

ATHERSYS, INC / NEW  
Form 424B4  
October 26, 2012  
**Table of Contents**

Filed Pursuant to Rule 424(b)(4)  
Registration Nos. 333-184333 and 333-184600

**PROSPECTUS**

**19,802,000 Shares**

**Athersys, Inc.**

**Common Stock**

We are offering 19,802,000 shares of our common stock. Our common stock is listed on The NASDAQ Capital Market under the symbol ATHX. The last sale price of our common stock on October 25, 2012, as reported by The NASDAQ Capital Market, was \$1.01 per share.

Investing in our common stock involves risk. Please read carefully the section entitled **Risk Factors** beginning on page 7 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.

	Per Share	Total
Public Offering Price	\$ 1.01	\$ 20,000,020
Underwriting Discounts and Commissions <sup>(1)</sup>	\$ 0.0606	\$ 1,200,001

Proceeds to Us, Before Expenses	\$ 0.9494	\$ 18,800,019
---------------------------------	-----------	---------------

(1) Additional compensation is further described in the section entitled "Underwriting" in this prospectus. We have granted the underwriters the right to purchase, exercisable within a 30-day period, up to an additional 2,970,300 shares of our common stock solely to cover over-allotments.

The underwriters expect to deliver the shares of common stock against payment on or about October 31, 2012.

*Sole Book-Running Manager*

**Piper Jaffray**

**First Analysis Securities Corporation**

**Prospectus dated October 25, 2012**

**Table of Contents**

## TABLE OF CONTENTS

	Page
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	7
<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	24
<u>USE OF PROCEEDS</u>	26
<u>CAPITALIZATION</u>	27
<u>COMMON STOCK PRICE RANGE</u>	28
<u>DIVIDEND POLICY</u>	28
<u>DILUTION</u>	29
<u>SELECTED CONSOLIDATED FINANCIAL DATA</u>	31
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	33
<u>BUSINESS</u>	49
<u>MANAGEMENT</u>	70
<u>CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS</u>	85
<u>BENEFICIAL OWNERSHIP OF COMMON STOCK</u>	86
<u>DESCRIPTION OF CAPITAL STOCK</u>	88
<u>MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS</u>	89
<u>UNDERWRITING</u>	92
<u>LEGAL MATTERS</u>	94
<u>EXPERTS</u>	94
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	94
<u>INFORMATION WE INCORPORATE BY REFERENCE</u>	94

We have not authorized anyone to provide any information other than that contained in or incorporated by reference into 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. We are not 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 incorporated herein by reference. 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 biotechnology company that is focused primarily in the field of regenerative medicine. We are committed to the discovery and development of best-in-class therapies designed to extend and enhance the quality of human life. We have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. We are developing our lead platform product, MultiStem<sup>®</sup>, a patented and proprietary allogeneic stem cell product that has been evaluated in two completed Phase I clinical trials and is currently being evaluated in two ongoing Phase II clinical trials. Our current clinical development programs are focused on treating inflammatory & immune disorders, neurological conditions, cardiovascular disease, 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 and could be used to treat a range of disease indications. MultiStem is a patented and proprietary product that enhances tissue repair and healing in multiple ways, including reducing inflammatory damage, protecting tissue that is at risk following acute or ischemic injury, and promoting formation of new blood vessels in regions of ischemic injury. The cells comprising MultiStem appear to be responsive to the environment in which they are administered, homing to sites of injury and active disease response and producing proteins that may provide benefit in acute or chronic conditions. In contrast to traditional pharmaceutical products or biologics that generally act through a single biological mechanism of action, the MultiStem product can enhance healing and tissue repair through multiple distinct mechanisms acting simultaneously, by producing a range of therapeutic factors and dynamically responding to the needs of the body resulting in a more effective therapeutic response.

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

We believe the therapeutic and commercial potential for MultiStem to be very broad, applying to many areas of significant unmet medical need. We are pursuing opportunities in several potential multi-billion dollar markets. While traditional pharmaceuticals 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 in different formulations and with different delivery approaches to efficiently treat a range of disease indications.

We have already evaluated the use of MultiStem as a potential treatment for a range of disease indications. Working with an international network of leading investigators and prominent research and

## **Table of Contents**

clinical institutions, and through our own internal efforts, we have explored the potential for MultiStem to be used in acute and chronic forms of inflammatory & immune disorders, neurological conditions, cardiovascular disease, certain pulmonary conditions, and other areas.

To date, we have successfully advanced MultiStem into five clinical stage programs, each of which addresses a significant area of medical need and represents a large commercial market opportunity. MultiStem has been evaluated in two completed clinical trials, one exploring the potential to treat patients that have suffered a heart attack, and the other evaluating the potential to reduce graft versus host disease, or GvHD, as well as other complications, and to provide supportive care to patients being treated for leukemia or related conditions. MultiStem is currently being evaluated in two additional clinical programs in the inflammatory & immune disease and neurological 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, a leading clinical center in Europe, and a research collaborator, has recently received authorization to conduct an initial clinical trial evaluating administration of MultiStem in patients that have received a solid organ transplant.

In addition to our MultiStem programs, we have applied our pharmaceutical discovery capabilities to identify and develop novel pharmaceuticals to treat obesity, related metabolic conditions such as diabetes, and certain neurological indications, such as schizophrenia, as well as 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. Our 5HT2c agonist program for obesity works by the same mechanism as Lorcaserin, which was recently approved by the U.S. Food and Drug Administration, or FDA, for the treatment of obesity, and we believe our compounds may have the potential for providing superior weight loss performance, while also achieving a superior safety and tolerability profile. In addition, we have demonstrated our compounds are complementary with other agents that have been approved by the FDA for treating obesity. Furthermore, certain compounds that we developed may also have relevance in other disease areas, such as the treatment of schizophrenia. We are actively exploring partnership opportunities for our 5HT2c program in both the obesity and schizophrenia areas.

## **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.*** MultiStem represents a novel therapeutic modality for the treatment of inflammatory & immune system disorders, neurological conditions and cardiovascular disease, as well as in other areas. MultiStem may be administered like other biologics, intravenously, via catheter, or by local injection. The cells appear to be responsive to their environment, homing to sites of injury and active disease response and producing proteins that may provide benefit in acute or chronic conditions. Additionally, MultiStem cell therapy may deliver therapeutic benefit through several distinct mechanisms of action, including reducing inflammatory damage, protecting tissue that is at risk following acute or ischemic injury, and promoting formation of new blood vessels in regions of ischemic injury. We are conducting a number of clinical studies with the intent to establish proof of concept and/or proof of biological activity in a number of important disease areas where the cell therapies would be expected to have benefit in inflammatory & immune system dysfunctions, neurological conditions and cardiovascular

**Table of Contents**

disease. Our focus is on conducting well-designed studies early in the clinical development process to establish a robust foundation for subsequent development, partnership and expansion into complementary areas. We are committed to a rigorous clinical and regulatory framework, which we believe has helped to advance our programs efficiently, and is also a result of the quality of our regulatory submissions and transparency in our discussions with the FDA have resulted in a successful regulatory partnership that has helped to advance our programs efficiently.

***Continue to Refine and Improve our Manufacturing and Related Processes and Deepen our Understanding of Therapeutic Mechanisms of Action.*** A key aspect of MultiStem is its substantial expansion capacity *ex vivo* relative to other cell types. This enables large scale production of the clinical product, which enables greater consistency, specificity and cost of goods advantages over other cell therapies. We plan to build on this intrinsic biological advantage by continuing to advance and optimize our production and process development approaches, further developing new manufacturing 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 licensing and product co-development arrangements with qualified commercial partners to achieve these objectives. We anticipate that this strategy will help us to develop a portfolio of high quality product development opportunities, enhance our clinical development and commercialization capabilities, and increase our ability to generate value from our proprietary technologies. Over the past decade, we have entered into technology licensing arrangements and established product commercialization and co-development partnerships with companies such as Pfizer, Angiotech Pharmaceuticals, Inc., or Angiotech, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Johnson & Johnson, Wyeth and RTI Biologics, Inc., or RTI. 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 inflammatory & immune disorders, neurological conditions, cardiovascular disease, and other areas. We are committed to exploring potential clinical indications where our therapies may achieve best-in-class profile, and where we can address significant unmet medical needs. In order to achieve this goal, over the past decade, we have established collaborative research relationships with investigators from many leading research and clinical institutions across the United States and Europe, including the Cleveland Clinic, Case Western Reserve University, University of Minnesota, the Medical College of Georgia, the University of Oregon Health Sciences Center, the University of Texas Health Science Center at Houston, the University of Pittsburgh Medical Center, the Katholieke Universiteit Leuven, or KUL, and other institutions. Through this network of collaborations, we have studied MultiStem in a range of preclinical models that reflect various types of human disease or injury in the

## **Table of Contents**

cardiovascular, neurological, and immunological areas. 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.*** We have a broad intellectual property estate that covers our proprietary products and technologies, as well as methods of production and methods of use. Our intellectual property is important to our business and we take significant steps to protect its value. We have ongoing research and development efforts, both through internal activities and through collaborative research activities with others, which aim to develop new intellectual property and enable us to file patent applications that cover new applications of our existing technologies or product candidates, including MultiStem and other opportunities.

### **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**

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B4

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. 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, other than documents that we file with the SEC that are incorporated by reference into this prospectus.



**Table of Contents**

**The Offering**

Common stock offered by us	19,802,000 shares (or 22,772,300 shares if the underwriters exercise their option to purchase additional shares to cover over-allotments in this offering in full).
Common stock to be outstanding immediately after this offering	49,317,343 shares (or 52,287,643 shares if the underwriters exercise their option to purchase additional shares to cover over-allotments in this offering in full).
Use of proceeds	We currently expect to use the net proceeds from this offering for working capital and general corporate purposes. See Use of Proceeds.
Risk factors	You should carefully read and consider the information set forth in Risk Factors beginning on page 7 of this prospectus before investing in our common stock.
NASDAQ Capital Market symbol	ATHX.
The number of shares of common stock to be outstanding after the offering is based on 29,515,343 shares of common stock outstanding as of June 30, 2012. Unless otherwise indicated, all information this prospectus assumes no exercise by the underwriters of their option to purchase additional shares of common stock to cover over-allotments in this offering and excludes:	

4,299,698 shares of common stock reserved for issuance upon the exercise of options and restricted stock units granted under our equity compensation plans with a weighted average exercise price of \$4.37 per option share as of June 30, 2012;

5,806,853 shares of common stock that may be issued upon exercise of outstanding warrants with a weighted average exercise price of \$2.48 per share as of June 30, 2012, 4,347,827 of which are issuable pursuant to warrants that currently have an exercise price of \$2.07 with full ratchet anti-dilution price protection, subject to certain exceptions;

500,000 shares of common stock that we issued from June 30, 2012 through September 30, 2012, and any additional shares that we may issue, to Aspire Capital Fund, LLC, or Aspire Capital, pursuant to a common stock purchase agreement we entered into on November 11, 2011 (the agreement, as amended, is referred to in this prospectus as the Aspire Purchase Agreement), which provides that, upon the terms and subject to the conditions and limitations set forth therein and as of September 30, 2012, Aspire Capital is committed to purchase up to an aggregate of an additional \$17.7 million of shares of our common stock over the term of the Aspire Purchase Agreement, should we elect to sell shares to Aspire Capital; and

37,500 shares of common stock that we issued from June 30, 2012 through September 30, 2012, and additional shares we intend to issue, to our former lenders as milestone payments under the terms of our loan agreement, as further described in the section entitled Dilution in this prospectus.



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

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

	Year Ended December 31,			Six Months Ended June 30,	
	2011	2010	2009	2012	2011
<b>Consolidated Statement of Operations Data:</b>					
Contract and grant revenues	\$ 10,344	\$ 8,939	\$ 2,159	\$ 5,404	\$ 5,425
Operating expenses	24,124	20,450	17,774	13,172	11,770
Loss from operations	(13,780)	(11,511)	(15,615)	(7,768)	(6,345)
Other income (expense), net	34	134	249	(281)	(808)
Net loss	\$ (13,746)	\$ (11,377)	\$ (15,366)	\$ (8,049)	\$ (7,153)
Basic and diluted net loss per common share	\$ (0.59)	\$ (0.60)	\$ (0.81)	\$ (0.29)	\$ (0.32)

Weighted average shares used in computing basic and diluted net loss per common share

	23,239	18,930	18,928	27,477	22,693
--	--------	--------	--------	--------	--------

Please see Note B to our audited consolidated financial statements incorporated by reference into 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,	June 30,
	2011	2012
<b>Consolidated Balance Sheet Data:</b>		
Cash, cash equivalents and available-for-sale securities	\$ 12,784	\$ 10,857
Working capital	6,986	7,810
Total assets	15,701	13,335
Warrant liabilities and note payable	983	4,684
Total stockholders' equity	7,298	4,503

---

**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 or incorporated by reference into this prospectus, including our consolidated financial statements and related notes incorporated by reference into this prospectus, 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 \$14 million in 2011, \$11 million in 2010 and \$15 million in 2009 and \$8 million for the six months ended June 30, 2012. As of June 30, 2012, we had an accumulated deficit of \$227 million, and anticipate incurring additional losses for at least the next several years. We expect to spend significant resources over the next several years to enhance our technologies and to fund research and development of our pipeline of potential products. To date, substantially all of Athersys' revenue has been derived from corporate collaborations, license agreements and government grants. In order to achieve profitability, we must develop products and technologies that can be commercialized by us or through our existing or future collaborations. Our ability to generate revenues and become profitable will depend on our ability, alone or with potential collaborators, to timely, efficiently and successfully complete the development of our product candidates. We have never earned revenue from selling a product and we may never do so, as none of our product candidates have been approved for sale, since they are currently being tested in humans and animal studies. We cannot assure you that we will ever earn revenue or that we will ever become profitable. If we sustain losses over an extended period of time, we may be unable to continue our business.

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

The development of our product candidates will require a commitment of substantial funds to conduct the costly and time-consuming research, which may include preclinical and clinical testing, necessary to obtain regulatory approvals and bring our products to market. Net cash used in our operations was \$14 million in 2011, \$11 million in 2010 and \$5 million in 2009, and \$10 million for the six months ended June 30, 2012.

At June 30, 2012, we had \$10.9 million of cash and cash equivalents, 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;

**Table of Contents**

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

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

the time and cost involved in obtaining regulatory approvals;

the cost of manufacturing our product candidates;

expenses related to complying with 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 Aspire 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 Aspire Purchase Agreement on any given day and during the term of the agreement is limited. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the Aspire 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 \$17.7 million remaining under the Aspire Purchase Agreement as of September 30, 2012, 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

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B4

at all. In recent years, it has been difficult for companies to raise capital due to a variety of factors, which may or may not continue. To the extent we raise additional capital through the sale of equity securities, including to Aspire Capital, the ownership position of our existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

Failure to successfully address ongoing liquidity requirements will have a material adverse effect on our business. If we are unable to obtain additional capital on acceptable terms when needed, we may be

## **Table of Contents**

required to take actions that harm our business and our ability to achieve cash flow in the future, including possibly the surrender of our rights to some technologies or product opportunities, delaying our clinical trials or curtailing or ceasing operations.

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

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

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

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

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.



