

ATHERSYS, INC / NEW

FORM 8-K (Current report filing)

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Table of Contents

[Table of Contents](#)

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **June 8, 2007**

BTHC VI, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other
Jurisdiction
of Incorporation)

0-52108

(Commission File
Number)

20-4494098

(I.R.S. Employer
Identification No.)

3201 Carnegie Avenue, Cleveland, Ohio

(Address of Principal Executive Offices)

44115-2634

(Zip Code)

Registrant's telephone number, including area code: **(216) 431-9900**

12890 Hilltop Road, Argyle, Texas 76226

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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CURRENT REPORT ON FORM 8-K
BTHC VI, INC.
TABLE OF CONTENTS

Item 1.01. Entry into a Material Definitive Agreement.

Item 2.01. Completion of Acquisition or Disposition of Assets.

Description of Business
Risk Factors
Financial Information
Properties
Security Ownership of Certain Beneficial Owners and Management
Directors and Executive Officers
Executive Compensation
Certain Relationships and Related Transactions, and Director Independence
Legal Proceedings
Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters
Recent Sales of Unregistered Securities
Description of Registrant's Capital Stock
Indemnification of Directors and Officers
Financial Statements and Supplementary Data
Change in and Disagreements With Accountants on Accounting and Financial Disclosure
Financial Statements and Exhibits

Item 3.02. Unregistered Sale of Equity Securities.

Item 3.03. Material Modification to Rights of Security Holders.

Item 4.01 Changes in Registrant's Certifying Accountant

Item 5.01. Changes in Control of Registrant.

**Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers;
Compensatory Arrangements of Certain Officers.**

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

Item 5.06. Change in Shell Company Status.

Item 9.01. Financial Statements and Exhibits.

EX-2.2
EX-3.1
EX-3.2
EX-4.1
EX-4.2
EX-4.3
EX-4.4
EX-10.1
EX-10.2
EX-10.3
EX-10.4
EX-10.5
EX-10.6
EX-10.7
EX-10.8
EX-10.9
EX-10.10
EX-10.11
EX-10.12
EX-10.13
EX-10.14
EX-10.15
EX-10.16
EX-10.17
EX-10.18
EX-10.19
EX-10.20
EX-10.21

EX-10.22
EX-10.23
EX-10.24
EX-10.25
EX-10.26
EX-10.27
EX-10.28
EX-10.29
EX-10.30
EX-10.31
EX-10.32
EX-10.33
EX-10.34
EX-10.35
EX-10.36
EX-16.1
EX-21.1
EX-99.1
EX-99.2
EX-99.3

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Current Report on Form 8-K contains forward-looking statements that involve risks and uncertainties. These forward-looking statements relate to, among other things, the expected timetable for development of our product candidates, our growth strategy, and our future financial performance, including our operations, economic performance, financial condition, prospects, and other future events. We have attempted to identify forward-looking statements by using such words as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “will,” or other similar expressions. These forward-looking statements are only predictions and are largely based on our current expectations. These forward-looking statements appear in a number of places in this Current Report.

In addition, a number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements, including the risks outlined under “Risk Factors” and elsewhere in this Current Report. Some of the more significant known risks that we face are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as human therapeutics, including the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues. These risks may cause our actual results, levels of activity, performance, or achievements to differ materially from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements.

Other important factors to consider in evaluating our forward-looking statements include:

- the possibility of delays in, adverse results of, and excessive costs of the development process;
- changes in external market factors;
- changes in our industry’s overall performance;
- changes in our business strategy;
- our ability to protect our intellectual property portfolio;
- our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;
- our possible inability to execute our strategy due to changes in our industry or the economy generally;
- changes in productivity and reliability of suppliers; and
- the success of our competitors and the emergence of new competitors.

Although we currently believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee our future results, levels of activity or performance. We do not expect to update any of the forward-looking statements after the date of this Current Report or to conform these statements to actual results, except as may be required by law. You should not place undue reliance on forward-looking statements contained in this report.

INDUSTRY AND MARKET DATA

Information about market and industry statistics contained in this report is included based on information available to Athersys that it believes 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.

Table of Contents

EXPLANATORY NOTE

Unless otherwise indicated or the context otherwise requires, all references below in this Current Report to “we,” “us” or the “Company” 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” or “PubCo,” while those relating only to Athersys, Inc. prior to the Merger reference “Athersys.”

Item 1.01. Entry into a Material Definitive Agreement.

