BTHC VI Inc
Form S-3/A
August 22, 2007

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As filed with the Securities and Exchange Commission on August 22, 2007
Registration No. 333-144433

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

AMENDMENT NO. 1
TO
FORM S-1
ON
FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BTHC VI, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**20-4864095**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*

3201 Carnegie Avenue
Cleveland, Ohio 44115-2634
Telephone: (216) 431-9900
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Dr. Gil Van Bokkelen
Chief Executive Officer
3201 Carnegie Avenue

Cleveland, Ohio 44115-2634
Telephone: (216) 431-9900
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Christopher M. Kelly
Jones Day
North Point
901 Lakeside Avenue
Cleveland, Ohio 44114
Telephone: (216) 586-3939

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. þ

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

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. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

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 this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

This Amendment No. 1 to Form S-1 on Form S-3 is being filed to convert the Registration Statement on Form S-1 (No. 333-144433) into a Registration Statement on Form S-3. The Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3.

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

SUBJECT TO COMPLETION, DATED AUGUST 22, 2007

18,508,251 Shares of Common Stock

BTHC VI, Inc.

This prospectus relates to offers and resales or other dispositions by certain of our stockholders or their transferees of up to 18,508,251 shares of our common stock, par value $0.001 per share, including 4,976,470 shares issuable upon the exercise of warrants.

These shares may be sold by the selling stockholders from time to time in the over-the-counter market or on any national securities exchange or automated interdealer quotation system on which our common stock is then listed or quoted, through negotiated transactions or otherwise. The prices at which the selling stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any of the proceeds from the disposition of these shares by the selling stockholders, other than as a result of the exercise for cash of warrants held by the selling stockholders. We will bear all costs, expenses and fees in connection with the registration of these shares. The selling stockholders will bear all commissions and discounts, if any, attributable to their respective sales of shares.

Our common stock is currently quoted on the OTC Bulletin Board under the symbol BVIC. On August 21, 2007, the last reported sales price of our common stock on the OTC Bulletin Board was $7.60 per share.

Investing in our common stock involves risks that are described in the Risk Factors section beginning on page 5 of this prospectus. You should carefully consider the risk factors before you decide whether to invest in shares of our common stock.

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.

The date of this prospectus is , 2007.

If it is against the law in any state or other jurisdiction to make an offer to sell the common stock, or to solicit an offer from someone to buy the common stock, registered pursuant to the registration statement of which this prospectus forms a part, then this prospectus does not apply to any person in that state or other jurisdiction, and no offer or solicitation is made by this prospectus to any such person.

You should rely only on the information contained in this prospectus or any related prospectus supplement. Neither we nor any selling stockholder has authorized anyone to provide you with different information. You should not assume that the information in this prospectus or any related prospectus supplement is accurate as of any date other than the date on the front of such document.

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INDUSTRY AND MARKET DATA

Information about market and industry statistics contained in this report is included based on information available to us that we believe is accurate in all material respects. It is generally based on academic and other publications that are not produced for purposes of securities offerings or economic analysis. We have not reviewed or included data from all sources, and we cannot assure potential investors of the accuracy or completeness of the data included in this report. Forecasts and other forward-looking information obtained from these sources, including estimates of future market size, revenue and market acceptance of products and services, are subject to the same qualifications and the additional uncertainties accompanying any forward-looking statements.

This prospectus contains references to our trademarks MultiStem™ and Random Activation of Gene Expression RAGE™. All other trademarks used in this prospectus are the property of their respective owners.

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PROSPECTUS SUMMARY

This summary highlights selected information that is contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, including the Risk Factors section and our consolidated financial statements and related notes appearing elsewhere in this prospectus before making an investment decision. In this prospectus, unless otherwise indicated or the context otherwise requires, all references to we or us are to BTHC VI, Inc., a Delaware corporation, together with its wholly owned subsidiary, Athersys, Inc., a Delaware corporation. Specific discussions or comments relating only to BTHC VI, Inc. prior to the merger described below reference BTHC VI, while those relating only to Athersys, Inc. prior to the merger reference Athersys.