## **Table of Contents**

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

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

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

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

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

Currently, our material collaborations and licensing arrangements are our collaboration with Pfizer to develop and commercialize MultiStem<sup>®</sup> for the treatment of IBD, our collaboration with RTI to develop and commercialize Multipotent Adult Progenitor Cell, or MAPC<sup>®</sup>, 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.

## **Table of Contents**

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

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

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

*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;

---

**Table of Contents**

levels of reimbursement and insurance coverage; and

activities by our competitors.

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

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

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

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

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

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

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

Many factors, known and unknown, can adversely affect clinical trials and the ability to evaluate a product's efficacy. During the course of treatment, patients can die or suffer other adverse events for

## **Table of Contents**

reasons that may or may not be related to the proposed product being tested. Even if unrelated to our product, certain events can nevertheless adversely impact our clinical trials. As a result, our ability to ultimately develop and market the products and obtain revenues would suffer.

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

the size of the patient population;

the proximity of patients to clinical sites;

the eligibility criteria for the trial;

the perceptions of investigators and patients regarding safety; and

the availability of other treatment options.

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

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

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

## **Table of Contents**

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

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

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

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

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

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

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

## **Table of Contents**

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 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;



**Table of Contents**

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.

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.

## **Table of Contents**

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

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

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

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

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

An adverse ruling arising out of any intellectual property dispute, including an adverse decision as to the priority of our inventions, could undercut or invalidate our intellectual property position. An adverse

---

**Table of Contents**

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 U.S., or 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 Limited, or Mesoblast, Pluristem Therapeutics Inc., or Pluristem, Arena Pharmaceuticals, Inc., or Arena Pharmaceuticals, Orexigen Therapeutics, Inc., or Orexigen Therapeutics, 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 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

## **Table of Contents**

compete effectively would have a significant adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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



## **Table of Contents**

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

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

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

changes and limits in import and export controls;

increases in custom duties and tariffs;

changes in currency exchange rates;

economic and political instability;

changes in government regulations and laws;

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

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

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

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

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

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

In some cases we may choose not to sell a product in a foreign country because it is uneconomical to do so under a system of government-imposed price controls, or because it could severely limit our profitability in the United States or other markets. In such cases, a foreign government or patent office may terminate any intellectual property rights we may obtain with respect to that product. Such a termination could enable competitors to produce and sell our product in that market. Furthermore, such products may be exported into the

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B4

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.

## **Table of Contents**

*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 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



## **Table of Contents**

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**

*Future sales, or availability for sale, of shares of common stock by stockholders could depress the market price of our common stock.*

Sales of a substantial number of shares of our common stock in the public market, or the perception that large sales could occur, could depress the market price of our common stock. As of June 30, 2012, we had 29,515,343 shares of our common stock outstanding. All of these shares are freely tradable, except for any shares held by our affiliates as defined in Rule 144 under the Securities Act. Also, as of June 30, 2012, up to 5,806,853 shares of common stock were issuable upon exercise of outstanding warrants with a weighted average exercise price of \$2.48 per share, 4,347,827 of which are issuable pursuant to warrants that currently have an exercise price of \$2.07 with full ratchet anti-dilution price protection, subject to certain exceptions.

*You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.*

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. If you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of approximately \$0.54 per share in the net tangible book value of the common stock. See the section entitled "Dilution" in this prospectus for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

*Sales of shares issuable upon the exercise of warrants will dilute your ownership interest in our company and may cause the market price of our shares to decline.*

On March 14, 2012, we closed a private placement in which we issued 4,347,827 shares of common stock and warrants to purchase up to 4,347,827 shares of common stock. The exercise of those warrants will dilute your investment. Additionally, the warrants issued in the March 2012 offering contain full-ratchet anti-dilution provision that would be triggered upon an issuance by us of shares of our common stock or securities convertible into or exchangeable for shares of our common stock at a price per share

**Table of Contents**

below the then current exercise price of the warrants, subject to certain exceptions, such as sales of common stock to Aspire Capital. To the extent that these anti-dilution provisions are triggered, including as a result of this offering, we would be required to reduce the exercise price of all of the March 2012 warrants on a full-ratchet basis, which would increase the dilutive effect that the exercise of warrants would have on your investment.

*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 documents incorporated by reference and 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 other similar expressions 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 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 and obtain all necessary regulatory approvals to commercialize our product candidates;

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

**Table of Contents**

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**

We expect to receive net proceeds of approximately \$18.3 million from the sale of shares of our common stock in this offering (or \$21.1 million if the underwriters exercise their option to purchase additional shares of common stock to cover over-allotments in this offering in full) after deducting underwriting discounts and commissions and estimated offering expenses.

We currently intend to use the net proceeds from this offering for working capital and general corporate purposes.

Pending the application of the net proceeds as described above, we may invest the net proceeds from this offering in short-term, investment grade, interest-bearing securities.

**Table of Contents****CAPITALIZATION**

The following table shows our cash and cash equivalents and capitalization as of June 30, 2012 on an actual basis and on an as adjusted basis to reflect the sale of 19,802,000 shares of our common stock offered in this offering, after deducting underwriting discounts and commissions and estimated offering expenses.

This table should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations contained elsewhere in this prospectus and our financial statements and the accompanying notes incorporated by reference into this prospectus.

	<b>As of June 30, 2012</b>	
	<b>Actual</b>	<b>As Adjusted</b>
	<b>(in thousands except share and per share data)</b>	
Cash and cash equivalents	\$ 10,857	\$ 29,157
Warrant liabilities and note payable	\$ 4,684	\$ 4,684
<b>Stockholders' equity:</b>		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at June 30, 2012, actual and as adjusted		
Common stock, \$0.001 par value; 100,000,000 shares authorized, and 29,515,343 shares issued and outstanding at June 30, 2012, actual, and                      shares issued and outstanding at June 30, 2012, as adjusted	30	50
Additional paid-in capital	231,482	249,762
Accumulated deficit	(227,009)	(227,009)
Total stockholders' equity	4,503	22,803
Total capitalization	\$ 9,187	\$ 27,487

**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.

	High	Low
<b>Year ended December 31, 2012:</b>		
First Quarter	\$ 2.33	\$ 1.49
Second Quarter	\$ 1.71	\$ 1.25
Third Quarter	\$ 1.75	\$ 1.35
Fourth Quarter (through October 25, 2012)	\$ 1.47	\$ 0.97
<b>Year ended December 31, 2011:</b>		
First Quarter	\$ 3.08	\$ 2.35
Second Quarter	\$ 3.10	\$ 2.50
Third Quarter	\$ 2.86	\$ 1.00
Fourth Quarter	\$ 2.42	\$ 1.13
<b>Year ended December 31, 2010:</b>		
First Quarter	\$ 4.40	\$ 2.32
Second Quarter	\$ 3.63	\$ 2.56
Third Quarter	\$ 3.55	\$ 2.34
Fourth Quarter	\$ 3.19	\$ 2.42

The last reported sales price for our common stock on October 25, 2012 is set forth on the cover page of this prospectus. As of September 30, 2012, there were approximately 629 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 two years or for the six months ended June 30, 2012. 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**

Investors in shares of our common stock offered in this offering will experience an immediate dilution in the net tangible book value of their common stock from the public offering price of the common stock. The net tangible book value of our common stock as of June 30, 2012 was approximately \$4.5 million, or approximately \$0.15 per share of common stock. Net tangible book value per share of our common stock is calculated by subtracting our total liabilities from our total tangible assets, which is equal to total assets less intangible assets, and dividing this amount by the number of shares of common stock outstanding.

Dilution per share represents the difference between the public offering price per share of our common stock and the adjusted net tangible book value per share of our common stock included in this offering after giving effect to this offering. After giving effect to the sale of shares of common stock offered in this offering at the offering price of \$1.01 per share and sales of common stock from June 30, 2012 through September 30, 2012, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of June 30, 2012 would have been approximately \$23.5 million, or approximately \$0.47 per share of common stock. This change represents an immediate increase in the net tangible book value of \$0.32 per share of common stock to our existing stockholders and an immediate and substantial dilution in net tangible book value of \$0.54 per share of common stock to new investors. The following table illustrates this per share dilution:

Offering price per share		\$ 1.01
Net tangible book value per share as of June 30, 2012	\$ 0.15	
Increase in net tangible book value per share attributable to new investors	\$ 0.32	
Net tangible book value per share after this offering		\$ 0.47
Dilution per share to new investors		\$ 0.54

The table and calculations set forth above are based on the number of shares of common stock outstanding as of June 30, 2012 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:

4,299,698 shares of common stock reserved for issuance upon the exercise of options and restricted stock units granted under our equity compensation plans with a weighted average exercise price of \$4.37 per option share as of June 30, 2012;

5,806,853 shares of common stock that may be issued upon exercise of outstanding warrants with a weighted average exercise price of \$2.48 per share as of June 30, 2012, 4,347,827 of which are issuable pursuant to warrants that currently have an exercise price of \$2.07 with full ratchet anti-dilution price protection, subject to certain exceptions;

shares of common stock that we may issue to Aspire Capital pursuant to the Aspire Purchase Agreement; and

shares of common stock that we intend to issue to our former lenders as milestone payments under the terms of our loan agreement, which was repaid in June 2008. Under the Loan and Security Agreement, and Supplement, dated as of November 2, 2004, by and among ABT Holding Company (formerly known as Athersys, Inc.), Advanced Biotherapeutics, Inc., Venture Lending & Leasing IV, Inc., and Costella Kirsch IV, L.P., as amended, the former lenders retain a right to receive a milestone payment of a portion of the amount from



**Table of Contents**

proceeds of certain equity financings of an amount equal to 10% of the proceeds above \$5.0 million in cumulative gross proceeds. The balance of this milestone obligation at September 30, 2012 is approximately \$300,000. As the loan agreement permits, we intend to pay 75% of the milestone payment due in connection with this offering in shares of common stock at the per-share offering price of this offering.

**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 included elsewhere in this prospectus and the consolidated financial statements and the notes thereto incorporated by reference into this prospectus.

	Year Ended December 31,					Six Months Ended June 30,	
	2011	2010	2009	2008	2007	2012	2011
	(in thousands, except share and per share data)						
<b>Consolidated Statement of Operations Data:</b>							
Revenues:							
Contract revenue	\$ 9,015	\$ 6,685	\$ 1,079	\$ 1,880	\$ 1,433	\$ 4,733	\$ 4,641
Grant revenue	1,329	2,254	1,080	1,225	1,827	671	784
<b>Total revenues</b>	<b>10,344</b>	<b>8,939</b>	<b>2,159</b>	<b>3,105</b>	<b>3,260</b>	<b>5,404</b>	<b>5,425</b>
Costs and expenses:							
Research and development	18,930	14,779	11,920	16,500	15,817	10,596	9,032
General and administrative	4,916	5,387	5,621	5,479	7,975	2,421	2,611
Depreciation	278	284	233	218	283	155	127
<b>Loss from operations</b>	<b>(13,780)</b>	<b>(11,511)</b>	<b>(15,615)</b>	<b>(19,092)</b>	<b>(20,815)</b>	<b>(7,768)</b>	<b>(6,345)</b>
Other (expense) income:							
Other (expense) income, net	(51)	(69)	(126)	48	2,017	(296)	(874)
Interest income	85	203	375	1,146	1,591	15	66
Interest expense				(94)	(1,263)		
Accretion of premium on convertible debt					(456)		
<b>Net loss</b>	<b>\$ (13,746)</b>	<b>\$ (11,377)</b>	<b>\$ (15,366)</b>	<b>\$ (17,992)</b>	<b>\$ (18,926)</b>	<b>\$ (8,049)</b>	<b>\$ (7,153)</b>
Preferred stock dividends					(659)		
Deemed dividend resulting from induced conversion of convertible preferred stock					(4,800)		
<b>Net loss attributable to common stockholders</b>	<b>\$ (13,746)</b>	<b>\$ (11,377)</b>	<b>\$ (15,366)</b>	<b>\$ (17,992)</b>	<b>\$ (24,385)</b>	<b>\$ (8,049)</b>	<b>\$ (7,153)</b>
<b>Basic and diluted net loss per common share attributable to common stockholders</b>							
	\$ (0.59)	\$ (0.60)	\$ (0.81)	\$ (0.95)	\$ (2.26)	\$ (0.29)	\$ (0.32)
Weighted average shares outstanding, basic and diluted							
	23,239,019	18,929,749	18,928,379	18,927,988	10,811,119	27,476,603	22,693,155

	December 31,					June 30,	
	2011	2010	2009	2008	2007	2012	2011
	(in thousands)						
<b>Consolidated Balance Sheet Data:</b>							
Cash and cash equivalents	\$ 8,785	\$ 2,105	\$ 11,167	\$ 12,552	\$ 13,248	\$ 10,857	\$ 4,719
Available-for-sale securities, short-term	3,999	13,076	10,135	15,460	22,477		16,194
Working capital	6,986	9,106	16,291	26,789	32,849	7,810	13,483
Available-for-sale securities, long-term			5,080	3,601	13,850		
<b>Total assets</b>	<b>15,701</b>	<b>19,106</b>	<b>28,331</b>	<b>33,877</b>	<b>52,225</b>	<b>13,335</b>	<b>23,088</b>

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B4

Warrant liabilities and note payable	983					4,684	1,873
Total stockholders' equity	7,298	9,005	18,957	31,563	47,631	4,503	12,843

31

**Table of Contents**

Effective January 1, 2012, we adopted the Financial Accounting Standards Board's, or FASB's, Accounting Standards Update, or ASU, No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income, as amended by ASU 2011-12, Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05. These updates revise the manner in which entities present comprehensive income in their financial statements. The following selected financial information revises historical information to illustrate the new presentation required by this pronouncement for the periods presented.

**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

	December 31, 2011	Year Ended December 31, 2010 (in thousands)	December 31, 2009
Net loss	\$ (13,746)	\$ (11,377)	\$ (15,366)
Items included in other comprehensive income (loss):			
Proportional share of comprehensive income of equity-method investment	28		
Unrealized loss on available-for-sale securities	(26)	(45)	(49)
Other comprehensive income (loss) items	2	(45)	(49)
<b>Comprehensive loss</b>	<b>\$ (13,744)</b>	<b>\$ (11,422)</b>	<b>\$ (15,415)</b>

---

**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 incorporated herein by reference. 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 biotechnology company that is focused primarily on 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 inflammatory & immune disorders, neurological conditions, cardiovascular disease, and other conditions. We are developing our lead platform product, MultiStem<sup>®</sup>, a patented and proprietary allogeneic stem cell product that has been evaluated in two completed 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, we have established therapeutic product development programs treating inflammatory & immune disorders, neurological conditions, cardiovascular disease, and other conditions. To date, we have advanced five programs to the clinical development stage, including the following:

**Inflammatory Bowel Disease:** IBD affects an estimated 4 million patients or more in the United States, Europe, and Japan. Current therapies for treating IBD consist of pharmaceutical and biologic drugs, representing an annual market of more than \$5 billion globally. Currently available therapies provide temporary relief or are not effective for many patients, and novel approaches are needed to improve the standard of care and help patients avoid surgical intervention. MultiStem is being evaluated in an ongoing Phase II clinical study involving administration of MultiStem to patients suffering from ulcerative colitis, or UC, the most common form of IBD. This study is being conducted with our partner, Pfizer, in UC patients who have an inadequate response or are refractory to current treatment, and is a double blind, placebo controlled trial that began enrolling patients in 2011. Enrollment of the trial is ongoing and is expected to include approximately 130 patients, with initial results expected to be reported in 2013.