SUMMARY OF MERGER

On May 24, 2007, BTHC VI, Inc., a Delaware corporation (“BTHC VI” or “PubCo”), and its wholly owned subsidiary, B-VI Acquisition Corp., a Delaware corporation (“Merger Sub”), entered into an Agreement and Plan of Merger (the “Merger Agreement”), with Athersys, Inc., a Delaware corporation (“Athersys”). Pursuant to the terms of the Merger Agreement, Merger Sub, which BTHC VI recently had incorporated in the state of Delaware for the purpose of completing the transaction described in this Current Report, merged with and into Athersys (the “Merger”) on June 8, 2007 (the “Closing” or the “Closing Date”), with Athersys continuing as the surviving entity in the Merger. 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 June 8, 2007, at which time the Merger was deemed effective (the “Effective Time”). At the Effective Time, each share of common stock of Athersys was converted into 0.0358493 shares of Company common stock, par value \$0.001 per share (the “Common Stock”).

Prior to the Merger, BTHC VI effected a 1-for-1.67 reverse stock split (the “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. In return, we issued 3,210,697 shares of Common Stock, resulting in a change in control of the Company. 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 “Board of Directors” or “Board”). 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 certain members of Athersys’ board of directors and other individuals selected by Athersys were appointed to the Board of Directors.

We believe that the issuances of our Common Stock in connection with the Merger were exempt from registration under Section 4(2) of the Securities Act. A copy of the Merger Agreement was filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on May 24, 2007.

SUMMARY OF OFFERING

On June 8, 2007, we entered into a Securities Purchase Agreement by and among BTHC VI, Athersys and the investors party thereto pursuant to which we completed an offering of 13,000,000 shares of our Common Stock (the “Offering”). Investors in the 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. The lead investor in the Offering, Radius Venture Partners II, L.P., Radius Venture Partners III, L.P. and certain of their respective affiliates (together, “Radius”), invested \$10,000,000 in the 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. We received gross proceeds of \$65 million from the Offering. Cowen & Co., LLC and National Securities

Table of Contents

Corporation acted as placement agents for the Offering and Punk Ziegel & Company, L.P. and Halter Financial Group, LP provided financial advice. The placement agents 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.

We believe that the issuances of our Common Stock and warrants to purchase Common Stock in connection with the Offering were exempt from registration under Section 4(2) of the Securities Act.

Item 2.01. Completion of Acquisition or Disposition of Assets.

As disclosed in this Current Report, on June 8, 2007, a new, wholly owned subsidiary of BTHC VI, Merger Sub, merged with and into Athersys, with Athersys continuing as the surviving entity in the Merger. As a result of the Merger, Athersys became our wholly owned subsidiary. Item 2.01(f) of Form 8-K provides that if a registrant is a shell company immediately before a transaction disclosed under Item 2.01, then the registrant must disclose the information that would be required if the registrant were filing a general form for registration of securities on Form 10. BTHC VI was a shell company immediately before the Merger. Accordingly, we are providing below the information that would be included in a Form 10 if we were to file a Form 10. Please note that the information provided below relates to the Company after the Merger, except that information relating to periods prior to the date of the Merger only relate to the party specifically indicated.

DESCRIPTION OF BUSINESS

Company Overview

We are a biopharmaceutical company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human life. Through the application of our proprietary technologies, we have established a pipeline of therapeutic product development programs in multiple disease areas that we intend to advance into clinical trials in 2007 and 2008. Our lead product candidate is ATHX-105, which is a novel treatment for obesity that acts by stimulating the 5HT_{2c} 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.

ATHX-105 has been approved to enter a Phase I clinical trial in the United Kingdom, which we intend to initiate as soon as possible using a portion of the net proceeds that we received in the Offering. 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 developing novel 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 and other cognitive disorders. These 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 nonembryonic stem cell product for the treatment of multiple disease indications. In May 2006, we entered into a product co-development collaboration with Angiotech Pharmaceuticals, Inc. ("Angiotech") 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.

Table of Contents

In addition to our current product development programs, we have developed our Random Activation of Gene Expression (“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. 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 Bristol-Myers Squibb, and some have been produced for our internal drug development programs.

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.

- *Apply our proprietary technologies toward the rapid identification, validation, and development of therapeutic product candidates.* We will continue to use our proprietary technologies to identify and validate therapeutic product candidates. We believe our technologies, including RAGE and MultiStem, provide us a competitive advantage in drug discovery and product development by allowing us to move products quickly from the discovery phase into clinical trials using a “fast follower” approach, thereby mitigating risk and reducing costs.
- *Enter into licensing or co-development arrangements for certain product candidates.* We intend to license certain of our product candidates to, or co-develop them with, qualified collaborators to broaden and accelerate our product development efforts. In order to enhance the value of our product candidates in these potential licensing or collaboration arrangements, we plan to internally develop our product candidates through at least Phase II clinical trials whenever possible. We anticipate that this strategy will help us to enhance our return on product candidates for which we enter into collaborations through the receipt of strategic equity investments, license fees, milestone payments, and profit sharing or royalties.
- *Internally develop, manufacture, and market other therapeutic products.* We will apply the capital we obtain from financing and collaborating activities toward the development of our other therapeutic product candidates. Our intention is to ultimately manufacture, market, and distribute these product candidates on our own after they have received FDA approval. We will select candidates for internal development based on several factors, including the required regulatory approval pathway and the potential market into which the product can be sold, and our ability to feasibly fund development activities through commercialization and marketing of the approved product.
- *Continue to expand our intellectual property portfolio.* Our intellectual property is important to our business and we take significant steps to protect its value. We have an ongoing research and development effort, both through internal activities and through collaborative research activities with others, which aims 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.
- *Out-license non-core applications of our technologies.* Certain elements of our technologies, such as their application toward the development of novel diagnostics or their use for the analysis and characterization of therapeutic product candidates, may not be relevant to the key elements of our corporate strategy. We believe these applications may have significant potential value, however, and can provide capital to us that can be applied to our other development efforts. Where appropriate, we may seek to license non-core applications of our technologies to others to realize this value.

