

ATHERSYS, INC / NEW
Form 10-Q
May 07, 2009

Table of Contents

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

(Mark One)

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

For the quarterly period ended March 31, 2009

OR

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

For the transition period from _____ to _____.

Commission file number: 001-33876

Athersys, Inc.

(Exact name of registrant as specified in its charter)

Delaware

*(State or other jurisdiction
of incorporation or organization)*

20-4864095

(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**

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Accelerated filer

Non-accelerated filer

Smaller reporting
company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes No

The number of outstanding shares of the registrant's common stock, \$0.001 par value, as of May 1, 2009 was 18,927,988.

ATHERSYS INC.
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

<u>ITEM 1. Financial Statements</u>	1
<u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	8
<u>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</u>	15
<u>ITEM 4. Controls and Procedures</u>	15

PART II. OTHER INFORMATION

<u>ITEM 6. Exhibits</u>	16
-------------------------	----

<u>SIGNATURES</u>	17
--------------------------	----

<u>EXHIBIT INDEX</u>	18
-----------------------------	----

Exhibit 31.1

Exhibit 31.2

Exhibit 32.1

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements.**

Athersys, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)

	March 31, 2009 (Unaudited)	December 31, 2008 (Note)
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,112	\$ 12,552
Available-for-sale securities	9,563	15,460
Accounts receivable	137	260
Receivable from Angiotech	543	234
Investment interest receivable	161	189
Prepaid expenses and other	371	408
Total current assets	23,887	29,103
Available-for-sale securities	5,658	3,601
Deposits	144	144
Equipment, net	666	701
Equity investments and other	327	328
Total assets	\$ 30,682	\$ 33,877
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 1,474	\$ 1,498
Accrued compensation and related benefits	219	97
Accrued clinical trial costs	26	58
Accrued expenses and other	565	661
Total current liabilities	2,284	2,314
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at March 31, 2009 and December 31, 2008		
Common stock, \$0.001 par value; 100,000,000 shares authorized, and 18,927,988 shares issued and outstanding at March 31, 2009 and December 31, 2008	19	19
Additional paid-in capital	210,408	209,895
Accumulated other comprehensive income	67	120
Accumulated deficit	(182,096)	(178,471)
Total stockholders equity	28,398	31,563

Total liabilities and stockholders' equity	\$	30,682	\$	33,877
--	----	--------	----	--------

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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

	Three months ended March 31,	
	2009	2008
Revenues		
License fees	\$ 188	\$ 390
Grant revenue	182	402
Total revenues	370	792
Costs and expenses		
Research and development	2,611	4,315
General and administrative	1,453	1,481
Depreciation	59	57
Total costs and expenses	4,123	5,853
Loss from operations	(3,753)	(5,061)
Interest income and other	128	459
Interest expense		(62)
Net loss	\$ (3,625)	\$ (4,664)
Basic and diluted net loss per share	\$ (0.19)	\$ (0.25)
Weighted average shares outstanding, basic and diluted	18,927,988	18,927,988
See accompanying notes to unaudited condensed consolidated financial statements.		

Table of Contents

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

	Three months ended March 31,	
	2009	2008
Operating activities		
Net loss	\$ (3,625)	\$ (4,664)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	59	57
Stock-based compensation	513	464
Other	1	29
Amortization of premium (discount) on available-for-sale securities	60	(57)
Changes in operating assets and liabilities:		
Accounts receivable	123	159
Receivable from Angiotech	(309)	(192)
Prepaid expenses and other assets	65	89
Accounts payable and accrued expenses	(30)	72
Net cash used in operating activities	(3,143)	(4,043)
Investing activities		
Purchase of available-for-sale securities	(4,073)	(10,102)
Maturities of available-for-sale securities	7,800	19,299
Purchases of equipment	(24)	(72)
Net cash provided by investing activities	3,703	9,125
Financing activities		
Principal payments on debt		(782)
Net cash used in financing activities		(782)
Increase in cash and cash equivalents	560	4,300
Cash and cash equivalents at beginning of the period	12,552	13,248
Cash and cash equivalents at end of the period	\$ 13,112	\$ 17,548

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Athersys, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Three-Month Periods Ended March 31, 2009 and 2008

1. Background and Basis of Presentation

We are a biopharmaceutical company engaged in the discovery and development of therapeutic products in one business segment. Our operations consist primarily of research and product development activities.