**Ischemic Stroke:** Ischemic stroke affects approximately 15 million people globally each year, and approximately 2 million in the United States, Europe and Japan combined. In an ongoing Phase II clinical study, we are evaluating the administration of MultiStem to patients that have suffered an ischemic stroke. In contrast to treatment with thrombolytics, which must be administered within 3 to 4 hours after a stroke, we are treating patients one to two days after the stroke has occurred. In preclinical studies, administration of a single dose of MultiStem, even several days after a stroke, resulted in significant and durable improvements. This double blind, placebo-controlled trial is being conducted at leading stroke centers across the United States and may include sites in Europe. The study is expected to enroll approximately 136 patients. We completed the first patient cohorts, and

## **Table of Contents**

the independent safety monitoring committee found that MultiStem was safe and well tolerated at both of the doses evaluated. Patient enrollment is ongoing and for the remainder of the trial, patients will be randomized to receive either high dose MultiStem or placebo. We believe this represents a potential market opportunity of more than \$15 billion annually.

**Acute Myocardial Infarction:** We have evaluated the administration of MultiStem in a Phase I clinical study to patients that have suffered an AMI. In 2010, we announced preliminary results for this study, demonstrating a favorable safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment. One-year follow-up data suggested that the benefit observed was sustained over time. We have completed preliminary planning for a Phase II trial, which has been discussed with the FDA. Our plans to move the AMI program forward into subsequent development will depend on the availability of capital resources, progress in our other clinical studies and our business development activities.

**Hematopoietic Stem Cell Transplant / GvHD:** We have completed a Phase I 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 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 2011 and in February 2012, we released data from the study, which demonstrated the safety of MultiStem in this indication and suggested that MultiStem may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. This program has been assigned orphan drug designation from the FDA, which provides us with seven years of market exclusivity upon approval, and certain other benefits. We met with the FDA to discuss the results of the clinical study and our proposed plans for the next phase of clinical development in this area. We are currently preparing our detailed clinical study plans and look forward to finalizing our design and undertaking operational planning. Based on current plans, we intend to be ready to start this study in the second half of 2013, but the initiation will depend on the progress in our clinical trials and the achievement of certain business development and financial objectives. There are approximately 25,000 bone marrow or peripheral blood stem cell allografts performed annually, but we believe many more transplants could be performed if the risks of GvHD could be meaningfully reduced. We believe this indication represents a potential market opportunity of \$500 million annually or more.

We are also collaborating with a leading transplant group at the University of Regensburg in Germany that has recently obtained authorization to initiate an institutional sponsored clinical trial exploring the administration of MultiStem in patients following a liver transplant. We plan to provide limited financial support for this investigator-sponsored Phase I study and provide clinical grade product to conduct the trial. According to a report by Reuters Business Insight, in 2009, approximately 91,000 organ transplants were conducted. We estimate that this represents a potential market of more than \$1.5 billion annually.

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

We are in discussions with third parties about collaborating in the development of MultiStem for our current clinical programs (outside of IBD) and preclinical programs and may, under the right terms, enter into one or more business partnership(s) to advance these programs.



## **Table of Contents**

We have also collaborated with RTI on the development of products for certain orthopedic applications in the bone graft substitutes market using our stem cell technologies. RTI's product development activities are progressing, and in September 2012, we amended our agreement with RTI to accelerate \$2.0 million of contingent milestone payments in connection with ongoing technical support to assist RTI in its initial product launch. As a result, we will receive these milestone payments in 2012, and in addition, RTI will compensate us for this technical assistance. We will also receive royalty revenue from product sales when they occur, as well as potential additional milestone payments.

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 favorable attributes, including outstanding receptor selectivity, as well as greater potency and activity than other 5HT<sub>2c</sub> agonists. We have also demonstrated our compounds are complementary with other agents and believe these compounds could achieve best in class weight loss, as well as a superior safety and tolerability profile. Furthermore, we have evaluated certain compounds that exhibit a particular type of selectivity profile in preclinical models of schizophrenia and observed that these compounds exhibit potent effects. We are in discussions with multiple companies and may elect to enter into a partnership to advance the development of our 5HT<sub>2c</sub> agonist program, either for the treatment of obesity, schizophrenia, or both indications.

### *Financial*

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of \$227 million at June 30, 2012. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We have used the financing proceeds from equity and debt offerings and other sources of capital to develop our technologies, to discover and develop therapeutic product candidates, develop business collaborations and to acquire certain technologies and assets.

In March 2012, we completed a private placement financing generating net proceeds of approximately \$8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of \$2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of \$2.07 per fixed combination.

In November 2011, we entered into the Aspire 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 over a two-year term, subject to our election to sell any such shares. Under the Aspire Purchase 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 of September 30, 2012, we have received aggregate gross proceeds of \$2.3 million under the Aspire Purchase Agreement since its inception.

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.

In 2012, we were awarded grant funding aggregating \$3.6 million to further advance our MultiStem programs and cell therapy platform, including further development of MultiStem for the treatment of

**Table of Contents**

traumatic brain injury, or TBI, and further development of our cell therapy formulations and manufacturing capabilities. The sources of funding including federal, state and European organizations and are generally focused on the advancement of our preclinical MultiStem programs, as well as process development and manufacturing activities.

**Results of Operations**

Since our inception, our revenues have consisted of license fees, contract revenues and milestone payments from our collaborators, and grant proceeds primarily from federal, state and foundation grants. We have derived no revenue from the commercial sale of therapeutic products to date. Research and development expenses consist primarily of external clinical and preclinical study 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,			Six Months Ended June 30,	
	2011	2010	2009	2012	2011
Contract revenue	\$ 9,015	\$ 6,685	\$ 1,079	\$ 4,733	\$ 4,641
Grant revenue	1,329	2,254	1,080	671	784
	\$ 10,344	\$ 8,939	\$ 2,159	\$ 5,404	\$ 5,425

**Research and Development Expenses**

Type of expense	Year Ended December 31,			Six Months Ended June 30,	
	2011	2010	2009	2012	2011
Personnel costs	\$ 4,641	\$ 4,124	\$ 3,607	\$ 2,623	\$ 2,392
Research supplies	1,316	1,218	907	732	659
Facilities	944	870	826	486	479
Clinical and preclinical development costs	7,495	4,394	1,904	4,775	3,078
Sponsored research	1,408	1,149	878	624	803
Patent legal fees	1,703	1,477	1,351	681	835
Other	1,218	1,002	1,151	599	672
Stock-based compensation	205	545	1,296	76	114
	\$ 18,930	\$ 14,779	\$ 11,920	\$ 10,596	\$ 9,032

**Table of Contents****General and Administrative Expenses**

<i>Type of expense</i>	Year Ended December 31,			Six Months Ended June 30,	
	2011	2010	2009	2012	2011
Personnel costs	\$ 1,927	\$ 1,897	\$ 1,975	\$ 1,057	\$ 1,060
Facilities	270	279	299	141	134
Legal and professional fees	1,008	1,007	916	479	569
Other	1,364	1,283	919	551	696
Stock-based compensation	347	921	1,512	193	152
	\$ 4,916	\$ 5,387	\$ 5,621	\$ 2,421	\$ 2,611

**Six Months Ended June 30, 2012 and 2011**

**Revenues.** Revenues remained consistent at \$5.4 million for the six months ended June 30, 2012 and 2011. Contract revenue increased \$92,000 for the six months ended June 30, 2012 compared to the comparable period in 2011 and reflects the impact of our arrangements with Pfizer and RTI. 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 payments for manufacturing services over the estimated performance period that ended in June 2012, as well as the amortization of a \$3.0 million guaranteed license fee from the RTI collaboration over the estimated performance period that ended in 2011. Our contract revenues may also include license fees, milestone payments and royalties on compounds developed by Bristol-Myers Squibb using one of our technologies. We expect our contract revenues to decline in the second half of 2012, absent any new collaborations, and will be comprised primarily of manufacturing service revenue under the Pfizer arrangement and RTI milestone payments. Grant revenue decreased \$113,000 for the six months ended June 30, 2012 compared to the six months ended June 30, 2011 primarily due to the timing of expenditures that are reimbursed with grant proceeds and the completion of grants in 2011. 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 \$10.6 million for the six months ended June 30, 2012 from \$9.0 million in the comparable period in 2011. The increase of \$1.6 million related primarily to an increase in clinical and preclinical development costs of \$1.7 million, an increase in personnel costs of \$231,000 and an increase in research supplies of \$73,000 for the six months ended June 30, 2012 from the comparable period in 2011. These increases were partially offset by a decrease in sponsored research costs of \$179,000, a decrease in patent legal fees of \$154,000, a decrease in other research and development expenses of \$73,000 and a decrease in stock compensation expense of \$38,000. The increase in clinical and preclinical development costs for the six months ended June 30, 2012 related primarily to costs associated with our MultiStem clinical trials, including contract research organization costs and clinical manufacturing costs. The increase in personnel costs related to the addition over the past twelve months of personnel supporting our preclinical and clinical programs and annual merit increases in salaries. Sponsored research costs decreased primarily due to a decrease in grant-funded programs that require collaboration with certain academic research institutions. The decrease in patent legal costs resulted from reduced patent prosecution costs during the period. Our annual research and development expenses are not expected to increase significantly through 2012 as compared to 2011 unless we receive proceeds from additional financing or business development activities to fund advancement of additional clinical programs. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

**General and Administrative Expenses.** General and administrative expenses decreased to \$2.4 million for the six months ended June 30, 2012 from \$2.6 million in the comparable period in 2011. The \$190,000 decrease was due primarily to a decrease in legal and professional fees of \$90,000 and a

---

**Table of Contents**

decrease in other general and administrative costs of \$145,000 related to outside services, offset by an increase of \$41,000 in stock compensation expense for the six months ended June 30, 2012 from the comparable period in 2011. We expect our general and administrative expenses to continue at similar levels during 2012.

**Depreciation.** Depreciation expense increased to \$155,000 for the six months ended June 30, 2012 from \$127,000 in the comparable period in 2011 due to depreciation on new capital purchases.

**Interest Income.** Interest income represents interest earned on our cash and available-for-sale securities. Interest income decreased to \$15,000 for the six months ended June 30, 2012 from \$66,000 for the comparable period in 2011 due to the decline in our investment balances as they are used to fund our operations. We expect our 2012 interest income to reflect the impact of declining cash balances resulting from our ongoing and planned clinical and preclinical development, and interest earned on proceeds from any new financings or business transactions.

**Other (Expense) Income, net.** Other (expense) income, net, includes foreign currency gains and losses related to our activities in Europe, realized gains and losses on the sale of our assets, and increase and decreases in our warrant liabilities. Also included in other expense are cash and stock-based milestone payments aggregating \$952,000 and \$810,000 for the six months ended June 30, 2012 and 2011, respectively, paid to our former lenders in connection with our equity offerings. The market value change in our warrant liabilities was income of \$479,000 for the six months ended June 30, 2012 and expense of \$78,000 for the six months ended June 30, 2011. Also, in the six-month period ended June 30, 2012, we recognized a gain of \$183,000 related to an equity-method investment that was liquidated in the period.

***Year Ended December 31, 2011 Compared to Year Ended December 31, 2010***

**Revenues.** Revenues increased to \$10.3 million for the year ended December 31, 2011 from \$8.9 million for 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 payments for manufacturing services over the estimated performance period, as well as the amortization of a \$3.0 million guaranteed license fee from the RTI collaboration over the estimated performance period. 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 \$2.3 million for the year ended December 31, 2011 compared to the year ended December 31, 2010 primarily as a result of our arrangements with Pfizer and RTI. The estimated performance period under the Pfizer arrangement ends mid-2012 and the RTI performance period was completed in 2011. Therefore, we expect our contract revenues to decline in the second half of 2012, absent any new collaborations, and will be comprised primarily of manufacturing service revenue under the Pfizer arrangement and potential RTI milestone payments. Grant revenue decreased \$0.9 million for the year ended December 31, 2011 compared to the year ended December 31, 2010 primarily due to the timing of expenditures that are reimbursed with grant proceeds and 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. 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 \$18.9 million for the year ended December 31, 2011 from \$14.8 million in 2010. The increase of approximately \$4.1 million related primarily to an increase in clinical and preclinical development costs of \$3.1 million, an increase in personnel costs of \$517,000, an increase in sponsored research costs of \$259,000, an increase in patent legal fees of \$226,000, an increase in other costs of \$216,000, and an increase in research supply and facilities costs of \$172,000 for the year ended December 31, 2011 compared to

---

**Table of Contents**

2010. These increases were partially offset by a decrease in stock-based compensation expense of \$340,000, which declined as a result of a significant number of options becoming fully vested in 2010. The increase in clinical and preclinical development costs for the year ended December 31, 2011 related primarily to costs associated with our MultiStem clinical trials, including increased manufacturing and process development costs. Our clinical costs for the year ended December 31, 2011 and 2010 are reflected net of Angiotech's cost-sharing amount of \$312,000 and \$628,000, respectively. The Angiotech collaboration was terminated late in 2011. The increase in personnel costs related to the addition over the past twelve months of personnel supporting our preclinical and clinical programs, and annual merit increases in salaries. 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 to remain relatively consistent in 2012, but would be expected to increase if we receive proceeds from additional financing or business development activities. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

**General and Administrative Expenses.** General and administrative expenses decreased to \$4.9 million in 2011 from \$5.4 million in 2010. The \$471,000 decrease in 2011 compared to 2010 was due primarily to a decrease in stock-based compensation expense of \$574,000 from a significant number of options becoming fully vested in 2010, partially offset by an increase in other expenses of \$81,000. We expect our general and administrative expenses to continue at similar levels in 2012.

**Depreciation.** Depreciation expense remained fairly consistent at \$278,000 in 2011 and \$284,000 in 2010.

**Interest Income.** Interest income represents interest earned on our cash and available-for-sale securities. Interest income decreased to \$85,000 in 2011 from \$203,000 in 2010 due to the decline in our investment balances as they are used to fund our operations. We expect our 2012 interest income to reflect the impact of declining cash balances resulting from our ongoing and planned clinical and preclinical development, and interest earned on proceeds from any new financings or business transactions.

**Other Expense, net.** Other 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. Also included in other expense in 2011 are milestone payments aggregating \$910,000 to our former lenders that was paid in connection with our February 2011 registered direct offering and our Aspire Capital equity purchase agreement, 75% of which was settled in shares of common stock. Also included in net other income is \$812,000 recorded in 2011, reflecting a decrease in the warrant liability that resulted from our February 2011 registered direct offering, with changes in market value reflected as either other income or expense.

***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. 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.

**Table of Contents**

**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. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

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

**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, net.** 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 registered direct offering.

**Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and any available-for-sale securities on hand. At June 30, 2012 and September 30, 2012, respectively, we had \$10.9 million and \$7.9 million in cash and cash equivalents and no available-for-sale securities. We have primarily financed our operations through business collaborations, grant funding and equity financings. We conduct all of our operations through our subsidiary, ABT Holding Company. Consequently, our ability to fund our operations depends on ABT Holding Company's financial condition and its ability to make dividend payments or other cash distributions to us. There are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us.

