

ATHERSYS, INC / NEW
Form S-1
October 09, 2012
Table of Contents

As filed with the Securities and Exchange Commission on October 9, 2012

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-1
REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Athersys, Inc.

(Exact name of registrant as specified in its charter)

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Delaware (State or other jurisdiction of incorporation or organization)	2834 (Primary Standard Industrial Classification Code Number) 3201 Carnegie Avenue Cleveland, Ohio 44115-2634 (216) 431-9900	20-4864095 (I.R.S. Employer Identification Number)
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(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Gil Van Bokkelen

Chief Executive Officer

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Cleveland, Ohio 44115-2634

(216) 431-9900

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Approximate date of commencement of proposed sale to the public: As soon as practical after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ...

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If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
 Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered ⁽¹⁾	Proposed Maximum Offering Price per Unit ⁽²⁾	Proposed Maximum Aggregate Offering Price ⁽²⁾	Amount of Registration Fee
Common Stock, \$0.001 par value per share	19,550,000	\$1.31	\$25,610,500	\$3,494

⁽¹⁾ Includes shares of common stock issuable pursuant to an option granted to the underwriter.

⁽²⁾ Estimated solely for calculating the amount of the registration fee, pursuant to Rule 457(c) promulgated under the Securities Act of 1933, on the basis of the average of the high and low sale prices of the Common Stock on The NASDAQ Capital Market on October 4, 2012, within five business days prior to filing.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities under this registration statement until the registration statement filed with the Securities and Exchange Commission is declared effective. This prospectus is not an offer to sell any securities, and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED OCTOBER 9, 2012

PROSPECTUS

17,000,000 Shares

Athersys, Inc.

Common Stock

We are offering 17,000,000 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 8, 2012, as reported by The NASDAQ Capital Market, was \$1.32 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		
Underwriting Discounts and Commissions		
Proceeds to Us, Before Expenses		

We have granted the underwriter the right to purchase, exercisable within a 30-day period, up to an additional 2,550,000 shares of our common stock solely to cover over-allotments.

The underwriter expects to deliver the shares of common stock against payment on or about _____, 2012.

Piper Jaffray

Prospectus dated _____, 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[®], 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

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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	17,000,000 shares (or 19,550,000 shares if the underwriter exercises its option to purchase additional shares to cover over-allotments in this offering in full).
Common stock to be outstanding immediately after this offering	46,515,343 shares (or 49,065,343 shares if the underwriter exercises its 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 underwriter of its 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
Consolidated Statement of Operations Data:					
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
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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, 2011	June 30, 2012
Consolidated Balance Sheet Data:		
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.