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, 2008. 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.

Certain prior year amounts have been reclassified to conform with current year presentations.

2. New Accounting Standards

In December 2007, the Financial Accounting Standards Board (FASB) ratified the consensus reached in EITF Issue No. 07-1 (EITF 07-0), *Accounting for Collaborative Arrangements*. The effective date of EITF 07-1 is January 1, 2009 for calendar year companies with retrospective application required for all periods presented for collaborative arrangements existing as of the effective date. EITF 07-1 requires certain disclosures related to collaborative arrangements where parties are active participants and exposed to significant risks and rewards dependent on the commercial success of the activity. The adoption of EITF 07-1 did not have a material impact on our financial statements since our accounting for our collaborative agreement was consistent with the provisions of EITF 07-1.

In May 2008, the FASB issued FASB Staff Position APB 14-1 (FSP 14-1), *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. FSP 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash on conversion to separately account for the liability and equity components in a manner that reflects the issuer's nonconvertible debt borrowing rate. We have no current convertible debt instruments, and concluded that all of our prior instruments were not within the scope of FSP 14-1, and therefore, there was no retrospective effect from the adoption of FSP 14-1 on our financial statements.

Table of Contents

In December 2007, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 141R, *Business Combinations*. This statement, which addresses the accounting for business acquisitions, is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited, and generally applies to business acquisitions completed after December 31, 2008. Among other things, SFAS No. 141R requires that all acquisition-related costs be expensed as incurred and that all restructuring costs related to acquired operations be expensed as incurred. SFAS No. 141R also addresses the current and subsequent accounting for assets and liabilities arising from contingencies acquired or assumed. The adoption of SFAS No. 141R had no impact on our financial statements. SFAS No. 141R could have a material impact on our financial statements in future periods if we complete a significant acquisition in the future.

In June 2008, the FASB issued EITF Issue No. 07-5 (EITF 07-5), *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*. EITF 07-5 clarifies the determination of whether certain instruments or features were indexed to an entity's own stock under EITF Issue No. 01-6. The statement is effective for fiscal years beginning after December 15, 2008. The adoption of the statement had no impact on our financial statements.

In April 2009, the FASB issued FASB Staff Position FAS 115-2 (FSP 115-2), *Recognition and Presentation of Other-Than-Temporary Impairments*. FSP 115-2 requires, among other things, that other-than-temporary impairments be separated into the amount recognized in earnings and the amount recognized in other comprehensive income. The statement is effective for periods ending after June 15, 2009, with early adoption permitted. We are evaluating the impact the adoption of this statement will have on our financial statements.

3. Net Loss per Share

Basic and diluted net loss per share 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 that are not 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 because their effects would be antidilutive:

- 1) Outstanding stock options to purchase 3,745,149 and 3,735,276 shares of common stock for the three-month periods ended March 31, 2009 and 2008, respectively; and
- 2) Warrants to purchase 5,125,496 shares of common stock for each of the three-month periods ended March 31, 2009 and 2008.

4. 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,	
	2009	2008
Net loss	\$ (3,625)	\$ (4,664)
Unrealized (loss) gain on available-for-sale securities	(53)	62
Comprehensive loss	\$ (3,678)	\$ (4,602)

Table of Contents**5. Fair Value of Financial Instruments**

On January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*, related to our financial assets and liabilities and the methods to measure fair value of assets and liabilities as set forth therein, and on January 1, 2009, we adopted the non-deferred provisions of SFAS No. 157 related to non-financial assets, which had no impact on our financial statements. Our available-for-sale securities include U.S. government obligations, corporate debt securities and commercial paper. As of March 31, 2009, approximately 77% of our investments were in U.S. government obligations.

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.

1

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.

3

The following table provides a summary of the fair values of our assets and liabilities measured at fair value on a recurring basis as of March 31, 2009 (in thousands):

Description	Balance as of March 31, 2009	Fair Value Measurements at March 31, 2009 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities	\$ 15,221	\$ 15,221	\$	\$

Fair value is based upon quoted market prices in active markets. We had no level 2 or level 3 assets at March 31, 2009. We 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.