In March 2012, we completed a private placement financing generating net proceeds of approximately \$8.1 million through the issuance of 4,347,827 shares of common stock and five-year warrants to purchase 4,347,827 shares of common stock with an exercise price of \$2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of \$2.07 per fixed combination. The warrants have full ratchet anti-dilution price protection, subject to certain exceptions.

---

**Table of Contents**

In November 2011, we entered into the Aspire 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 over a two-year term, subject to our election to sell any such shares. Under the Aspire Purchase 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. During the quarter ended June 30, 2012, we sold 100,000 shares to Aspire Capital at an average price of \$1.45 per share, and during the six-month period ended June 30, 2012, we sold 300,000 shares to Aspire Capital at an average price of \$1.72 per share. As of September 30, 2012, we received aggregate gross proceeds of \$2.3 million under the equity purchase agreement since its inception.

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.

In connection with our equity offerings, our former lenders are entitled to milestone payments until the remaining balance of an original \$2.25 million milestone is paid, and we can elect to settle up to 75% of any milestone payments through the issuance of our common stock. The remaining balance of the milestone is \$389,000 at June 30, 2012. We made cash and stock-based milestone payments of \$952,000 to our former lenders during the six-month period ended June 30, 2012. 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 until the milestone amount is paid in full. The milestone payment is payable in cash, except that if the milestone event is (2) above, we may elect to pay 75% of the milestone in shares of common stock at the per-share offering price. The lenders also received seven-year 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 June 30, 2012. As the loan agreement permits, we intend to pay 75% of the milestone payment due in connection with this offering in shares of common stock at the per share offering price of this offering.

Under the terms of our agreement with Pfizer, we are eligible to receive milestone payments of up to \$105 million upon the successful achievement of certain development, regulatory and commercial milestones, though there can be no assurance that we will achieve any milestones. No significant milestone payments have been received as of June 30, 2012. 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 would then 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, we regained ownership of all rights for developing our stem cell technologies and products for cardiovascular disease indications, including AMI, congestive heart failure, chronic ischemia, and peripheral vascular disease, and Angiotech no longer has any license rights or options with respect to our technologies and products. In the case of a new AMI collaboration, Angiotech will be entitled to a future payment from us equal to a percentage of cash license fee payments we receive 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

## **Table of Contents**

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, (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 we have 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 we have spent \$5.0 million on the clinical trial, and within 36 months of the termination agreement.

Under the terms of our RTI agreement, we initially received \$3.0 million of guaranteed license fee payments and were entitled to an additional \$2.0 million in license fee payments that were contingent upon future events. In September 2012, RTI agreed to make these payments in full by December 31, 2012, and we agreed to provide RTI with certain technical support. In accordance with the agreement, we are also eligible to receive an additional \$35.5 million in cash payments upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved. In addition, we will receive tiered royalties on worldwide commercial sales of implants using our technologies.

We remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb under our completed 2001 collaboration, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology, though there can be no assurance that we will achieve any such milestones or royalties. As of June 30, 2012, we received an aggregate amount of \$1.7 million in milestone payments and \$9.6 million in license fees since the inception of our collaboration with Bristol-Myers Squibb.

In April 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic Foundation in which we are entitled to proceeds of up to \$500,000 in the form of a forgivable loan to fund certain remaining preclinical work using MultiStem to treat congestive heart failure and for preparing the program for an investigational new drug application, or IND, with the FDA. Interest on the loan accrues at a fixed rate of 4.25% per annum, and is added to the outstanding principal. The loan will be forgiven based on the achievement of a certain milestone, unrelated to the preclinical work, within three to four years. As of June 30, 2012, we have drawn \$50,000 of this financing.

In February 2012, we were awarded grant funding aggregating \$3.6 million to further advance our MultiStem product programs and cell therapy platform. Specifically, we were awarded a Small Business Innovation Research Fast-Track grant of up to \$1.9 million from the National Institute of Neurological Disorders and Stroke to develop MultiStem for the treatment of traumatic brain injury. In addition, our subsidiary based in Belgium was awarded a \$1.2 million ( 0.9 million) grant from Belgium's Agency for Innovation by Science and Technology to further develop cell therapy formulations and manufacturing capabilities, as well as \$0.5 million in funding from a local grant to work in other areas, such as using MultiStem to treat chronic cardiovascular disease.

In 2011, we entered into an alliance with 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, or MS, through the filing of an IND. 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.

When we hold investments, our available-for-sale securities typically include United States government obligations and corporate debt securities. We have been investing conservatively due to the ongoing economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially



## **Table of Contents**

higher returns. As a result, we have experienced no losses on the principal of our investments and have held our investments until maturity. All available-for-sale securities were matured as of June 30, 2012. Also, although the unfavorable market and economic conditions have resulted in a decrease to our market capitalization, there has been no impairment to the value of our assets. Our fixed assets are used for internal research and development and, therefore, are not directly 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 June 30, 2012, we had available cash and cash equivalents of \$10.9 million. Assuming no new financings or collaborations and based on our current business and operational plans, we would expect to have available cash to fund our planned operations into the first quarter of 2013. However, we expect to have access to additional capital through business development opportunities, which we are actively exploring for certain of our MultiStem programs and our 5HT2c small molecule program for obesity and potentially other indications, as well as grant-funding opportunities. 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 over the next twelve months by accessing the capital markets through the sale of equity, including pursuant to this offering and through the Aspire Purchase Agreement, subject to its volume and price limitations. Further, we may consider alternative financing approaches, such as debt or monetizing future royalty streams. Although no assurance on the future success of the aforementioned actions can be provided, we also manage our cash through deferring certain discretionary costs and staging certain development costs to extend our operational runway, as needed.

Our capital requirements over time depend on a number of factors, including progress in our clinical development programs, our clinical and preclinical pipeline of additional opportunities and their stage of development, additional external costs such as contract research organizations and contract manufacturing organizations, additional personnel costs, and the costs in filing and prosecuting patent applications and enforcing patent claims. The availability of funds impacts our ability to advance multiple clinical programs concurrently, and any shortfall in funding could result in our having to delay or curtail research and development efforts. Further, these requirements may change at any time due to technological advances, business development activity or competition from other companies. We cannot assure you that adequate funding will be available to us or, if available, that it will be available on acceptable terms.

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

### *Cash Flow Analysis*

Net cash used in operating activities was \$10.4 million for the six months ended June 30, 2012 and \$5.8 million for the six months ended June 30, 2011, and represented the use of cash in funding preclinical and clinical product development activities. Net cash used in operating activities has fluctuated significantly over the past several quarters primarily due to the receipt of milestone payments and specific clinical trial costs. Taking into account working capital fluctuations, which reflect the receipt of milestone payments and timing of certain payments related to clinical activities, the increase in recent quarters reflects predominantly an increase in clinical development costs during the periods. Such increases include the cost impact of the Phase II stroke trial and the upfront costs associated with its launch, and the timing of payments for manufacturing product for the Phase II IBD clinical trial and reimbursements from Pfizer. We anticipate that net cash used in operating activities will fluctuate in the

**Table of Contents**

remaining quarters of 2012 in connection with the fluctuations and changes in activity associated with the MultiStem clinical trials, the timing of clinical manufacturing, and the receipt of potential milestone payments.

Net cash provided by investing activities was \$4.0 million for the six months ended June 30, 2012, and net cash used in investing activities was \$3.4 million for the six months ended June 30, 2011. 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 \$237,000 and \$377,000 for the first half of 2012 and 2011, respectively. We anticipate that our overall capital equipment expenditures will be similar in 2012 compared to 2011.

Net cash provided from financing activities was \$8.5 million for the six months ended June 30, 2012 and \$11.8 million for the six months ended June 30, 2011 primarily as a result of our equity offerings during each of those periods.

Net cash used in operating activities was \$14.5 million, \$10.6 million and \$4.6 million in 2011, 2010 and 2009, respectively, and represented the use of cash in funding preclinical and clinical development activities. We expect that net cash used in operating activities will increase in 2012 compared to 2011 in connection with increased research and development expenses of our MultiStem clinical trials and later stage clinical development.

Net cash provided by investing activities was \$8.6 million, \$1.5 million and \$3.2 million in 2011, 2010 and 2009, respectively. The fluctuations from period to period were due to the timing of purchases and maturity dates of investments and the purchase of equipment. Purchases of equipment were \$590,000, \$390,000 and \$381,000 in 2011, 2010 and 2009, respectively. We expect that our capital equipment expenditures will continue at similar levels in 2012 compared to 2011.

Financing activities provided cash of \$12.6 million in 2011 related to the February 2011 registered direct offering and the initial Aspire Capital investment in November 2011, and financing activities neither used nor provided cash in 2010 and 2009.

Investors in our March 2012 private placement received five-year warrants to purchase an aggregate of 4,347,827 shares of common stock with an exercise price of \$2.07 per share, and investors in our February 2011 registered direct 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. Our former lenders also received seven-year 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 have been exercised at June 30, 2012.

Our contractual payment obligations as of December 31, 2011 are as follows:

Contractual Obligations	Total	Payment due by Period			
		Less than 1 Year	1 3 Years	3 5 Years	More than 5 Years
Operating leases for facilities and equipment leases	\$ 456,000	\$ 384,000	\$ 72,000	\$	\$
Research funding	135,000	135,000			
Total	\$ 591,000	\$ 519,000	\$ 72,000	\$	\$

## **Table of Contents**

We lease office and laboratory space under an operating lease. The lease began in 2000 and currently expires in March 2013, and we expect to extend the lease option periods. Our rent is \$267,000 per year and our rental rate has not changed since the lease inception in 2000. Also, we lease office and laboratory space for our Belgian subsidiary that 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 December 31, 2012. Our annual rent in Belgium was \$93,000 in 2011.

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

In connection with our private placement in March 2012, we were required to file a resale registration statement with the SEC for 8,695,654 shares of common stock, which includes all shares of common stock issued in the equity offering in March 2012 and shares of common stock issuable upon exercise of the warrants issued in the offering. If the registration statement, which has been declared effective, ceases to remain effective, a 1% cash penalty will be assessed upon a default under the registration rights agreement and for each 30-day period until the default is cured during the first year after the closing of the private placement, capped at 10% the aggregate gross proceeds we received from the private placement. 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 are required to be 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 United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates on experience and on various assumptions that we believe 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*. Effective January 1, 2011, we adopted ASU 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU 2009-13, which amended the guidance in ASC 605-25 on the accounting for arrangements involving the delivery of more than one element. Pursuant to the new standard, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has stand-alone value to the customer. The arrangement's consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

---

**Table of Contents**

We adopted this new accounting standard on a prospective basis for agreements containing multiple elements entered into on or after January 1, 2011, and for any agreements entered into prior to January 1, 2011, but materially modified on or after that date.

The primary impact of adopting the new standard is expected to be the earlier recognition of revenue for multiple element arrangements. The adoption of ASU 2009-13 did not have a material impact on our consolidated results of operations for the year ended December 31, 2011, or on our financial position as of December 31, 2011. The impact of adopting this new accounting standard is dependent on the terms and conditions of any future arrangements that we may enter into that include multiple elements and arrangements entered into prior to January 1, 2011 that are materially modified. Depending on the terms of any such arrangements, the adoption of this accounting standard may have a material impact on our consolidated results of operations or financial position as it may have the potential effect of less revenue deferral for new collaborations than we have historically experienced. We recognized revenue of \$7.9 million for the year ended December 31, 2011 and deferred revenue of \$3.0 million as of December 31, 2011 pertaining to collaborations which were entered into prior to our adoption of ASU 2009-13 and which were not modified on or after January 1, 2011. The performance period for our multiple element arrangements has concluded.

For agreements entered into prior to January 1, 2011 and not materially modified thereafter, we continue to apply our prior accounting policy with respect to such arrangements. Under this policy, the deliverables under the arrangement are evaluated to assess whether they have standalone value and objective and reliable evidence of fair value, and if so, are accounted for as a single unit. We then recognize revenue for each unit based on the culmination of the earnings process under ASC 605-S25, issued as Staff Accounting Bulletin, or SAB, Topic 13, and our estimated performance period for the single units of accounting based on the specific terms of each collaborative agreement. We subsequently adjust the estimated performance periods, if appropriate, on a prospective basis based upon available facts and circumstances. Future changes in estimates of the performance period may materially impact the timing of future revenue recognized. Amounts received prior to satisfying the revenue recognition criteria for contract revenues are recorded as deferred revenue in the accompanying balance sheets. Reimbursement amounts (other than those accounted for using collaboration accounting) paid to us are recorded on a gross basis in the statements of operations as contract revenues.

Effective January 1, 2011, we adopted ASU 2010 17, *Revenue Recognition Milestone Method*. The adoption of the new standard did not have a material impact on our consolidated results of operations for the year ended December 31, 2011 or on our financial position as of December 31, 2011 as we had been recognizing revenue from at-risk, performance milestones that are substantive in the period that the milestone is achieved, as defined in the respective contracts.

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

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

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

## **Table of Contents**

### *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, which was terminated in 2011.

### *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, and if we are invoiced based on progress payments as opposed to actual costs, we develop estimates of work completed to date. Accrued clinical trial costs may be subject to revisions as clinical trials progress, and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

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

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

### *Stock-Based Compensation*

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

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

## **Table of Contents**

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 Not Yet Adopted at December 31, 2011**

In May 2011, the FASB issued changes to fair value measurement. This change clarifies the concepts related to highest and best use and valuation premise, blockage factors and other premiums and discounts, the fair value measurement of financial instruments held in a portfolio and of those instruments classified as a component of shareholders' equity. The guidance includes enhanced disclosure requirements about recurring Level 3 fair value measurements, the use of nonfinancial assets, and the level in the fair value hierarchy of assets and liabilities not recorded at fair value. The provisions are effective prospectively for interim and annual periods beginning on or after December 15, 2011 and became effective for us on January 1, 2012. Early application was prohibited. This required changes in presentation only and did not have a material impact on our consolidated financial statements.

In June 2011, the FASB issued changes to the presentation of comprehensive income. These changes give an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements; the option to present components of other comprehensive income as part of the statement of changes in shareholders' equity was eliminated. The items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income were not changed. Additionally, no changes were made to the calculation and presentation of earnings per share. These changes became effective for us on January 1, 2012. We chose to present comprehensive income in a single continuous statement. Other than the change in presentation, which is further described elsewhere in this prospectus under Selected Consolidated Financial Data, the adoption of this pronouncement did not have an impact on our consolidated financial statements.

### **Quantitative and Qualitative Disclosures about Market Risk**

#### ***Interest Rate Risk***

Our exposure to interest rate risk is related to our investment portfolio and our borrowings. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Due in part to these factors, our future investment income may fall short of expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates. We invest our excess cash primarily in debt instruments of the United States government and its agencies, and corporate debt securities. As of June 30, 2012, we had no investments. We have been investing conservatively due to the current economic conditions and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments.

We enter into loan arrangements with financial institutions when needed and when available to us. At June 30, 2012, we had no borrowings outstanding other than a forgivable note payable associated with local grant funding bearing fixed, forgivable interest of 4.25% per annum.

