ATHERSYS, INC / NEW Form 10-Q May 08, 2008

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549 **FORM 10-Q**

(Mark One)

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QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES þ **EXCHANGE ACT OF 1934** For the quarterly period ended March 31, 2008

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES 0 **EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 000-52108

Athersys, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

3201 Carnegie Avenue, Cleveland, Ohio

(Address of principal executive offices) (Zip Code) Registrant s telephone number, including area code: (216) 431-9900 Former name, former address and former fiscal year, if changed since last report: Not Applicable

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes b No o Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

| Large accelerated filer o | Accelerated filer þ | Non-accelerated filer o | Smaller reporting |
|-----------------------------|-----------------------------|------------------------------------|-------------------------|
| | | | company o |
| | (De | o not check if a smaller reporting | company) |
| Indicate by check mark whe | ther the registrant is a sh | ell company (as defined in Rule 1 | 2b-2 of the Exchange |
| Act): Yes o No þ | - | | - |
| The number of outstanding s | shares of the registrant s | common stock, \$0.001 par value | , as of May 1, 2008 was |
| 18,927,988. | | - | |

44115-2634

20-4864095

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

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PART I. FINANCIAL INFORMATION Item 1. Financial Statements.

Athersys, Inc. Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

| | March 31, 2008 | December 31, 2007 |
|--|-------------------|----------------------|
| | (Unaudited) | (Note) |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 17,548 | \$ 13,248 |
| Available-for-sale securities | 21,883 | 22,477 |
| Accounts receivable | 676 | 836 |
| Receivable from Angiotech | 255 | 63 |
| Investment interest receivable | 272 | 262 |
| Deposit | 163 | 163 |
| Prepaid expenses and other | 286 | 394 |
| Total current assets | 41,083 | 37,443 |
| Available-for-sale securities | 5,366 | 13,850 |
| Deposits | 109 | 100 |
| Note receivable, net | 68 | 86 |
| Equipment, net | 402 | 387 |
| Accounts receivable, net | 43 | 42 |
| Equity investments | 317 | 317 |
| Total assets | \$ 47,388 | \$ 52,225 |
| Liabilities and stockholders equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,858 | \$ 1,011 |
| Accrued compensation and related benefits | 162 | 71 |
| Accrued clinical trial costs | 230 | 735 |
| Accrued expenses and other | 632 | 993 |
| Current portion of long-term debt, net | 1,013 | 1,784 |
| Total current liabilities | 3,895 | 4,594 |
| Stockholders equity: Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at March 31, 2008 and December 31, 2007 Common stock, \$0.001 par value; 100,000,000 shares authorized, and 18,927,988 shares issued and outstanding at March 31, 2008 and | | |
| December 31, 2007 | 19 | 19 |
| Additional paid-in capital | 208,503 | 208,039 |

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| Accumulated other comprehensive income Accumulated deficit | 114 (165,143) | 52 (160,479) |
|---|------------------|-----------------|
| Total stockholders equity | 43,493 | 47,631 |
| Total liabilities and stockholders equity | \$ 47,388 | \$ 52,225 |

Note: The balance sheet at December 31, 2007 has been derived from audited financial statements at 1

that date. It does not include, however, all of the information and notes required by U.S. generally accepted accounting principles for complete financial statements.

See accompanying notes to unaudited condensed consolidated financial statements.

Athersys, Inc. Condensed Consolidated Statements of Operations (In thousands, except share and per share data) (Unaudited)

| | Three months ended March 31, | | | |
|--|---------------------------------|-----------|----|---------|
| | | 2008 | , | 2007 |
| Revenues | | | | |
| License fees | \$ | 390 | \$ | 310 |
| Grant revenue | | 402 | | 569 |
| Total revenues | | 792 | | 879 |
| Costs and expenses | | | | |
| Research and development | | 4,315 | | 2,365 |
| General and administrative | | 1,481 | | 608 |
| Depreciation | | 57 | | 80 |
| Total costs and expenses | | 5,853 | | 3,053 |
| Loss from operations | | (5,061) | | (2,174) |
| Interest income and other | | 459 | | 47 |
| Interest expense | | (62) | | (333) |
| Accretion of premium on convertible debt | | | | (260) |
| Net loss | \$ | (4,664) | \$ | (2,720) |
| Preferred stock dividends | \$ | | \$ | (375) |
| Net loss attributable to common stockholders | \$ | (4,664) | \$ | (3,095) |
| Basic and diluted net loss per common share attributable to common | | | | |
| stockholders | \$ | (0.25) | \$ | (10.54) |
| Weighted average shares outstanding, basic and diluted | 18 | 3,927,988 | 4 | 293,770 |
| See accompanying notes to unaudited condensed consolidated financial statemer 3 | nts. | | | |

