ATHERSYS, INC / NEW
Form 424B3
April 17, 2012
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Registration No. 333-178418

PROSPECTUS

8,000,000 Shares

Athersys, Inc.

Common Stock

This prospectus relates to a common stock purchase agreement that we entered into with Aspire Capital Fund, LLC (referred to in this prospectus as Aspire Capital or the selling stockholder) and the potential sale of up to 8,000,000 shares of our common stock by Aspire Capital, consisting of 6,866,666 shares that we may issue at our option to Aspire Capital in the future pursuant to the terms of that purchase agreement, 866,667 shares that we previously sold to Aspire Capital pursuant to that purchase agreement, and 266,667 shares that we previously issued to Aspire Capital as consideration for entering into that purchase agreement. The prices at which Aspire Capital may sell the shares pursuant to this prospectus will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of our shares by Aspire Capital. However, we may receive proceeds of up to an additional $18.6 million from the sale of our common stock to Aspire Capital pursuant to that purchase agreement we entered into with Aspire Capital.

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

Our common stock is listed on The NASDAQ Capital Market under the symbol ATHX. The last sale price of our common stock on April 13, 2012, as reported by The NASDAQ Capital Market, was $1.40 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.

Prospectus dated April 16, 2012.

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

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the section entitled Risk Factors and the documents that we incorporate by reference into this prospectus, before making an investment decision.

The Company

We are an international biopharmaceutical company that is focused in the field of regenerative medicine. We are committed to the discovery and development of best-in-class therapies designed to extend and enhance the quality of human life and have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. We are developing our lead platform product, MultiStem®, a patented and proprietary allogeneic stem cell product that has been evaluated in two 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 has demonstrated the ability to enhance 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 MultiStem 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. In contrast to traditional pharmaceutical products or biologics that are capable of acting through a single biological mechanism of action, the MultiStem product can enhance healing and tissue repair through multiple distinct mechanisms in parallel, by producing multiple therapeutic factors and dynamically responding to the needs of the body resulting in a more effective therapeutic response.

The MultiStem product is unique because, unlike other approaches to regenerative medicine, it can be manufactured on a large scale, it may be administered in an off-the-shelf manner with minimal processing, can augment healing in multiple ways (and in ways that other cell therapy approaches do not appear to be capable of). 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. Even so, the therapeutic effects of treatment with MultiStem cells appear to be durable.

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

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

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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 completed clinical trials, one exploring the potential to treat patients that have suffered a heart attack and the other evaluating the potential to provide supportive care and reduce graft versus host disease, or GvHD, as well as other complications in patients being treated for leukemia or related conditions. MultiStem is also being evaluated in two additional ongoing 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, which is also 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 indentify and develop novel pharmaceuticals to treat obesity, related metabolic conditions such as diabetes, and certain neurological indications, and small molecule compounds that may be used to enhance the production or therapeutic effectiveness of MultiStem or related products, increase the product s biological potency for certain indications and lead to second or third generation products in the regenerative medicine area.

Recent Developments

On March 9, 2012, we entered into a securities purchase agreement with certain investors pursuant to which we completed an offering of 4,347,827 shares of our common stock. We refer to this offering throughout this prospectus as the private placement. Investors in the private placement also 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. The exercise price of the warrants is subject to adjustment upon certain transactions, including stock splits, stock dividends, consolidations, reclassifications or similar events effecting our common stock. We received gross proceeds of approximately $9.0 million from the private placement.

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.

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Corporate Information

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

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The Offering

Common stock being offered by the selling stockholder	8,000,000 shares
Common stock outstanding	29,398,024 shares (as of March 31, 2012)
Use of proceeds	The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to an additional $18.6 million in proceeds from the sale of our common stock to the selling stockholder under the common stock purchase agreement described below, which we currently intend to use for working capital and general corporate purposes. See Use of Proceeds.
Risk factors	See Risk Factors beginning on page 7 and other information included in this prospectus for a discussion of factors you should carefully consider before deciding whether to invest in our common stock.
NASDAQ symbol	Our common stock is listed on The NASDAQ Capital Market, or NASDAQ, under the symbol ATHX.

Unless otherwise indicated, all information in this prospectus reflects or assumes:

- the exclusion of 4,557,826 shares of common stock authorized and reserved for future issuance under outstanding awards under our equity incentive plans;
- the exclusion of 942,174 shares of common stock authorized and reserved for future issuance under our equity incentive plans;
- the exclusion of 1,075 shares of common stock issuable upon exercise of additional outstanding stock options;
- the exclusion of 10,783,323 shares of common stock issuable upon exercise of outstanding warrants; and
- the exclusion of any additional milestone payments to our former lenders, whether in the form of cash or shares of common stock.

On November 11, 2011, we entered into a common stock purchase agreement (the agreement, as amended, is referred to in this prospectus as the Purchase Agreement), with Aspire Capital Fund, LLC, an Illinois limited liability company (referred to in this prospectus as Aspire Capital or the selling stockholder), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $20.0 million of shares of our common stock over the approximately 24-month term of the Purchase Agreement, should we elect to sell shares to Aspire Capital. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 266,667 shares of our common stock, which we refer to as the Commitment Shares, as a commitment fee. Upon execution of the Purchase Agreement, we sold to Aspire Capital 666,667 shares of common stock, which we refer to as the Initial Purchase Shares, for an aggregate purchase price of $1,000,000. Also, in February 2012, we sold 200,000 shares of common stock to Aspire Capital at an average price of $1.85 per share. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, which we refer to as the Registration Rights Agreement, pursuant to which

we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

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As of March 31, 2012, there were 29,398,024 shares of our common stock outstanding. The 8,000,000 shares of our common stock offered hereby represent approximately 27.2% of the total number of shares of our common stock outstanding as of March 31, 2012. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering under the Securities Act 8,000,000 shares of our common stock, which includes the Commitment Shares, the Initial Purchase Shares and the 200,000 shares that have already been issued to Aspire Capital and an additional 6,866,666 shares of common stock that we may issue to Aspire Capital. All 8,000,000 shares of common stock are being offered pursuant to this prospectus.