Our Business

We are a biopharmaceutical company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human life. Through the application of our proprietary technologies, we have established a pipeline of therapeutic product development programs in multiple diseases. We have one product candidate in clinical development (ATHX-105) and intend to advance two to three additional product development programs (from MultiStem® cardiovascular, oncology support or stroke, or from our histamine H3 antagonist program) into clinical trials in 2007 and 2008. Our ability to initiate these trials will depend on the success of our ongoing preclinical development efforts and our obtaining necessary regulatory approvals. Our lead product candidate is ATHX-105, which is a treatment for obesity we are independently developing that acts by stimulating the 5HT2c receptor, a key neurotransmitter receptor in the brain, which regulates appetite. ATHX-105 has been shown in preclinical testing in animal models to reduce food intake and body weight by suppressing appetite without appearing to cause the adverse side effects that have been observed with other weight loss drugs. Results from clinical trials we conduct in humans may differ from our preclinical results.

In July 2007, we initiated a Phase I clinical trial for ATHX-105 in the United Kingdom. The primary objective of the Phase I clinical trial is to assess the short-term safety of ATHX-105 and to establish an appropriate dose range for subsequent clinical studies that will be conducted in order to assess safety and effectiveness. Following successful completion of the Phase I clinical trial and concurrent non-clinical studies that must be completed, we intend to initiate a Phase II clinical trial in the United States that will examine safety and effectiveness in clinically overweight or obese patients. In addition to ATHX-105, we have a portfolio of other compounds that we are developing as potential treatments for obesity.

We are also independently developing orally active pharmaceutical products for the treatment of central nervous system disorders, including sleep disorders such as narcolepsy or excessive daytime sleepiness, and other potential indications such as attention deficit hyperactivity disorder, or ADHD, and other cognitive disorders. These histamine H3 antagonist compounds are designed to act by elevating levels of neurotransmitters in the sleep and cognitive centers of the brain and stimulating neurological tone, resulting in an enhanced state of wakefulness and cognition, without causing hyperactivity or addiction.

In addition to our pharmaceutical development programs, we are developing MultiStem, a proprietary stem cell product for the treatment of multiple disease indications. MultiStem is a biologic product that consists of human stem cells obtained from adult bone marrow or other nonembryonic tissue sources. After cells are isolated from a qualified donor, the cells may be produced on a large scale for future clinical use and stored in frozen form until needed. We believe that MultiStem may potentially be used to treat a range of distinct disease indications, with each indication representing a distinct product development program requiring separate clinical trials. In May 2006, we entered into a

product co-development collaboration with Angiotech Pharmaceuticals, Inc. to jointly develop and ultimately market MultiStem for the treatment of damage caused by myocardial infarction and peripheral vascular disease. We are also independently developing MultiStem for bone marrow transplant/oncology support, ischemic stroke and potentially other disease indications. We retain the commercial rights to these programs and other potential applications of MultiStem.

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In addition to our current product development programs, we have developed our Random Activation of Gene Expression, or RAGE, technology, a patented technology that provides us with the ability to produce human cell lines that express specific, biologically well validated drug targets without relying upon cloned and isolated gene sequences. While our RAGE technology is not a product, it is a commercial technology that we have been successfully applying in our collaborations 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 splicing) in order to create a cell line that expresses a drug target of interest. Researchers may then use the genetically modified cell line to identify pharmaceutical compounds that inhibit or stimulate the target of interest. The RAGE technology enables us to turn on or amplify the expression of a drug target without having to physically clone or isolate the gene. In effect, the technology works through the random insertion of tiny, proprietary genetic switches that randomly turn genes on without requiring their physical isolation, or any advance knowledge of their structure. This technology provides us with broad freedom to work with targets that may be inaccessible to most other companies as a result of intellectual property restrictions on the use of specific cloned and isolated genes.

Over the past several years, we have produced cell lines that express drug targets in a range of disease areas such as metabolic disease, infectious disease, oncology, cardiovascular disease, inflammation, and central nervous system disorders. Many of these were produced for drug development programs at major pharmaceutical companies that we have collaborated with, such as our ongoing collaboration with the Bristol-Myers Squibb Company, and some have been produced for our internal drug development programs.