Athersys, Inc. Condensed Consolidated Statements of Cash Flows (In thousands) (Unaudited)

| | Three months ended March 31, | |
|---|---------------------------------|------------------|
| | 2008 | 2007 |
| Operating activities | | |
| Operating activities Net loss | \$ (4,664) | \$(2,720) |
| Adjustments to reconcile net loss to net cash used in operating activities: | Φ (+,00+) | $\varphi(2,720)$ |
| Depreciation | 57 | 80 |
| Accretion of premium on convertible debt | 57 | 260 |
| Stock-based compensation | 464 | 44 |
| Provision on note receivable | 18 | |
| Expense related to warrants issued to lenders | 10 | |
| Amortization of discount on available-for-sale securities | (57) | |
| Changes in operating assets and liabilities: | (37) | |
| Accounts receivable | 159 | 572 |
| Receivable from Angiotech | (192) | 512 |
| Prepaid expenses and other assets | 89 | (87) |
| Accounts payable and accrued expenses | 72 | (229) |
| Accounts payable and accrucit expenses | 12 | (22)) |
| Net cash used in operating activities | (4,043) | (2,080) |
| Investing activities | | |
| Purchase of available-for-sale securities | (10,102) | |
| Maturities of available-for-sale securities | 19,299 | |
| Purchases of equipment | (72) | (3) |
| | | |
| Net cash provided by (used in) investing activities | 9,125 | (3) |
| Financing activities | | |
| Principal payments on debt | (782) | (1,134) |
| Proceeds from convertible promissory note | | 5,000 |
| | | |
| Net cash (used in) provided by financing activities | (782) | 3,866 |
| | | |
| Increase in cash and cash equivalents | 4,300 | 1,783 |
| Cash and cash equivalents at beginning of the period | 13,248 | 1,528 |
| | | |
| Cash and cash equivalents at end of the period | \$ 17,548 | \$ 3,311 |
| | | |

See accompanying notes to unaudited condensed consolidated financial statements.

Athersys, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

1. Background

We are a biopharmaceutical company engaged in the development and commercialization of therapeutic products in one business segment. Our operations consist primarily of research and product development activities. On May 24, 2007, BTHC VI, Inc. (BTHC VI) and its wholly owned subsidiary, B-VI Acquisition Corp., entered into an Agreement and Plan of Merger with Athersys, Inc. (Old Athersys). Pursuant to the terms of the Agreement and Plan of Merger, B-VI Acquisition Corp., which BTHC VI recently had incorporated for the purpose of completing the merger transaction described herein, merged with and into Old Athersys on June 8, 2007, with Old Athersys continuing as the surviving entity in the merger (the Merger). BTHC VI was a shell corporation with substantially no assets, liabilities or operations as of the date of the Merger, and had 299,622 shares of common stock outstanding. As a result of the Merger, Old Athersys became our wholly-owned subsidiary, and the business of Old Athersys became our sole operations. On August 31, 2007, Old Athersys changed its name to ABT Holding Company and BTHC VI changed its name to Athersys, Inc. Unless otherwise indicated, all references in this quarterly report to the Company or Athersys are (a) prior to the Merger, to ABT Holding Company (i.e., Old Athersys) and its subsidiaries and (b) following the Merger, to Athersys, Inc. and its subsidiaries, including ABT Holding Company. BTHC VI s acquisition of Old Athersys on June 8, 2007 effected a change in control and was accounted for as a reverse acquisition whereby Old Athersys is the accounting acquirer for financial statement purposes. Accordingly, the financial statements of the Company presented reflect the historical results of Old Athersys and do not include the historical financial results of BTHC VI prior to the consummation of the Merger. The Company s authorized and issued shares of common and preferred stock have been retroactively restated for all historical periods presented to reflect the Merger exchange rate of 0.0358493. Basic and diluted net loss per share attributable to common

stockholders have been computed using the retroactively restated common stock. Immediately after the Merger, we completed an offering of 13,000,000 shares of common stock for aggregate gross proceeds of \$65.0 million in June 2007, which included the issuance of warrants to purchase 3,250,000 shares of common stock to the investors with an exercise price of \$6.00 and a five-year term. We also issued warrants to purchase 500,000 shares of common stock to the lead investor and warrants to purchase 1,093,525 shares of common

stock to the placement agents, each with an exercise price of \$6.00 and a five-year term.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2007. The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair presentation of financial position and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Our critical accounting policies, estimates and assumptions are described in Management s Discussion and Analysis of Financial Condition and Results of Operations, which is included below in this Quarterly Report on Form 10-Q.

