our former lenders were entitled to a milestone payment in the amount of \$100,000, of which \$25,000 was paid in cash and \$75,000 was paid through the issuance of our common stock to the former lenders at our election at \$1.50 per share in November 2011.

---

**Table of Contents**

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

Our former lenders have a right to receive a milestone payment of \$1.44 million as of September 30, 2011, after taking into account a payment of \$810,000 in conjunction with our February 2011 registered direct offering. Further payments will be made upon the occurrence of certain events as follows: (1) the entire amount upon (a) the merger with or into another entity where our stockholders do not hold at least a majority of the voting power of the surviving entity, (b) the sale of all or substantially all of our assets, or (c) our liquidation or dissolution; or (2) a portion of the amount from proceeds of equity financings not tied to specific research and development activities that are part of a research or development collaboration, in which case, the lenders will receive an amount equal to 10% of proceeds above \$5.0 million in cumulative gross proceeds until the milestone amount is paid in full. The milestone payment is payable in cash, except that if the milestone event is (2) above, we may elect to pay 75% of the milestone in shares of common stock at the per-share offering price. In connection with the registered direct offering in February 2011, the former lenders were entitled to a milestone payment under this commitment in the amount of \$810,000, of which \$202,500 was paid in cash and \$607,500 was paid through the issuance of our common stock at \$2.96 per share in February 2011. The former lenders also received warrants to purchase 149,026 shares of common stock with an exercise price of \$5.00 upon the closing of our equity offering in June 2007. The exercise of such warrants could provide us with cash proceeds. No warrants were exercised as of September 30, 2011.

Under the terms of our agreement with Pfizer, we receive research funding and support, and we are also eligible to receive milestone payments of up to \$105 million upon the successful achievement of certain development, regulatory and commercial milestones, though there can be no assurance that we will achieve any milestones. No significant milestone payments have been received as of September 30, 2011. Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase III clinical development.

In November 2011, we reached an agreement with Angiotech to terminate the collaboration agreement and license between the parties, reflecting a change in Angiotech's business and financial strategy. As a result of the termination, Athersys will again own all rights for developing its stem cell technologies and products for cardiovascular disease indications, including AMI, congestive heart failure, chronic ischemia, and peripheral vascular disease, and Angiotech will no longer have any license rights or options with respect to Athersys' technologies and products. Additionally, while Angiotech holds 1.9 million shares of Athersys common stock, Athersys will receive advance notice of Angiotech's intention to sell these shares, and the parties will cooperate in such sale. Angiotech will make its final cost-sharing payment of \$160,000 in connection with collaboration activities through September 30, 2011 and will have no further obligations to Athersys. Though the termination will affect Athersys' future costs of development for ongoing cardiovascular programs, such as AMI, it significantly improves the Company's ability to explore cardiovascular and more comprehensive collaborative development and commercialization arrangements with other pharmaceutical, biotechnology and medical products companies. In the case of a new AMI collaboration, Angiotech will be entitled to a future payment from Athersys equal to a percentage of cash license fee payments Athersys receives within the first six months from a third-party related to such AMI collaboration, and is not entitled to other downstream payments, such as milestone payments, royalties or any profit-sharing payments. The future payment, if any, will be either (i) 25% of third-party license fees if an AMI collaboration is established prior to the initiation of enrollment in a Phase II AMI clinical trial and within 12 months of the termination agreement, or (ii) 15% of third-party license fees if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, but before



---

**Table of Contents**

Athersys has spent \$5.0 million on the clinical trial, and within 24 months of the termination agreement, or (iii) 10% of third-party license fees up to a maximum of \$5.0 million to Angiotech if an AMI collaboration is established after the initiation of enrollment in a Phase II AMI clinical trial, and after Athersys has spent \$5.0 million on the clinical trial, and within 36 months of the termination agreement.

Under the terms of our RTI agreement, we received \$3.0 million of guaranteed license fee payments and are entitled to an additional \$2.0 million of license fee payments contingent on future events. We are also eligible to receive an additional \$35.5 million in cash payments upon the successful achievement of certain development and commercial milestones, though there can be no assurance that we will achieve any milestones. None of these milestone payments have been received as of September 30, 2011. In addition, we will receive tiered royalties on worldwide commercial sales of implants using our technologies.

We will remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb under our completed 2001 collaboration, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology, though there can be no assurance that we will achieve any such milestones or royalties. As of September 30, 2011, we have received an aggregate amount of \$2.0 million in milestone payments and \$8.6 million in license fees since the inception of our collaboration with Bristol-Myers Squibb.

Our available-for-sale securities consist of U.S. government obligations as of September 30, 2011. We have been investing conservatively due to the ongoing economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments and have held our investments until maturity. Also, although these unfavorable market and economic conditions have resulted in a decrease to our market capitalization, there has been no impairment to the value of our assets. Our fixed assets are used for internal research and development and, therefore, are not impacted by these external factors.

We will require substantial additional funding in order to continue our research and product development programs, including preclinical evaluation and clinical trials of our product candidates. At September 30, 2011, we had available cash, cash equivalents and investments of \$16.5 million. Assuming no new financings or collaborations and based on our current business and operational plans, we expect to have available cash to fund our planned operations into the third quarter of 2012. However, we expect to have access to additional capital through financing and business development opportunities, which we are actively exploring. We also have the ability to defer certain discretionary costs and stage certain development costs to extend our operational runway, if needed. We will continue to explore and consider new opportunities for funding our operations through grants and business partnerships involving our technologies and product candidates. Additionally, we expect to raise capital by accessing the capital markets through the sale of equity, including through the Purchase Agreement with Aspire Capital, and possibly new borrowings from financial institutions. Our capital requirements over time will depend on a number of factors, including scientific progress in our research and development programs, additional personnel costs, progress in preclinical testing and clinical trials, and the costs in filing and prosecuting patent applications and enforcing patent claims. Further, these requirements may change at any time due to technological advances, business development activity or competition from other companies. We cannot assure you that adequate funding will be available to us or, if available, that it will be available on acceptable terms. Any shortfall in funding could result in our having to curtail research and development efforts.

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

Net cash used in operating activities was \$10.0 million for the nine months ended September 30, 2011 and \$8.0 million for the nine months ended September 30, 2010, and represented the use of cash in funding

## **Table of Contents**

preclinical and clinical development activities. We expect that net cash used in operating activities will increase for the remainder of 2011 in connection with increased research and development expenses of our MultiStem clinical trials.

Net cash provided by investing activities was \$4.6 million for the nine months ended September 30, 2011 and net cash used in investing activities was \$1.0 million for the nine months ended September 30, 2010. The fluctuations from period to period were due to the timing of purchases and maturity dates of investments and the purchase of equipment. Purchases of equipment were \$565,000 and \$384,000 for the first nine months of 2011 and 2010, respectively. We expect that our capital equipment expenditures will continue at similar levels in 2011 compared to 2010.

Net cash provided from financing activities was \$11.8 million for the nine months ended September 30, 2011 and \$0 for the nine months ended September 30, 2010 as a result of our February 2011 registered direct offering.

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

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

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

Investors in our February 2011 registered offering received five-year warrants to purchase an aggregate of 1,310,000 shares of common stock with an exercise price of \$3.55 per share. The exercise of such warrants could provide us with cash proceeds. No warrants have been exercised at September 30, 2011.

Investors in our equity offering in June 2007 received five-year warrants to purchase an aggregate of 3,250,000 shares of common stock with an exercise price of \$6.00 per share. The lead investor in the June offering received additional five-year warrants to purchase an aggregate of 500,000 shares of common stock with a cash or cashless exercise price of \$6.00 per share. The placement agents for the June 2007 offering received five-year warrants to purchase an aggregate of 1,093,525 shares of common stock with a cash or cashless exercise price of \$6.00 per share. Also, investors that participated in a bridge financing in 2006 received in the June 2007 offering five-year warrants to purchase an aggregate of 132,945 shares of common stock with an exercise price of \$6.00 per share. The exercise of such warrants could provide us with cash proceeds. No warrants have been exercised at September 30, 2011.

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

**Table of Contents**

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

Contractual Obligations	Total	Payment due by Period			More than 5 Years
		Less than 1 Year	1 - 3 Years	3 - 5 Years	
Operating leases for facilities and equipment lease	\$ 487,000	\$ 390,000	\$ 97,000	\$	\$
Research funding	465,000	327,000	138,000		
<b>Total</b>	<b>\$ 952,000</b>	<b>\$ 717,000</b>	<b>\$ 235,000</b>	<b>\$</b>	<b>\$</b>

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

The research funding in the table above represents our current funding commitment for a research program that began in 2007 and ends in August 2012.

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

We have no off-balance sheet arrangements.

**Critical Accounting Policies and Management Estimates**

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

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

**Revenue Recognition**

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

## **Table of Contents**

whether they have standalone value and objective and reliable evidence of fair value, and if so, are accounted for as a single unit. We then recognize revenue for each unit based on the culmination of the earnings process under ASC 605-S25 (issued as SAB Topic 13) and our estimated performance period for the single units of accounting based on the specific terms of each collaborative agreement. We subsequently adjust the estimated performance periods, if appropriate, on a prospective basis based upon available facts and circumstances. Future changes in estimates of the performance period may materially impact the timing of future revenue recognized. Amounts received prior to satisfying the revenue recognition criteria for contract revenues are recorded as deferred revenue in the accompanying balance sheets. Reimbursement amounts (other than those accounted for using collaboration accounting) paid to us are recorded on a gross basis in the statements of operations as contract revenues.

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

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

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

### ***Collaborative Arrangements***

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

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

Clinical trial costs are accrued based on work performed by outside contractors who manage and perform the trials. We obtain initial estimates of total costs based on enrollment of subjects, project management estimates and other activities. Actual costs are typically charged to us and recognized as the tasks are completed by the contractor. Accrued clinical trial costs may be subject to revisions as clinical trials progress, and any revisions are recorded in the period in which the facts that give rise to the revisions become known. Since such actual costs are typically invoiced as incurred or based on contractual amounts for services rendered, the amounts are generally not susceptible to significant changes in estimates.

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

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

---

**Table of Contents**

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

***Stock-Based Compensation***

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

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

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

**Recently Issued Accounting Standards**

In September 2009, Accounting Standards Codification, or ASC, 605-25, *Multiple-Element Arrangements*, was updated (Accounting Standards Update, or ASU, No. 2009-13) related to revenue recognition for arrangements with multiple elements. The revised guidance provides for two significant changes to the existing guidance, the first relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting, which will likely result in the requirement to separate more deliverables within an arrangement leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Together, these changes are likely to result in earlier recognition of revenue for multiple-element arrangements than under previous guidance. The new guidance also significantly expands the disclosures required for multiple-element revenue arrangements. The new guidance was effective for us for new arrangements or modifications to existing arrangements entered into on or after January 1, 2011 and had no effect on our financial statements for the nine months ended September 30, 2011. The adoption of this new guidance may have the potential effect of less future revenue deferral for new collaborations than we have historically experienced.

In March 2010, ASC 605-28, *Milestone Method of Revenue Recognition*, was amended (ASU No. 2010-17) related to the ratification of the application of the proportional performance model of revenue recognition when applied to milestones in research and development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The new guidance was

**Table of Contents**

effective for us for new arrangements entered into on or after January 1, 2011. The adoption of this guidance had no effect on our financial statements, since we have been historically recognizing milestone revenue consistent with this guidance.

**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, fixed income mutual funds and a corporate security. As of September 30, 2011, all of our investments were in U.S. government obligations. We have been investing conservatively due to the current economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments.

We enter into loan arrangements with financial institutions when needed and when available to us. At September 30, 2011, we had no borrowings outstanding.

---

**Table of Contents**

**BUSINESS**

We are an international biopharmaceutical company that is focused in the field of regenerative medicine. We are committed to the discovery and development of best-in-class therapies designed to extend and enhance the quality of human life and have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. We are developing our lead platform product, MultiStem, a patented and proprietary allogeneic stem cell product that has been evaluated in two fully-enrolled Phase I clinical trials and is currently being evaluated in ongoing Phase II clinical trials. Our current clinical development programs are focused on treating cardiovascular disease, neurological conditions, inflammatory & immune disorders, and other conditions. These represent major areas of clinical need, as well as substantial commercial opportunities.

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

**Business Strategy**

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

*Efficiently conduct clinical development to establish clinical proof of concept and biological activity with our lead product candidates.* The MultiStem products represent a novel therapeutic modality for the treatment of cardiovascular disease, neurological conditions, and inflammatory and immune system disorders, as well as in other areas. The products may be administered like other biologics, intravenously, via catheter, or directly. The cells appear to be responsive to their environment, homing to sites of injury and active disease response and producing proteins responsive to specific disease conditions. Additionally, the cell therapies deliver therapeutic benefit through multiple mechanisms of action. We are conducting clinical development in a discreet number of clinical studies with the intent to establish proof of concept and/or proof of biological activity in a number of important disease areas where the cell therapies would be expected to have benefit cardiovascular disease, neurological conditions and inflammatory and immune system dysfunctions. Our focus is on conducting well-designed studies early in the clinical development process to establish a robust foundation for subsequent development, partnership and for expansion into adjacent areas.

*Advance the development of the MultiStem therapeutic modality and supporting capabilities.* A key aspect of the MultiStem cells is their substantial expansion capacity ex vivo relative to other cell types. This enables large scale production of the MultiStem products, which drives product consistency, specificity and cost of goods advantages over other cell therapies. We plan to build on this intrinsic biological advantage by further optimizing our current production approaches, further developing new manufacturing approaches including our bioreactor platform, and optimizing the plant to bedside supply chain to support late stage development and commercialization. Additionally, we will continue to refine our understanding of our products activities and mechanisms of action to enable optimization of administration and dosing and to prepare the foundation for product enhancements and next generation opportunities.

*Enter into licensing or product co-development arrangements in certain areas, while out-licensing opportunities in non-core areas.* In addition to our internal development efforts, an important part of our product development strategy is to work with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercialization capabilities. We have entered into multiple licensing and product co-development arrangements with qualified commercial partners to achieve these objectives. We anticipate that this strategy will help us to develop a portfolio

## **Table of Contents**

of high quality product development opportunities, enhance our clinical development and commercialization capabilities, and increase our ability to generate value from our proprietary technologies. Over the past decade, we have entered into technology licensing arrangements and established product commercialization and co-development partnerships with multiple companies, including as Pfizer, Angiotech, Bristol-Myers Squibb, Johnson & Johnson Research Development Institute, Wyeth Pharmaceuticals, RTI, and other organizations. These partnerships generate revenue and provide capital that allows us to advance certain programs further in development.

*Efficiently explore new high potential therapeutic applications, leveraging third-party research collaborations and our results from related areas.* Our product candidates have shown promise in multiple disease areas, including in treating cardiovascular disease, neurological conditions, and inflammatory and immune disorders, as well as in other areas. We are committed to exploring potential clinical indications where our therapies may achieve best-in-class profile, and where we can address significant unmet medical needs. In order to achieve this goal, over the past decade, we have established collaborative research relationships with investigators from many leading research and clinical institutions across the United States and Europe. These collaborative relationships have enabled us to cost effectively explore where MultiStem may have therapeutic relevance, and how it may be utilized to advance treatment over current clinical care. Additionally, we have shown that we can leverage clinical safety data and preclinical results from some programs to support accelerated clinical development efforts in other areas, saving substantial development time and resources compared to traditional drug development where generally each program is separately developed.

*Continue to expand our intellectual property portfolio.* Our intellectual property is important to our business and we take significant steps to protect its value. We have ongoing research and development efforts, both through internal activities and through collaborative research activities with others, which aim to develop new intellectual property and enable us to file patent applications that cover new applications of our existing technologies or product candidates, including MultiStem and other opportunities.

### **Our Current Programs**

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

**Inflammatory Bowel Disease:** MultiStem is being evaluated in an ongoing Phase II clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, the most common form of IBD. This study was authorized by the FDA in November 2010 and is being conducted with our partner, Pfizer. This trial began enrolling patients in the study in February 2011 and is expected to enroll approximately 130 patients. Enrollment of this trial is expected to be completed in 2012.

**Ischemic Stroke:** We recently initiated a Phase II clinical study to evaluate the administration of MultiStem to patients that have suffered an ischemic stroke, an area of significant unmet clinical need. In preclinical studies, administration of a single dose of MultiStem, even several days after a stroke, resulted in significant and durable improvements. We will evaluate the potential clinical benefits of MultiStem in this ongoing double blind, placebo controlled trial being conducted at leading stroke centers across the United States. The study is expected to include approximately 140 patients, and patient enrollment was initiated in the fall of 2011.

**Acute Myocardial Infarction:** We have evaluated the administration of MultiStem to patients that have suffered an AMI, more commonly referred to as a heart attack in a Phase I clinical study. In July 2010, we announced results for this study, demonstrating a consistent safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment and who received treatment after experiencing a heart attack. One year follow-up



---

## **Table of Contents**

data suggested that the benefit observed was sustained over time. We are currently preparing for a Phase II study. In light of the recent termination of our license and collaboration agreement with Angiotech, we expect to review the study design, objectives and expected timelines to streamline the study where possible and to ensure optimal alignment with our ongoing clinical development, business development and financial objectives. This is expected to delay our Phase II study initiation into 2012.