We are in the early stage of product development, and we do not have any approved therapeutic products. As of June 30, 2007, we had an accumulated deficit of $151.3 million. We incurred net losses of $15.2 million in 2004, $14.6 million in 2005, $10.6 million in 2006 and $9.8 million in the first six months of 2007, and we anticipate incurring losses for at least the next several years.

Recent Developments

On May 24, 2007, BTHC VI, Inc., a Delaware corporation, and its wholly owned subsidiary, B-VI Acquisition Corp., a Delaware corporation, entered into an Agreement and Plan of Merger with Athersys, Inc., a Delaware corporation. Pursuant to the terms of the Agreement and Plan of Merger, B-VI Acquisition Corp., which BTHC VI recently had incorporated in the state of Delaware for the purpose of completing the merger transaction described in this subsection, merged with and into Athersys on June 8, 2007, with Athersys continuing as the surviving entity in the merger. We refer to the merger transaction as the merger, and to June 8, 2007 as the closing or closing date. As a result of the merger, Athersys became our wholly owned subsidiary, and the business of Athersys became our sole operations. After receiving the requisite approval of the stockholders of Athersys pursuant to a written consent of stockholders, a Certificate of Merger was filed with the Secretary of State of the State of Delaware on the closing date, at which time the merger was deemed effective. At the time the merger was deemed effective, each share of common stock of Athersys was converted into 0.0358493 shares of our common stock, par value $0.001 per share.

Prior to the merger, BTHC VI effected a 1-for-1.67 reverse stock split of the shares of its common stock. Following the reverse stock split, 299,622 shares of our common stock were issued and outstanding. BTHC VI amended its certificate of incorporation to effect the reverse stock split and to increase the number of authorized shares of common stock to 100,000,000.

As of the closing date, we acquired ownership of all of the outstanding capital stock of Athersys, resulting in a change in control of BTHC VI. As further described below, Athersys is a biopharmaceutical company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human

life. Following the merger, the business of Athersys constitutes our only operations. We experienced, as of the closing date, a change in control of our ownership, management and board of directors. The sole officer and director of BTHC VI resigned immediately prior to the closing of the merger and, immediately following the merger, Athersys existing officers were elected as our officers, and

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certain members of Athersys board of directors and other individuals selected by Athersys were appointed to the board of directors.

BTHC VI s acquisition of Athersys on June 8, 2007 effected a change in control and was accounted for as a reverse acquisition whereby Athersys is the accounting acquiror for financial statement purposes. Accordingly, for all periods after the June 8, 2007 reverse acquisition transaction, our historical financial statements reflect the financial statements of Athersys since its inception and the operations of BTHC VI subsequent to June 8, 2007.

On June 8, 2007, we entered into a Securities Purchase Agreement by and among BTHC VI, Athersys and certain investors pursuant to which we completed an offering of 13,000,000 shares of our common stock. We refer to this offering throughout this document as the June offering. Investors in the June offering also received five-year warrants to purchase an aggregate of 3,250,000 shares of common stock with an exercise price of $6.00 per share. Radius Venture Partners II, L.P., Radius Venture Partners III, L.P. and certain of their respective affiliates, whom we refer to collectively as Radius, acted as the lead investors in the June offering and received additional five-year warrants to purchase an aggregate of 500,000 shares of common stock with a cash or cashless exercise price of $6.00 per share in connection with their $10.0 million investment. OrbiMed Advisors LLC, RA Capital Fund, LP, Accipiter Capital Management LLC and Hambrecht & Quist Capital Management LLC and their respective affiliates also invested $15.0 million, $6.0 million, $6.0 million and $4.0 million, respectively, in the June offering. We received gross proceeds of $65.0 million from the June offering. The placement agents for the June offering received five-year warrants to purchase an aggregate of 1,093,525 shares of common stock with a cash or cashless exercise price of $6.00 per share.

Corporate Information

We were incorporated in Delaware in June 2005. Our executive offices are located at 3201 Carnegie Avenue, Cleveland, Ohio 44115. Our telephone number is (216) 431-9900. Our website address is www.athersys.com. The information on or accessible through our website is not a part of this prospectus.