3. New Accounting Standard

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Accounting Standards (SFAS) No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements. The FASB delayed the effective date of SFAS No. 157 for non-financial assets and liabilities to fiscal years beginning after November 15, 2008. We adopted the provisions of SFAS No. 157 related to our financial assets and liabilities on January 1, 2008. See Note 6.

4. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders are presented in conformity with SFAS No. 128, *Earnings per Share*, for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per share has been computed using the weighted-average number of common stock outstanding during the period. We have outstanding options and warrants, and prior to June 8, 2007, also had outstanding convertible debt and convertible preferred stock, which have not been used in the calculation of diluted net loss per share because to do so would be anti-dilutive. The following instruments were excluded from the calculation of diluted net loss per share attributable to common stockholders because their effects would be antidilutive:

- 1) Outstanding stock options to purchase 3,735,276 and 103,368 shares of common stock for the three-month periods ended March 31, 2008 and 2007, respectively;
- 2) Warrants to purchase 5,125,496 and 25,639 shares of common stock for the three-month periods ended March 31, 2008 and 2007, respectively;
- 3) Shares of common stock issuable upon the conversion of convertible preferred stock in the amount of 364,524 for the three-month period ended March 31, 2007; and
- 4) Shares of common stock issuable upon the conversion of convertible promissory notes in the approximate amount of 245,762 for the three-month period ended March 31, 2007.

5. Comprehensive Loss

In accordance with SFAS No. 130, *Reporting Comprehensive Loss*, all components of comprehensive loss, including net loss, are reported in the financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources.

Below is a reconciliation, in thousands, of net loss to comprehensive loss for all periods presented.

| | Three months ended March 31, | |
|--|------------------------------|-----------|
| | 2008 | 2007 |
| Net loss Unrealized gain on available-for-sale securities | \$ (4,664) 62 | \$(2,720) |
| Comprehensive loss | \$ (4,602) | \$(2,720) |

6. Fair Value of Financial Instruments

On January 1, 2008, we adopted SFAS No. 157 related to our financial assets and liabilities and the methods to measure fair value of assets and liabilities as set forth therein. Our available-for-sale securities include U.S. government obligations, corporate debt securities, floating rate notes and commercial paper. SFAS No. 157 classifies the inputs used to measure fair value into the following hierarchy:

Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 Unadjusted quoted prices in active markets for similar assets or liabilities, or unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are observable for the asset or liability.

Level 3 Unobservable inputs for the asset or liability.

The following table provides a summary of the fair values of our assets and liabilities under SFAS No. 157 (in thousands):

| | | Fair Value M | leasurements at Mai | rch 31, 2008 Using |
|-------------|----------------------------|----------------------------|----------------------|--------------------|
| | | Quoted Prices in Active | Significant Other | |
| | | Markets for | Observable | Significant |
| | Balance as of March 31, | Identical | Inputs | Unobservable |
| Description | 2008 | Assets (Level 1) | (Level 2) | Inputs (Level 3) |

Available-for-sale securities \$ 27,249 \$ 27,249 \$ \$ Fair value is based upon quoted market prices in active markets. We had no level 2 or level 3 assets at March 31, 2008. We will review and reassess the fair value hierarchy classifications on a quarterly basis. Changes from one quarter to the next related to the observability of inputs to a fair value measurement may result in a reclassification between hierarchy levels.

7. Stock-based Compensation

In 2007, we adopted two incentive plans that authorized an aggregate of 4,500,000 shares of common stock for awards to employees, directors and consultants. These equity incentive plans authorize the issuance of equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units, and other stock-based awards to qualified employees, directors and consultants. 7

As of March 31, 2008, a total of 769,000 shares are available for issuance under our equity compensation plans and 3,731,000 options to purchase shares of common stock were outstanding. Also, options to purchase 4,276 shares of common stock are outstanding related to our old option plans prior to the Merger in June 2007. For the three-month period ended March 31, 2008, stock compensation expense was approximately \$464,000. During the three-month period ended March 31, 2008, we issued options to purchase 103,000 shares of common stock to employees and a consultant. At March 31, 2008, total unrecognized estimated compensation cost related to unvested stock options was approximately \$4.6 million, which is expected to be recognized by January 2012 using the straight-line method. **8. Long-Term Debt**