**Hematopoietic Stem Cell Transplant / GvHD:** We are engaged in a clinical study of the administration of MultiStem to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a hematopoietic stem cell, or HSC, transplant. Such patients are at risk for serious complications, including GvHD, an imbalance of immune system function caused by transplanted immune cells that attack various tissues and organs in the patient. In May 2011, we released preliminary data from the single dose arm of the study, which demonstrated the safety of MultiStem in this indication and suggested that MultiStem may have a beneficial effect in reducing incidence and severity of GvHD. We recently completed enrollment of the repeat dose arm and expect to release additional data by early 2012.

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

We are also working with our collaborator, RTI, to develop products for certain orthopedic applications in the bone graft substitutes market using our stem cell technologies.

We are also engaged in the development of novel small molecule therapies to treat obesity and other conditions. Currently, we are focused on the development of potent, highly selective compounds that act through stimulation of a specific receptor in the brain, the 5HT<sub>2c</sub> serotonin receptor. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit outstanding receptor selectivity and are working towards the selection of a clinical development candidate for this program.

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

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

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

MultiStem is a patented biologic product that is manufactured from human stem cells obtained from adult bone marrow. The product consists of a special class of human stem cells that have the ability to express a range of therapeutically relevant proteins and other factors, as well as form multiple cell types. Factors expressed by MultiStem have the potential to deliver a therapeutic benefit in several ways, such as the reduction of inflammation, regulation of immune system function, protection of damaged or injured tissue, the formation of new blood vessels in regions of ischemic injury and augmenting tissue repair and healing in other ways. Like drugs, these cells may be stored for an extended period of time (in frozen form) and used off-the-shelf. Following administration, the cells have been shown to express multiple therapeutically relevant proteins and are subsequently cleared from the body over time.

---

## Table of Contents

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

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

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

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

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

*Off-the-shelf utility.* Unlike traditional bone marrow or hematopoietic stem cell transplants that require extensive genetic matching between donor and recipient, MultiStem is administered without tissue matching or the requirement for immune suppressive drugs. MultiStem is administered as a cryogenically preserved allogeneic product, meaning that these cells are not genetically matched between donor and recipient. This feature, combined with the ability to establish large MultiStem banks, could make it practical for clinicians to efficiently deliver stem cell therapy to a large number of patients.

*Safety.* Other stem cell types, such as embryonic stem cells, can pose serious safety risks, such as the formation of ectopic tissue or tumor-like growths. In contrast, MultiStem cells have an outstanding safety profile that has been compiled over several years of preclinical study in a range of animal models by a variety of investigators and that is supported by emerging clinical data.

At each step of the MultiStem production process, cells are analyzed according to pre-established criteria to ensure that a consistent, well characterized product candidate is produced. Cells are harvested from a pre-qualified donor and then expanded to form a Master Cell Bank from which we subsequently produce clinical grade material. In multiple animal models, MultiStem has been shown to be non-immunogenic, and is administered without the genetic matching that is typically required for conventional bone marrow or stem cell transplantation.

MultiStem allows us to pursue multiple high value commercial opportunities from a single product platform, because, based upon work that we and independent collaborators have conducted over the past several

---

**Table of Contents**

years, we believe that MultiStem has the potential to treat a range of distinct disease indications, including ischemic injury and cardiovascular disease, certain neurological diseases, autoimmune disease, transplant support (including in oncology patients), and a range of orphan disease indications. As a result, we believe we will be able to leverage our foundation of safety and efficacy data to add clinical indications efficiently, enabling us to reduce development costs and timelines substantially.

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

Healthcare represents a significant part of the global economy. In the United States, it currently represents approximately 16% of all economic activity, or about \$2.34 trillion dollars annually. However, the United States, along with many other nations, is experiencing an unprecedented demographic shift that is resulting in a significantly expanded population of older individuals. According to U.S. Census data, in the next few years there will be a dramatic increase in the number of individuals over the age of 65, as this segment of the population increases from 40.2 million individuals in 2010 to more than 72 million people in 2030, representing an increase of approximately 80%. The aging of the population will create enormous financial pressure on the healthcare system in the U.S. and other countries around the world, resulting in significant clinical challenges, but also resulting in substantial commercial opportunities.

Data from the National Center for Health Statistics (NCHS) shows that as we get older, we are more susceptible to a variety of age related conditions, including heart disease, stroke, certain forms of cancer, diabetes, progressive neurological disorders, various chronic inflammatory and immune conditions, renal disease and a range of others. As a consequence, as we get older we spend far more on healthcare – on average we spend 3 to 7 times more on healthcare annually at age 65 than when we are young and healthy. According to the Alliance for Aging Research, 83% of healthcare spending is associated with chronic conditions, and 62% of healthcare spending is associated with multiple chronic conditions. Traditional medical approaches have failed to adequately address this problem.

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

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

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

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

Cardiovascular disease is an area of significant clinical need that is expected to expand significantly in the years ahead. Despite treatment advances in recent years, cardiovascular disease remains the leading cause of death, and represents one of the leading causes of disability around the world. In the United States, approximately 1,255,000 patients suffer a heart attack each year, and approximately 5.7 million individuals in the

**Table of Contents**

U.S. are currently suffering from heart failure. Another eight million suffer from peripheral arterial disease, which is associated with significant morbidity and mortality. According to projections published recently by the American Heart Association in February, 2011 in the journal *Circulation*, aggregate costs for treating heart disease in the U.S. are expected to soar in the coming years. In 2010, annual direct costs for treating cardiovascular disease were \$273 billion, but by 2030 these are expected to more than triple, to a projected \$818 billion per year. This increase will occur primarily as a result of the aging population, and may not fully reflect the impact of the dramatic escalation in obesity rates that has occurred for both adults and children in recent years, which could further exacerbate the long term challenges and increase costs associated with cardiovascular disease and other conditions.

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

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

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

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

Inflammatory and immune disorders also represent a significant burden to society. There are over 80 recognized autoimmune disorders, which are conditions caused by an acute or chronic imbalance in the immune system. In these conditions, cells of the immune system begin to attack certain tissues or organs in the body, resulting in tissue damage and loss of function. Some inflammatory and immune conditions are associated with aging related conditions, (e.g. rheumatoid arthritis), but some are due to other causes that may be genetic, environmental or a combination of both, (e.g. Type 1 diabetes, IBD). Still other conditions may reflect complications associated with the treatment of other conditions (e.g. GvHD, a frequent complication associated with treating leukemia or related blood-borne cancers). Each of these conditions shares certain biological characteristics, in that the immune system imbalance results from the inappropriate activation of certain populations of immune cells results in significant tissue damage and destruction. This immune imbalance may

## **Table of Contents**

result in a complex cascade of inflammation that can result in pain, progressive tissue deterioration and loss of function. While currently available immunomodulatory drugs have proven to be effective for many patients, they have failed to adequately address the needs of many other patients that suffer from inflammatory and immune disorders.

In multiple studies, MultiStem has shown potent immunomodulatory properties, including the ability to reduce active inflammation through multiple modes of action, and restore immune system imbalance. Accordingly, we believe that MultiStem could have broad application in the area of treating immune system disorders, including certain autoimmune diseases and other conditions, including GvHD, which is a frequent immunological complication associated with bone marrow or HSC transplantation. In 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem for the treatment of IBD for the worldwide market. IBD is a group of inflammatory and autoimmune conditions that affect the colon and small intestine, typically resulting in severe abdominal pain, weight loss, vomiting and diarrhea. The most common forms of the disease include ulcerative colitis and Crohn's disease, which are estimated to affect nearly 2.4 million people in the United States, five major European markets (United Kingdom, Germany, France, Italy and Spain) and Japan. Chronic IBD can be a severely debilitating condition, and advanced cases may require surgery to remove the affected region of the bowel, and may also require temporary or permanent colostomy or ileostomy. In many cases, surgery does not achieve a permanent cure, and patients suffer a return of the disease. Enrollment commenced in February 2011 in our Phase II clinical study being conducted with our partner, Pfizer, to administer MultiStem to patients suffering from ulcerative colitis.

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

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

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

We are engaged in a Phase I clinical trial examining the safety and tolerability of a single dose or repeat dosing of MultiStem product administered intravenously to patients receiving a bone marrow or hematopoietic stem cell transplant related to their treatment for hematologic malignancy. The trial is an open label, multicenter trial that involves leading experts in the field of bone marrow transplantation. In the second quarter of 2011, we announced preliminary results from the single dose arm of this clinical trial. In this arm, a single dose of

## **Table of Contents**

MultiStem was administered intravenously to patients at risk for GvHD following radiation therapy and a donor derived hematopoietic stem cell transplant from bone marrow or peripheral blood. We observed a consistent safety profile at all dose levels tested, and meaningful improvement in multiple clinical parameters relative to historical clinical experience, including reduced incidence and severity of acute GvHD, improved relapse free survival, no graft failures, and enhanced engraftment rates relative to other forms of treatment. In October 2011, we announced the completion of enrollment of the repeat dose arm, and we expect to release additional data by early 2012.

In September 2010, we announced that we had been granted orphan drug designation by the U.S. Food and Drug Administration for the prevention of GvHD. In November 2010, we announced that we had been awarded a Therapeutic Discovery Project grant supporting our work in this area. This grant award was more than \$240,000.

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

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

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

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

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

Our initial clinical focus in the neurological area involves evaluating administration of MultiStem to treat ischemic stroke. Ischemic stroke is a leading cause of death and disability globally, and accounts for approximately 85% of all strokes. Recent progress toward the development of safer and more effective

## **Table of Contents**

treatments for ischemic stroke has been disappointing. Despite the fact that ischemic stroke is one of the leading causes of death and disability in the United States, affecting more than 700,000 new patients annually according to the United States Centers for Disease Control and Prevention, or CDC, there has been little progress toward the development of treatments that improve the prognosis for stroke victims. The only FDA-approved drug currently available for ischemic stroke is the anti-clotting factor, tPA. According to current clinical guidelines, tPA must be administered to stroke patients within several hours after the occurrence of the ischemic stroke to remove the clot while minimizing potential risks, such as bleeding into the brain. Administration of tPA after three to four hours is not recommended, since it can cause cerebral bleeding or even death. Given this limited therapeutic window, it is estimated that less than 5% of ischemic stroke victims currently receive treatment with tPA.

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

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

In 2008, we completed additional preclinical safety studies and submitted an IND for this application, which has been authorized by the FDA. The Phase I safety clinical trial authorized by the FDA was a double blind, placebo controlled study that allows for administration of MultiStem to approximately 48 patients following an ischemic stroke. However, since this study was authorized, we have generated additional preclinical and clinical data that demonstrates the consistent safety profile of MultiStem, as well as supporting preclinical efficacy data that demonstrates how MultiStem can provide multiple therapeutic benefits. Accordingly, we modified the design of this study, including increasing the trial size, so that we can evaluate clinical safety and efficacy in a more robust manner.

In November 2011, we announced the initiation of patient enrolment for a 140 patient Phase II clinical trial exploring the administration of MultiStem to patients that have suffered an ischemic stroke. In this trial, MultiStem will be administered 24 to 36 hours after a stroke has occurred. If shown to be safe and effective, this would represent a significant extension of the treatment window relative to existing standard of care. We believe that the potential market for a new therapy to treat stroke could be more than \$15 billion annually.

We are also interested in the application of MultiStem for other neurological indications that represent areas of significant unmet medical need, such as Traumatic Brain Injury, or TBI, which represents the leading cause of disability among children and young adults, and a leading cause of death. Approximately 1.7 million cases of TBI are seen in the U.S. each year, nearly half a million cases of which are children age 0 to 14 years old. The CDC estimates that more than three million individuals have a long-term or lifelong need for help to perform activities of daily living as a result of a traumatic brain injury. The annual direct and indirect costs for TBI are

**Table of Contents**

approximately \$60 billion a year, according to the National Institute of Neurological Disorders and Stroke, which is part of the National Institutes of Health. In preclinical studies of TBI, administration of MultiStem dramatically reduced the extent of damage caused by a TBI, and promoted accelerated healing of the blood-brain barrier.

We are also conducting preclinical work exploring the application of MultiStem toward in other neurological indications. In June 2010, we announced that we and collaborators at the Center for Stem Cell and Regenerative Medicine and Case Western Reserve University, were awarded \$1 million through the Ohio Third Frontier Biomedical Program to support preclinical and translational research into the treatment of spinal cord injury (SCI) with MultiStem. In addition, in November 2010, we announced that we have been awarded a \$140,000 grant from the Michael J. Fox Foundation for Parkinson's Research to advance research and development of MultiStem as a potential treatment for Parkinson's disease. The research funded by the grant is intended to confirm and extend previous observations regarding the efficacy of MultiStem in rodent models of Parkinson's disease, with the goal of accelerating the potential clinical application of these cells for patients who suffer from the disease. In October 2011, we announced the award of grant funding of up to \$640,000 to investigate the potential for MultiStem to treat chronic progressive Multiple Sclerosis, based on initial results in preclinical models.

***Pharmaceutical Programs******Novel 5HT2c agonists for the treatment of obesity and related conditions***

Obesity is a substantial contributing factor to a range of diseases that represent the major causes of death and disability in the developed world today. Individuals that are clinically obese have elevated rates of cardiovascular disease, stroke, certain types of cancer and diabetes. According to the CDC, the incidence of obesity in the United States has increased at an epidemic rate during the past 20 years. CDC now estimates that 66% of all Americans are overweight, including more than 30% that are considered clinically obese. The percentage of young people who are overweight has more than tripled since 1980. There has also been a dramatic rise in the rate of obesity in Europe and Asia. Despite the magnitude of this problem, current approaches to clinical obesity are largely ineffective, and we are aware of relatively few new therapeutic approaches in clinical development.

We are developing novel pharmaceutical treatments for obesity, which are compounds designed to act by stimulating a key receptor in the brain that regulates appetite and food intake—the 5HT2c receptor. The role of this receptor in regulating food intake is well understood in both animal models and humans. In 1996, Wyeth launched the anti-obesity drug Redux® (dexfenfluramine), a non-specific serotonin receptor agonist that was used with the stimulant phentermine in a combination commonly known as fen-phen. This diet drug combination gained rapid and widespread acceptance in the clinical marketplace and was shown to be highly effective at regulating appetite, reducing food intake, and causing significant weight loss. Unfortunately, in addition to stimulating the 5HT2c receptor, Redux also stimulated the 5HT2b receptor that is found in the heart. The activation of 5HT2b by Redux is believed to have caused significant cardiovascular problems in a number of patients and, as a result, Redux was withdrawn from the market in 1997. In 1996, doctors wrote 18 million monthly prescriptions for drugs constituting the fen-phen combination. In that same year, these drugs generated sales of greater than \$400 million, serving as a benchmark for the substantial market opportunity for an effective drug to treat clinical obesity.

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



**Table of Contents**

We initiated a drug development program focused on creating potent and selective compounds that stimulate the 5HT2c receptor, but that avoid the 5HT2b receptor and other receptors, such as 5HT2a. Our specific goal has been to develop an orally administered pill that reduces appetite by stimulating the 5HT2c receptor, but that does not stimulate the 5HT2b receptor, the 5HT2a receptor, or other receptors that could cause adverse side effects. Based on extensive preclinical studies that we have conducted with compounds that we have generated, we have demonstrated the ability to develop compounds that are highly potent and selective for the 5HT2c receptor, and that lack activity at either 5HT2a or 5HT2b. We believe that this achievement represents a significant advance in the field, and that the potency and selectivity profile displayed by compounds we are developing will result in substantially better efficacy and a cleaner safety and tolerability profile in clinical trials, as well as a more convenient dosing schedule than other 5HT2c agonist programs. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit outstanding receptor selectivity and are working towards the selection of a clinical development candidate for this program.

*Other Small Molecule Programs & Key Technologies*

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

In addition to our current product development programs, we developed our patented RAGE technology that provides us with the ability to produce human cell lines that express specific, biologically well validated drug targets without relying upon cloned and isolated gene sequences. While our RAGE technology is not a therapeutic product, it is a commercial technology that we have successfully applied for the benefit of our partners and that we have also used for our own internal drug development programs. Modern drug screening approaches typically require the physical isolation and structural modification of a gene of interest, an approach referred to as gene cloning, in order to create a cell line that expresses a drug target of interest. Researchers may then use the genetically modified cell line to identify pharmaceutical compounds that inhibit or stimulate the target of interest. The RAGE technology enables us to turn on or amplify the expression of a drug target without having to physically clone or isolate the gene. In effect, the technology works through the random insertion of tiny, proprietary genetic switches that randomly turn genes on without requiring their physical isolation, or any advance knowledge of their structure. This technology provides us with broad freedom to work with targets that may be otherwise unavailable as a result of intellectual property restrictions on the use of specific cloned and isolated genes. Over the past several years, we have produced cell lines that express drug targets in a range of disease areas such as metabolic disease, infectious disease, oncology, cardiovascular disease, inflammation, and central nervous system disorders. Many of these were produced for drug development programs at major pharmaceutical companies that we have collaborated with, such as Bristol-Myers Squibb, and some have been produced for our internal drug development programs.

**Competition**

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

Osiris is currently engaged in multiple Phase II and Phase III clinical trials involving Prochymal, an allogeneic stem cell product based on mesenchymal stem cells, or MSCs, that are obtained from healthy consenting donors, and are administered without tissue matching. However, in contrast to MultiStem, MSCs display limited expansion potential and more limited biological plasticity. In November 2008, Osiris announced a

## **Table of Contents**

partnership in which Genzyme acquired development rights to Prochymal for certain markets outside the United States and Canada in exchange for \$130 million in license fees, up to \$1.25 billion in clinical and sales milestones, and royalties. Osiris retains commercial development rights to Prochymal for the United States and Canada.