**Table of Contents**

**BUSINESS**

We are an international biotechnology company that is focused primarily in the field of regenerative medicine. We are committed to the discovery and development of best-in-class therapies designed to extend and enhance the quality of human life. We have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. We are developing our lead platform product, MultiStem<sup>®</sup>, a patented and proprietary allogeneic stem cell product that has been evaluated in two completed Phase I clinical trials and is currently being evaluated in two ongoing Phase II clinical trials. Our current clinical development programs are focused on treating inflammatory & immune disorders, neurological conditions, cardiovascular disease, 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 and could be used to treat a range of disease indications. MultiStem is a patented and proprietary product that enhances tissue repair and healing in multiple ways, including reducing inflammatory damage, protecting tissue that is at risk following acute or ischemic injury, and promoting formation of new blood vessels in regions of ischemic injury. The cells comprising MultiStem appear to be responsive to the environment in which they are administered, homing to sites of injury and active disease response and producing proteins that may provide benefit in acute or chronic conditions. In contrast to traditional pharmaceutical products or biologics that generally act through a single biological mechanism of action, the MultiStem product can enhance healing and tissue repair through multiple distinct mechanisms acting simultaneously, by producing a range of therapeutic factors and dynamically responding to the needs of the body resulting in a more effective therapeutic response.

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

We believe the therapeutic and commercial potential for MultiStem to be very broad, applying to many areas of significant unmet medical need. We are pursuing opportunities in several potential multi-billion dollar markets. While traditional pharmaceuticals 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 in different formulations and with different delivery approaches to efficiently treat a range of disease indications.

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

To date, we have successfully advanced MultiStem product candidates into five clinical stage programs, each of which addresses a significant area of medical need, and represents a large commercial market opportunity. MultiStem has been evaluated in two completed clinical trials, one exploring the potential to treat patients that have suffered a heart attack and the other evaluating the potential to reduce GvHD, as well as other complications, and to provide supportive care to patients being treated for leukemia or related conditions. MultiStem is currently being evaluated in two additional clinical programs in the inflammatory & immune disease and neurological areas. In one study, which is being conducted with our

## **Table of Contents**

partner Pfizer, MultiStem is being administered to patients with IBD. In another ongoing study, we are evaluating the potential to treat patients that have suffered neurological damage from a stroke. In addition, a leading clinical center in Europe, and a research collaborator, has recently received authorization to conduct an initial clinical trial evaluating administration of MultiStem in patients that have received a solid organ transplant.

In addition to our MultiStem programs, we have applied our pharmaceutical discovery capabilities to identify and develop novel pharmaceuticals to treat obesity, related metabolic conditions such as diabetes, and certain neurological indications such as schizophrenia, as well as 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. Our 5HT2c agonist program for obesity works by the same mechanism as Lorcaserin, which was recently approved by the FDA for the treatment of obesity. However, we believe our compounds may have the potential for providing superior weight loss performance, while also achieving a superior safety and tolerability profile. In addition, we have demonstrated our compounds are complementary with other agents that have been approved by the FDA for treating obesity. Furthermore, certain compounds that we developed may also have relevance in other disease areas, such as the treatment of schizophrenia. We are actively exploring partnership opportunities for our 5HT2c program in both the obesity and schizophrenia areas.

## **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.*** MultiStem represents a novel therapeutic modality for the treatment of inflammatory & immune system disorders, neurological conditions and cardiovascular disease, as well as in other areas. MultiStem may be administered like other biologics, intravenously, via catheter, or by local injection. The cells appear to be responsive to their environment, homing to sites of injury and active disease response and producing proteins that may provide benefit in acute or chronic conditions. Additionally, MultiStem cell therapy may deliver therapeutic benefit through several distinct mechanisms of action, including reducing inflammatory damage, protecting tissue that is at risk following acute or ischemic injury, and promoting formation of new blood vessels in regions of ischemic injury. We are conducting a number of clinical studies with the intent to establish proof of concept and/or proof of biological activity in a number of important disease areas where the cell therapies would be expected to have benefit in inflammatory & immune system dysfunctions, neurological conditions and cardiovascular disease. Our focus is on conducting well-designed studies early in the clinical development process to establish a robust foundation for subsequent development, partnership and expansion into complementary areas. We are committed to a rigorous clinical and regulatory framework, which we believe has helped to advance our programs efficiently, and is also a result of the quality of our regulatory submissions and transparency in our discussions with the FDA have resulted in a successful regulatory partnership that has helped to advance our programs efficiently.

***Continue to Refine and Improve our Manufacturing and Related Processes and Deepen our Understanding of Therapeutic Mechanisms of Action.*** A key aspect of MultiStem is its substantial expansion capacity *ex vivo* relative to other cell types. This enables large scale production of the clinical product, which enables greater consistency, specificity and cost of goods advantages over other cell therapies. We plan to build on this intrinsic biological advantage by continuing to advance and optimize our production and process development



## **Table of Contents**

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 licensing and product co-development arrangements with qualified commercial partners to achieve these objectives. We anticipate that this strategy will help us to develop a portfolio of high quality product development opportunities, enhance our clinical development and commercialization capabilities, and increase our ability to generate value from our proprietary technologies. Over the past decade, we have entered into technology licensing arrangements and established product commercialization and co-development partnerships with companies such as Pfizer, Angiotech, Bristol-Myers Squibb, Johnson & Johnson, Wyeth and RTI. 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 inflammatory & immune disorders, neurological conditions, cardiovascular disease, and other areas. We are committed to exploring potential clinical indications where our therapies may achieve best-in-class profile, and where we can address significant unmet medical needs. In order to achieve this goal, over the past decade, we have established collaborative research relationships with investigators from many leading research and clinical institutions across the United States and Europe, including the Cleveland Clinic, Case Western Reserve University, University of Minnesota, the Medical College of Georgia, the University of Oregon Health Sciences Center, the University of Texas Health Science Center at Houston, the University of Pittsburgh Medical Center, KUL, and other institutions. Through this network of collaborations, 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. 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.*** We have a broad intellectual property estate that covers our proprietary products and technologies, as well as methods of production and methods of use. Our intellectual property is important to our business and we take significant steps to protect its value. We have ongoing research and development efforts, both through internal activities and through collaborative research activities with others, which aim to develop new intellectual property and enable us to file patent applications that cover new applications of our existing technologies or product candidates, including MultiStem and other opportunities.

---

## **Table of Contents**

### **Our Current Programs**

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

**Inflammatory Bowel Disease:** IBD affects an estimated 4 million patients or more in the United States, Europe, and Japan. Current therapies for treating IBD consist of pharmaceutical and biologic drugs, representing an annual market of more than \$5 billion globally. Currently available therapies provide temporary relief or are not effective for many patients, and novel approaches are needed to improve the standard of care and help patients avoid surgical intervention. MultiStem is being evaluated in an ongoing Phase II clinical study involving administration of MultiStem to patients suffering from UC the most common form of IBD. This study is being conducted with our partner, Pfizer, in UC patients who have an inadequate response or are refractory to current treatment, and is a double blind, placebo controlled trial that began enrolling patients in 2011. Enrollment of the trial is ongoing and designed to include approximately 130 patients, with initial results expected to be reported in 2013.

**Ischemic Stroke:** Ischemic stroke affects approximately 15 million people globally each year and approximately 2 million in the United States, Europe and Japan combined. The clot-dissolving drug tPA must be administered within 3 to 4 hours after the stroke, and as a result of this narrow window, a limited number of patients are treated with it. We are evaluating in a Phase II clinical study the administration of MultiStem to patients one to two days after they have suffered an ischemic stroke. In preclinical studies, administration of a single dose of MultiStem, even several days after a stroke, resulted in significant and durable improvements. This double blind, placebo-controlled trial is being conducted at leading stroke centers across the United States and may include sites in Europe. The study is expected to include approximately 136 patients. We completed the first patient cohorts, and the independent safety monitoring committee found that MultiStem was safe and well tolerated at both of the doses evaluated. Patient enrollment is ongoing and for the remainder of the trial, patients will be randomized to receive either high dose MultiStem or placebo. We believe this represents a potential market opportunity of more than \$15 billion annually.

**Acute Myocardial Infarction:** We have evaluated the administration of MultiStem in a Phase I clinical study to patients that have suffered an AMI. In 2010, we announced preliminary results for this study, demonstrating a favorable safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment. One-year follow-up data suggested that the benefit observed was sustained over time. We have completed preliminary planning for a Phase II trial, which has been discussed with the FDA. Our plans to move the AMI program forward into subsequent development will depend on the availability of capital resources, progress in our other clinical studies and our business development activities.

**Hematopoietic Stem Cell Transplant / GvHD:** We have completed a Phase I 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 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 2011 and in February 2012, we released data from the study, which demonstrated the safety of MultiStem in this indication and suggested that MultiStem may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. This program has been assigned

---

**Table of Contents**

orphan drug designation from the FDA, which provides us with seven years of market exclusivity upon approval, and certain other benefits. We met with the FDA to discuss the results of the clinical study and our proposed plans for the next phase of clinical development in this area. We are currently preparing our detailed clinical study plans and look forward to finalizing our design and undertaking operational planning. Based on current plans, we intend to be ready to start this study in the second half of 2013, but the initiation will depend on the progress in our clinical trials and the achievement of certain business development and financial objectives. There are approximately 25,000 bone marrow or peripheral blood stem cell allografts performed annually, but we believe many more transplants could be performed if the risks of GvHD could be meaningfully reduced. We believe this indication represents a potential market opportunity of \$500 million annually or more.

We are also collaborating with a leading transplant group at the University of Regensburg in Germany that has recently obtained authorization to initiate an institutional sponsored clinical trial exploring the administration of MultiStem in patients following a liver transplant. We plan to provide limited financial support for this investigator-sponsored Phase I study and provide clinical grade product to conduct the trial. According to a report by Reuters Business Insight, in 2009, approximately 91,000 organ transplants were conducted. We estimate that this represents a potential market of more than \$1.5 billion annually.

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 inflammatory & immune disorder, neurological and cardiovascular disease 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 in discussions with third parties about collaborating in the development of MultiStem for our current clinical programs (outside of IBD) and preclinical programs and may, under the right terms, enter into one or more business partnership(s) to advance the programs.

We have also collaborated with RTI on the development of products for certain orthopedic applications in the bone graft substitutes market using our stem cell technologies. RTI's product development activities are progressing, and in September 2012, we amended our agreement with RTI to accelerate \$2.0 million of contingent milestone payments in connection with ongoing technical support to assist RTI in its initial product launch. As a result, we will receive these milestone payments in 2012, and in addition, RTI will compensate us for this technical assistance. We will also receive royalty revenue from product sales when they occur, as well as potential additional milestone payments.

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 favorable attributes, including outstanding receptor selectivity, as well as greater potency and activity than other 5HT<sub>2c</sub> agonists. We have also demonstrated complementarity of our compounds with other agents and believe these compounds could achieve best in class weight loss, as well as a superior safety and tolerability profile. Furthermore, we have evaluated certain compounds that exhibit a particular type of selectivity profile in preclinical models of schizophrenia and observed that these compounds exhibit potent effects. We are in discussions with multiple companies and may elect to enter into a partnership to advance the development of our 5HT<sub>2c</sub> agonist program, either for the treatment of obesity, schizophrenia, or both indications.

---

## **Table of Contents**

### ***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 INDs for the study of MultiStem in distinct clinical indications, and a collaborating institution recently obtained authorization in Europe to initiate a clinical program through an investigator sponsored clinical trial application, obtained with our permission and support.

MultiStem is a patented biologic product that is manufactured from human stem cells obtained from adult bone marrow, although these cells may alternatively be obtained from other tissue sources, which are also covered under our intellectual property. The product consists of a special class of human stem cells that have the ability to express a range of therapeutically relevant proteins and other factors, as well as form multiple cell types. Factors expressed by 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, but unlike a traditional transplant, are subsequently cleared from the body over time like a drug or biologic.

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

A stem cell therapy that has the potential to address the challenges mentioned above could represent a breakthrough in the field of regenerative medicine, since it could greatly expand the clinical application of stem cell therapy or other forms of regenerative medicine. In 2003, we acquired technology originally developed at the University of Minnesota related to a novel stem cell type, 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. We refer to the current product platform as MultiStem. During several years of preclinical work, MultiStem has demonstrated the potential to address many of the fundamental limitations observed with traditional bone marrow or hematopoietic stem cell transplants.

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

***Broad Plasticity and Multiple Potential Mechanisms of Action.*** MultiStem cells have a demonstrated ability in animal models to form a range of cell types and also appear to be

## **Table of Contents**

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

***Off-the-Shelf Utility.*** Unlike traditional bone marrow or hematopoietic stem cell transplants that require extensive genetic matching between donor and recipient, MultiStem 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 or induced pluripotent stem cells have shown the capacity to form ectopic tissue or teratomas, which are tumor-like growths. These could pose serious safety risks to patients. In contrast, MultiStem cells have shown a consistent and outstanding safety profile that has been compiled over several years of preclinical study in a range of animal models by a variety of investigators and that is supported by emerging clinical data.

At each step of the MultiStem production process, cells are analyzed according to pre-established criteria to ensure that a consistent, well characterized product candidate is produced. Cells are harvested from a pre-qualified 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.

The distinctive profile of MultiStem allows us to pursue multiple high value commercial opportunities from a single product platform. Based upon work that we and independent collaborators have conducted over the past several years, we believe that MultiStem 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 solid organ transplant areas), and a range of orphan disease indications. As a result, we believe we will be able to leverage our foundation of safety and efficacy data to add clinical indications efficiently, enabling us to reduce development costs and timelines substantially.

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

Healthcare represents a significant part of the global economy. In the United States, it represented approximately 18% of all economic activity in 2009, or about \$2.49 trillion dollars annually. However, the United States, along with many other nations, is experiencing an unprecedented demographic shift that is resulting in a significantly expanded population of older individuals. According to United States Census data, in the next few years there will be a dramatic increase in the number of individuals over the age of 65, as this segment of the population increases from 40.2 million individuals in 2010 to more than 72 million people in 2030, representing an increase of approximately 80%. The aging of the population will create enormous financial pressure on the healthcare system in the United States and other countries around the world, resulting in significant clinical challenges, but also resulting in substantial commercial opportunities.

## **Table of Contents**

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

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, the University of Texas Health Science Center at Houston, KUL and other institutions. Through this network of collaborations, 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 and our collaborators have published research results illustrating the potential benefits of MultiStem in a range of indications including myocardial infarction, vascular disease, ischemic stroke, TBI, brain damage due to restricted blood flow in newborns, spinal cord injury, and bone marrow transplant support/GvHD. In addition, we have explored and intend to further explore, 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 UC); support in the hematologic malignancy setting to reduce certain complications associated with traditional bone marrow or HSC transplantation; treatment for stroke caused by a blockage of blood flow in the brain; and treatment of damage caused by myocardial infarction. Additionally, in collaboration with a leading transplant center in Europe, a fifth program in the solid organ transplant area has been advanced to clinical development.

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

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

Inflammatory & 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 & 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 transplant procedures used to treat leukemia or related blood-borne cancers). Each of these conditions shares certain biological characteristics, in that the immune system imbalance results from the inappropriate activation of certain populations of immune cells that results in significant tissue damage and destruction. This immune imbalance may result in a complex cascade of inflammation that can result in pain, progressive tissue deterioration and loss of function. While currently available immunomodulatory drugs have proven to be effective for many patients, they have failed to adequately address the needs of many other patients that suffer from inflammatory & immune disorders.