A summary of our long-term debt outstanding is as follows (in thousands):

| | March 31, 2008 | December 31, 2007 |
|--------------------------------------|-------------------|-------------------------|
| Notes payable to lenders | \$1,018 | \$ 1,800 |
| Discount related to warrant issuance | (5) | (16) |
| Total, net | 1,013 | 1,784 |
| Less current portion | 1,013 | 1,784 |
| | \$ | \$ |

In November 2004, we issued \$7.5 million of notes payable to lenders, the proceeds of which are unrestricted and used for general corporate purposes. The notes are payable in 30 monthly payments after the initial interest-only period that expired December 1, 2005, with a fixed interest rate of 13% and a maturity date of June 1, 2008. The lenders have the right to receive a milestone payment of \$2.25 million upon the occurrence of certain events. In October 2007, an amendment to the loan agreement was executed to clarify the milestone events as follows: (1) cumulative equity financing proceeds in excess of \$5 million, whereby 10% of such proceeds that are not directly tied to the collaboration activities will be used to pay the milestone; (2) our merger with or into another entity where our stockholders do not hold at least a majority of the voting power of the surviving entity; (3) the sale of all or substantially all of our assets; and (4) our liquidation or dissolution. The milestone payment is payable in cash, except that if the milestone event is (1) above, we may elect to pay 75% of the milestone as of March 31, 2008. Upon the closing of our equity offering in June 2007, warrants to purchase 149,026 shares of common stock with an exercise price of \$5.00 per share and a seven-year term were issued to our lenders in accordance with the loan agreement. The value of the warrants was \$492,000 based on the Black-Scholes valuation of the underlying security, which has been recognized as a debt discount over the remaining term of the loan.

9. Convertible Notes

Upon the closing of our equity offering in June 2007, convertible promissory notes issued to Angiotech pursuant to a collaboration and to our bridge financing investors in 2006 were converted along with accrued interest into shares of common stock. The bridge notes, if not converted, were repayable with accrued interest at maturity, plus a repayment fee of 200% of the outstanding principal. We computed a premium on the debt in the amount of \$5.25 million due upon redemption, which was being accreted over the term of the notes using the effective interest method. The unamortized premium was reversed

and recorded in additional paid-in-capital when the notes were converted into common stock upon the closing of our equity offering in June 2007.

10. Warrants

As of March 31, 2008, we had the following outstanding warrants to purchase shares of common stock:

| Number of underlying shares | Exercise Price | Expiration |
|-----------------------------------|----------------|-----------------|
| 4,976,470 | \$ 6.00 | June 8, 2012 |
| 149,026 | \$ 5.00 | June 8, 2014 |

5,125,496

11. Income Taxes

We have net operating loss and research and development tax credit carryforwards that may be used to reduce future taxable income and tax liabilities. However, as a result of the change in ownership related to our capital restructuring and equity offering in June 2007, we lost the use of a significant portion of our pre-Merger net operating loss carryforwards under Section 382 of the Internal Revenue Code. Our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses.

12. Contingency

We initially filed a shelf registration statement with the SEC in July 2007 covering the resale of 18,508,251 shares of common stock, which includes all shares of common stock issued in our equity offering in June 2007 and shares of common stock issuable upon exercise of warrants issued in the offering (as well as the 531,781 shares of common stock issued to the bridge noteholders and the 132,945 shares underlying their warrants). The registration statement was declared effective by the SEC on October 18, 2007. Subject to certain exceptions, if the registration statement ceases to remain effective, a 1% cash penalty will be assessed for each 30-day period until the registration statement becomes effective again, capped at 10%.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

This discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statement and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2007. Operating results are not necessarily indicative of results that may occur in future periods.

Overview and Recent Developments

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. In July 2007, we initiated a Phase I clinical trial in the United Kingdom with our lead candidate in clinical development (ATHX-105 for the treatment of obesity) and completed this trial in January 2008. The primary objective of the Phase I clinical trial was 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. There were no severe or serious adverse events observed in the clinical trial, no negative effects on cardiovascular, hematology or other clinical parameters, and no discontinuations due to adverse events. Following a detailed analysis of the results of the clinical trial, the completion of certain required non-clinical studies and regulatory approval, we

intend to initiate a Phase II clinical trial in the United States that will examine safety and effectiveness in clinically obese patients in the second half of 2008.