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

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

We also face competition in our efforts to develop compounds for the treatment of obesity. There is currently one approved therapeutic product on the market for obesity, Xenical (also known as Alli), which is marketed by Roche. Potential side effects associated with taking Xenical / Alli include cramping, intestinal discomfort, flatulence, diarrhea, and leakage of oily stool. Another obesity drug, Meridia, was approved for clinical use and marketed by Abbott Pharmaceuticals, but was recently withdrawn from the market due to concerns regarding increased risk of cardiovascular disease and stroke among patients taking the drug.

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

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

---

**Table of Contents**

**Intellectual Property**

We rely on a combination of patent applications, patents, trademarks, and contractual provisions to protect our proprietary rights. We believe that to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. Currently, we require our officers, employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, and other advisors to execute confidentiality agreements in connection with their employment, consulting, or advisory relationships with us, where appropriate. We also require our employees, consultants, and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, developed using our property, or which relate to our business. We currently have an aggregate of 119 patents for our technologies.

We have a broad patent estate with claims directed to compositions, methods of production, and methods of use of certain non-embryonic stem cells and related technologies. We acquired ownership of part of our stem cell technology and intellectual property as a result of our 2003 acquisition of a holding company, which held the rights to the technology originally discovered at the University of Minnesota. We also have an exclusive license to additional MAPC-related inventions (or in other words, improvements) developed by the University of Minnesota through May 2009, and under a collaborative research agreement with the KUL we have an exclusive license to MAPC-related inventions developed at KUL using the MAPC technology or intellectual property or that result from sponsored research funded by us. We also own and license additional intellectual property developed by us and others. We have 69 issued patents (nine U.S. patents and 60 international patents) and more than 160 patent applications related to our stem cell technologies that currently provide patent coverage through as late as 2030. Of the 69 patents related to our stem cell technologies, six U.S. patents and 32 non-U.S. patents apply to MAPC-based and related products. Additional patent applications are pending that, if issued, could extend patent coverage beyond 2030. Furthermore, in certain jurisdictions (such as the United States) a patent term may be extended to reflect the length of time a product is under regulatory review, and/or an extended period of market exclusivity may apply for certain products (e.g. exclusivity periods for orphan drug designation or biologics).

We have established a broad intellectual property portfolio related to our functional genomics technologies and small molecule product candidates. We have a broad patent estate with claims directed to compositions, methods of making, and methods of using our small molecule drug candidates. We have five U.S. patents and four patent applications with broad claims directed to selective 5HT2c agonists discovered at Athersys that currently provide patent coverage through as late as 2029. From our Histamine H3 program, we have five U.S. patents and four patent applications with broad claims directed to compounds discovered at Athersys from two distinct chemical series that currently provide patent coverage through as late as 2028. In addition, we currently have 37 issued patents (sixteen U.S. patents and 21 international patents) and four patent applications relating to compositions and methods for the RAGE technology that currently provide patent coverage through as late as 2019, and three U.S. patents and eight patent applications relating to human proteins and candidate drug targets that we identified through the application of RAGE and our other technologies that currently provide patent coverage through as late as 2022. The RAGE technology was developed by Dr. John Harrington and other Athersys, Inc. scientists internally in the mid-1990s.

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

## **Table of Contents**

### **Research and Development**

Our research and development costs, which consist primarily of costs associated with external clinical trial costs, preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property application processes, and laboratory supply and reagent costs, were \$13.4 million for the nine months ended September 30, 2011, \$14.8 million in 2010, \$11.9 million in 2009 and \$16.5 million in 2008.

### **Government Regulation**

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

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

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

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

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

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

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

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

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

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

Preclinical studies can take several years to complete, and there is no guarantee that an IND based on those studies will become effective to permit clinical trials to begin. The clinical development phase generally takes five to seven years, or longer, to complete (i.e., from the initiation of Phase 1 through completion of Phase 3 studies). After successful completion of clinical trials for a new drug or biologic product, FDA approval of the NDA or BLA must be obtained. This process requires substantial time and effort and there is no assurance that the FDA will accept the NDA or BLA for filing and, even if filed, that the FDA will grant approval. In the past,



## **Table of Contents**

the FDA's approval of an NDA or BLA has taken, on average, one to two years, but in some instances may take substantially longer. If questions regarding safety or efficacy arise, additional studies may be required, followed by a resubmission of the NDA or BLA. Review and approval of an NDA or BLA can take up to several years.

In addition to obtaining FDA approval for each product, each drug manufacturing facility must be inspected and approved by the FDA. All manufacturing establishments are subject to inspections by the FDA and by other federal, state, and local agencies, and must comply with GMP requirements. We do not currently have any GMP manufacturing capabilities, and will rely on contract manufacturers to produce material for any clinical trials that we may conduct.

We must also obtain regulatory approval in other countries in which we intend to market any drug. The requirements governing conduct of clinical trials, product licensing, pricing, and reimbursement vary widely from country to country. FDA approval does not ensure regulatory approval in other countries. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In some countries, the sale price of the drug must also be approved. The pricing review period often begins after market approval is granted. Even if a foreign regulatory authority approves a drug product, it may not approve satisfactory prices for the product.

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

## **Employees**

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

As of December 31, 2011, we employed 48 full-time employees, 21 with Ph.D. degrees. In addition to our employees, we also use the service and support of outside consultants and advisors. None of our employees is represented by a union, and we believe relationships with our employees are good.

## **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.

## **Properties**

Our principal offices are located at 3201 Carnegie Avenue in Cleveland, Ohio. We currently lease approximately 45,000 square feet of space for our corporate offices and laboratories, with state-of-the-art laboratory space. The lease currently expires in March 2012, and we have an option to extend the lease in annual increments through March 2013 at our current rent of \$267,000 per year. Also, we currently lease office and laboratory space for our Belgian subsidiary. The lease currently expires in December 2012, and we have an option to renew annually through December 2014. The annual rent in Belgium is subject to adjustments based on an inflationary index.

**Table of Contents****MANAGEMENT****Executive Officers and Directors**

The following table sets forth certain information regarding our executive officers and directors as of December 31, 2011.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Gil Van Bokkelen, Ph.D.	50	Chief Executive Officer and Chairman
William (BJ) Lehmann, Jr., J.D.	45	President and Chief Operating Officer
John J. Harrington, Ph.D.	44	Chief Scientific Officer, Executive Vice President and Director
Robert J. Deans, Ph.D.	60	Executive Vice President, Regenerative Medicine
Laura K. Campbell, CPA	47	Vice President of Finance
Lee E. Babiss	55	Director
Ismail Kola	54	Director
George M. Milne, Jr.	68	Director
Lorin J. Randall	68	Director
Jack L. Wyszomierski	56	Director

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

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

*Dr. Harrington* has served as our Chief Scientific Officer, Executive Vice President and Director since our founding. Dr. Harrington co-founded Athersys in October 1995. Dr. Harrington led the development of the RAGE technology as well as its application for gene discovery, drug discovery and commercial protein production applications. He is a listed inventor on over 20 issued or pending United States patents, has authored numerous scientific publications, and has received numerous awards for his work, including being named one of the top international young scientists by MIT Technology Review in 2002. Dr. Harrington has overseen the

---

**Table of Contents**

therapeutic product development programs at Athersys since their inception, and during his career, he has also held positions at Amgen and Scripps Clinic. He received his B.A. in Biochemistry and Cell Biology from the University of California at San Diego and his Ph.D. in Cancer Biology from Stanford University. Dr. Harrington's scientific experience and deep understanding of our Company, combined with his drive for innovation and excellence, position him well to serve on the Board of Directors.

*Dr. Deans* has served as our Executive Vice President since 2011. Dr. Deans has led Athersys' regenerative medicine research and development activities since February 2003, initially as Vice President of Regenerative Medicine, until he was named Senior Vice President of Regenerative Medicine in June 2006, and Executive Vice President in June 2011. Dr. Deans is highly regarded as an expert in stem cell therapeutics, with over 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, 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.

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

*Dr. Babiss* has served as our Director since August 2010. Dr. Babiss is currently Executive Vice President of Global Laboratory Services of PPD, Inc., a contract research organization, where he has served since February 2010, providing strategic direction and scientific leadership. Dr. Babiss was formerly President and Director of Global Pharmaceutical Research at Roche, a pharmaceutical company, in Switzerland, from 1998 until his appointment at PPD, Inc. Prior to Roche, Dr. Babiss spent seven years with Glaxo, Inc., now GlaxoSmithKline, a pharmaceutical company, where he held senior positions, including Vice President of Biological Sciences and Genetics. Dr. Babiss received his doctorate in Microbiology from Columbia University and completed his postdoctoral fellowship at the Rockefeller University, where he served as an assistant and associate professor. Dr. Babiss has received numerous fellowship awards and grants and serves on several scientific advisory committees. Dr. Babiss has authored over 60 technical publications in scientific and medical journals. Dr. Babiss brings over 20 years of experience developing and leading research and development programs. His strategic leadership and product development knowledge provide a valuable perspective to our Board of Directors.

*Dr. Kola* has served as our Director since October 2010. Dr. Kola is currently Executive Vice President of UCB S.A. in Belgium, a biopharmaceutical company dedicated to the development of innovative medicines focused on the fields of central nervous system and immunology disorders, and President of UCB New Medicines, UCB's discovery research through proof-of-concept organization, since November 2009. Dr. Kola was formerly Senior Vice President, Discovery Research and Early Clinical Research & Experimental Medicine at Schering-Plough Research Institute, the pharmaceutical research arm of Schering-Plough Corporation, a pharmaceutical company, and Chief Scientific Officer at Schering-Plough Corporation, from March 2007 until his appointment at UCB. Prior to Schering-Plough, Dr. Kola held senior positions from January 2003 to March 2007 at Merck, a pharmaceutical company, where he was Senior Vice President and Site Head, Basic Research, and responsible for atherosclerosis and cardiovascular diseases, diabetes, obesity, infectious diseases, immunology and rheumatology, animal pharmacology and basic and medicinal chemistry. From 2000 to 2003, Dr. Kola was Vice President, Research, and Global Head, Genomics Science and Biotechnology, with Pharmacia Corporation. Prior to his position with Pharmacia, Dr. Kola spent 15 years as Professor of Human Molecular



**Table of Contents**

Genetics and was Director of the Centre for Functional Genomics and Human Disease at Monash Medical School in Melbourne, Australia. Dr. Kola received his Ph.D. in Medicine from the University of Cape Town, South Africa, his B.Sc. from the University of South Africa, and his B.Pharm. from Rhodes University, South Africa. Dr. Kola currently serves on the boards of directors of Astex Therapeutics since May 2010, Biotie (and previously Synosia who merged with Biotie) since February 2011, and Ondek since 2009, and previously served on the board of directors of Promega Corporation from 2003 to 2007. Dr. Kola has authored 159 technical publications in scientific and medical journals and is the named inventor on at least a dozen patents. Dr. Kola holds Adjunct Professorships of Medicine at Washington University in St. Louis, Missouri, and Monash University Medical School; a Foreign Adjunct Professorship at the Karolinska Institute in Stockholm, Sweden; and was elected William Pitt Fellow at Pembroke College, Cambridge University, United Kingdom in 2008, among many other awards and distinctions. For more than 20 years, Dr. Kola has created a bridge between the scientific and academic worlds through various projects funded by renowned institutes, such as the National Health & Medical Research Council in Australia, the National Institutes of Health in the USA, and Monash University in Australia. Dr. Kola's experience and leadership in taking numerous drugs from the research stage to market or late stage development brings a unique and valuable perspective to our Board of Directors.

*Dr. Milne* has served as our Director since January 2003 after his retirement in 2002 from Pfizer Inc., a pharmaceutical company, where he most recently served as President of Worldwide Strategic and Operations Management and Executive Vice President of Global Research and Development. He joined Pfizer in 1970 and was President of Pfizer Central Research with global responsibility for all pharmaceutical and animal health research and development from 1993 to 2000. Dr. Milne is a Venture Partner of Radius Venture Partners II, L.P., a health and life sciences venture capital firm. Dr. Milne is also a director of Mettler-Toledo International Inc. since 1999 and Charles River Laboratories, Inc. since 2002. He was a director of Aspreva, Inc. from 2004 to 2008, Conor Medsystems, Inc. from 2003 to 2006 and MedImmune, Inc. from 2005 to 2007. He also serves on the board of the New York Botanical Garden and the Mystic Aquarium/Institute for Exploration. Dr. Milne received his B.S. in Chemistry from Yale University and his Ph.D. in Organic Chemistry from Massachusetts Institute of Technology. With his long tenure at Pfizer, his work as a venture partner with Radius and through his service on multiple life science boards, Dr. Milne has a deep understanding of research and development processes and the services, tools and technologies being used in the life sciences industry, which helps the Board of Directors understand industry trends and assess product development opportunities.

*Mr. Randall* has served as our Director since September 2007. Mr. Randall is an independent financial consultant and previously was Senior Vice President and Chief Financial Officer of Eximias Pharmaceutical Corporation, a development-stage drug development company, from 2004 to 2006. From 2002 to 2004, Mr. Randall served as Senior Vice President and Chief Financial Officer of i-STAT Corporation, a publicly-traded manufacturer of medical diagnostic devices that was acquired by Abbott Laboratories in 2004. From 1995 to 2001, Mr. Randall was Vice President and Chief Financial Officer of CFM Technologies, Inc., a publicly-traded manufacturer of semiconductor manufacturing equipment. Mr. Randall currently serves on the boards of directors of Acorda Therapeutics, Inc. (NASDAQ: ACOR) since 2006, Nanosphere, Inc. since 2008 (NASDAQ: NSPH) and Tengion, Inc. (NASDAQ: TNGN) since 2008, and previously served on the board of directors of Opexa Therapeutics, Inc. (NASDAQ: OPXA) from 2007 to 2009. Mr. Randall received a B.S. in accounting from The Pennsylvania State University and an M.B.A. from Northeastern University. Mr. Randall's strong financial and human resources background and his service on the audit and compensation committees of other companies provides financial and human resources expertise to the Board of Directors, including an understanding of financial statements, compensation policies and practices, corporate finance, developing and maintaining effective internal controls, accounting, employee benefits, investments and capital markets. These qualities also formed the basis for the Board's decision to appoint Mr. Randall as chairman of the Audit Committee and the Compensation Committee.

*Mr. Wyszomierski* has served as our Director since June 2010 and is currently retired. From 2004 until his retirement in June 2009, Mr. Wyszomierski served as the Executive Vice President and Chief Financial Officer of VWR International, LLC, a supplier and distributor of laboratory supplies, equipment and supply chain

---

## **Table of Contents**

solutions to the global research laboratory industry. From 1982 to 2004, Mr. Wyszomierski held positions of increasing responsibility within the finance group at Schering-Plough Corporation, a pharmaceutical company, culminating with his appointment as Executive Vice President and Chief Financial Officer in 1996. Prior to joining Schering-Plough, he was responsible for capitalization planning at Joy Manufacturing Company, a producer of mining equipment, and was a management consultant at Data Resources, Inc., a distributor of economic data. Mr. Wyszomierski currently serves on the board of directors of Xoma, Ltd. (NASDAQ: XOMA) since 2010, where he also serves on both the audit and compensation committees, and Exelixis, Inc. (NASDAQ: EXEL) since 2004, where he also serves as chairman of the audit committee. Mr. Wyszomierski holds a M.S. in Industrial Administration and a B.S. in Administration, Management Science and Economics from Carnegie Mellon University. Mr. Wyszomierski's extensive financial reporting, accounting and finance experience and his service on the audit committee of another public company, as well as his experience in the healthcare and life sciences industries provides financial expertise to the Board of Directors, including an understanding of financial statements, corporate finance, developing and maintaining effective internal controls, accounting, investments and capital markets.

### **Director Independence**

The Board of Directors reviews the independence of each Director at least annually. During these reviews, the Board of Directors will consider transactions and relationships between each Director (and his or her immediate family and affiliates) and our company and our management to determine whether any such transactions or relationships are inconsistent with a determination that the Director was independent. The Board of Directors conducted its annual review of Director independence to determine if any transactions or relationships exist that would disqualify any of the individuals who serve as a Director under the rules of the NASDAQ Capital Market or require disclosure under SEC rules. Based upon the foregoing review, the Board of Directors determined the following individuals are independent under the rules of the NASDAQ Capital Market: Lee E. Babiss, Ismail Kola, George M. Milne, Jr., Lorin J. Randall and Jack L. Wyszomierski. In making this determination with respect to Mr. Babiss, the Board determined that the provision of certain contract research services to the Company by PPD, Inc., of which Mr. Babiss serves as an executive officer, did not create a material relationship or impair the independence of Mr. Babiss because Mr. Babiss receives no material direct or indirect benefit from such transactions, which were undertaken in the ordinary course of business. Currently, we have two members of management who also serve on the Board of Directors: Dr. Van Bokkelen, who is also our Chairman and Chief Executive Officer, and Dr. Harrington, who is our Executive Vice President and Chief Scientific Officer. Neither Dr. Van Bokkelen nor Dr. Harrington is considered independent under the independence rules of the NASDAQ Capital Market.