The Offering

This prospectus relates to the resale by the selling stockholders identified in this prospectus of up to 18,508,251 shares of common stock, of which 13,531,781 shares are issued and outstanding as of August 21, 2007, and 4,976,470 shares are issuable upon the exercise of certain warrants. All of the shares, when sold, will be sold by these selling stockholders. The selling stockholders may sell their shares of common stock from time to time at market prices prevailing at the time of sale, at prices related to the prevailing market price, or at negotiated prices. We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders, other than as a result of the exercise of warrants held by the selling stockholders for cash.

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Summary Consolidated Financial Data

The following is a summary of our results of operations and financial position (in thousands, except share and per share data). You should read this information together with our financial statements and the related notes appearing at the end of this prospectus and the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this prospectus.

	Year Ended December 31,			Six Months Ended June 30,	
	2004	2005	2006	2006	2007
				(Unaudited)	
Consolidated Statement of Operations Data:					
License fee and grant revenues	$ 3,138	$ 3,596	$ 3,725	$ 1,119	$ 1,602
Operating expenses	18,536	17,566	13,616	6,992	11,614
Loss from operations	(15,398)	(13,970)	(9,891)	(5,873)	(10,012)
Other income		18	208	208	1,500
Interest income (expense), net	244	(647)	(928)	(423)	(821)
Accretion of premium on convertible debt			(260)		(456)
Cumulative effect of change in accounting principle			306	306	
Net loss	$ (15,154)	$ (14,599)	$ (10,565)	$ (5,782)	$ (9,789)
Preferred stock dividends	$ (2,325)	$ (2,253)	$ (1,408)	$ (695)	$ (659)
Net loss attributable to common stockholders	$ (17,479)	$ (16,852)	$ (11,973)	$ (6,477)	$ (10,448)
Basic and diluted net loss per common share	$ (59.82)	$ (57.79)	$ (40.84)	$ (22.14)	$ (4.10)
Weighted average shares used in computing basic and diluted net loss per common share	292,173	291,612	293,142	292,513	2,547,265

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 and basic and diluted net loss per common share.

	June 30, 2007 (Unaudited)
Consolidated Balance Sheet Data:	

Cash, cash equivalents and investments	$	58,939
Working capital		54,401
Total assets		61,065
Total stockholders equity		55,710

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RISK FACTORS

An investment in our common stock involves a substantial degree of risk. Accordingly, you should carefully consider the following risk factors, together with all the other information contained in this prospectus, before making a decision to invest 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, prospects, reputation, financial condition, and results of operations could be seriously harmed. In that case, the market price of our common stock could decline, and you could lose all or a part of your investment. For more information, see Forward-Looking Statements.

Risks Related To Our Business and Our Industry

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

Since Athersys inception in 1995, it has incurred significant losses and negative cash flows from operations. Athersys has incurred net losses of $15.2 million in 2004, $14.6 million in 2005 and $10.6 million in 2006. As of June 30, 2007, Athersys had an accumulated deficit of $151.3 million, and anticipates incurring additional losses for at least the next several years. We expect to spend significant resources over the next several years to enhance our technologies and to fund research and development of our pipeline of potential products. To date, substantially all of Athersys revenue has been derived from corporate collaborations, license agreements, and government grants. In order to achieve profitability, we must develop products and technologies that can be commercialized by us or through future collaborations. Our ability to generate revenues and become profitable will depend on our ability, alone or with potential collaborators, to timely, efficiently and successfully complete the development of our product candidates. We have never earned revenue from selling a product and we may never do so, as none of our product candidates have been tested yet in humans. We cannot assure you that we will ever earn revenue or that we will ever become profitable. If we sustain losses over an extended period of time, we may be unable to continue our business.