In the fourth quarter of 2007, we received FDA authorization to advance two MultiStem product development programs into clinical trials, in the areas of transplant support and for treatment of damage from myocardial infarction. The application of MultiStem for certain cardiovascular applications, including myocardial infarction and peripheral vascular disease, is being developed with our partner, Angiotech Pharmaceuticals, Inc. We intend to initiate both of these trials in 2008 and file an additional investigational new drug application, or IND, for treatment of ischemic stroke in 2008. We are also developing pharmaceutical products for the treatment of certain conditions affecting the central nervous system, such as ADHD, narcolepsy and other cognitive or attention disorders. In addition to these drug development programs, we are also developing MultiStem for certain other disease indications.

In June 2007, we completed a merger with BTHC VI, Inc. and its wholly owned subsidiary that was formed for the purpose of completing the merger. BTHC VI was a public shell corporation with substantially no assets, liabilities or operations. We continued as the surviving entity in the merger and our business became the sole operations of BTHC VI after the merger. BTHC VI s acquisition of us effected a change in control and was accounted for as a reverse acquisition whereby we were the accounting acquirer for financial statement purposes. Accordingly, our financial statements present our historical results and do not include the historical financial results of BTHC VI prior to the merger.

Immediately after the merger, we completed an offering of 13,000,000 shares of common stock for aggregate gross proceeds of \$65.0 million in June 2007, which included the issuance of warrants to purchase 3,250,000 shares of common stock to the investors. We also issued warrants to purchase 500,000 shares of common stock to the lead investor and warrants to purchase 1,093,525 shares of common stock to the placement agents.

We have incurred losses since inception of operations in December 1995 and had an accumulated deficit of \$165 million at March 31, 2008. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We have used the financing proceeds from private equity and debt offerings and other sources of capital to develop our technologies, such as RAGE, and to acquire our stem cell technology. We have also built drug development capabilities that have enabled us to advance product candidates into clinical trials. We have established strategic collaborations that provide revenues and capabilities to help to further advance our product candidates, and we have also built a substantial portfolio of intellectual property.

Results of Operations

Since our inception, our revenues have consisted of license fees from our collaborators and grant proceeds from federal and state grants. We have derived no revenue on the sale of FDA-approved products to date. Research and development expenses consist primarily of costs associated with external clinical and preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property application processes, and laboratory supply and reagent costs. We expense research and development costs as they are incurred. We expect to continue to make significant investments in research and development to enhance our technologies, advance clinical trials of our product candidates, expand our regulatory affairs and product development capabilities, conduct preclinical studies of our products and manufacture our products. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees and other corporate expenses. Our expenses are expected to increase as we expand our business development activities and support our operating activities. To date, we have financed our operations through private equity and debt financing and investments by strategic collaborators. We expect to continue to incur substantial losses through at least the next several years. 10

The following tables set forth our revenues and expenses for the periods indicated. The following tables are stated in thousands.

Revenues

| | Three mont March | |
|---------------|---------------------|--------|
| | 2008 | 2007 |
| License fees | \$ 390 | \$ 310 |
| Grant revenue | 402 | 569 |
| | \$ 792 | \$ 879 |

Research and development expenses

| | Three months ended March 31, | |
|--|---------------------------------|----------|
| Type of expense | 2008 | 2007 |
| Personnel costs | \$ 765 | \$ 597 |
| Research supplies | 183 | 204 |
| Facilities | 211 | 191 |
| Clinical and preclinical development costs | 2,298 | 808 |
| Sponsored research | 105 | 133 |
| Patent legal fees | 230 | 276 |
| Other | 333 | 125 |
| Stock-based compensation | 190 | 31 |
| | \$ 4,315 | \$ 2,365 |

General and administrative expenses

| | Three months ended March 31, | |
|-----------------------------|---------------------------------|--------|
| Type of expense | 2008 | 2007 |
| Personnel costs | \$ 489 | \$ 358 |
| Facilities | 87 | 77 |
| Legal and professional fees | 296 | 82 |
| Other | 335 | 78 |
| Stock-based compensation | 274 | 13 |
| | \$ 1,481 | \$ 608 |

Three Months Ended March 31, 2008 and 2007

Revenues. Revenues decreased to \$792,000 for the three months ended March 31, 2008 from \$879,000 in the comparable period in 2007. Grant revenue decreased \$167,000 for the three months ended March 11

31, 2008 compared to the three months ended March 31, 2007. The decrease in grant revenue was due to the timing of expenditures that are reimbursed with grant proceeds. License fee revenues increased \$80,000 for the three months ended March 31, 2008 compared to the three months ended March 31, 2007. The increase in license fee revenue over this period was a result of the nature and timing of target acceptances under our collaboration agreement with Bristol-Myers Squibb.