### **Committees of Our Board of Directors**

The Board of Directors has three standing committees: the Audit Committee, the Compensation Committee and the Nominations and Corporate Governance Committee. The Board of Directors adopted a written charter for each of the committees of the Board of Directors. These charters, as well as our Code of Business Conduct and Ethics, are posted and available under the Investor page on our website at [www.athersys.com](http://www.athersys.com). Stockholders may request copies of these corporate governance documents, free of charge, by writing to Athersys, Inc., 3201 Carnegie Avenue, Cleveland, Ohio 44115, Attention: Corporate Secretary.

#### ***Audit Committee***

The Audit Committee is responsible for overseeing the accounting and financial reporting processes of the Company and the audits of the financial statements of the Company. The Audit Committee is also directly responsible for the appointment, compensation, retention and oversight of the work of the Company's independent auditors, including the resolution of disagreements between management and the auditors regarding financial reporting. Additionally, the Audit Committee approves all related-party transactions that are required to

## **Table of Contents**

be disclosed pursuant to Item 404 of Regulation S-K. The current members of the Audit Committee are Lorin J. Randall, Jack L. Wyszomierski, George M. Milne, Jr. and Ismail Kola. The Board of Directors has determined that each of Mr. Randall and Mr. Wyszomierski is an audit committee financial expert, as defined in Item 407(d)(5)(ii) of Regulation S-K, and an independent director, as defined in the NASDAQ listing standards. The Audit Committee held five meetings during fiscal year 2011.

### ***Compensation Committee***

The Compensation Committee is responsible for, among other things, annually reviewing and recommending to the Board of Directors the salaries and other compensation, including stock incentives, of our executive officers, including our Chief Executive Officer, reviewing and recommending to the Board of Directors the compensation of our non-employee Directors, engaging and determining the fees of compensation consultants, if any, and overseeing regulatory compliance with respect to compensation matters. The Compensation Committee reviews and recommends corporate goals and objectives relevant to the compensation of the executive officers and evaluates the performance of the executive officers in light of those corporate goals and objectives. The Compensation Committee also considers the duties and responsibilities of the executive officers and recommends to the Board of Directors the compensation levels for those executive officers based on those evaluations and any other factors as it deems appropriate. In recommending incentive compensation, the Compensation Committee also considers the Company's performance and relative stockholder return, the value of similar awards to executive officers of comparable companies, and the awards given to the Company's executive officers in past years. The current members of the Compensation Committee are Lorin J. Randall, Jack L. Wyszomierski, George M. Milne, Jr. and Lee E. Babiss. The Compensation Committee held five meetings during fiscal year 2011.

### ***Nominations and Corporate Governance Committee***

The Nominations and Corporate Governance Committee is responsible for, among other things, evaluating and recommending to the Board of Directors qualified nominees for election as Directors and qualified Directors for committee membership, as well as developing and recommending to the Board corporate governance principles applicable to the Company. The current members of the Nominations and Corporate Governance Committee are Lee E. Babiss, Lorin J. Randall, George M. Milne, Jr. and Jack L. Wyszomierski. The Nominations and Corporate Governance Committee held one meeting during fiscal year 2011.

The Nominations and Corporate Governance Committee shall identify individuals qualified to become members of the Board of Directors and recommend candidates to the Board to fill new or vacant positions. Except as may be required by rules promulgated by NASDAQ or the SEC, there are currently no specific, minimum qualifications that must be met by each candidate for the Board of Directors, nor are there specific qualities or skills that are necessary for one or more of the members of the Board of Directors to possess. In recommending candidates, the Nominations and Corporate Governance Committee considers such factors as it deems appropriate, consistent with criteria approved by the Board of Directors. These factors may include judgment, skill, diversity, integrity, experience with businesses and other organizations of comparable size, experience in corporate governance, experience in business and human resource management, the interplay of the candidate's experience with the experience of other members of the Board of Directors, and the extent to which the candidate would be a desirable addition to the Board of Directors and any committees of the Board. When considering diversity, the Nominations and Corporate Governance Committee considers the breadth and diversity of experience brought by the various nominees for Director in functional areas including pharmaceutical, capital markets, biotechnology, clinical and financial. The Nominations and Corporate Governance Committee recommends candidates to the Board of Directors based on these factors and also considers possible conflicts of interest when making its recommendations to the Board.

### ***Compensation Committee Interlocks and Insider Participation***

In 2011, none of our Directors was a member of the board of directors of any other company where the relationship would be construed to constitute a committee interlock within the meaning of the rules of the SEC.

## **Table of Contents**

### **Compensation Discussion and Analysis**

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

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

We are a biopharmaceutical company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human life. Through the application of our proprietary technologies, we have established a pipeline of therapeutic product development programs in multiple disease areas. As further discussed in this section, our compensation and benefit programs help us attract, retain and motivate individuals who will maximize our business results by working to meet or exceed established company or individual objectives. In addition, we reward our executive officers for meeting certain developmental milestones, such as completing advancements in product candidate development, strategic partnerships or other financial transactions that add to the capital resources of the Company or create value for stockholders.

The following are the highlights of our 2011 compensation and benefit programs:

increased the base salaries of our named executive officers; and

a decision has not yet been made regarding grants of cash bonuses to our named executive officers.

The following discussion and analysis of our compensation and benefit programs for 2011 should be read together with the compensation tables and related disclosures that follow this section. This discussion includes forward-looking statements based on our current plans, considerations, expectations and determinations about our compensation program. Actual compensation decisions that we may make for 2012 and beyond may differ materially from our recent past.

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

Our compensation programs are designed to:

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

Provide incentives to promote and reward superior performance throughout the organization;

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

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

The Compensation Committee seeks to achieve these objectives by:

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

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

When appropriate, given the nature of our business, rewarding our executive officers for both company and individual achievements with discretionary bonuses.

---

## **Table of Contents**

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

Our executive compensation program includes the following elements:

Base salary;

Cash bonuses;

Long-term equity incentive plan awards; and

Retirement and health insurance benefits.

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

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

Historically, our Chief Executive Officer has taken the lead in providing our Board of Directors with advice regarding executive compensation. For 2011, the Compensation Committee will consider recommendations from our Chief Executive Officer regarding the compensation for and performance of our executive officers in relation to company-specific strategic goals that were established by the Compensation Committee and approved by the Board of Directors related to potential bonus payments and salary adjustments. The Compensation Committee considers the recommendations made by our Chief Executive Officer because of his knowledge of the business and the performance of the other executive officers. The Compensation Committee is not bound by the input it receives from our Chief Executive Officer. Instead, the Compensation Committee exercises independent discretion when making executive compensation decisions. We describe and discuss the particular compensation decisions made by the Compensation Committee regarding the 2011 compensation of our named executive officers below under Elements of Executive Compensation.

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

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

In 2011, the Compensation Committee and the Board of Directors approved that each of the named executive officers be entitled to receive a 3.52% increase in such officer's salary for 2011 as compared to 2010 based primarily on Company performance for the year ending December 31, 2010. Effective April 1, 2011, Dr. Deans' salary was further increased to a base of \$300,000 per annum based on his performance.

In 2011, the Compensation Committee and the Board of Directors approved that the Chief Executive Officer will be entitled to receive a 6.30% increase in salary for 2012 as compared to 2011, an adjustment based primarily on competitive information provided to the Compensation Committee by its independent compensation consultant. The Compensation Committee has not yet made a recommendation to the Board of Directors for increases in salary for the other named executive officers.

**Cash Bonuses.** We utilize annual incentive bonuses to reward officers and other employees for achieving financial and operational goals and for achieving individual annual performance objectives. These objectives vary depending on the individual executive and employee, but relate generally to strategic factors, including establishment and maintenance of key strategic relationships, advancement of our product candidates, identification and advancement of additional programs or product candidates, and to financial factors, including raising capital and improving our results of operations.



**Table of Contents**

In 2005, in connection with a restructuring of the Company's internal programs, the Board established an incentive program designed to retain and motivate our executives. The program provided for payments to the executives upon the occurrence of certain business transactions and time-limited financing milestones. The program continues to provide the named executive officers financial protection in the event of certain merger or acquisition or asset sale transactions. In the event of a defined transaction, we would be obligated to make a payment to the named executive officers representing five percent of the consideration received from the transaction, and in the event of a stock-based transaction, the executives would receive fifty percent of any payments due to them in stock. There were no payments under this program in 2011.

In addition, given the nature of our business, when appropriate, we reward our executive officers with discretionary bonuses. Discretionary bonuses have not yet been evaluated by the Compensation Committee for 2011. Discretionary bonuses were paid to our named executive officers in 2010, as described in the following paragraph.

The Compensation Committee recommended and the Board of Directors approved a cash bonus incentive program for the year ended December 31, 2010 for our named executive officers. Under the 2010 incentive program, each named executive officer could, at the discretion of the Compensation Committee and the Board of Directors, receive a bonus at a target level of 25% of such officer's 2010 salary based 80% on the achievement of specified corporate goals and 20% on the assessment of such officer's individual performance, based on input from the Chief Executive Officer (with respect to the named executive officers other than the Chief Executive Officer whose bonus potential was based 100% on achievement of specified corporate goals). The corporate goals included the achievement of progress on MultiStem clinical development, execution against the established budget and operating plan, and achievement of one or more strategic partnerships. However, any bonus ultimately paid under the 2010 incentive program was to be at the discretion of the Board of Directors based on the recommendation of the Compensation Committee, after good faith consideration of executive officer performance, overall company performance, market conditions and cash availability. There was no formally adopted plan document for the 2010 incentive program, although the Compensation Committee recommended and the Board of Directors approved the specific corporate goals and target bonus levels. The Compensation Committee and the Board of Directors agreed that each of our named executive officers would be entitled to 54% of their respective target bonus under the 2010 incentive program as a result of the achievement of operational and strategic objectives in 2010, specifically the achievement of patient enrollment goals for the Company's clinical trials in heart attack and bone marrow transplant support, and obtaining authorization from the FDA to proceed with a clinical trial in IBD in 2010. The achievement of these clinical goals combined with operating according to the approved budget and individual performance resulted in the payment of bonuses equal to 13.5% of such officers' 2010 base salaries. Such cash bonus payments paid to our executive officers in 2011 were as follows: Dr. Van Bokkelen \$52,750; Dr. Harrington \$45,214; Mr. Lehmann \$45,214; Dr. Deans \$35,418; and Ms. Campbell \$29,389.

For the year ending December 31, 2011, the Compensation Committee recommended and the Board of Directors approved a cash bonus incentive plan for our named executive officers. The 2011 plan provides that each participant is eligible to earn a target bonus of a specified percentage of the named executive officer's salary during the award term, weighted on the achievement of specified corporate goals, with the remainder based on individual/functional performance, as set forth below:

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



---

**Table of Contents**

The evaluation of goal achievement is based on input from the Chief Executive Officer (with respect to the named executive officers other than the Chief Executive Officer, whose bonus potential is based 100% on achievement of specified corporate goals). The corporate goals include advancing our clinical programs for MultiStem, executing against the established operating plan and capital acquisition objectives, and advancement of strategic partnership and program activities. Goal achievement and discretionary bonuses have not yet been evaluated by the Compensation Committee for 2011.

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

Our equity compensation plans authorize us to grant, among other types of awards, options, restricted stock and restricted stock units to our employees, Directors and consultants. To date, we have not granted any restricted stock or restricted stock units under our equity compensation plans. We anticipate that to implement our long-term incentive goals, we may grant restricted stock or restricted stock units in the future. Historically, we have elected to use stock options as our primary long-term equity incentive vehicle. We expect to continue to use stock options as a long-term incentive vehicle because we believe:

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

The value of stock options is based on our performance, because all the value received by the recipient of a stock option is based on the growth of our stock price;

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

The vesting period of stock options encourages executive retention and efforts to preserve stockholder value.

In the past, in determining the number of stock options to be granted to executives, we took into account the individual's position, scope of responsibility, ability to affect results and stockholder value, the individual's historic and recent performance and the value of stock options in relation to other elements of the individual executive's total compensation. Currently, awards of stock options are granted from time to time under the guidance and approval of the Compensation Committee and the Board of Directors. The Compensation Committee and the Board of Directors periodically review and approve stock option awards to executive officers based upon a review of competitive compensation data, an assessment of individual performance, a review of each executive's existing long-term incentives, retention considerations and a subjective determination of the individual's potential to positively impact future stockholder value. No stock option grants awards were conferred to our named executive officers in 2011.

*Retirement and Health Insurance Benefits.* Consistent with our compensation philosophy, we maintain benefits for our executive officers, including medical, dental, vision, life and disability insurance coverage and the ability to contribute to a 401(k) retirement plan. The executive officers and employees have the ability to participate in these benefits at the same levels. We provide such retirement and health insurance benefits to our employees to retain qualified personnel. In addition, Dr. Van Bokkelen, Dr. Harrington, Mr. Lehmann, Dr. Deans and Ms. Campbell also receive Company-paid life insurance benefits in the amounts of \$2 million for

## **Table of Contents**

Dr. Van Bokkelen, Dr. Harrington and Mr. Lehmann, and \$1 million for Dr. Deans and Ms. Campbell. These additional life insurance policies are provided to these officers due to their extensive travel requirements and contributions to the Company. We have no current plans to change the level of these benefits provided to our named executive officers.

### ***Severance Arrangements***

See the disclosure under **Potential Payments Upon Termination or Change of Control** for more information about severance arrangements with our named executive officers. We provide such severance arrangements to attract and retain qualified personnel.

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

We believe that entering into employment agreements with each of our named executive officers was necessary for us to attract and retain talented and experienced individuals for our senior level positions. In this way, the employment agreements help us meet the initial objective of our compensation program. Each agreement contains terms and arrangements that we agreed to through arms-length negotiation with our named executive officers. We view these employment agreements as reflecting the minimum level of compensation that our named executive officers require to remain employed with us, and thus the bedrock of our compensation program for our named executive officers. For more details of our employment agreements and arrangements, see the disclosure under **2011 Summary Compensation Table**.

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

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

**Table of Contents****2011 Summary Compensation Table**

The following table and narrative set forth certain information with respect to the compensation earned during the fiscal year ended December 31, 2011 by our named executive officers.

Name and Principal Position (a)	Year (b)	Salary (\$)(c)	Bonus (\$)(d)	Option Award (\$) (1)(f)	All Other Compensation (\$)(i)	Total (4)(j)
Gil Van Bokkelen, Chief Executive Officer (2)	2011	\$ 404,500	\$ 0(3)	\$ 0	\$ 12,620	\$ 417,120
	2010	\$ 390,741	\$ 52,750	\$ 0	\$ 9,620	\$ 453,111
	2009	\$ 383,079	\$ 76,616	\$ 98,250	\$ 5,000	\$ 562,945
Laura Campbell, Vice President of Finance	2011	\$ 225,365	\$ 0(3)	\$ 0	\$ 5,109	\$ 230,474
	2010	\$ 217,699	\$ 29,389	\$ 0	\$ 2,109	\$ 249,197
	2009	\$ 213,430	\$ 42,686	\$ 68,775	\$ 0	\$ 324,891
William (BJ) Lehmann, Jr., President and Chief Operating Officer	2011	\$ 346,714	\$ 0(3)	\$ 0	\$ 4,673	\$ 351,387
	2010	\$ 334,921	\$ 45,214	\$ 0	\$ 1,673	\$ 381,808
	2009	\$ 328,354	\$ 65,671	\$ 88,425	\$ 1,000	\$ 483,450
John Harrington, Chief Scientific Officer and Executive Vice President (2)	2011	\$ 346,714	\$ 0(3)	\$ 0	\$ 4,355	\$ 351,069
	2010	\$ 334,921	\$ 45,214	\$ 0	\$ 1,355	\$ 381,490
	2009	\$ 328,354	\$ 65,671	\$ 88,425	\$ 1,000	\$ 483,450
Robert Deans, Executive Vice President, Regenerative Medicine	2011	\$ 292,898	\$ 0(3)	\$ 0	\$ 5,620	\$ 298,518
	2010	\$ 262,355	\$ 35,418	\$ 0	\$ 5,620	\$ 303,393
	2009	\$ 257,211	\$ 51,442	\$ 78,600	\$ 6,000	\$ 393,253

- (1) Amounts in column (f) do not necessarily reflect compensation actually received by Athersys named executive officers. The amounts in column (f) reflect the full grant date fair value of the equity awards made during the fiscal year ended December 31, 2009 in accordance with Accounting Standards Codification 718, or (ASC 718). Assumptions used in the calculation of these amounts are included in Note B to the audited consolidated financial statements included elsewhere in this prospectus.
- (2) Drs. Van Bokkelen and Harrington also served as our Directors for 2011, 2010 and 2009, but did not receive any compensation as our Directors.
- (3) Discretionary bonuses have not yet been evaluated by the Compensation Committee for 2011.

**Employment Agreements and Arrangements**

*Dr. Gil Van Bokkelen.* On December 1, 1998, we entered into a one-year employment agreement, effective April 1, 1998, with Dr. Gil Van Bokkelen, to serve initially as President and Chief Executive Officer. The agreement automatically renews for subsequent one-year terms on April 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Van Bokkelen was entitled to an initial base salary of \$150,000, which may be increased at the discretion of our Board of Directors, and an annual discretionary incentive bonus of up to 33% of his base salary. His salary for 2011 is \$404,500 and his target annual incentive bonus is 40% of his base salary. Dr. Van Bokkelen also received options to purchase shares of Common Stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. Dr. Van Bokkelen is also entitled to life insurance coverage for the benefit of his family in the amount of at least \$1 million and is provided the use of a company automobile for business use. For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control. Dr. Van Bokkelen has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of 18 months thereafter, he is restricted from, among other things, competing with us.