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

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

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

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

On January 17, 2012, the SEC declared effective the registration statement, of which this prospectus is a part, and on January 26, 2012 all conditions to commencement were satisfied and we may now sell shares of our common stock to Aspire Capital pursuant to the Purchase Agreement. In February 2012, we sold 200,000 shares to Aspire Capital at an average price of $1.85 per share.

In March 2012, in connection with the private placement financing, we agreed not to sell any shares of common stock, including to Aspire Capital, until the earlier of the 180th day after the closing date or the 30th day after the resale registration statement covering the resale of the shares sold in the financing is declared effective.

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Summary Consolidated Financial Data

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

	Year Ended December 31,		
	2011	2010	2009
	(in thousands, except per share data)		
Consolidated Statement of Operations Data:			
Contract and grant revenues	$ 10,344	$ 8,939	$ 2,159
Operating expenses	24,124	20,450	17,774
Loss from operations	(13,780)	(11,511)	(15,615)
Other income, net	34	134	249
Net loss	$ (13,746)	$ (11,377)	$ (15,366)
Basic and diluted net loss per common share	$ (0.59)	$ (0.60)	$ (0.81)
Weighted average shares used in computing basic and diluted net loss per common share	23,239	18,930	18,928

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

	December 31, 2011	December 31, 2010
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities	$ 12,784	$ 15,181
Working capital	6,986	9,106
Total assets	15,701	19,106
Warrant liability	983	
Total stockholders equity	7,298	9,005

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RISK FACTORS

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

Risks Related To Our Business and Our Industry

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

Since our inception in 1995, we have incurred significant losses and negative cash flows from operations. We incurred net losses of $15 million in 2009, $11 million in 2010 and $14 million in 2011. As of December 31, 2011, we had an accumulated deficit of $219 million, and anticipate incurring additional losses for at least the next several years. We expect to spend significant resources over the next several years to enhance our technologies and to fund research and development of our pipeline of potential products. To date, substantially all of Athersys revenue has been derived from corporate collaborations, license agreements and government grants. In order to achieve profitability, we must develop products and technologies that can be commercialized by us or through future collaborations. Our ability to generate revenues and become profitable will depend on our ability, alone or with potential collaborators, to timely, efficiently and successfully complete the development of our product candidates. We have never earned revenue from selling a product and we may never do so, as none of our product candidates have been approved for sale, since they are currently being tested yet in humans and animal studies. We cannot assure you that we will ever earn revenue or that we will ever become profitable. If we sustain losses over an extended period of time, we may be unable to continue our business.

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

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

At December 31, 2011, we had $12.8 million of cash, cash equivalents and investments, and we will need substantially more to advance our product candidates through development. Furthermore, we will need to add additional capital to fund our operations through the completion of our current clinical trials. Our future capital requirements will depend on many factors, including:

- our ability to raise capital to fund our operations;
- the progress and costs of our research and development programs, including our ability to develop our current portfolio of therapeutic products, or discover and develop new ones;
- our ability, or our partners ability and willingness, to advance partnered products or programs, and the speed in which they are advanced;
- the cost of prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the progress, scope, costs, and results of our preclinical and clinical testing of any current or future pharmaceutical or MultiStem related products;

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- 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 Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the agreement is limited. See The Aspire Capital Transaction section of this prospectus for additional information. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement during the continuance of an event of default or at a purchase price of less than $1.45. Even if we are able to access the full $20.0 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans. In March 2012, in connection with the private placement financing, we agreed not to sell any shares of common stock, including to Aspire Capital, until the earlier of the 180th day after the closing date and the 30th day after the resale registration statement covering the resale of the shares sold in the financing is declared effective.

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

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

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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.

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.

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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 for the treatment of IBD, and our collaboration with RTI Biologics Inc., or RTI, to develop and commercialize Multipotent Adult Progenitor Cell, or MAPC, technology-based biologic implants for certain orthopedic applications in the bone graft substitutes market, and our license with the University of Minnesota pursuant to which we license certain aspects of the MultiStem technology. These arrangements do not have specific termination dates; rather, each arrangement terminates upon the occurrence of certain events.

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

Our success depends on the performance by our collaborators of their responsibilities under our collaboration arrangements. Some potential collaborators may not perform their obligations in a timely fashion or in a manner satisfactory to us. Typically, we cannot control the amount of resources or time our collaborators may devote to our programs or potential products that may be developed in collaboration with us. We are currently involved in multiple research and development collaborations with academic and research institutions. These collaborators frequently depend on outside sources of funding to conduct or complete research and development, such as grants or other awards. In addition, our academic collaborators may depend on graduate students, medical students, or research assistants to conduct certain work, and such individuals may not be fully

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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;
- 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.

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

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

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

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

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

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

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

- the size of the patient population;
- the proximity of patients to clinical sites;

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- 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 th