Research and Development Expenses. Research and development expenses increased to \$4.3 million for the three months ended March 31, 2008 from \$2.4 million in the comparable period in 2007. The increase of approximately \$2.0 million related primarily to an increase in clinical and preclinical development costs of \$1.5 million, an increase in other expenses of \$208,000, an increase in stock compensation expense of \$159,000 and an increase in personnel and facilities costs of \$188,000 in the three months ended March 31, 2008 compared to the comparable period in 2007. These increases were partially offset by a decrease in patent legal fees of \$46,000 and a decrease in sponsored research and research supplies of \$49,000 in the three months ended March 31, 2008 compared to the comparable period in 2007. The \$1.5 million increase in preclinical and clinical costs was a result of the continuation of the ATHX-105 clinical trial, which was completed in January 2008, preparation for a phase II clinical trial of ATHX-105, which includes certain non-clinical studies, and preparation for phase I clinical trials for two or more MultiStem disease indications in 2008. Our clinical costs for the three months ended March 31, 2008 are reflected net of a reimbursement from Angiotech related to our MultiStem acute myocardial infarction collaboration in the amount of \$192,000. We expect these expenses to continue to increase in 2008 as we expect to initiate our ATHX-105 Phase II clinical trial and two or more MultiStem clinical trials. The increase in other expenses for the three-month period ended March 31, 2008 was primarily a result of increased outside service costs and travel costs. We do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

General and Administrative Expenses. General and administrative expenses increased to \$1.5 million for the three months ended March 31, 2008 from \$608,000 in the comparable period in 2007. The increase of \$873,000 relates primarily to a \$261,000 increase in stock compensation expense, a \$257,000 increase in other expenses, a \$214,000 increase in legal and professional fees and a \$141,000 increase in personnel and facilities costs. The increase in legal and professional fees for the three months ended March 31, 2008 was primarily a result of accounting and auditing fees incurred in connection with our annual audit and annual report, legal fees incurred in connection with our annual report and fees for our board of directors. The increase in other expenses for the three-month period ended March 31, 2008 was primarily a result of costs such as printing costs for SEC filings, Nasdaq listing fees, directors and officers insurance costs, investor and public relations costs and costs related to compliance with Section 404 of the Sarbanes-Oxley Act of 2002.

Depreciation. Depreciation expense decreased to \$57,000 for the three months ended March 31, 2008 from \$80,000 for the comparable period in 2007. The decrease was due to more equipment becoming fully depreciated. *Interest Income and Other.* Interest income represents interest income earned on our cash and available-for-sale securities and other income consists of foreign currency gains related to our activities in Europe and certain contracts denominated in foreign currencies. Interest income and other increased to \$459,000 for the three months ended March 31, 2008 from \$47,000 for the comparable period in 2007 due to the increase in our average cash balances as a result of our equity offering in June 2007. Due to declining interest rates and lower cash balances as a result of our ongoing and planned clinical and preclinical development, we expect our 2008 interest income to decline over the remaining quarters of 2008.

Interest Expense. Interest expense decreased to \$62,000 for the three months ended March 31, 2008 from \$333,000 for the comparable period in 2007. Interest expense in the three-month period ended March 31, 2008 consists primarily of interest on our senior loan. Included in interest expense for the three-month period ended March 31, 2007 is interest on our senior loan and subordinated convertible

promissory notes issued to our bridge investors in October 2006 and to Angiotech, which were converted into common stock upon the closing of our equity offering in June 2007. Unless we enter into a new debt arrangement, we expect our interest expense to decrease in the second half of 2008 as a result of the maturity of our senior loan in June 2008.

Accretion of Premium on Convertible Debt. The accretion of premium on convertible debt for the three months ended March 31, 2007 relates to the subordinated convertible promissory notes issued to bridge investors in October 2006. The notes, if not converted, were repayable with accrued interest at maturity, plus a repayment fee of 200% of the outstanding principal. We computed a premium on the debt in the amount of \$5.25 million due upon redemption, which was being accreted over the term of the notes using the effective interest method. The unamortized premium was reversed and recorded in additional paid-in-capital when the notes were converted into common stock upon the closing of our equity offering in June 2007.