In multiple studies, MultiStem has shown potent immunomodulatory properties, including the ability to reduce active inflammation through various modes of action, and restore immune system imbalance.

## **Table of Contents**

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 UC and Crohn's disease, which are estimated to affect 4 million people or more in the United States, five major European markets (United Kingdom, Germany, France, Italy and Spain) and Japan. Chronic IBD can be a severely debilitating condition, and advanced cases may require surgery to remove the affected region of the bowel, and may also require temporary or permanent colostomy or ileostomy. In many cases, surgery does not achieve a permanent cure, and patients suffer a return of the disease. In 2011, enrollment commenced in our Phase II clinical study being conducted with our partner, Pfizer, to administer MultiStem to patients suffering from UC.

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 completed a Phase I clinical trial examining the safety and tolerability of a single dose or repeat dosing of MultiStem administered intravenously to patients receiving a bone marrow or hematopoietic stem cell transplant as part of their treatment of leukemia or other hematological condition. The trial was an open label, multicenter trial that involved leading experts in the field of bone marrow transplantation. In February 2012, we announced the top-line results from the trial. We observed a consistent safety profile in both the single and multiple dose arms of the study, and at all dose levels tested. Although the trial was not specifically designed to demonstrate efficacy, we also observed

## **Table of Contents**

clinically meaningful improvement in medically important parameters relative to historical clinical experience, including reduced incidence and severity of acute GvHD, improved relapse free survival, no graft failures, and enhanced engraftment rates relative to other forms of treatment.

In September 2010, we announced that we had been granted orphan drug designation by the FDA for MultiStem in the prevention of GvHD. We met with the FDA to review the results from the Phase I trial and discuss plans for the next phase of clinical development, which could include a Phase II/III study of MultiStem for GvHD prophylaxis and HSCT support. We are currently preparing our detailed clinical study plans and look forward to finalizing our design and undertaking operational planning. Based on current plans, we intend to be ready to start this study in the second half of 2013, but the initiation will depend on the progress in our clinical trials and the achievement of certain business development and financial objectives.

### **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 800,000 individuals in the United States that suffer a stroke each year, more than two million stroke victims in the United States, Europe and Japan combined, and approximately 15 million people that suffer a stroke each year globally. The vast majority of these (approximately 85% to 90%) are ischemic strokes, that are caused by a blockage of blood flow in the brain, that cuts off the supply of oxygen and nutrients, resulting in eventual tissue loss and long-term damage and disability. The remainder of these are hemorrhagic strokes, which occur when a blood vessel bursts and bleeding into the brain ensues.

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

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



## **Table of Contents**

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

In preclinical studies conducted by investigators, including at both the University of Minnesota, the Medical College of Georgia, and the University of Texas Health Science Center at Houston, significant functional improvements have been observed in rodents that have undergone an experimentally induced stroke, or that have incurred significant neurological damage due to similar types of ischemic events, such as a result of neonatal hypoxic ischemia or TBI, and then received 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 and 2012 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, and are consistent with prior results that show MultiStem can provide significant benefits even when administered up to one week after the initial stroke event.

We are currently enrolling patients in a 136-patient Phase II clinical trial exploring the administration of MultiStem to patients that have suffered an ischemic stroke. In this trial, MultiStem is 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 and could provide an important new therapeutic option for stroke patients. We believe that the potential market for a new therapy to treat stroke could be \$15 billion or more annually.

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

## **Table of Contents**

and promoted accelerated healing of the blood-brain barrier. Early in 2012, we announced grant funding aggregating \$3.6 million to further advance our MultiStem programs and cell therapy platform, including further development of MultiStem for the treatment of TBI and further development of our cell therapy formulations and manufacturing capabilities.

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 \$1.0 million through the Ohio Third Frontier Biomedical Program to support preclinical and translational research into the treatment of spinal cord injury, or SCI, with MultiStem. 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 MS based on initial results in preclinical models. In October 2012, in collaboration with scientists from Case Western Reserve University, and with the support of Fast Forward and the National Multiple Sclerosis Society, we reported research results that demonstrate the potential benefits of MultiStem therapy for treating MS. In standard preclinical models of MS, researchers observed that MultiStem administration results in sustained behavioral improvements, arrests the demyelination process that is central to the pathology of MS, and supports remyelination of affected axons.

### **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 United States 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 United States are expected to soar in the coming years. In 2010, annual direct costs for treating cardiovascular disease were \$273 billion, but by 2030 these are expected to nearly triple, to a projected \$818 billion per year. This increase will occur primarily as a result of the aging population, and may not fully reflect the impact of the dramatic escalation in obesity rates that has occurred for both adults and children in recent years, which could further exacerbate the long-term challenges and increase costs associated with cardiovascular disease and other conditions.

In a Phase I clinical trial, we have explored the use of MultiStem as a treatment for damage caused by AMI. 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 2012 Statistical Update, there were approximately 935,000 cases of myocardial infarction that occurred in the United States in 2008 and approximately 7.9 million individuals living in the United States that had previously suffered a heart attack. In addition, there were approximately 812,000 deaths that occurred from all forms of cardiovascular disease, including 462,000 individuals that died as a result of coronary heart disease or 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

## **Table of Contents**

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 the study is now completed. In July 2010, we announced the preliminary 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. These results were recently published in *Circulation Research* in November 2011.

### ***Pharmaceutical Programs***

#### ***Novel 5HT2c Agonists for the Treatment of Obesity and Other Conditions***

Obesity is a substantial contributing factor to a range of diseases that represent the major causes of death and disability in the developed world today. Individuals that are clinically obese have elevated rates of cardiovascular disease, stroke, certain types of cancer and diabetes. According to the CDC, the incidence of obesity in the United States has increased at an epidemic rate during the past 20 years. CDC now estimates that almost 70% of all Americans are overweight, including more than one-third that are considered clinically obese. The percentage of young people 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.

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 the amount of sugar in the blood, as measured by fasting blood glucose and HbA1c levels, which are both clinically relevant measures for patients suffering from diabetes.

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

## **Table of Contents**

Our drug development program is 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 including Lorcaserin. We also evaluated certain of our compounds when administered as a monotherapy or in conjunction with other weight loss agents, and have observed effectiveness with both approaches and complementarity with other agents. We are conducting preclinical evaluation of novel compounds that we have developed that exhibit outstanding receptor selectivity and are working toward the selection of a clinical development candidate for this program.

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

We are currently exploring partnering opportunities for this program and may elect to enter into a partnership to advance the development of this program for the treatment of obesity and related indications, schizophrenia, or multiple indications.

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

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

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.

---

**Table of Contents**

**Collaborations and Partnerships**

*Pfizer*

Late in 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem for the treatment of IBD for the worldwide market. Under the terms of the agreement, we received a non-refundable up-front cash payment of \$6.0 million from Pfizer and will receive research funding and support during the initial phase of the collaboration. In addition, we are also eligible to receive milestone payments of up to \$105 million upon the successful achievement of certain development, regulatory and commercial milestones, though there can be no assurance that we will achieve these milestones, and no significant milestone payments were received as of June 30, 2012. We are responsible for manufacturing and Pfizer pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at Phase III clinical development.

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

*RTI*

In 2010, we entered into an agreement with RTI to develop and commercialize MAPC technology-based biologic implants for certain orthopedic applications in the bone graft substitutes market. Under the terms of our RTI agreement, we are entitled to a \$5.0 million license fee in installments, of which \$3.0 million was received in 2010 and 2011, and \$2.0 million was contingent upon future events. In September 2012, RTI agreed to make these \$2.0 million license fee payments by December 31, 2012, and we agreed to provide RTI with certain technical support. In accordance with the agreement, we are also eligible to receive an additional \$35.5 million in cash payments upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved. In addition, we will receive tiered royalties on worldwide commercial sales of implants using our technologies.

*Angiotech*

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, we regained ownership of all rights for developing our stem cell technologies and products for cardiovascular disease indications, including AMI, congestive heart failure, chronic ischemia, and peripheral vascular disease, and Angiotech no longer has any license rights or options with

## **Table of Contents**

respect to our technologies and products. Angiotech made its final cost-sharing payment in 2011 in connection with collaboration activities and has no further obligations to us. Though the termination will affect our future costs of development for ongoing cardiovascular programs, such as AMI, it significantly improves our 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 us equal to a percentage of cash license fee payments we receive 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, (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 we have 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 we have spent \$5.0 million on the clinical trial, and within 36 months of the termination agreement.

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

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

We remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb under our completed 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 June 30, 2012, we received an aggregate amount of \$1.7 million in milestone payments and \$9.6 million in license fees since the inception of our collaboration with Bristol-Myers Squibb.

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

## **Table of Contents**

### **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 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 greater donor to donor variability, limited expansion potential, and limited biological plasticity. In November 2008, Osiris announced a partnership in which Genzyme acquired development rights to Prochymal and Chondrogen 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. In February 2011, Sanofi acquired Genzyme, and in October 2012, Sanofi announced that the partnership had been terminated, and Osiris had regained commercial development rights to Prochymal and Chondrogen.

Mesoblast is currently engaged in clinical trials evaluating the safety and efficacy of Revascor, an allogeneic stem cell product based on mesenchymal stem cell precursors that are obtained from healthy consenting donors. These cells also appear to display limited expansion potential and biological plasticity. 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 Mesoblast. In addition, total regulatory milestone payments to Mesoblast could reach \$1.7 billion, assuming that the agreement results in commercial treatments for conditions including congestive heart failure, AMI, Parkinson's disease and Alzheimer's disease. In October 2011, Teva Pharmaceuticals announced that it had acquired Cephalon.

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 and Cytori. In addition, private companies, such as Gamida Cell Ltd., Plureon Corporation, NeoStem, Inc., Tigenix NV and others, are also developing cell therapy related products or capabilities. Given the magnitude of the potential opportunity for stem cell therapy, we expect competition in this area to intensify in the coming years.

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

There are many other companies that have previously attempted or are attempting to develop novel treatments for obesity, and a wide range of approaches are being taken. Some of these companies include large, multinational pharmaceutical companies such as Bristol-Myers Squibb, Merck & Co., Inc., Roche, Sanofi, GlaxoSmithKline, Eli Lilly and Company and others. There are also a variety of biotechnology companies developing treatments for obesity, including Orexigen Therapeutics, Neurosearch, Amgen Inc., or Amgen, Regeneron Pharmaceuticals, Inc., Nastech Pharmaceutical Company, Alizyme plc, Amylin Pharmaceuticals, Inc., Neurocrine Biosciences, Inc., Shionogi & Co., Ltd., Metabolic Pharmaceuticals Limited, Kyorin Pharmaceutical Co., Ltd., and others. It is likely that, given the

## **Table of Contents**

magnitude of the market opportunity, many companies will continue to focus on the obesity area, and that competition will remain high. If we are successful at developing a 5HT2c agonist as a safe and effective treatment for obesity, it is likely that other companies will attempt to develop safer and more effective compounds in the same class, or will attempt to combine therapies in an effort to establish a safer and more effective therapeutic product.

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

## **Intellectual Property**

We rely on a combination of patent applications, patents, trademarks, and contractual provisions to protect our proprietary rights. We believe that to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. Currently, we require our officers, employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, and other advisors to execute confidentiality agreements in connection with their employment, consulting, or advisory relationships with us, where appropriate. We also require our employees, consultants, and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, developed using our property, or which relate to our business. We currently have an aggregate of 129 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 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. Our broad intellectual property portfolio consists of more than 78 issued patents (of which eleven are United States patents) and more than 183 global patent applications around our stem cell technology and MultiStem product platform. This includes nine United States patents and 39 international patents that apply to MAPC and related products, such as MultiStem. The current intellectual property estate, which incorporates additional filings and may broaden over time, could provide coverage for our stem cell product candidates, manufacturing processes and methods of use through 2030 and beyond. Furthermore, an extended period of market exclusivity may apply for certain products (e.g., exclusivity periods for orphan drug designation or biologics).

We have established a broad intellectual property portfolio related to our 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 six United States patents and two patent applications with broad claims directed to selective 5HT2c agonists discovered at Athersys that currently provide patent coverage through as late as 2029. From our Histamine H3 program, we have six United States patents with broad claims directed to compounds discovered at Athersys from two distinct chemical series that currently provide patent coverage through as late as 2028. In addition, we currently have 35 issued patents (sixteen United States patents and



## **Table of Contents**

nineteen international patents) and three patent applications relating to compositions and methods for the RAGE technology that currently provide patent coverage through as late as 2017, and four United States patents and seven patent applications relating to human proteins and candidate drug targets that we identified through the application of RAGE and our other technologies that currently provide patent coverage through as late as 2022. The RAGE technology was developed by Dr. John Harrington and other Athersys scientists internally in the mid-1990s.

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

## **Research and Development**

Our research and development costs, which consist primarily of costs associated with external clinical trial costs, preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property application processes, and laboratory supply and reagent costs, were \$10.6 million for the six months ended June 30, 2012, \$18.9 million in 2011, \$14.8 million in 2010 and \$11.9 million in 2009.

## **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 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 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.

## **Table of Contents**

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 I through completion of Phase III studies). After successful completion of clinical trials for a new drug or biologic product, FDA approval of the NDA or BLA must be obtained. This process requires substantial time and effort and there is no assurance that the FDA will accept the NDA or BLA for filing and, even if filed, that the FDA will grant approval. In the past, the FDA's approval of an NDA or BLA has taken, on average, one to two years, but in some instances may take substantially longer. If questions regarding safety or efficacy arise, additional studies may be required, followed by a resubmission of the NDA or BLA. Review and approval of an NDA or BLA can take up to several years.

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

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

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.

## **Table of Contents**

### **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 September 30, 2012, we employed 48 employees, 17 with Ph.D. degrees. In addition to our employees, we also use the service and support of outside consultants and advisors. None of our employees is represented by a union, and we believe relationships with our employees are good.

### **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 began in 2000 and currently expires in March 2013, and we expect to extend the lease option periods. Our rent is \$267,000 per year and our rental rate has not changed since the lease inception in 2000. Also, we currently lease office and laboratory space for our Belgian subsidiary. The lease currently expires on December 31, 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. Our annual rent in Belgium was \$93,000 in 2011.

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

The following table sets forth certain information regarding our executive officers and directors as of September 30, 2012:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Gil Van Bokkelen, Ph.D.	51	Chief Executive Officer and Chairman
William (BJ) Lehmann, Jr., J.D.	46	President and Chief Operating Officer
John J. Harrington, Ph.D.	45	Chief Scientific Officer, Executive Vice President and Director
Robert J. Deans, Ph.D.	61	Executive Vice President, Regenerative Medicine
Laura K. Campbell, CPA	48	Vice President of Finance
Lee E. Babiss	56	Director
Ismail Kola	55	Director
Lorin J. Randall	68	Director
Kenneth H. Traub	51	Director
Jack L. Wyszomierski	56	Director

*Dr. Van Bokkelen* co-founded Athersys in October 1995 and has served as our Chief Executive Officer and Chairman since August 2000. Dr. Van Bokkelen 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 leadership, extensive business, operating, financial and scientific experience, and tremendous knowledge of our Company and the biopharmaceutical industry. Dr. Van Bokkelen also brings his broad strategic vision for our Company to the Board of Directors and his service as the Chairman and CEO of Athersys creates a critical link between management and the Board, enabling the Board to perform its oversight function with the benefit of management's perspectives on the business. In addition, having the CEO, and Dr. Van Bokkelen, in particular, on our Board of Directors provides our Company with ethical, decisive and effective leadership.