*Dr. John J. Harrington.* On December 1, 1998, we entered into a one-year employment agreement, effective April 1, 1998, with Dr. John J. Harrington to serve initially as Executive Vice President and Chief Scientific Officer.

**Table of Contents**

The agreement automatically renews for subsequent one-year terms on April 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Harrington was entitled to an initial base salary of \$150,000, which may be increased at the discretion of our Board of Directors, and an annual discretionary incentive bonus of up to 33% of his base salary. His salary for 2011 is \$346,714 and his target annual incentive bonus is 33% of his base salary. Dr. Harrington also received options to purchase shares of Common Stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. Dr. Harrington is also entitled to life insurance coverage for the benefit of his family in the amount of at least \$1 million. For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control. Dr. Harrington has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of 18 months thereafter, he is restricted from, among other things, competing with us.

*Laura K. Campbell.* On May 22, 1998, we entered into a two-year employment agreement with Laura K. Campbell to serve initially as Controller. The agreement automatically renews for subsequent one-year terms on May 22 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Ms. Campbell was entitled to an initial base salary of \$70,200, which may be increased at the discretion of our Board of Directors. Her salary for 2011 is \$225,365 and her target annual incentive bonus is 25% of her base salary. Ms. Campbell also received options to purchase shares of Common Stock upon her employment that were terminated in 2007, and her current stock options are described in the table below. For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control.

*William (B.J.) Lehmann, Jr.* On January 1, 2004, we entered into a four-year employment agreement with Mr. Lehmann to serve initially as Executive Vice President of Corporate Development and Finance. The agreement automatically renews for subsequent one-year terms on January 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Mr. Lehmann was entitled to an initial base salary of \$250,000, which may be increased at the discretion of our Board of Directors. His salary for 2011 is \$346,714 and his target annual incentive bonus is 33% of his base salary. Mr. Lehmann also received options to purchase shares of Common Stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control. Mr. Lehmann has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of six months thereafter, he is restricted from, among other things, competing with us.

*Dr. Robert Deans.* On October 3, 2003, we entered into a four-year employment agreement with Dr. Robert Deans to serve initially as Vice President of Regenerative Medicine. The agreement automatically renews for subsequent one-year terms on October 3 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Deans was entitled to an initial base salary of \$200,000, which may be increased at the discretion of our Board of Directors, and an annual discretionary incentive bonus of up to 30% of his base salary. His salary for 2011 is \$300,000 (effective April 1, 2011) and his target annual incentive bonus is 30% of his base salary. Dr. Deans also received options to purchase shares of Common Stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control. Dr. Deans has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of six months thereafter, he is restricted from, among other things, competing with us.

***Equity Compensation Plans***

In June 2007, we adopted two equity compensation plans, which authorize the Board of Directors, or a committee thereof, to provide equity-based compensation in the form of stock options, restricted stock, restricted stock units and other stock-based awards, which are used to attract and retain qualified employees, Directors and

**Table of Contents**

consultants. Equity awards are granted from time to time under the guidance and approval of the Compensation Committee. Total awards under these plans, as amended, are limited to 6,500,000 shares of Common Stock.

**401(k) Plan**

We have a tax-qualified employee savings and retirement plan, also known as a 401(k) plan that covers all of our employees. Under our 401(k) plan, eligible employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit, which was \$16,500 in both 2011 and 2010, and have the amount of the reduction contributed to the 401(k) plan. The trustees of the 401(k) plan, at the direction of each participant, invest the assets of the 401(k) plan in designated investment options. We may make matching or profit-sharing contributions to the 401(k) plan in amounts to be determined by our Board of Directors. We made matching contributions to the 401(k) plan during fiscal 2011 at a maximum rate of fifty cents for every dollar of the first 6% of participant contributions, up to a dollar maximum of \$3,000 per participant. We did not make any matching or profit-sharing contributions to the 401(k) plan during fiscal 2010 or 2009. The 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code, so that contributions to the 401(k) plan and income earned on the 401(k) plan contributions are not taxable until withdrawn, and so that any contributions we make will be deductible when made.

**Outstanding Equity Awards at 2011 Fiscal Year-End**

The following table sets forth outstanding options held by our named executive officers at December 31, 2011.

Name (a)	Option Awards			
	Number	Number of	Option	Option Expiration Date (f)
	of	Securities	Exercise	
	Securities	Underlying	Price	
Underlying	Unexercised	(\$)(e)		
	Options	Options		
	(#)	(#)		
	Exercisable	Unexercisable		
	(b)	(c)		
Gil Van Bokkelen	712,500	0	\$ 5.00	June 8, 2017(1)
	25,000	0	\$ 5.28	December 23, 2019(2)
Laura Campbell	200,000	0	\$ 5.00	June 8, 2017(1)
	17,500	0	\$ 5.28	December 23, 2019(2)
William (BJ) Lehmann, Jr.	400,000	0	\$ 5.00	June 8, 2017(1)
	22,500	0	\$ 5.28	December 23, 2019(2)
John Harrington	700,000	0	\$ 5.00	June 8, 2017(1)
	22,500	0	\$ 5.28	December 23, 2019(2)
Robert Deans	240,000	0	\$ 5.00	June 8, 2017(1)
	20,000	0	\$ 5.28	December 23, 2019(2)

- (1) These options were granted on June 8, 2007, vested at a rate of 40% on the grant date and vested 20% in each of the three years thereafter (on a quarterly basis), and were fully exercisable on June 8, 2010.
- (2) These options were granted on December 23, 2009, vested at a rate of 25% per quarter and were fully exercisable on December 24, 2010.

**Table of Contents**

**2011 Options Exercised and Stock Vested**

None of our named executive officers exercised any stock options during 2011. As of December 31, 2011, our named executive officers did not have any other stock awards other than options.

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

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

The agreements define "cause" to mean willful and continuous neglect of such executive officer's duties or responsibilities or willful misconduct by the executive officer that is materially and manifestly injurious to Athersys. "Good reason" includes, among other things, demotion, salary reduction, relocation, failure to provide an executive officer with adequate and appropriate facilities and termination by the executive officer within 90 days of a change in control. A "change in control" occurs when (1) a person or group of persons purchases 50% or more of our consolidated assets or a majority of our voting shares, or (2) if, following a public offering, the directors of Athersys immediately following the offering no longer constitute a majority of the Board of Directors. Upon a change in control, or if the named executive officer should die or become permanently disabled, all unvested stock options become immediately vested and exercisable. As of December 31, 2011, none of the named executive officers held unvested stock options.

In the event that an executive officer is terminated for cause or as a result of death, we would be obligated to pay full base salary and other benefits, including any unpaid expense reimbursements, through the date of termination, and would have no further obligations to the executive officer. In the event that an executive officer is unable to perform duties as a result of a disability, we would be obligated to pay full base salary and other benefits until employment is terminated and for a period of twelve months from the date of such termination.

Additionally, in 2005, in connection with the restructuring of the Company's internal programs, the Board established an incentive program intended to promote retention and motivation of our executives. The program provides the named executive officers financial protection in the event of certain merger or acquisition or asset sale transactions, obligating us to make a payment to the named executive officers representing five percent of the consideration received from the transaction.

**Table of Contents**

The table below reflects the amount of compensation payable to each named executive officer in the event of termination of such executive's employment, pursuant to such executive's employment agreement. The amounts shown assume that such termination was effective as of December 31, 2011 and thus includes amounts earned through such time and are estimates of the amounts that would be paid out to executives upon their termination.

	<b>Executive Benefit and Payments Upon Separation</b>	<b>Termination Without Cause or Voluntary For Good Reason(1)</b>
<b>Gil Van Bokkelen</b>	Cash Severance Payment	\$ 606,750
	Continuation of Benefits	\$ 23,944
	Total	\$ 630,694
<b>William (BJ) Lehmann, Jr.</b>	Cash Severance Payment	\$ 173,357
	Continuation of Benefits	
	Total	\$ 173,357
<b>John Harrington</b>	Cash Severance Payment	\$ 520,071
	Continuation of Benefits	\$ 23,944
	Total	\$ 544,015
<b>Robert Deans</b>	Cash Severance Payment	\$ 150,000
	Continuation of Benefits	
	Total	\$ 150,000
<b>Laura Campbell</b>	Cash Severance Payment	\$ 112,682
	Continuation of Benefits	
	Total	\$ 112,682

- (1) Does not include any amounts payable upon a change in control pursuant to the incentive program established in 2005 as described on the preceding page.

**Table of Contents****Director Compensation Table for 2011**

The following table summarizes compensation paid to our non-employee Directors in 2011:

Name(a)	Fees Earned or Paid in Cash (\$)(b)	Option Awards (\$)(1)(d)	Total (\$)(h)
Lee E. Babiss	\$ 47,250	\$ 34,950	\$ 82,200
Ismail Kola	\$ 44,625	\$ 34,950	\$ 79,575
George M. Milne, Jr.	\$ 52,625	\$ 34,950	\$ 87,575
Lorin J. Randall	\$ 66,500	\$ 34,950	\$ 101,450
Jack L. Wyszomierski	\$ 53,125	\$ 34,950	\$ 88,075

(1) Amounts in column (d) do not necessarily reflect compensation actually received by our Directors. The amounts in column (d) reflect the full grant date fair value of the equity awards made during the fiscal year ended December 31, 2011, in accordance with ASC 718.

Assumptions used in the calculation of these amounts will be included in the notes to the 2011 audited consolidated financial statements.

The Directors had option awards outstanding as of December 31, 2011 for shares of Common Stock as follows: Lee Babiss 90,000; Ismail Kola 90,000; George Milne 135,000; Lorin Randall 135,000; and Jack Wyszomierski 90,000.

Under our Director compensation program for non-employee Directors prior to 2011, new Directors received an initial stock option grant to purchase 75,000 shares of Common Stock at fair market value on the date of grant, which options vest at a rate of 50% in the first year (on a quarterly basis) and 25% in each of the two years (on a quarterly basis) thereafter. Effective April 1, 2011, the Board of Directors approved a revised initial grant for new directors equal to 30,000 shares of Common Stock, which options vest at a rate of 50% in the first year (on a quarterly basis) and 25% in each of the two years (on a quarterly basis) thereafter.

Additionally, the non-employee Directors receive, at each anniversary of service, an option award to purchase 15,000 shares of Common Stock at fair market value on the date of grant. These additional awards will vest at a rate of 50% in the first year (on a quarterly basis), and 25% in each of the two years (on a quarterly basis) thereafter. Effective April 1, 2011, the Board of Directors approved a change to the vesting schedule for anniversary stock option awards such that new awards will vest quarterly over a one-year period, with such anniversary awards issued in June of each year, in connection with our annual stockholder meeting. In June 2011, all five of our non-employee Directors each received such an anniversary stock option award. Also, effective April 1, 2011, all new initial and anniversary stock option awards granted to non-employee Directors will have a term of ten years and upon the termination of the Director's service, the Director will have 18 months in which to exercise the vested portion of his options prior to forfeiture.



**Table of Contents**

For 2010, the non-employee Directors also received cash compensation of \$30,000 per year, paid quarterly, plus daily fees of \$1,500 for participating in person, or \$500 for participating by telephone, at Board of Directors meetings. The chair of the Audit Committee received additional cash compensation of \$10,000 per year, paid quarterly, and the chair of the Compensation Committee received additional cash compensation of \$6,000 per year, paid quarterly. All Audit Committee and Compensation Committee members also received additional meeting fees of \$1,000 for participating in person, or \$500 for participating by telephone, at each Audit Committee or Compensation Committee meeting. Directors, however, could not receive more than \$2,500 in any one day for participation in Board and committee meetings. Effective April 1, 2011, the Board of Directors approved a revised cash compensation program for Directors with annual retainers paid quarterly as set forth below, with no meeting fees:

Board Member	\$ 40,000
Audit Committee Chairman	\$ 15,000
Audit Committee Member	\$ 7,500
Compensation Committee Chairman	\$ 10,000
Compensation Committee Member	\$ 5,000
Nominations and Corporate Governance Committee Chairman	\$ 6,000
Nominations and Corporate Governance Committee Member	\$ 3,000

Directors are reimbursed for reasonable out-of-pocket expenses incurred while attending Board and committee meetings.

**Table of Contents**

**CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS**

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

we were, are or are to be a participant;

the amount involved exceeds \$120,000; and

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

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

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

The following table sets forth certain information known to us regarding the beneficial ownership of our Common Stock as of December 31, 2011 by:

each person known by us to beneficially own more than 5% of our Common Stock;

each of our Directors;

each of our named executive officers; and

all of our Directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock that could be issued upon the exercise of outstanding options and warrants held by that person that are exercisable within 60 days of December 31, 2011 are considered outstanding. These shares, however, are not considered outstanding when computing the percentage ownership of each other person.

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

<b>Name of Beneficial Owner</b>	<b>Number of Shares</b>	<b>Percent of Class</b>
<b>Greater Than 5% Stockholders</b>		
OrbiMed Advisors LLC and affiliates (1)	2,460,388	9.7%
Radius Venture Partners and affiliates (2)	2,400,000	9.5%
Angiotech Pharmaceuticals, Inc. (3)	1,885,890	7.7%
Aspire Capital (4)	1,266,334	5.2%
<b>Directors and Executive Officers</b>		
Gil Van Bokkelen (5)	962,304	3.8%
Lee Babiss (6)	49,688	*
John Harrington (7)	824,462	3.3%
Ismail Kola (8)	45,000	*
George Milne (9)	2,535,000	10.0%
Lorin Randall (10)	118,126	*
Jack Wyszomierski (11)	54,375	*
Laura Campbell (12)	230,829	*
Robert Deans (13)	260,000	1.1%
William (BJ) Lehmann, Jr. (14)	430,650	1.7%
All Directors and executive officers as a group (10 persons)	5,510,434	19.6%

\* Less than 1%.

- (1) A Schedule 13D/A filed with the SEC on April 29, 2011 reported that OrbiMed Advisors LLC ( OrbiMed ) beneficially owned 1,615,700 shares (1,600,450 shares beneficially owned by OrbiMed Private Investments III, LP ( OPI III ) and 15,250 shares beneficially owned by OrbiMed Associates III, LP ( Associates )) of Common Stock, 750,000 shares (742,925 shares beneficially owned by OPI III and 7,075 shares beneficially owned by Associates) of Common Stock issuable upon the exercise of warrants at \$6.00 per share and vested options for 94,688 shares of Common Stock at a weighted average exercise price of \$4.45 per share. OrbiMed Capital GP III LLC is the general partner of OPI III, pursuant to the terms of its limited partnership agreement. OrbiMed Advisors LLC acts as investment manager of

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

Associates, pursuant to the terms of its investment advisory agreement. Pursuant to these agreements and relationships, OrbiMed Advisors LLC and OrbiMed Capital GP III LLC have discretionary investment management authority with respect to the assets of these investment accounts and such authority includes the power to vote and otherwise dispose of securities purchased by OPI III and Associates. Samuel Isaly owns, pursuant to the terms of the limited liability company agreement of each of OrbiMed Advisors LLC and OrbiMed Capital GP III LLC, a controlling interest in the outstanding limited liability company interests of each such entity.