LIQUIDITY AND CAPITAL RESOURCES

Our sources of liquidity include our cash balances and available-for-sale securities. At March 31, 2008, we had \$17.5 million in cash and cash equivalents and \$27.3 million in available-for-sale securities. We have primarily financed our operations through private equity and debt financings that have resulted in aggregate cumulative proceeds of approximately \$200 million.

We will require substantial additional funding in order to continue our research and product development programs, including preclinical testing and clinical trials of our product candidates. We anticipate using \$23 million to \$25 million to fund our activities in 2008, which is an increase in cash expenditures reflecting the impact of the ATHX-105 Phase II clinical trial. With the anticipated completion of the ATHX-105 Phase II clinical trial, we expect lower clinical development costs in 2009, and as a result, expect to have available cash to fund our operations into 2010 based on our current business and operational plans and assuming no new financings. Our funding requirements may change at any time due to technological advances, competition from other companies or for other reasons. Our future capital requirements will also depend on numerous other factors, including scientific progress in our research and development programs, additional personnel costs, progress in preclinical testing and clinical trials, the time and cost related to proposed regulatory approvals, if any, and the costs in filing and prosecuting patent applications and enforcing patent claims. We cannot assure you that adequate funding will be available to us or, if available, that it will be available on acceptable terms. Any shortfall in funding could result in our having to curtail our research and development efforts.

We expect to continue to incur substantial losses through at least the next several years and may incur losses in subsequent periods. The amount and timing of our future losses are highly uncertain. Our ability to achieve and thereafter sustain profitability will be dependent upon, among other things, successfully developing, commercializing and obtaining regulatory approval or clearances for our technologies and products resulting from these technologies. Net cash used in operating activities was \$4.0 million for the three months ended March 31, 2008 and \$2.1 million for the three months ended March 31, 2007, and represented the use of cash in funding preclinical and product development initiatives and administrative costs. We expect that net cash used in operating activities will increase as we increase our clinical trial activity for ATHX-105 and MultiStem and as we continue to advance our various research and product development activities.

Net cash provided by (used in) investing activities was \$9.1 million for the three months ended March 31, 2008 and \$(3,000) for the three months ended March 31, 2007. The fluctuations from period to period were due to the timing of purchases and maturity dates of investments and purchases of equipment.

Financing activities used cash of \$(782,000) for the three months ended March 31, 2008 and provided cash of \$3.9 million for the three months ended March 31, 2007. This fluctuation relates primarily to the issuance of a convertible promissory note in the first quarter of 2007 to Angiotech.

Investors in our equity offering in June 2007 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 June offering, Radius Venture Partners, invested \$10.0 million 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. 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 of such warrants could provide us with cash proceeds.

Our senior loan, which had a balance of \$1.0 million at March 31, 2008, will be repaid in full in June 2008. The senior lenders have the right to receive a milestone payment of \$2.25 million upon the occurrence of certain events as clarified in the October 2007 amendment to the senior loan as follows: (1) the entire amount upon (a) the merger with or into another entity where our stockholders do not hold at least a majority of the voting power of the surviving entity, (b) the sale of all or substantially all of our assets, and (c) our liquidation or dissolution; or (2) a portion of the amount from proceeds of equity financings not tied to specific research and development activities that are part of a research or development collaboration, in which case, the senior lenders will receive an amount equal to 10% of proceeds above \$5.0 million in cumulative gross proceeds until the milestone amount is paid in full. The milestone payment is payable in cash, except that if the milestone event is (2) above, we may elect to pay 75% of the milestone in shares of common stock at the per-share offering price. No milestone events occurred in the three-month period ended March 31, 2008. The senior lenders also received warrants to purchase 149,026 shares of common stock with an exercise price of \$5.00 upon the closing of our equity offering in June 2007. We are considering entering into a new debt facility in 2008.

In connection with developing MultiStem for the treatment of the cardiovascular disorders of myocardial infarction and peripheral vascular disease as part of a commercial collaboration with Angiotech that was entered into in May 2006, in support of the collaboration, Angiotech purchased subordinated convertible promissory notes in the aggregate principal amount of \$10.0 million, which were converted along with accrued interest into common stock upon the closing of our equity offering in June 2007. Upon the successful achievement of specified clinical development and commercialization milestones, we may also receive up to \$3.75 million of additional equity investments and \$63.75 million of aggregate cash payments, though there can be no assurance that we will achieve any milestones.