*Mr. Lehmann* joined Athersys in September 2001 and has served as our President and Chief Operating Officer since June 2006. Prior to that time, Mr. Lehmann was Athersys' Executive Vice President of Corporate Development and Finance from August 2002 until June 2006, when he became Athersys' President and Chief Operating Officer. From 1994 to 2001, Mr. Lehmann was with 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* co-founded Athersys in October 1995 and has served as our Chief Scientific Officer, Executive Vice President and Director since our founding. Dr. Harrington led the development of the RAGE technology as well as its application for gene discovery, drug discovery and commercial protein

---

**Table of Contents**

production applications. He is a listed inventor on over 20 issued or pending United States patents, has authored numerous scientific publications, and has received numerous awards for his work, including being named one of the top international young scientists by MIT Technology Review in 2002. Dr. Harrington has overseen the therapeutic product development programs at Athersys since their inception, and during his career, he has also held positions at Amgen and Scripps Clinic. He received his B.A. in Biochemistry and Cell Biology from the University of California at San Diego and his Ph.D. in Cancer Biology from Stanford University. 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* joined Athersys in February 2003 to lead the Company's regenerative medicine research and development activities and has served as our Executive Vice President since June 2011. Prior to that time, Dr. Deans was Vice President of Regenerative Medicine, until he was named Senior Vice President of Regenerative Medicine in June 2006, and Executive Vice President in June 2011. Dr. Deans is highly regarded as an expert in stem cell therapeutics, with over twenty years of experience in this field. From 2001 to 2003, Dr. Deans worked for early-stage biotechnology companies. Dr. Deans was formerly the Vice President of Research at Osiris, a biotechnology company, from 1998 to 2001 and Director of Research and Development with the Immunotherapy Division of Baxter International, Inc., a global healthcare company, from 1992 to 1998. Dr. Deans was also previously on faculty at USC Medical School in Los Angeles, between 1981 and 1998, in the departments of Microbiology and Neurology at the Norris Comprehensive Cancer Center. Dr. Deans was an undergraduate at MIT, received his Ph.D. at the University of Michigan, and did his post-doctoral work at UCLA in Los Angeles.

*Ms. Campbell* joined Athersys in January 1998 and has served as our Vice President of Finance since June 2006. Ms. Campbell joined Athersys initially as Controller, followed by Director of Finance and Senior Director of Finance, 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 firm's audit practice. During her tenure with Ernst & Young LLP, Ms. Campbell specialized in entrepreneurial services and the biotechnology industry sector and participated in several initial public offerings. Ms. Campbell received her B.S., with distinction, in Business Administration from The Ohio State University.

*Dr. Babiss* has served as our Director since August 2010. Dr. Babiss is currently Chief Scientific Officer and 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 in Switzerland, a pharmaceutical company, from 1998 until his appointment at PPD, Inc. Prior to Roche, Dr. Babiss spent seven years with Glaxo, Inc., now GlaxoSmithKline, a pharmaceutical company, where he held senior positions, including Vice President of Biological Sciences and Genetics. Dr. Babiss received his doctorate in Microbiology from Columbia University and completed his postdoctoral fellowship at the Rockefeller University, where he served as an assistant and associate professor. Dr. Babiss has received numerous fellowship awards and grants and serves on several scientific advisory committees. 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 the Board.

*Dr. Kola* has served as a Director since October 2010. Dr. Kola serves as 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

**Table of Contents**

Schering-Plough Corporation, and Chief Scientific Officer at Schering-Plough Corporation, a pharmaceutical company, from March 2007 until his appointment at UCB. Prior to Schering-Plough, Dr. Kola held senior positions from January 2003 to March 2007 at Merck, a pharmaceutical company, where he was Senior Vice President and Site Head, Basic Research. From 2000 to 2003, Dr. Kola was Vice President, Research, and Global Head, Genomics Science and Biotechnology, at Pharmacia Corporation. Prior to his position with Pharmacia, Dr. Kola spent 15 years as Professor of Human Molecular Genetics and was Director of the Centre for Functional Genomics and Human Disease at Monash Medical School in Australia. Dr. Kola received his Ph.D. in Medicine from the University of Cape Town, South Africa, his B.Sc. from the University of South Africa, and his B.Pharm. from Rhodes University, South Africa. Dr. Kola currently serves on the boards of directors of Astex Therapeutics (NASDAQ: ASTX) since May 2010, Biotie Therapies (and previously Synosia who merged with Biotie) since February 2011, and previously served on the board of directors of Ondek Pty Ltd from 2009 to 2011 and Promega Corporation from 2003 to 2007. Dr. Kola has authored 160 technical publications in scientific and medical journals and is the named inventor on at least a dozen patents. Dr. Kola holds Adjunct Professorships of Medicine at Washington University in St. Louis, Missouri, and Monash University Medical School; a Foreign Adjunct Professorship at the Karolinska Institute in Stockholm, Sweden; and was elected William Pitt Fellow at Pembroke College, Cambridge University, United Kingdom in 2008. Dr. Kola has also been appointed a Visiting Professor at Oxford University, Nuffield School of Medicine, Oxford UK since September 2012. For more than 20 years, Dr. Kola has created a bridge between the scientific and academic worlds through various projects funded by renowned institutes, and Dr. Kola's experience and leadership in taking numerous drugs from the research stage to market or late stage development brings a unique and valuable perspective to our Board.

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

*Mr. Traub* has served as a Director since June 2012. Mr. Traub has been the President and Chief Executive Officer of Ethos Management LLC, a private consulting and investment firm since 2009. Mr. Traub served as President, Chief Executive Officer and a director of American Bank Note Holographics, Inc., or ABNH, a global leader in product and document security, from 1999 until its sale in 2008 to JDS Uniphase Corporation, or JDSU, a provider of optical products and measurement solutions for the communications industry. Mr. Traub managed the rebuilding, growth and sale of ABNH. Following the sale of ABNH, Mr. Traub served as vice president of JDSU in 2008. In 1994,

**Table of Contents**

Mr. Traub co-founded Voxware, Inc., a pioneer in Voice over IP, and acted as its Executive Vice President, Chief Financial Officer and director until January 1998. Prior to Voxware, he was Vice President of Finance of Trans-Resources, Inc. Mr. Traub currently serves on the boards of the following publicly traded companies: MRV Communications, Inc. (OTC: MRVC) since November 2011 and as Chairman since January 2012 where he is a member of the Audit Committee, Compensation Committee and Nominating and Governance Committee; iPass Inc. (NASDAQ: IPAS) since June 2009, where he is a member of the Compensation Committee and Corporate Governance and Nominating Committee; DSP Group, Inc. (NASDAQ: DSPG) since May 2012; and MIPS Technologies, Inc. (NASDAQ: MIPS) since December 2011 where he is a member of the Audit Committee. Mr. Traub also served on the board of Phoenix Technologies Ltd. (NASDAQ: PTEC) from November 2009 through its sale in December 2010, where he was a member of the Audit Committee and Compensation Committee. Mr. Traub received a Master's in Business Administration from Harvard Business School in 1988 and a Bachelor of Arts degree from Emory University in 1983. As a director for Athersys, Mr. Traub contributes his extensive experience and expertise in managing and growing companies to maximize shareholder value.

*Mr. Wyszomierski* has served as a Director since June 2010 and is currently retired. From 2004 until his retirement in June 2009, Mr. Wyszomierski served as the Executive Vice President and Chief Financial Officer of VWR International, LLC, a supplier and distributor of laboratory supplies, equipment and supply chain solutions to the global research laboratory industry. From 1982 to 2004, Mr. Wyszomierski held positions of increasing responsibility within the finance group at Schering-Plough Corporation, a pharmaceutical company, culminating with his appointment as Executive Vice President and Chief Financial Officer in 1996. Prior to joining Schering-Plough, he was responsible for capitalization planning at Joy Manufacturing Company, a producer of mining equipment, and was a management consultant at Data Resources, Inc., a distributor of economic data. Mr. Wyszomierski currently serves on the board of directors of Xoma Corporation (NASDAQ: XOMA) since 2010, where he serves as chairman of the compensation committee and as a member of the audit committee, Unigene Laboratories, Inc. (OTC:UGNE) since 2012, where he serves as chairman of the audit committee, and Exelixis, Inc. (NASDAQ: EXEL) since 2004, where he 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 committees of other public companies, as well as his experience in the healthcare and life sciences industries, provides financial expertise to the Board, including an understanding of financial statements, corporate finance, developing and maintaining effective internal controls, accounting, investments and capital markets.

**Director Independence**

The Board reviews the independence of each Director at least annually. During these reviews, the Board will consider transactions and relationships between each Director (and his or her immediate family and affiliates) and the Company and our management to determine whether any such transactions or relationships are inconsistent with a determination that the Director was independent. The Board conducted its annual review of Director independence to determine if any transactions or relationships exist that would disqualify any of the individuals who serve as a Director under the rules of The NASDAQ Capital Market or require disclosure under Securities and Exchange Commission, or SEC, rules. Based upon the foregoing review, the Board determined the following individuals are independent under the rules of The NASDAQ Capital Market: Lee E. Babiss, Ismail Kola, Lorin J. Randall, Kenneth H. Traub and Jack L. Wyszomierski. In making this determination with respect to Dr. Babiss, the Board determined that the provision of certain contract research services to the Company by PPD, Inc., of which Dr. Babiss serves as an executive officer, did not create a material relationship or impair the independence of Dr. Babiss because Dr. 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: Dr. Van Bokkelen, who is also our Chairman and

## **Table of Contents**

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.

### **Compensation Discussion and Analysis**

#### *Executive Summary*

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

We are an international biotechnology company that is focused 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 we have established a portfolio of therapeutic product development programs to address significant unmet medical needs 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 our capital resources 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

made awards 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;

## **Table of Contents**

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 company goals; and

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

### ***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 considered recommendations from our Chief Executive Officer regarding the compensation for and performance of our executive officers in relation to company-specific strategic goals that were established by the Compensation Committee and approved by the Board of Directors 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.

**Table of Contents**

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. Also for 2012, the Compensation Committee and the Board of Directors approved that each of the named executive officers be entitled to receive an increase in such officer's salary for 2012 as compared to 2011 based primarily on company performance for the year ended December 31, 2011. The increases are as follows: Mr. Lehmann 3.5%; Dr. Harrington 3.0%; Dr. Deans 2.5% (taking into consideration his salary adjustment in April 2011); and Ms. Campbell 2.75%.

**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.

In 2005, in connection with a restructuring of our 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 participation 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 were paid to our named executive officers in 2012, for the year ended December 31, 2011, as described in the following paragraph.

The Compensation Committee recommended and the Board approved a cash bonus incentive program for the year ended December 31, 2011 for our named executive officers. Under the 2011 incentive program, 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 specific 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%

The evaluation of goal achievement is at the discretion of the Compensation Committee of the Board of Directors 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 2011 corporate goals included 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 2011 incentive program is 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

**Table of Contents**

conditions and cash availability. There was no formally adopted plan document for the 2011 incentive program, although the Compensation Committee recommended and the Board of Directors approved the specific corporate goals, target bonus levels and weightings between corporate and functional performance. The Compensation Committee and the Board of Directors agreed that each of our named executive officers would be entitled to a bonus under the 2011 incentive program as a result of individual performance and the achievement of operational and strategic objectives in 2011, specifically the achievement of patient enrollment goals for the Company's clinical trials and other program development goals, resulting in the payment of bonuses based on a percentage of such officers' 2011 base salaries as follows:

	Bonus Achieved	Cash Bonus Paid
Dr. Van Bokkelen	9.9%	\$ 40,000
Dr. Harrington	7.8%	\$ 27,000
Mr. Lehmann	7.8%	\$ 27,000
Dr. Deans	8.1%	\$ 24,300
Ms. Campbell	6.8%	\$ 15,300

For the year ending December 31, 2012, the Compensation Committee recommended and the Board of Directors approved a similar cash bonus incentive plan for our named executive officers. The 2012 plan has no change to the target bonus percentage or the functional performance weightings for our named executive officers. The 2012 corporate goals include advancing and achieving enrollment goals for our clinical programs for MultiStem, executing against the established operating plan and capital acquisition objectives, and advancement of strategic partnership and program activities.

**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. Historically, we elected to use stock options as our primary long-term equity incentive vehicle. To date, we have not granted any restricted stock or restricted stock units under our equity compensation plans to our named executive officers or Directors. However, in 2011, we granted restricted stock units to our other employees. We expect to continue to use equity-based awards as a long-term incentive vehicle because we believe:

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

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

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

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

## **Table of Contents**

In the past, in determining the number of equity-based awards 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 equity-based awards in relation to other elements of the individual executive's total compensation. Currently, awards of equity-based awards 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 equity-based 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 equity-based 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 began making employer contributions to our 401(k) retirement plan in 2011 and contributed approximately \$88,000 in 2011. 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 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 our 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."

The 2005 incentive program for our named executive officers provides substantial equity participation in the event of the sale of the Company or substantially all of its assets. The Compensation Committee believes that this program coupled with existing, vested stock option holdings provides strong equity incentives to our named executive officers.

### ***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

**Table of Contents**

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.

**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 Awards (\$) (1) (f)	All Other Compensation (\$) (i)	Total (j)
Gil Van Bokkelen,	2011	\$ 404,500	\$ 40,000	\$ 0	\$ 12,620	\$ 457,120
Chief Executive Officer <sup>(2)</sup>	2010	\$ 390,741	\$ 52,750	\$ 0	\$ 9,620	\$ 453,111
Laura Campbell,	2011	\$ 225,365	\$ 15,300	\$ 0	\$ 5,109	\$ 245,774
Vice President of Finance	2010	\$ 217,699	\$ 29,389	\$ 0	\$ 2,109	\$ 249,197
William (BJ) Lehmann, Jr.,	2009	\$ 213,430	\$ 42,686	\$ 68,775	\$ 0	\$ 324,891
President and Chief Operating Officer	2011	\$ 346,714	\$ 27,000	\$ 0	\$ 4,673	\$ 378,387
John Harrington,	2010	\$ 334,921	\$ 45,214	\$ 0	\$ 1,673	\$ 381,808
Chief Scientific Officer	2009	\$ 328,354	\$ 65,671	\$ 88,425	\$ 1,000	\$ 483,450
and Executive Vice President <sup>(2)</sup>	2011	\$ 346,714	\$ 27,000	\$ 0	\$ 4,355	\$ 378,069
Robert Deans,	2010	\$ 334,921	\$ 45,214	\$ 0	\$ 1,355	\$ 381,490
Executive Vice President, Regenerative Medicine	2009	\$ 328,354	\$ 65,671	\$ 88,425	\$ 1,000	\$ 483,450
	2011	\$ 292,898	\$ 24,300	\$ 0	\$ 5,620	\$ 322,818
	2010	\$ 262,355	\$ 35,418	\$ 0	\$ 5,620	\$ 303,393
	2009	\$ 257,211	\$ 51,442	\$ 78,600	\$ 6,000	\$ 393,253

<sup>(1)</sup> Amounts in column (f) do not necessarily reflect compensation actually received by our 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 the notes to the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

<sup>(2)</sup> Drs. Van Bokkelen and Harrington also served as our Directors for 2011, 2010 and 2009, but did not receive any compensation as our Directors.