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

The development of our product candidates will require a commitment of substantial funds to conduct the costly and time-consuming research, which may include preclinical and clinical testing, necessary to obtain regulatory approvals and bring our products to market. Net cash used in Athersys operations was $11.7 million in 2004, $12.1 million in 2005 and $8.4 million in 2006. Our current monthly burn rate, excluding capital expenditures and non-cash charges, is approximately $1.2 million to $1.6 million per month, and we anticipate a higher monthly burn rate over certain periods during the next several years as we begin costly clinical trials of ATHX-105 and MultiStem and continue to advance our various research and product development activities. We believe that our planned capital needs will be met at least through 2009 from our current cash on hand from the June offering as well as our cash from operations. Our future capital requirements will depend on many factors, including:

- the progress and costs of our research and development programs, including our ability to develop our current portfolio of therapeutic products, or discover and develop new ones;
- our ability, or our partners ability and willingness, to advance partnered products or programs;
- the cost of prosecuting, defending and enforcing patent claims and other intellectual property rights;

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

the time and cost involved in obtaining regulatory approvals;

the cost of manufacturing our product candidates;

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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.

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

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

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

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

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

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 United States Food and Drug Administration, or FDA, because of changes in the regulatory approval process;

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

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

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

This prospectus discusses the safety and efficacy seen in preclinical testing of our lead product candidates, including ATHX-105 and MultiStem, in animals, but we may not see positive results when ATHX-105, MultiStem or any of our other product candidates undergo clinical testing in humans in the future. Preclinical studies and Phase I clinical trials are not primarily designed to test the efficacy of a product candidate in humans, but rather to:

test safety;

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

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

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

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

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

We are in the early stage of product development, and we are dependent on the application of our technologies to discover or develop therapeutic product candidates. We currently do not sell any approved therapeutic products and do not expect to have any products commercially available for several years, if at all. You must evaluate us in light of the uncertainties and complexities affecting an early stage biotechnology company. Our product candidates require additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals or clearances before marketing. To date, no one to our knowledge has developed or commercialized any therapeutic products using our technologies and we might never commercialize any product using our technologies and strategy.

In addition, we may not succeed in developing new product candidates as an alternative to our existing portfolio of product candidates. If our current product candidates are delayed or fail, or we fail to successfully develop and commercialize new product candidates, our financial condition may be negatively affected, and we may have to curtail or cease our operations.

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

A key element of our business strategy is to commercialize some of our product candidates through collaborations with other companies. Our pharmaceutical strategy includes establishing collaborations and licensing agreements with one or more pharmaceutical, biotechnology or device companies, preferably after

we have advanced product candidates through the initial stages of clinical development. However, we may not be able to establish or maintain such licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

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

Currently, our material collaborations and licensing arrangements are our product co-development collaboration with Angiotech to jointly develop and ultimately market MultiStem for the treatment of damage caused by myocardial infarction and peripheral vascular disease, our collaboration agreement with Bristol-Myers Squibb pursuant to which we provide cell lines produced using our RAGE technology, and our license with the University of Minnesota pursuant to which we license certain of the MultiStem technology.

The Angiotech collaboration terminates upon the earliest to occur of (a) the five-year anniversary if we and Angiotech have not approved any clinical development program, (b) if at least one cell therapy product has obtained regulatory approval and we and Angiotech have shared profits with respect to sales of at least one cell therapy product, the date that there has been no sales for 12 months of any cell therapy product that has been the subject of profit-sharing, unless a clinical development candidate is in at least a Phase III clinical trial or later, or (c) the later of (1) the expiration date of the last-to-expire patent licensed to Angiotech or (2) the 15-year anniversary. Neither we nor Angiotech may terminate the collaboration at will. However, Angiotech has the right to terminate the collaboration if, among other things, Angiotech, in its reasonable judgment, determines that a primary endpoint in a clinical study within a clinical development plan has not been fulfilled or met, at least one investigational new drug application, or IND, has not been filed prior to the three-year anniversary, the clinical efficacy and/or safety with respect to cells, a clinical development candidate or a cell therapy product have not been demonstrated.

The Bristol-Myers Squibb collaboration terminates when Bristol-Myers Squibb no longer has an obligation to pay us royalties, which obligation generally continues until the later of the expiration of the Bristol-Myers Squibb patent covering a product utilizing our cell line or ten years after commercial sales of that product began.

The University of Minnesota license agreement terminates when the last patent licensed to us expires. We may terminate the