**Table of Contents**

- As a result, Isaly, OrbiMed Advisors LLC and OrbiMed Capital GP III LLC share power to direct the vote and to direct the disposition of the Common Stock. The address for OrbiMed Advisors LLC and its affiliates is 767 3rd Avenue, 30th Floor, New York, New York 10017.
- (2) A Schedule 13D/A filed with the SEC on May 7, 2008 reported that Radius Venture Partners (defined below) beneficially owned 1,600,000 shares (800,000 shares beneficially owned by Radius Venture Partners II, L.P. ( Radius II ), 103,766 shares beneficially owned by Radius Venture Partners III, L.P. ( Radius III ) and 696,234 shares beneficially owned by Radius Venture Partners III QP, L.P. ( Radius III QP )) of Common Stock and 800,000 shares (400,000 shares beneficially owned by Radius II, 51,883 shares beneficially owned by Radius III and 348,117 shares beneficially owned by Radius III QP) of Common Stock issuable upon the exercise of warrants at \$6.00 per share. Radius Venture Partners II, LLC is the general partner of Radius II. Radius Venture Partners III, LLC (together with Radius Venture Partners II, LLC, Radius Venture Partners ) is the general partner of Radius III and Radius III QP. Daniel C. Lubin and Jordan S. Davis are the managing members of Radius Venture Partners II, LLC and Radius Venture Partners III, LLC. Radius II has the sole power to vote or direct the vote and to dispose or direct the disposition of the shares beneficially owned by Radius II. Messrs. Lubin and Davis, by virtue of their positions as managing members of the general partner of Radius II, may be deemed to have the shared power to vote or direct the vote of and shared power to dispose or direct the disposition of the shares held by Radius II. Radius III has the sole power to vote or direct the vote and to dispose or direct the disposition of the shares beneficially owned by Radius III, and Radius III QP has the sole power to vote or direct the vote and to dispose or direct the disposition of the shares beneficially owned by Radius III QP. Messrs. Lubin and Davis, by virtue of their positions as managing members of the general partner of Radius III and Radius III QP, may be deemed to have the shared power to vote or direct the vote of and shared power to dispose or direct the disposition of the shares beneficially owned by Radius III and Radius III QP. Additionally, each of Daniel C. Lubin, Jordan S. Davis, Radius Venture Partners II, LLC and Radius Venture Partners III, LLC disclaim beneficial ownership of the shares beneficially owned by Radius II, Radius III and Radius III QP. The address for Radius Venture Partners and its affiliates is 400 Madison Avenue, 8th Floor, New York, New York 10017.
- (3) A Schedule 13G filed with the SEC on June 18, 2007 reported that Angiotech beneficially owned 1,885,890 shares of Common Stock and that Angiotech has sole voting and dispositive power over such shares. The address for Angiotech is 1618 Station Street, Vancouver, British Columbia, Canada V6A 1B6.
- (4) A Schedule 13G filed with the SEC on December 2, 2011 reported that Aspire Capital has direct beneficial ownership of 1,266,334 shares of Common Stock. In addition, Aspire Capital holds warrants to purchase 99,900 shares of Common Stock; however, these warrants are exercisable only if the holder beneficially owns less than 4.99% of the outstanding shares of Common Stock and, therefore, the shares underlying these warrants are not beneficially owned by Aspire Capital as of the date hereof. Aspire Capital Partners, LLC ( Aspire Partners ), as the managing member of Aspire Capital, SGM Holdings Corp. ( SGM ), as the managing member of Aspire Partners, Steven G. Martin, the president and sole shareholder of SGM and a principal of Aspire Partners, Erik J. Brown, a principal of Aspire Partners, and Christos Komissopoulos, a principal of Aspire Partners, may be deemed to have beneficial ownership of the shares of Common Stock beneficially owned by Aspire Capital. Each of Aspire Partners, SGM, Mr. Martin, Mr. Brown, and Mr. Komissopoulos disclaims beneficial ownership of the shares of Common Stock held by Aspire Capital. The address for Aspire Capital and its affiliates is 155 North Wacker Drive, Suite 1600, Chicago, Illinois 60606.
- (5) Includes warrants to purchase 5,318 shares of Common Stock at \$6.00 per share. Also includes vested options for 737,500 shares of Common Stock at a weighted average exercise price of \$5.01 per share.
- (6) Includes vested options for 49,688 shares of Common Stock at a weighted average exercise price of \$3.12 per share.
- (7) Includes warrants to purchase 5,318 shares of Common Stock at \$6.00 per share. Also includes vested options for 722,500 shares of Common Stock at a weighted average exercise price of \$5.01 per share.
- (8) Includes vested options for 45,000 shares of Common Stock at a weighted average exercise price of \$2.80 per share.
- (9) Includes 10,000 shares beneficially owned individually and warrants to purchase 5,000 shares of Common Stock at \$6.00 per share beneficially owned individually. Also includes 1,600,000 shares (800,000 shares beneficially owned by Radius II, 103,766 shares beneficially owned by Radius III, and 696,234 shares beneficially owned by Radius III QP) of Common Stock. Also includes 800,000 shares (400,000 shares beneficially owned by Radius II, 51,883 shares beneficially owned by Radius III, and 348,117 shares beneficially owned by Radius III QP) of Common Stock issuable upon the exercise of warrants at \$6.00 per share. Dr. Milne is a venture partner of each of Radius II, Radius III and Radius III QP and disclaims beneficial ownership of the reported securities except to the

**Table of Contents**

- extent of his pecuniary interest therein. Also includes vested options for 120,000 shares of Common Stock owned by Dr. Milne at a weighted average exercise price of \$4.06 per share.
- (10) Includes vested options for 118,126 shares of Common Stock at a weighted average exercise price of \$5.75 per share.
  - (11) Includes vested options for 54,375 shares of Common Stock at a weighted average exercise price of \$3.04 per share.
  - (12) Includes warrants to purchase 266 shares of Common Stock at \$6.00 per share. Also includes vested options for 217,500 shares of Common Stock at a weighted average exercise price of \$5.02 per share.
  - (13) Includes vested options for 260,000 shares of Common Stock at a weighted average exercise price of \$5.02 per share.
  - (14) Includes warrants to purchase 1,250 shares of Common Stock at \$6.00 per share. Also includes vested options for 422,500 shares of Common Stock at a weighted average exercise price of \$5.01 per share.

**Table of Contents****SELLING STOCKHOLDER**

The following table presents information regarding the selling stockholder as of December 31, 2011. Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us.

<b>Selling Stockholder</b>	<b>Shares Beneficially Owned Before Offering (1)</b>	<b>Percentage of Outstanding Shares Beneficially Owned Before Offering</b>	<b>Shares to be Sold in the Offering</b>	<b>Shares Beneficially Owned After Offering</b>	<b>Percentage of Outstanding Shares Beneficially Owned After Offering</b>
Aspire Capital (2)	1,266,334(3)	5.2%	8,000,000	432,900	1.8%

- (1) Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In general, a person is deemed to be the beneficial owner of (i) any shares of our common stock over which such person has sole or shared voting power or investment power, plus (ii) any shares which such person has the right to acquire beneficial ownership of within 60 days, whether through the exercise of options, warrants or otherwise. The percentage of ownership set forth above assumes the sale by the Company to Aspire Capital of all shares being offered pursuant to this prospectus and is based on 24,487,260 shares of our common stock outstanding as of December 31, 2011 in addition to the Commitment Shares and the Initial Purchase Shares issued pursuant to the Purchase Agreement, together with securities exercisable or convertible into shares of common stock within 60 days of the date hereof for the selling stockholder.
- (2) Steven G. Martin, Erik J. Brown and Christos Komissopoulos, the principals of Aspire Partners, may be deemed to have shared voting and investment power over the shares being offered under this prospectus. Aspire Capital is not a registered broker-dealer or an affiliate of a registered broker-dealer.
- (3) Prior to its acquisitions under the Purchase Agreement, Aspire Capital beneficially owned 333,000 shares of our common stock and warrants to purchase an additional 99,900 shares of common stock; however, these warrants are exercisable only if the holder beneficially owns less than 4.99% of the outstanding shares of common stock and, therefore, the shares underlying these warrants are not beneficially owned by Aspire Capital as of the date hereof. As of the date hereof, 933,334 shares of our common stock have been acquired by Aspire Capital under the Purchase Agreement, consisting of the Commitment Shares and the Initial Purchase Shares. The Company may elect in its sole discretion to sell to Aspire Capital up to an additional number of shares under the Purchase Agreement equal to \$19.0 million in value, but Aspire Capital does not presently beneficially own those shares as determined in accordance with the rules of the SEC.

---

**Table of Contents**

**THE ASPIRE CAPITAL TRANSACTION**

**General**

On November 11, 2011, we entered into the Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over the 24-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital the Commitment Shares and Aspire Capital purchased the Initial Purchase Shares. Concurrently with entering into the Purchase Agreement, we also entered into the Registration Rights Agreement, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement. On November 17, 2011, we entered into Amendment No. 1 to the Purchase Agreement, which raised the Floor Price (as defined below) from \$1.40 to \$1.45 per share, as required by The NASDAQ Capital Market for compliance with its rules.

As of December 31, 2011, there were 24,487,260 shares of our common stock outstanding. The 8,000,000 shares of our common stock offered hereby represent approximately 32.7% of the total number of shares of our common stock outstanding as of December 31, 2011. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering under the Securities Act 8,000,000 shares of our common stock, which includes the Commitment Shares and the Initial Purchase Shares that have already been issued to Aspire Capital and an additional 7,066,666 shares of common stock that we may issue to Aspire Capital after the registration statement of which this prospectus is a part is declared effective under the Securities Act. All 8,000,000 shares of common stock are being offered pursuant to this prospectus.

After the SEC has declared effective the registration statement of which this prospectus is a part, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per business day, up to \$19.0 million of our common stock in the aggregate at a Purchase Price calculated by reference to the prevailing market price of our common stock over a preceding 12-business day period (as more specifically described below); however, no sale pursuant to a Purchase Notice may exceed \$500,000 per trading day.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 100,000 shares, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on The NASDAQ Capital Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that in no event will any shares of common stock be sold at a Purchase Price less than \$1.45, or the Floor Price, unless and until such time as the stockholders of the Company approve the transaction contemplated by the Purchase Agreement. This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. Additionally, the Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement if such shares proposed to be issued and sold, when aggregated with all other shares of the Company's common stock that Aspire Capital and its affiliates beneficially own, would result in Aspire Capital and its affiliates beneficially owning more than 19.99% of the Company's then issued and outstanding common stock.



---

## **Table of Contents**

There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us. The rights and obligations of Aspire Capital under the Purchase Agreement are not assignable or transferable.

### **Purchase of Shares under the Purchase Agreement**

Under the Purchase Agreement, we may direct Aspire Capital to purchase up to 100,000 shares of our common stock per trading day so long as no sale pursuant to such Purchase Notice may exceed \$500,000 per trading day. The Purchase Price of such shares is equal to the lesser of:

the lowest sale price of our common stock on the purchase date on the principal market of the common stock, or the Principal Market, during normal trading hours; or

the arithmetic average of the three lowest closing sale prices for our common stock on the Principal Market during the twelve consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 100,000 shares we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on The NASDAQ Capital Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 90% of the closing price on the Principal Market on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by the Company in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of (a) 95% of the volume-weighted average price for our common stock traded on the Principal Market during normal trading hours:

on the VWAP Purchase Date, if the aggregate shares traded on the Principal Market have exceeded the VWAP Purchase Share Volume Maximum; or

the portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the Principal Market has exceeded the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of the common stock falls below the VWAP Minimum Price Threshold;

or (b) the closing price on the VWAP Purchase Date.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the period(s) used to compute the Purchase Price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

### **Compliance with NASDAQ Capital Market Rules**

The Purchase Agreement provides that, absent approval of the transactions contemplated by the Purchase Agreement by our stockholders, we and Aspire Capital shall not effect any sales under the Purchase Agreement at a purchase price less than \$1.45 per share. We currently do not intend to seek stockholder approval of the transactions contemplated by the Purchase Agreement.

## **Table of Contents**

### **Beneficial Ownership Limitation**

Under the Purchase Agreement, the Company and Aspire Capital may not effect any sales of shares of our common stock if such shares proposed to be issued and sold, when aggregated with all other shares of our common stock beneficially owned by Aspire Capital and its affiliates, would result in the beneficial ownership by Aspire Capital and its affiliates of more than 19.99% of our then issued and outstanding shares of common stock.

### **Events of Default**

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following events of default:

the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale of our shares of common stock, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; provided, however, that in connection with any post-effective amendment to such registration statement that is required to be declared effective by the SEC, such lapse or unavailability may continue for a period of no more than thirty consecutive business days, which such period shall be extended for an additional thirty business days if we receive a comment letter from the SEC in connection therewith;

the suspension from trading or failure of our common stock to be listed on a Principal Market (as defined in the Purchase Agreement) for a period of three (3) consecutive business days;

the delisting of our common stock from the NASDAQ Capital Market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the NASDAQ Global Select Market, the NASDAQ Global Market, the NYSE Amex Equities or the OTC Bulletin Board;

our transfer agent's failure to issue to Aspire Capital shares of our common stock which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;

any breach by us of the representations, warranties, covenants or other term or condition contained in the Purchase Agreement or any related agreements that would reasonably be expected to have a material adverse effect except, in the case of a breach of a covenant which is reasonably curable, only if such breach continues for a period of at least five business days;

if we become insolvent or are generally unable to pay our debts as they become due; or

any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

### **Our Termination Rights**

The Purchase Agreement may be terminated by us at any time, at our discretion, without any cost to us.

### **No Short-Selling or Hedging by Aspire Capital**

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging, which establishes a net short position with respect to our common stock during any time prior to the termination of the Purchase

Agreement.

**Table of Contents****Effect of Performance of the Purchase Agreement on Our Stockholders**

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 8,000,000 shares registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 24 months from the date of this prospectus. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline or to be highly volatile. Sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

**Amount of Potential Proceeds to be Received under the Purchase Agreement**

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to \$20.0 million of shares of our common stock. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement, which could exceed 8,000,000 shares, and is subject to daily limits. The following table sets forth the amount of proceeds we would receive from Aspire Capital from the sale of shares at varying purchase prices in addition to the 666,667 Initial Purchase Shares that were sold to Aspire Capital for \$1.0 million:

Assumed Average Purchase Price	Number of Additional Shares to be Sold if Full Purchase(1)	Percentage of Outstanding Shares After Giving Effect to the Aspire Capital Transaction(2)	Proceeds from the Sale of Shares to Aspire Capital Under the Common Stock Purchase Agreement
\$1.45	7,066,666	22.4%	\$ 10,246,666
\$2.00	7,066,666	22.4%	\$ 14,133,332
\$2.50	7,066,666	22.4%	\$ 17,666,665
\$3.00	6,333,333	20.5%	\$ 18,999,999
\$3.50	5,428,571	18.1%	\$ 18,999,999

- (1) Excludes 266,667 Commitment Shares and 666,667 Initial Purchase Shares issued under the Purchase Agreement.
- (2) All denominators used include the number of shares outstanding as of December 31, 2011, which includes the Commitment Shares and the Initial Purchase Shares previously issued to Aspire Capital, and the number of additional shares set forth in the adjacent column which we would have sold to Aspire Capital. The numerator is based on the number of additional shares which we would have sold under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column.

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

We are authorized to issue 100,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share.

**Common Stock**

This section describes the general terms and provisions of our common stock. For more detailed information, you should refer to our Certificate of Incorporation and Bylaws, copies of which have been filed with the SEC.

Holders of shares of common stock will be entitled to receive dividends if and when declared by the board of directors from funds legally available therefor, and, upon liquidation, dissolution or winding-up of our company, will be entitled to share ratably in all assets remaining after payment of liabilities. The holders of shares of common stock will not have any preemptive rights, but will be entitled to one vote for each share of common stock held of record. Stockholders will not have the right to cumulate their votes for the election of directors. The shares of common stock offered hereby, when issued, will be fully paid and nonassessable.

**Preferred Stock**

This section describes the general terms and provisions of our preferred stock. For more detailed information, you should refer to our Certificate of Incorporation and Bylaws, copies of which have been filed with the SEC.

Our board of directors is authorized, without action by our stockholders, to designate and issue up to 10,000,000 shares of preferred stock, par value \$0.001 per share, in one or more series. The board of directors can fix the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings, acquisitions and other corporate purposes could, under certain circumstances, have the effect of delaying, deferring or preventing a change in control of us and could adversely affect the market price of our common stock. We do not have any shares of preferred stock outstanding, and we have no current plans to issue any preferred stock.

**Transfer Agent and Registrar**

We have appointed Computershare Investor Services as the transfer agent and registrar for our common stock.

**Listing**

Our common stock is listed on The NASDAQ Capital Market under the symbol ATHX.

---

**Table of Contents**

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS**

**General**

The following is a discussion of the material U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common stock by a non-U.S. holder, as defined below, that acquires our common stock pursuant to this offering. This discussion assumes that a non-U.S. holder will hold our common stock issued pursuant to this offering as a capital asset within the meaning of Section 1221 of the Code. This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular investor in light of the investor's individual circumstances. In addition, this discussion does not address (i) U.S. federal non-income tax laws, such as gift or estate tax laws, (ii) state, local or non-U.S. tax consequences, (iii) the special tax rules that may apply to certain investors, including, without limitation, banks, insurance companies, financial institutions, controlled foreign corporations, passive foreign investment companies, broker-dealers, grantor trusts, personal holding companies, taxpayers who have elected mark-to-market accounting, tax-exempt entities, regulated investment companies, real estate investment trusts, a partnership or other entity or arrangement classified as a partnership for United States federal income tax purposes or other pass-through entities, or an investor in such entities or arrangements, or U.S. expatriates or former long-term residents of the United States, (iv) the special tax rules that may apply to an investor that acquires, holds, or disposes of our common stock as part of a straddle, hedge, constructive sale, conversion or other integrated transaction, or (v) the impact, if any, of the alternative minimum tax.

This discussion is based on current provisions of the Code, applicable U.S. Treasury Regulations promulgated thereunder, judicial opinions, and published rulings of the Internal Revenue Service, or the IRS, all as in effect on the date of this prospectus and all of which are subject to differing interpretations or change, possibly with retroactive effect. We have not sought, and will not seek, any ruling from the IRS or any opinion of counsel with respect to the tax consequences discussed herein, and there can be no assurance that the IRS will not take a position contrary to the tax consequences discussed below or that any position taken by the IRS would not be sustained.

As used in this discussion, the term "U.S. person" means a person that is, for U.S. federal income tax purposes, (i) a citizen or individual resident of the United States, (ii) a corporation (or other entity taxed as a corporation) created or organized (or treated as created or organized) in the United States or under the laws of the United States or any state thereof or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (iv) a trust if (A) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust, or (B) it has in effect a valid election under applicable U.S. Treasury Regulations to be treated as a U.S. person. As used in this discussion, the term "non-U.S. holder" means a beneficial owner of our common stock (other than a partnership or other entity treated as a partnership or as a disregarded entity for U.S. federal income tax purposes) that is not a U.S. person.

The tax treatment of a partnership and each partner thereof will generally depend upon the status and activities of the partnership and such partner. A holder that is treated as a partnership for U.S. federal income tax purposes or a partner in such partnership should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it and its partners of the acquisition, ownership and disposition of our common stock.