**Employment Agreements and Arrangements**

**Dr. Gil Van Bokkelen.** On December 1, 1998, we entered into a one-year employment agreement, effective April 1, 1998, with Dr. Gil Van Bokkelen, to serve initially as President and Chief Executive Officer. The agreement automatically renews for subsequent one-year terms on April 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Van Bokkelen was entitled to an initial base salary of \$150,000, which may be increased at the discretion of the Board of

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B4

Directors, and an annual discretionary incentive bonus of up to 33% of his base salary. His salary for 2012 is \$430,000 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 \$1.0 million (which is \$2.0 million for 2012) 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.

---

**Table of Contents**

**Dr. John J. Harrington.** On December 1, 1998, we entered into a one-year employment agreement, effective April 1, 1998, with Dr. John J. Harrington to serve initially as Executive Vice President and Chief Scientific Officer. The agreement automatically renews for subsequent one-year terms on April 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Harrington was entitled to an initial base salary of \$150,000, which may be increased at the discretion of the Board of Directors, and an annual discretionary incentive bonus of up to 33% of his base salary. His salary for 2012 is \$357,116 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 \$1.0 million (which is \$2.0 million for 2012). For more information about severance arrangements under the agreement, see the disclosure under Potential Payments Upon Termination or Change of Control. Dr. Harrington has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of 18 months thereafter, he is restricted from, among other things, competing with us.

**Laura K. Campbell.** On May 22, 1998, we entered into a two-year employment agreement with Laura K. Campbell to serve initially as Controller. The agreement automatically renews for subsequent one-year terms on May 22 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Ms. Campbell was entitled to an initial base salary of \$70,200, which may be increased at the discretion of the Board of Directors. Her salary for 2012 is \$231,562 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 the Board of Directors. His salary for 2012 is \$358,849 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 the Board of Directors, and an annual discretionary incentive bonus of up to 30% of his base salary. His salary for 2012 is \$307,500 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



**Table of Contents**

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 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 5,500,000 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 the 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, which amounted to approximately \$88,000 in 2011. 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
	of	Securities		
	Securities	Underlying	Exercise	Date
Underlying	Unexercised	Price		
Unexercised	Options	Unexercisable		
Options	(#)	(c)	(\$)(e)	(f)
(b)	Exercisable	Unexercisable		
Gil Van Bokkelen	712,500	0	\$ 5.00	June 8, 2017 <sup>(1)</sup>
	25,000	0	\$ 5.28	December 23, 2019 <sup>(2)</sup>
Laura Campbell	200,000	0	\$ 5.00	June 8, 2017 <sup>(1)</sup>
	17,500	0	\$ 5.28	December 23, 2019 <sup>(2)</sup>
William (BJ) Lehmann, Jr.	400,000	0	\$ 5.00	June 8, 2017 <sup>(1)</sup>
	22,500	0	\$ 5.28	December 23, 2019 <sup>(2)</sup>
John Harrington	700,000	0	\$ 5.00	June 8, 2017 <sup>(1)</sup>
	22,500	0	\$ 5.28	December 23, 2019 <sup>(2)</sup>
Robert Deans	240,000	0	\$ 5.00	June 8, 2017 <sup>(1)</sup>
	20,000	0	\$ 5.28	December 23, 2019 <sup>(2)</sup>

<sup>(1)</sup> 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.



**Table of Contents**

(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.

**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 of Directors established an incentive program intended to promote retention and motivation of our executives. The program provides the named executive officers financial participation 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:

	Executive Benefit and Payments Upon Separation	Termination Without Cause or Voluntary For Good Reason <sup>(1)</sup>
<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

<sup>(1)</sup> 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.

**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 \$( <sup>(1)</sup> (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

## Edgar Filing: ATHERSYS, INC / NEW - Form 424B4

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 are included in the notes to the 2011 audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011. 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.

**Table of Contents**

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, after consultation with the independent compensation advisor, the Board 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 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, after consultation with the independent compensation advisor, the Board approved a change to the vesting schedule for anniversary stock option awards such that new awards 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 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.

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 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 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 of Director 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.

In November 2011, we entered into the Aspire Purchase Agreement with Aspire Capital, which provides that Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of shares of our common stock over a two-year term, subject to our election to sell any such shares, and the terms and conditions set forth therein. As part of the Aspire Purchase 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. As a result of this transaction, combined with shares of our common stock that Aspire Capital held prior to the November 2011 transaction, Aspire Capital became one of our largest stockholders, owning more than 5% of our shares of common stock outstanding upon completion of the transaction.

As of September 30, 2012, we sold an additional 800,000 shares to Aspire Capital pursuant to the Aspire Purchase Agreement at an average price of \$1.57 per share. Also, in our March 2012 private placement, Aspire Capital purchased an additional 966,184 shares of common stock and five-year warrants to purchase 966,184 shares of common stock with an exercise price of \$2.07 per share. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase one share of common stock at an offering price of \$2.07 per fixed combination, for a total purchase price to Aspire Capital of approximately \$2.0 million.

**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 October 15, 2012 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 October 15, 2012 are considered outstanding. These shares, however, are not considered outstanding when computing the percentage ownership of each other person.

Percentage ownership calculations for beneficial ownership for each person or entity are based on 30,052,843 shares of common stock outstanding as of October 15, 2012.

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

Name of Beneficial Owner	Number of Shares	Percent of Class
<b>Greater Than 5% Stockholders</b>		
Radius Venture Partners and affiliates <sup>(1)</sup>	1,600,000	5.3%
Aspire Capital Fund, LLC <sup>(2)</sup>	2,261,200	7.5%
Sabby Management, LLC <sup>(3)</sup>	2,036,956	6.8%
<b>Directors, Director Nominees and Executive Officers</b>		
Gil Van Bokkelen <sup>(4)</sup>	976,986	3.2%
Lee Babiss <sup>(5)</sup>	79,688	*
John Harrington <sup>(6)</sup>	819,144	2.7%
Ismail Kola <sup>(7)</sup>	75,000	*
Lorin Randall <sup>(8)</sup>	60,938	*
Kenneth Traub <sup>(9)</sup>	3,750	*
Jack Wyszomierski <sup>(10)</sup>	79,688	*
Laura Campbell <sup>(11)</sup>	240,563	*
Robert Deans <sup>(12)</sup>	264,000	*
William (BJ) Lehmann, Jr. <sup>(13)</sup>	429,400	1.4%
All directors and executive officers as a group (10 persons)	3,029,157	9.3%

\* Less than 1%.

<sup>(1)</sup> 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., or Radius II, 103,766 shares beneficially owned by Radius Venture Partners III, L.P., or Radius III, and 696,234 shares beneficially owned by Radius Venture Partners III QP, L.P., or Radius III QP) of common stock. Radius Venture Partners II, LLC is the general partner of Radius II.



## Edgar Filing: ATHERSYS, INC / NEW - Form 424B4

Radius Venture Partners III, LLC (which together with Radius Venture Partners II, LLC, we refer to as 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

*footnotes continued on following page*

**Table of Contents**

Venture Partners. 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.

- <sup>(2)</sup>To our knowledge, Aspire Capital has direct beneficial ownership of 2,261,200 shares of common stock. Aspire Capital also holds warrants to purchase 1,066,084 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, or Aspire Partners, as the managing member of Aspire Capital, SGM Holdings Corp., or 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 shared voting and investment power over shares of common stock 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.
- <sup>(3)</sup>A Schedule 13G filed with the SEC on October 9, 2012 reported that Sabby Management, LLC beneficially owned 2,036,956 shares (1,512,423 shares beneficially owned by Sabby Healthcare Volatility Master Fund, Ltd. and 524,533 shares beneficially owned by Sabby Volatility Warrant Master Fund, Ltd.) of common stock.
- <sup>(4)</sup>Includes vested options for 737,500 shares of common stock at a weighted average exercise price of \$5.01 per share.
- <sup>(5)</sup>Includes vested options for 79,688 shares of common stock at a weighted average exercise price of \$3.02 per share.
- <sup>(6)</sup>Includes vested options for 722,500 shares of common stock at a weighted average exercise price of \$5.01 per share.
- <sup>(7)</sup>Includes vested options for 75,000 shares of common stock at a weighted average exercise price of \$2.72 per share.
- <sup>(8)</sup>Includes vested options for 60,938 shares of common stock at a weighted average exercise price of \$2.20 per share.
- <sup>(9)</sup>Includes vested options for 3,750 shares of common stock at a weighted average exercise price of \$1.43 per share.
- <sup>(10)</sup>Includes vested options for 79,688 shares of common stock at a weighted average exercise price of \$2.94 per share.
- <sup>(11)</sup>Includes vested options for 217,500 shares of common stock at a weighted average exercise price of \$5.02 per share.
- <sup>(12)</sup>Includes vested options for 260,000 shares of common stock at a weighted average exercise price of \$5.02 per share.
- <sup>(13)</sup>Includes vested options for 422,500 shares of common stock at a weighted average exercise price of \$5.01 per share.

**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 as exhibits to the registration statement of which this prospectus forms a part.

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 as exhibits to the registration statement of which this prospectus forms a part.

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**

---

**Table of Contents**

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.

**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),

---

**Table of Contents**

- (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 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%, 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****UNDERWRITING**

We are offering the shares of common stock described in this prospectus to the underwriters named below through Piper Jaffray & Co. as sole book-running manager. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and the underwriters have agreed to purchase from us, the respective number of shares of common stock appearing opposite their names below:

Underwriter	Number of Shares
Piper Jaffray & Co.	17,601,998
First Analysis Securities Corporation	2,200,002
<b>Total</b>	<b>19,802,000</b>

The underwriters are committed to purchase all the shares of common stock offered by us if it purchases any shares, other than those shares covered by the over-allotment option described below.

The underwriters have advised us that they propose to offer the shares of common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that same price less a concession not in excess of \$0.0364 per share. After the offering, these figures may be changed by the underwriters.

We have granted to the underwriters an option to purchase up to an additional 2,970,300 shares of common stock from us at the same price to the public as set forth above to cover over-allotments. The underwriters may exercise this option any time during the 30-day period after the date of this prospectus, but only to cover over-allotments, if any.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The following table shows the per share and total underwriting discounts to be paid to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

	No Exercise	Full Exercise
Per share	\$ 0.0606	\$ 0.0606
Total	\$ 1,200,001	\$ 1,380,001

Leerink Swann LLC and WBB Securities LLC are acting as financial advisors in connection with this offering and each is entitled to a financial advisory fee of \$60,000, which amounts will be paid out of the underwriting commissions. From time to time during 2012, First Analysis Securities Corporation provided financial and other strategic advice to the Company, for which it received a fee in the amount of \$30,000. The fee may be deemed underwriting compensation.

We estimate that the total fees and expenses payable by us, excluding underwriting discounts and commissions, will be approximately \$500,000.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

We and each of our directors and executive officers are subject to lock-up agreements that prohibit us and them from offering for sale, pledging, announcing the intention to sell, selling, contracting to sell, selling any option or contract to purchase, purchasing any option or contract to sell, granting any option, right or warrant to purchase, or otherwise transferring or disposing of, directly or indirectly, any shares

## **Table of Contents**

of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, or from entering into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock, for a period of at least 90 days following the date of the underwriting agreement without the prior written consent of Piper Jaffray & Co. The lock-up agreements do not prohibit our directors and executive officers from transferring shares of our common stock for bona fide estate or tax planning purposes, subject to certain requirements, including that the transferee be subject to the same lock-up terms, participating in any exchange of underwater options with us, acquiring or exercising stock options issued pursuant to our existing stock option plans, or entering into plans that satisfy the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act, provided that no sales are made under such plans during the lock-up period.

The lock-up agreements do not prohibit us from issuing shares upon the exercise or conversion of securities outstanding on the date of this prospectus. The lock-up provisions do not prevent us from selling shares to the underwriters pursuant to the underwriting agreement, or prevent us from granting options to acquire securities under our existing stock option plans or issuing shares upon the exercise or conversion of securities outstanding on the date of this prospectus.

The 90-day lock-up period in all of the lock-up agreements is subject to extension if (i) during the last 17 days of the lock-up period we issue an earnings release or material news or a material event relating to us occurs or (ii) prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions imposed in these lock-up agreements shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event, unless Piper Jaffray & Co. waives the extension in writing.

Our shares are quoted on The NASDAQ Capital Market under the symbol ATHX.

To facilitate the offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock during and after the offering. Specifically, the underwriters may over-allot or otherwise create a short position in the common stock for their own accounts by selling more shares of common stock than we have sold to them. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. The underwriters may close out any short position by either exercising their option to purchase additional shares or purchasing shares in the open market.

The underwriters may also engage in passive market making transactions in our common stock. Passive market making consists of displaying bids on The NASDAQ Capital Market limited by the prices of independent market makers and effecting purchases limited by those prices in response to order flow. Rule 103 of Regulation M promulgated by the SEC limits the amount of net purchases that each passive market maker may make and the displayed size of each bid. Passive market making may stabilize the market price of our common stock at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

This prospectus in electronic format may be made available on web sites maintained by the underwriters, and the underwriters may distribute prospectus supplements electronically.

From time to time in the ordinary course of their respective businesses, the underwriters and certain of their affiliates may in the future engage in commercial banking or investment banking transactions with us and our affiliates.



## **Table of Contents**

### **LEGAL MATTERS**

The validity of the issuance of the common stock offered by this prospectus will be passed upon for us by Jones Day. Goodwin Procter LLP, New York, New York has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

### **EXPERTS**

The consolidated financial statements of Athersys, Inc. appearing in Athersys, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2011 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference 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 our 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.

### **INFORMATION WE INCORPORATE BY REFERENCE**

The SEC allows us to incorporate by reference into this prospectus the information in documents we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. Any statement contained in any document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded to the extent that a statement contained in or omitted from this prospectus, or in any other subsequently filed document that also is or is deemed to be incorporated by reference, modifies or supersedes such statement. Any such statement so modified or

**Table of Contents**

superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We incorporate by reference the documents listed below:

our annual report on Form 10-K for the year ended December 31, 2011;

our quarterly reports on Form 10-Q for the quarters ended March 31, 2012 and June 30, 2012;

our definitive proxy statement on Schedule 14A filed with the SEC on April 27, 2012;

our current reports on Form 8-K filed on February 27, 2012, March 15, 2012 and June 22, 2012; and

the description of our common stock set forth in the registration statement on Form 8-A filed on December 6, 2007, and all amendments and reports filed for the purpose of updating that description.

We do not, however, incorporate by reference in this prospectus any documents or portions thereof that are not deemed filed with the SEC, including any information furnished pursuant to Item 2.02 or Item 7.01 of our current reports on Form 8-K.

You may obtain copies of these filings without charge by accessing the investors section of [www.athersys.com](http://www.athersys.com) or by requesting the filings in writing or telephoning us at the following address and telephone number:

Athersys, Inc.

3201 Carnegie Avenue

Cleveland, Ohio 44115-2634

(216) 431-9900 Attn: Secretary

**Table of Contents**

**19,802,000 Shares**

**Athersys, Inc.**

**Common Stock**

**PROSPECTUS**

*Sole Book-Running Manager*

**Piper Jaffray**

**First Analysis Securities Corporation**

October 25, 2012