Under the terms of the collaboration, the parties plan to jointly fund clinical development activity, whereby preclinical costs will be borne solely by us, costs for phase I and phase II studies will be borne 50% by us and 50% by Angiotech, costs for the first phase III study will be borne 33% by us and 67% by Angiotech, and costs for any phase III studies subsequent to the first phase III study will be borne 25% by us and 75% by Angiotech. We have lead responsibility for preclinical and early clinical development and manufacturing of the MultiStem product, and Angiotech will take the lead on pivotal and later clinical trials and commercialization. Late in 2007, the parties began to share costs for phase I clinical development, of which \$255,000 was due from Angiotech at March 31, 2008. We will receive nearly half of the net profits from the sale of any jointly developed, approved products. In addition, we will retain the commercial rights to MultiStem for all other therapeutic applications, including treatment of stroke, bone marrow transplantation and oncology support, blood and immune system disorders, autoimmune disease, and other indications that we may elect to pursue. In December 2007, we achieved a clinical development milestone upon the authorization of our IND by the FDA. This milestone event required Angiotech to either purchase \$5.0 million of our common stock, or forego the purchase and allow us to select from two pre-defined milestone replacements. Angiotech opted to forego the purchase, and we elected to increase our share of the net profits from the sale of approved products as the milestone replacement.

We have an operating lease for our office and laboratory space with options to renew through March 2013 at the existing rental rate, which is approximately \$267,000 per year. We exercised options to renew the lease through March 2010. In February 2008, we entered into a three-year lease agreement for office and laboratory space for our Belgian subsidiary, with an annual rent of approximately \$45,000, subject to annual adjustments based on an inflationary index. The lease includes an option to renew for four additional years, through December 31, 2014. We have no off-balance sheet arrangements.

CRITICAL ACCOUNTING POLICIES AND MANAGEMENT ESTIMATES

The SEC defines critical accounting policies as those that are, in management s view, important to the portrayal of our financial condition and results of operations and demanding of management s judgment. Our discussion and analysis of financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates on experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates. A description of these accounting policies and estimates is included in Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2007. There have been no material changes in our accounting policies, see Note B to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2007.

New Accounting Standard

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements. The FASB delayed the effective date of SFAS No. 157 for non-financial assets and liabilities to fiscal years beginning after November 15, 2008. We adopted the provisions of SFAS No. 157 related to our financial assets and liabilities on January 1, 2008, which did not have a material impact on our financial position or results. See Note 6 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 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 s 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 quarterly report on Form 10-Q. In addition, a number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. 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:

our ability to successfully complete clinical trials for our product candidates;

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 enter into licensing or co-development arrangements for certain product candidates;

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 undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are advised, however, to consult any further disclosures we make on related subjects in our reports on Forms 10-Q, 8-K and 10-K furnished to the SEC. You should understand that it is not possible to predict or identify all risk factors. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties. **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

Interest Rate Risk

Our exposure to interest rate risk is related to our investment portfolio and our borrowings. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Due in part to these factors, our future investment income may fall short of expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates. We invest our excess cash primarily in debt instruments of the U.S. government and its agencies, corporate debt securities, floating-rate notes and A1+/P1 commercial paper.

We enter into loan arrangements with financial institutions when needed. At March 31, 2008, we had borrowings of approximately \$1.0 million outstanding under our senior loan, which bears interest at a fixed rate of approximately 13%.

Item 4. Controls and Procedures.

Disclosure controls and procedures

Our management, under the supervision of and with the participation of our Chief Executive Officer and our Vice President of Finance, has evaluated the effectiveness of our disclosure controls and procedures, 16

as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as of the end of the period covered by this quarterly report on Form 10-Q. Based upon this evaluation, our Chief Executive Officer and Vice President of Finance have concluded that, as of the end of the period covered by this quarterly report on Form 10-Q, our disclosure controls and procedures were effective.

Changes in internal control over financial reporting

During the first quarter of 2008, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION Item 6. Exhibits.

| Exhibit No. | Description |
|-------------|--|
| 10.1 | Summary of Athersys, Inc. 2008 Cash Bonus Incentive Plan |
| 31.1 | Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Laura K. Campbell, Vice President of Finance, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, and Laura Campbell, Vice President of Finance, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ATHERSYS, INC.

Date: May 8, 2008

/s/ Gil Van Bokkelen Gil Van Bokkelen Chairman and Chief Executive Officer (principal executive officer authorized to sign on behalf of the registrant)

/s/ Laura K. Campbell Laura K. Campbell Vice President, Finance (principal financial and accounting officer authorized to sign on behalf of the registrant)

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