THIS DISCUSSION IS ONLY A SUMMARY OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, INCLUDING THE APPLICABILITY AND EFFECT OF ANY STATE, LOCAL, AND NON-U.S. TAX LAWS, AS WELL AS U.S. FEDERAL ESTATE AND GIFT TAX LAWS, AND ANY APPLICABLE TAX TREATY.

**Table of Contents****Income Tax Consequences of an Investment in Common Stock*****Distributions on Common Stock***

As discussed under **Dividend Policy**, we do not anticipate paying dividends. If we pay cash or distribute property to holders of shares of common stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the holder's adjusted tax basis in our common stock. Any remaining excess will be treated as gain from the sale or exchange of the common stock and will be treated as described under **Gain or Loss on Sale, Exchange or Other Taxable Disposition of Common Stock** below.

Dividends paid to a non-U.S. holder that are not effectively connected with the non-U.S. holder's conduct of a trade or business in the United States generally will be subject to withholding of U.S. federal income tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder that wishes to claim the benefit of an applicable tax treaty withholding rate generally will be required to (i) complete IRS Form W-8BEN (or other applicable form) and certify under penalties of perjury that such holder is not a U.S. person and is eligible for the benefits of the applicable tax treaty or (ii) if our common stock is held through certain foreign intermediaries, satisfy the relevant certification requirements of applicable U.S. Treasury Regulations. These forms may need to be periodically updated.

A non-U.S. holder eligible for a reduced rate of withholding of U.S. federal income tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under an applicable income tax treaty and the manner of claiming the benefits of such treaty (including, without limitation, the need to obtain a U.S. taxpayer identification number).

Dividends that are effectively connected with a non-U.S. holder's conduct of a trade or business in the United States, and, if required by an applicable income tax treaty, attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States, are subject to U.S. federal income tax on a net income basis at the U.S. federal income tax rates generally applicable to a U.S. holder and are not subject to withholding of U.S. federal income tax, provided that the non-U.S. holder establishes an exemption from such withholding by complying with certain certification and disclosure requirements. Any such effectively connected dividends (and, if required, dividends attributable to a U.S. permanent establishment or fixed base) received by a non-U.S. holder that is treated as a foreign corporation for U.S. federal income tax purposes may be subject to an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty.

***Gain or Loss on Sale, Exchange or Other Taxable Disposition of Common Stock***

Any gain recognized by a non-U.S. holder on a sale or other taxable disposition of our common stock generally will not be subject to U.S. federal income tax, unless:

- (i) the gain is effectively connected with a trade or business of the non-U.S. holder in the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment or fixed base of the non-U.S. holder),
- (ii) the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met, or
- (iii) we are or have been a United States real property holding corporation, or a USRPHC, for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the non-U.S. holder held the common stock, and, in the case where the shares of our common stock are regularly traded on an established securities market, the non-U.S. holder holds or held (at any time during the shorter of the five-year period ending on the date of disposition or the

## **Table of Contents**

non-U.S. holder's holding period) more than 5% of our common stock. A corporation generally is a USRPHC if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we currently are a USRPHC, and we expect to remain a USRPHC.

Any gain recognized by a non-U.S. holder that is described in clause (i) or (iii) of the preceding paragraph generally will be subject to tax at the U.S. federal income tax rates generally applicable to a U.S. person and be required to file a U.S. tax return. Such non-U.S. holders are urged to consult their tax advisors regarding the possible application of these rules. Any gain of a corporate non-U.S. holder that is described in clause (i) above may also be subject to an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. An individual non-U.S. holder that is described in clause (ii) of such paragraph generally will be subject to a flat 30% tax (or a lower applicable tax treaty rate) on the U.S. source capital gain derived from the disposition, which may be offset by U.S. source capital losses during the taxable year of the disposition.

## **Information Reporting and Backup Withholding**

We generally must report annually to the IRS and to each non-U.S. holder of our common stock the amount of dividends paid to such holder on our common stock and the tax, if any, withheld with respect to those dividends. Copies of the information returns reporting those dividends and withholding may also be made available to the tax authorities in the country in which the non-U.S. holder is a resident under the provisions of an applicable income tax treaty or agreement. Information reporting also is generally required with respect to the proceeds from sales and other dispositions of our common stock to or through the U.S. office (and in certain cases, the foreign office) of a broker.

Under some circumstances, U.S. Treasury Regulations require backup withholding of U.S. federal income tax, currently at a rate of 28% (scheduled to increase to 31% in 2011), on reportable payments with respect to our common stock. A non-U.S. holder generally may eliminate the requirement for information reporting (other than in respect to dividends, as described above) and backup withholding by providing certification of its foreign status, under penalties of perjury, on a duly executed applicable IRS Form W-8 or by otherwise establishing an exemption. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that a holder is a U.S. person.

Backup withholding is not a tax. Rather, the amount of any backup withholding will be allowed as a credit against a non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such non-U.S. holder to a refund, provided that certain required information is timely furnished to the IRS. Non-U.S. holders should consult their own tax advisors regarding the application of backup withholding and the availability of and procedure for obtaining an exemption from backup withholding in their particular circumstances.



**Table of Contents**

**PLAN OF DISTRIBUTION**

The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

ordinary brokers transactions;

transactions involving cross or block trades;

through brokers, dealers, or underwriters who may act solely as agents;

at the market into an existing market for the common stock;

in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;

in privately negotiated transactions; or

any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling stockholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling stockholder may transfer the shares of common stock by other means not described in this prospectus.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions. The selling stockholder and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

Aspire Capital is an underwriter within the meaning of the Securities Act.

Neither we nor Aspire Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Aspire Capital, any other shareholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information. Pursuant to a requirement of the Financial Industry Regulatory Authority, or FINRA, the maximum commission or discount and other compensation to be received by any FINRA member or independent broker-dealer shall not be greater than eight percent (8%) of the gross proceeds received by us for the sale of any securities being registered pursuant to Rule 415 under the Securities Act.

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have agreed to indemnify Aspire Capital and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is

**Table of Contents**

unavailable, to contribute amounts required to be paid in respect of such liabilities. Aspire Capital has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Aspire Capital specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

**Table of Contents**

**LEGAL MATTERS**

The validity of the issuance of the shares of common stock offered by this prospectus will be passed upon for us by Jones Day.

**EXPERTS**

The consolidated financial statements of Athersys, Inc. at December 31, 2010 and 2009, and for each of the three years in the period ended December 31, 2010, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act to register our common stock being offered in this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement or the exhibits and schedules filed thereto. For further information about us and the common stock offered by this prospectus, we refer you to the registration statement and the exhibits and schedules filed with the registration statement. Any statement contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement is not necessarily complete and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

You may read and copy any materials we file with the SEC, including the registration statement, at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549, on official business days during the hours of 10:00 a.m. to 3:00 p.m. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is <http://www.sec.gov>. Information on or accessible through the SEC's website is not a part of this prospectus. You may also inspect our SEC reports and other information at our website at [www.athersys.com](http://www.athersys.com). Information on or accessible through our website is not a part of this prospectus.

We are subject to the information reporting requirements of the Exchange Act, as amended, and file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above.

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<b>AUDITED CONSOLIDATED FINANCIAL STATEMENTS</b>	
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2009 and 2010</u>	F-3
<u>Consolidated Statements of Operations for each of the years ended December 31, 2008, 2009 and 2010</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for each of the years ended December 31, 2008, 2009 and 2010</u>	F-5
<u>Consolidated Statements of Cash Flow for each of the years ended December 31, 2008, 2009 and 2010</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
<b>UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS</b>	
<u>Unaudited Condensed Consolidated Balance Sheets as of December 31, 2010 and September 30, 2011</u>	I-1
<u>Unaudited Condensed Consolidated Statements of Operations for the nine months ended September 30, 2010 and 2011</u>	I-2
<u>Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2010 and 2011</u>	I-3
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	I-4

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Athersys, Inc.

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

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

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

Cleveland, Ohio

/s/ ERNST & YOUNG LLP

March 25, 2011

**Table of Contents**

Athersys, Inc.

Consolidated Balance Sheets

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

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

*See accompanying notes to consolidated financial statements.*





**Table of Contents**

Athersys, Inc.

## Consolidated Statements of Operations

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

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

F-4

**Table of Contents**

Athersys, Inc.

## Consolidated Statements of Stockholders Equity

*(In Thousands, Except Share Amounts)*

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

*See accompanying notes to consolidated financial statements.*

**Table of Contents**

Athersys, Inc.

## Consolidated Statements of Cash Flows

*(In Thousands)*

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

*See accompanying notes to consolidated financial statements.*

---

**Table of Contents**

*Athersys, Inc.*

*Notes to Consolidated Financial Statements*

**A. Background**

We are a biopharmaceutical company engaged in the discovery and development of therapeutic products in one business segment. Operations consist primarily of research and product development activities.

**B. Accounting Policies**

**Principles of Consolidation**

The consolidated financial statements include our accounts and results of operations and those of our wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Investments in joint ventures are accounted for using the equity method when we do not control the investee, but have the ability to exercise significant influence over the investee's operations and financial policies.

**Revenue Recognition**

Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, manufacturing revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under Accounting Standards Codification (ASC) 605-25, *Multiple-Element Arrangements*, (which originated primarily from the guidance in EITF 00-21) to assess whether they have standalone value and objective and reliable evidence of fair value, and if so, are accounted for as a single unit. We then recognize revenue for each unit based on the culmination of the earnings process under ASC 605-S25 (issued as SAB Topic 13) and our estimated performance period for the single units of accounting based on the specific terms of each collaborative agreement. We subsequently adjust the estimated performance periods, if appropriate, on a prospective basis based upon available facts and circumstances. Future changes in estimates of the performance period may materially impact the timing of future revenue recognized. Amounts received prior to satisfying the revenue recognition criteria for contract revenues are recorded as deferred revenue in the accompanying balance sheets. Reimbursement amounts (other than those accounted for using collaboration accounting) paid to us are recorded on a gross basis in the statements of operations as contract revenues.

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

Similarly, grant revenue consists of funding under cost reimbursement programs primarily from federal and state sources for qualified research and development activities performed by us, and as such, are not based on estimates that are susceptible to change. Such amounts are invoiced (unless prepaid) and recorded as revenue as tasks are completed. Included in 2010 grant revenues is a grant of \$733,000 received from the Internal Revenue Service under section 48D of the Internal Revenue Code for qualifying therapeutic discovery investments that have been incurred.

**Cash and Cash Equivalents**

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

**Table of Contents**

*Athersys, Inc.*

*Notes to Consolidated Financial Statements, (continued)*

**B. Accounting Policies, continued**

**Research and Development**

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

**Collaborative Arrangements**

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

**Clinical Trial Costs**

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

**Royalties**

We may be required to make royalty payments to certain parties based on product sales under license agreements. We did not pay any royalties during the three-year period ended December 31, 2010.

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

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

**Table of Contents**

*Athersys, Inc.*

*Notes to Consolidated Financial Statements, (continued)*

**B. Accounting Policies, continued**

**Long-Lived Assets**

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

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.

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

**Patent Costs and Rights**

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

**Comprehensive Income (Loss)**

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

**Concentration of Credit Risk**

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

**Use of Estimates**

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

**Stock-Based Compensation**

We recognize stock-based compensation expense on the straight-line method and use a Black-Scholes option-pricing model to estimate the grant-date fair value of share-based awards. The expected term of options granted represent the period of time that option grants are expected to be outstanding. We use the simplified method to calculate the expected life of option grants given our limited history and beginning in 2010, determine volatility



**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements, (continued)***B. Accounting Policies, continued****Stock-Based Compensation, continued**

by using our historical stock volatility. Prior to 2010, we determined volatility by using the historical stock volatility of other companies with similar characteristics since we did not have meaningful historical volatility of our own stock at that time. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

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

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

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

	2008	December 31, 2009	2010
Volatility	69.6%	89.5%	<b>119.5%</b>
Risk-free interest rate	3.0%	2.4%	<b>1.0%</b>
Expected life of option	5.09 years	5.01 years	<b>4.09 years</b>
Expected dividend yield	0.0%	0.0%	<b>0.0%</b>

**Income Taxes**

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

We had no liability for uncertain income tax positions as of December 31, 2010 and 2009. Our policy is to recognize potential accrued interest and penalties related to the liability for uncertain tax benefits, if applicable, in income tax expense. Net operating loss and credit carryforwards since inception remain open to examination by taxing authorities, and will for a period post utilization.

**Net Loss per Share**

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



Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

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

Warrants to purchase 5,125,496 shares of common stock for each of the years ended December 31, 2010, 2009 and 2008.

F-10

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements, (continued)***B. Accounting Policies, continued****Recently Issued Accounting Standards**

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

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

**Reclassifications**

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

**C. Equipment**

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

**D. Financial Instruments***Investments in Available-for-Sale Securities*

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



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

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

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

The following table provides a summary of the financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2010 (in thousands):

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

Fair value is based upon quoted market prices in active markets. We had no Level 2 or Level 3 assets at December 31, 2010. We review and reassess the fair value hierarchy classifications on a quarterly basis. Changes from one quarter to the next related to the observability of inputs to a fair value measurement may result in a reclassification between hierarchy levels. There have been no such reclassifications.

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

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

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

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

F-12

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

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

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

*Financing Arrangements*

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

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

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

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

In December 2009, we entered into a collaboration with Pfizer to develop and commercialize MultiStem to treat inflammatory bowel disease (IBD) for the worldwide market. Under the terms of the agreement, we received a non-refundable up-front license and technology access payment of \$6.0 million from Pfizer and receive research



---

**Table of Contents**

*Athersys, Inc.*

*Notes to Consolidated Financial Statements, (continued)*

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

funding and support. In addition, we are also eligible to receive milestone payments upon the successful achievement of certain development, regulatory and commercial milestones, for which we evaluated the nature of the events triggering these contingent payments and concluded that these events constituted substantive milestones that will be recognized as revenue in the period in which the underlying triggering event occurs. No revenue for milestones was recognized in 2010 or 2009.

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

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

*Angiotech*

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

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

*RTI Biologics, Inc.*

In September 2010, we entered into an agreement with RTI, a provider of orthopedic and other biologic implants, under which we provided RTI a license to our Multipotent Adult Progenitor Cell (MAPC) technologies to enable RTI to develop and commercialize MAPC technology-based biologic implants exclusively for certain



**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements, (continued)***E. Collaborations and Revenue Recognition, continued**

orthopedic applications in the bone graft substitutes market. Under the terms of the agreement, we will receive a \$5 million license fee in installments, of which \$3.0 million is guaranteed and \$2.0 million is contingent on future milestone events. The first \$1.0 million of guaranteed fees was received at inception, with the remaining \$2.0 million to be received in \$1.0 million installments in each of December 2010 and March 2011. The December 2010 installment was received timely, and the final \$1.0 million to be received in March 2011 is reflected in receivables on the balance sheet at December 2010. We are also eligible to receive milestone payments upon the successful achievement of certain development and commercial milestones. Included in these milestones are two \$1.0 million license fee payments that are contingent on certain events. We evaluated the nature of the events triggering these contingent payments and concluded that these events are substantive and that revenue will be recognized in the period in which the underlying triggering event occurs. In addition, we will receive tiered royalties on worldwide commercial sales, if any, of implants using our technologies. No milestone or royalty revenue was recognized in 2010.

We evaluated the facts and circumstances and determined the RTI agreement had obligations constituting deliverables and concluded that it has multiple deliverables, including deliverables relating to the grant of a license to our technology and performance of research and development services, and concluded that these deliverables should be combined into a single unit of accounting. We recognize the license fee ratably on a straight-line basis over the estimated performance period, which began in September 2010 and is estimated to be completed in the fourth quarter of 2011.

**F. Capitalization**

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

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

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

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

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

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements, (continued)***G. Stock-Based Compensation**

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

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

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

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

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

**Table of Contents***Athersys, Inc.**Notes to Consolidated Financial Statements, (continued)***G. Stock-Based Compensation, 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
\$1.35 3.20	584,938	5.28	\$ 2.59	234,317	4.62	\$ 2.40
\$4.00 4.99	137,000	6.89	\$ 4.32	101,209	6.83	\$ 4.34
\$5.00 7.80	3,585,000	5.63	\$ 5.07	3,585,000	5.63	\$ 5.07
\$90.66	1,075	2.39	\$ 90.66	1,075	2.39	\$ 90.66
	<b>4,308,013</b>			<b>3,921,601</b>		

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

**H. Income Taxes**

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

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

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

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

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

**I. Profit Sharing Plan and 401(k) Plan**

We have a profit sharing and 401(k) plan that covers substantially all employees and allows for discretionary contributions by us. We made no contributions to this plan for the three-year period ended December 31, 2010.