Table of Contents

Our Current Programs

By applying our core technologies and capabilities, we have established preclinical drug development programs in the areas of obesity and central nervous system disorders. In addition, applying our proprietary cell therapy platform, MultiStem, we have established therapeutic product development programs in the areas of cardiovascular disease, oncology support and stroke. We currently intend to advance multiple programs into clinical development in 2007 and 2008.

Pharmaceutical Programs

ATHX-105 for Obesity

Obesity is a substantial contributing factor to a range of diseases that represent the major causes of death and disability in the developed world today. Individuals that are clinically obese have elevated rates of cardiovascular disease, stroke, certain types of cancer and diabetes. The percentage of individuals who are defined as clinically obese has risen dramatically over the past several decades. According to the United States Centers for Disease Control and Prevention (“CDC”), the incidence of obesity in the United States has increased at an epidemic rate during the past 20 years. CDC now estimates that 66% of all Americans are overweight and more than 30% are obese. This increase is not limited to adults. The percentage of young people who are overweight has more than tripled since 1980. Among children and teens aged six to 19 years, 16% (over nine million young people) are considered overweight. There has been a similar dramatic rise in the rate of obesity in Europe and Asia. Furthermore, the cost of this epidemic is significant. The FDA estimates that the total economic cost of obesity is currently about \$117 billion per year in the United States, including more than \$50 billion in avoidable medical costs. Despite the magnitude of this problem, current approaches to clinical obesity are largely ineffective, and we are aware of relatively few new therapeutic approaches in clinical development.

We are developing novel pharmaceutical treatments for obesity. Our most advanced drug development candidate is ATHX-105, a compound we discovered internally and have extensively analyzed and validated in preclinical studies. We believe that ATHX-105 represents a potential “best-in-class” obesity drug, based on its well validated mechanism of action, as well as the potency and overall safety profile we have observed in preclinical studies. We are developing ATHX-105 as a once-per-day orally administered pill to regulate appetite and reduce food intake in clinically obese individuals, defined as those individuals with a body mass index greater than 30. In addition to ATHX-105, we are developing a diverse portfolio of back-up compounds that act by the same mechanism as ATHX-105, as well as complementary obesity programs that act according to different biological mechanisms of action.

ATHX-105 is designed to act by stimulating a key receptor in the brain that regulates appetite and food intake – the 5HT_{2c} receptor. The role of this receptor in regulating food intake is well understood in both animal models and humans. In 1996, Wyeth Pharmaceuticals launched the anti-obesity drug Redux[®] (dexfenfluramine), a non-specific serotonin receptor agonist that was used with the stimulant phentermine in a combination commonly known as “fen-phen.” This diet drug combination gained rapid and widespread acceptance in the clinical marketplace, and was shown to be highly effective at regulating appetite, reducing food intake, and causing weight loss. Unfortunately, in addition to stimulating the 5HT_{2c} receptor, fen-phen also stimulated the 5HT_{2b} receptor that is found in the heart. The activation of 5HT_{2b} by fen-phen is believed to have caused significant cardiovascular problems in a number of patients and, as a result, Redux[®] was withdrawn from the market in 1997. In 1996, doctors wrote 18 million monthly prescriptions for drugs constituting the fen/phen combination. In that same year, these drugs generated sales of greater than \$400 million, serving as a benchmark for the substantial market opportunity for an effective drug to treat clinical obesity.

Since the withdrawal of Redux from the market, several groups have published research that implicates stimulation of the 5HT_{2b} receptor as the underlying cause of the cardiovascular problems. These findings suggest that highly selective compounds that stimulate the 5HT_{2c} receptor, but that do not appreciably stimulate the 5HT_{2b} receptor, could be developed that maintain the desired appetite suppressive effects without the cardiovascular toxicity. Recently, Arena Pharmaceuticals developed a selective 5HT_{2c} agonist, Lorcaserin, which exhibits significant selectivity for the 5HT_{2c} receptor relative to the 5HT_{2b} receptor. In a Phase II clinical trial recently conducted by Arena Pharmaceuticals, Lorcaserin was demonstrated to reduce appetite and cause