F-17

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

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

	2010				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Revenues	\$ 1,740	\$ 1,871	\$ 1,996	\$ 3,332	\$ 8,939
Net loss	\$ (2,561)	\$ (3,077)	\$ (3,688)	\$ (2,051)	\$ (11,377)
Basic and diluted net loss per common share	\$ (0.14)	\$ (0.16)	\$ (0.19)	\$ (0.11)	\$ (0.60)

  

	2009				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Revenues	\$ 370	\$ 436	\$ 484	\$ 869	\$ 2,159
Net loss	\$ (3,625)	\$ (3,347)	\$ (3,380)	\$ (5,014)	\$ (15,366)
Basic and diluted net loss per common share	\$ (0.19)	\$ (0.18)	\$ (0.18)	\$ (0.26)	\$ (0.81)

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

(In thousands, except share and per share data)

	December 31, 2010	September 30, 2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,105	\$ 8,539
Available-for-sale securities	13,076	8,003
Accounts receivable	2,328	177
Receivable from Angiotech	106	160
Prepaid expenses and other	329	636
Total current assets	17,944	17,515
Equipment, net	955	1,318
Deposits and other	207	28
Total assets	\$ 19,106	\$ 18,861
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,498	\$ 2,087
Accrued compensation and related benefits	580	466
Accrued clinical trial costs	207	865
Accrued expenses and other	1,012	798
Deferred revenue	5,541	2,966
Total current liabilities	8,838	7,182
Warrant liability		1,100
Deferred revenue	1,263	
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at December 31, 2010 and September 30, 2011		
Common stock, \$0.001 par value; 100,000,000 shares authorized, and 18,930,678 and 23,503,926 shares issued and outstanding at December 31, 2010 and September 30, 2011, respectively		
	19	23
Additional paid-in capital	214,174	225,228
Accumulated other comprehensive income	26	36
Accumulated deficit	(205,214)	(214,708)
Total stockholders' equity	9,005	10,579
Total liabilities and stockholders' equity	\$ 19,106	\$ 18,861

See accompanying notes to unaudited condensed consolidated financial statements.



**Table of Contents****Athersys, Inc.****Unaudited Condensed Consolidated Statements of Operations**

(In thousands, except share and per share data)

	Nine months ended September 30,	
	2010	2011
<b>Revenues</b>		
Contract revenue	\$ 4,515	\$ 6,712
Grant revenue	1,092	1,067
Total revenues	5,607	7,779
<b>Costs and expenses</b>		
Research and development	10,569	13,360
General and administrative	4,249	3,721
Depreciation	216	202
Total costs and expenses	15,034	17,283
Loss from operations	(9,427)	(9,504)
Interest income, net	165	75
Other income (expense), net	(64)	(65)
<b>Net loss</b>	<b>\$ (9,326)</b>	<b>\$ (9,494)</b>
Basic and diluted net loss per share	\$ (0.49)	\$ (0.41)
Weighted average shares outstanding, basic and diluted	18,929,436	22,966,047

*See accompanying notes to unaudited condensed consolidated financial statements.*



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

(In thousands)

	Nine months ended September 30,	
	2010	2011
<b>Operating activities</b>		
Net loss	\$ (9,326)	\$ (9,494)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	216	202
Realized gain on available-for-sale securities		(55)
Stock-based compensation	1,246	401
Issuance of common stock to former lenders		607
Change in fair value of warrant liability		(695)
Amortization of premium on available-for-sale securities and other	192	55
Changes in operating assets and liabilities:		
Accounts receivable	(2,387)	2,151
Receivable from Angiotech	97	(54)
Prepaid expenses and other assets		(206)
Accounts payable and accrued expenses	793	919
Deferred revenue	1,157	(3,838)
Net cash used in operating activities	(7,992)	(10,007)
<b>Investing activities</b>		
Purchase of available-for-sale securities	(8,834)	(12,508)
Maturities of available-for-sale securities	8,253	17,672
Purchase of equipment	(384)	(565)
Net cash (used in) provided by investing activities	(965)	4,599
<b>Financing activities</b>		
Proceeds from issuance of common stock and warrants, net of offering costs		11,842
Net cash provided by financing activities		11,842
(Decrease) increase in cash and cash equivalents	(8,957)	6,434
Cash and cash equivalents at beginning of the period	11,167	2,105
Cash and cash equivalents at end of the period	\$ 2,210	\$ 8,539

*See accompanying notes to unaudited condensed consolidated financial statements.*

**Table of Contents**

**Athersys, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Background and Basis of Presentation**

We are a biopharmaceutical company engaged in the discovery and development of therapeutic products in one business segment. Our operations consist primarily of research and product development activities.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in this filing. The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ( GAAP ) for interim financial information and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair presentation of financial position and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Our critical accounting policies, estimates and assumptions are described in Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

**2. Recently Issued Accounting Standards**

In September 2009, Accounting Standards Codification ( ASC ) 605-25, *Multiple-Element Arrangements*, was updated (Accounting Standards Update ( ASU ) No. 2009-13) related to revenue recognition for arrangements with multiple elements. The revised guidance provides for two significant changes to the existing guidance, the first relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting, which will likely result in the requirement to separate more deliverables within an arrangement leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Together, these changes are likely to result in earlier recognition of revenue for multiple-element arrangements than under previous guidance. The new guidance also significantly expands the disclosures required for multiple-element revenue arrangements. The new guidance was effective for us for new arrangements or modifications to existing arrangements entered into on or after January 1, 2011 and had no effect on our financial statements for the nine months ended September 30, 2011. The adoption of this new guidance may have the potential effect of less future revenue deferral for new collaborations than we have historically experienced.

In March 2010, ASC 605-28, *Milestone Method of Revenue Recognition*, was amended (ASU No. 2010-17) related to the ratification of the application of the proportional performance model of revenue recognition when applied to milestones in research and development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The new guidance was effective for us for new arrangements entered into on or after January 1, 2011. The adoption of this guidance had no effect on our financial statements, since we have been historically recognizing milestone revenue consistent with this guidance.

**Table of Contents****3. Net Loss per Share**

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

	Nine months ended September 30,	
	2010	2011
Outstanding options	4,188,950	4,490,601
Restricted stock units		39,300
Outstanding warrants	5,125,496	6,435,496
	9,314,446	10,965,397

**4. Comprehensive Loss**

All components of comprehensive loss, including net loss, are reported in the financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources.

Below is a reconciliation, in thousands, of net loss to comprehensive loss for all periods presented.

	Nine months ended September 30,	
	2010	2011
Net loss	\$ (9,326)	\$ (9,494)
Unrealized loss on available-for-sale securities	(24)	(26)
Proportionate share of comprehensive income for equity method investment		36
Comprehensive loss	\$ (9,350)	\$ (9,484)

**5. Fair Value of Financial Instruments**

Our available-for-sale securities are comprised of U.S. government obligations as of September 30, 2011.

The inputs used to measure fair value are classified into the following hierarchy:

Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.

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

Level 3 Unobservable inputs for the asset or liability.

The following table provides a summary of the fair values of our assets and liabilities measured at fair value on a recurring basis as of September 30, 2011 (in thousands):

Edgar Filing: ATHERSYS, INC / NEW - Form 424B3

Description	Fair Value Measurements at September 30, 2011 Using			
	Balance as of September 30, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities	\$ 8,003	\$ 8,003	\$	\$
Warrant liability	\$ 1,100	\$	\$	\$ 1,100

I-5

**Table of Contents****5. Fair Value of Financial Instruments, continued**

Fair value is based upon quoted market prices in active markets for our level 1 investments. The estimated fair value of warrants accounted for as liabilities, representing a level 3 fair value measure, was determined on the issuance date and subsequently adjusted to its fair value at each financial reporting date. The fair value of the warrants is estimated using the expected volatility based on the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization, using a Black-Scholes valuation model with the following inputs at September 30, 2011:

Exercise price	\$ 3.55
Market value of stock at end of period	\$ 1.76
Expected volatility	82.96%
Risk-free interest rate	0.98%
Expected life (in years)	4.34

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

	Nine months ended September 30, 2011
Balance January 1, 2011	\$ 0
Issuance of warrants February 2011	1,795
Gain included in other (income) expense, net for the period	(695)
Balance September 30, 2011	\$ 1,100

We review and reassess the fair value hierarchy classifications on a quarterly basis. Changes from one quarter to the next related to the observability of inputs in a fair value measurement may result in a reclassification between fair value hierarchy levels.

The following is a summary of available-for-sale securities (in thousands) at September 30, 2011 and December 31, 2010, respectively:

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Estimated Fair Value
<b>September 30, 2011:</b>				
U.S. government obligations, including government-backed agencies	\$ 8,003	\$	\$	\$ 8,003
<b>December 31, 2010:</b>				
U.S. government obligations, which included government-backed agencies	\$ 11,034	\$	\$ 23	\$ 11,057
Corporate debt securities	2,016		3	2,019
	\$ 13,050	\$	\$ 26	\$ 13,076

We had \$55,000 in realized gains during the nine months ended September 30, 2011 and no realized losses on the sale of available-for-sale securities for any of the periods presented. Unrealized gains and losses on our available-for-sale securities are excluded from earnings and are reported as a separate component of stockholders' equity within accumulated other comprehensive income until realized. When and if available-for-sale securities are sold in the future, the cost of the securities will be specifically identified and used.



**Table of Contents****5. Fair Value of Financial Instruments, continued**

to determine any realized gain or loss. The net unrealized gain on available-for-sale securities was \$0 and \$26,000 as of September 30, 2011 and December 31, 2010, respectively.

The amortized cost of and estimated fair value of available-for-sale securities at September 30, 2011 by contractual maturity are shown below (in thousands). Actual maturities may differ from contractual maturities because the issuers of the securities may have the right to repay the obligations without prepayment penalties.

	September 30, 2011	
	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 8,003	\$ 8,003

**6. Collaborative Arrangements and Revenue Recognition***Pfizer Inc.*

In December 2009, we entered into a collaboration with Pfizer Inc. ( Pfizer ) to develop and commercialize MultiStem to treat inflammatory bowel disease ( IBD ) for the worldwide market. Under the terms of the agreement, we received a non-refundable up-front payment from Pfizer and receive research funding and support. In addition, we are eligible to receive milestone payments upon the successful achievement of certain development, regulatory and commercial milestones, for which we evaluated the nature of the events triggering these contingent payments and concluded that these events constituted substantive milestones that will be recognized as revenue in the period in which the underlying triggering event occurs.

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

We evaluated the facts and circumstances of the agreement and determined the Pfizer agreement has multiple deliverables that should be combined into a single unit of accounting. We recognize the license and technology access fee and research and development funding ratably on a straight-line basis over the estimated performance period, which is estimated to be completed in 2012. Further, we are measuring manufacturing revenue beginning upon the culmination of the earnings process and recognizing it over the remainder of the performance period of the bundled unit of accounting. Prepaid license and technology access fee and prepaid research and development funding are recorded as deferred revenue and are amortized on a straight-line basis over the performance period.

*Angiotech Pharmaceuticals, Inc.*

In 2006, we established a co-development partnership with Angiotech Pharmaceuticals, Inc. ( Angiotech ) to develop and commercialize MultiStem to treat certain cardiovascular diseases, such as acute myocardial infarction ( AMI ). As part of the collaboration, Angiotech made an equity investment and agreed to share in the costs of clinical development, and we were entitled to receive cash payments and an additional equity investment based on the successful achievement of specified clinical development and commercialization milestones. We evaluated the nature of the events triggering these contingent payments and concluded that these events constituted substantive milestones that will be recognized as revenue in the period in which the underlying triggering event occurs. The parties jointly fund clinical development activity and would share net profits from the future sale of approved products.

## **Table of Contents**

### **6. Collaborative Arrangements and Revenue Recognition, continued**

We jointly fund clinical development activities with Angiotech in accordance with our co-development collaboration, and \$160,000 was due from Angiotech as of September 30, 2011. Our clinical costs for the nine months ended September 30, 2011 and 2010 are reflected net of Angiotech's cost-sharing amount of \$312,000 and \$521,000, respectively. See Note 11 regarding termination of this collaboration in November 2011.

#### *RTI Biologics, Inc.*

In September 2010, we entered into an agreement with RTI Biologics, Inc. ( RTI ), a provider of orthopedic and other biologic implants, under which we provided RTI a license to our technologies to enable RTI to develop and commercialize biologic implants exclusively for certain orthopedic applications in the bone graft substitutes market. Under the terms of the agreement, we received \$3.0 million of guaranteed license fee payments and are entitled to receive \$2.0 million of license fee payments contingent on future milestone events. We are also eligible to receive milestone payments upon the successful achievement of certain development and commercial milestones, including the \$2.0 million contingent license fee payments mentioned above. We evaluated the nature of the events triggering these contingent payments and concluded that these events are substantive and that revenue will be recognized in the period in which the underlying triggering event occurs. In addition, we will receive tiered royalties on worldwide commercial sales, if any, of implants using our technologies.

We evaluated the facts and circumstances and determined that the RTI agreement has multiple deliverables that should be combined into a single unit of accounting. We recognize the \$3.0 million guaranteed license fee ratably on a straight-line basis over the estimated performance period, which is estimated to be completed in the fourth quarter of 2011.

### **7. Stock-Based Compensation**

Our equity incentive plans authorize an aggregate of 5,500,000 shares of common stock for awards to employees, directors and consultants. Our 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.

As of September 30, 2011, a total of 971,174 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 4,529,901 shares of common stock were outstanding (which includes options to purchase 1,075 shares of common stock related to our old option plans prior to our merger in June 2007). For the nine-month periods ended September 30, 2011 and 2010, stock compensation expense was approximately \$401,000 and \$1,246,000, respectively. At September 30, 2011, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately \$931,000, which is expected to be recognized by the end of 2015 using the straight-line method.

### **8. Issuance of Common Stock and Warrants**

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

In connection with the registered direct offering in February 2011, our former lenders were entitled to a milestone payment in the amount of \$810,000, of which \$202,500 was paid in cash and \$607,500 was paid through the issuance of our common stock to the former lenders at \$2.96 per share in February 2011. This milestone payment is included in other expense in the consolidated statement of operations.



**Table of Contents**

In September 2011, we issued 1,345 shares of our common stock to Katholieke Universiteit Leuven as the last of four annual stock issuances pursuant to a license agreement.

**9. Warrant Liability**

We account for common stock warrants as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. Registered common stock warrants that could require cash settlement are accounted for as liabilities. We classify these warrant liabilities on the consolidated balance sheet as a non-current liability, which is revalued to fair value at each reporting date subsequent to the initial issuance. We use a Black-Scholes valuation model to value the warrant liability at its fair value (see Note 5). Changes in the fair market value of the warrant are reflected in the consolidated statement of operations as other income (expense).

The warrants issued in the February 2011 registered direct offering contain a provision for net cash settlement in the event that there is a fundamental transaction (e.g., merger, sale of substantially all assets, tender offer, or share exchange). If a fundamental transaction occurs in which the consideration issued consists of all cash or stock in a non-public company, then the warrant holder has the option to receive cash equal to the fair value of the remaining unexercised portion of the warrant. Also, the warrants generally provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, the warrant agreements do not expressly state that a net cash settlement is prohibited. Therefore, even though a cashless exercise feature is available to the holder, in the absence of an express prohibition on net cash settlement, the warrants may be subject to cash settlement, as it is not within the absolute control of the Company to provide freely-tradable shares in all circumstances.

The warrants issued in February 2011 have been classified as liabilities, as opposed to equity, due to the potential cash settlement upon the occurrence of certain events as described above, and are recorded at a fair value of \$1.1 million at September 30, 2011.

As of September 30, 2011, we had the following outstanding warrants to purchase shares of common stock:

Number of underlying shares	Exercise Price	Expiration
4,976,470	\$6.00	June 8, 2012
149,026	\$5.00	June 8, 2014
1,310,000	\$3.55	February 2, 2016
6,435,496		

**10. Income Taxes**

We have net operating loss and research and development tax credit carryforwards that may be used to reduce future taxable income and tax liabilities. Our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses.

**11. Subsequent Events**

In November 2011, we entered into a Common Stock Purchase Agreement with Aspire Capital Fund, LLC (Aspire Capital), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock through an equity purchase agreement over a two-year term, subject to our election to sell any such shares. Under the agreement, we have the right to sell shares, subject to certain volume limitations and a minimum floor price, at a modest discount to the prevailing market price. As part of the agreement, Aspire Capital made an initial investment of \$1.0 million in us through the purchase of our common stock and will receive additional

**Table of Contents**

shares as compensation for the commitment. In connection with this initial investment, our former lenders were entitled to a milestone payment in the amount of \$100,000, of which \$25,000 was paid in cash and \$75,000 was paid through the issuance of our common stock to the former lenders at our election in November 2011.

In November 2011, we reached an agreement with Angiotech to terminate the collaboration agreement and license between the parties, reflecting a change in Angiotech's business and financial strategy. As a result of the termination, Athersys regained all rights for developing its stem cell technologies and products for cardiovascular disease indications, including acute myocardial infarction, congestive heart failure, chronic ischemia, and peripheral vascular disease, and Angiotech will no longer have any license rights or options with respect to Athersys technologies and products. Additionally, while Angiotech will retain its 1.9 million shares of Athersys common stock, Athersys will receive advance notice of Angiotech's intention to sell these shares and the parties will cooperate in such sale. Angiotech will make its final payment of \$160,000 in connection with collaboration activities through September 30, 2011, but will have no further obligations to Athersys. The receivable from Angiotech on the September 30, 2011 balance sheet reflects the amount to be collected. Though the termination will affect Athersys' future costs of development for ongoing cardiovascular programs, such as AMI, it also removes a significant encumbrance affecting the Company's business development opportunities with other pharmaceutical, biotechnology and medical products companies. In the case of a new AMI collaboration, Angiotech shall be entitled to a future payment from Athersys equal to a percentage of the upfront cash license fees we receive from the third-party partner, but shall be entitled to no other payments or residual economic participation, such as milestones, royalties and profit-sharing.

Table of Contents

**8,000,000 Shares**

**Athersys, Inc.**

**Common Stock**

**PROSPECTUS**

**January 17, 2012**