6. Collaboration

Collaborative arrangements that involve cost or revenue sharing are reviewed to determine the nature of the arrangement and the nature of the collaborative parties' businesses. The arrangements are also reviewed to determine if one party has sole or primary responsibility for an activity, or whether the parties have shared responsibility for the activity. If responsibility for an activity is shared and there is no principal party, then the related costs of that activity are recognized by us on a net basis in the statement of operations (e.g., total cost, less reimbursement from collaborator). If we are deemed to be the principal party for an activity, then the costs and revenues associated with that activity are recognized on a gross basis in the statement of operations.

In 2006, we entered into a co-development collaboration with Angiotech and received \$10 million in initial funding. Upon the successful achievement of specified clinical development and commercialization milestones, we may 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. We continue to jointly fund clinical development activities with Angiotech in accordance with our collaboration, and, as of March 31, 2009, \$543,000 was due from

Angiotech. Of this amount, \$236,000 was repaid in April 2009 representing its share of fourth quarter 2008 costs, and we expect the balance to be paid on a timely basis. Our clinical costs for the three months ended March 31, 2009 and 2008 are reflected net of Angiotech's cost-sharing amount in the amount of \$309,000 and \$192,000, respectively, since the responsibilities under this collaboration are shared with no principal party. The parties will share net profits from the future sale of approved products.

Table of Contents**7. Stock-based Compensation**

We adopted two incentive plans that authorize 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. As of March 31, 2009, a total of 757,000 shares were available for issuance under our equity compensation plans and options to purchase 3,745,149 shares of common stock were outstanding (which includes options to purchase 2,149 shares of common stock related to our old option plans prior to our merger in June 2007). For the three-month period ended March 31, 2009, stock compensation expense was approximately \$513,000. At March 31, 2009, total unrecognized estimated compensation cost related to unvested stock options was approximately \$2.6 million, which is expected to be recognized by the end of 2012 using the straight-line method.

8. Warrants

As of March 31, 2009, 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

9. 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.

10. Contingencies

In 2004, we issued \$7.5 million of notes payable to lenders, which was repaid in June 2008. The lenders retain a right to receive a milestone payment of \$2.25 million upon the occurrence of certain events as follows: (1) the entire amount upon (a) 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; (b) the sale of all or substantially all of our assets; or (c) our liquidation or dissolution; or (2) a portion of the amount from proceeds of equity financings not tied to research and development activities that are part of a research or development collaboration, in which case, the lenders will receive an amount equal to 10% of proceeds above \$5 million in cumulative gross proceeds until the milestone amount is paid in full. The milestone amount is payable in cash, except that if the milestone event is (2) above, we may elect to pay 75% in shares of common stock at the per-share offering price. No amounts have been recorded in relation to the milestone as of March 31, 2009.

Table of Contents

We filed a resale registration statement with the SEC in July 2007 covering the resale of 18,508,251 shares of common stock, which was declared effective by the SEC in 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% of the aggregate gross proceeds in the June 2007 offering. Because the penalty is based on the number of unregistered shares of common stock held by investors in the June 2007 offering, our maximum penalty exposure will decline over time as investors sell their shares of common stock that were included in the registration statement.

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, 2008. 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 disease areas. Our current product development portfolio includes MultiStem[®], a patented and proprietary stem cell product that we are developing as a treatment for multiple disease indications, and is currently being evaluated in two ongoing clinical trials. In addition, we are developing novel pharmaceuticals to treat indications such as obesity and certain neurological conditions that affect attention, cognition or wakefulness, such as narcolepsy, excessive daytime sleepiness, and chronic fatigue associated with Parkinson's disease and other conditions.

Current Programs

In 2008, we advanced two MultiStem programs into clinical development, initiating phase I studies in cardiovascular disease (treating patients that have suffered an acute myocardial infarction) and in oncology treatment support (administering MultiStem to leukemia or lymphoma patients who are receiving a traditional bone marrow or hematopoietic stem cell transplant to reduce the risk or severity of graft-versus-host disease, or GVHD). We are conducting the acute myocardial infarction clinical trial with our partner, Angiotech Pharmaceuticals, Inc. (Angiotech). In 2006, we entered into a 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. We retain the exclusive commercial rights to the development of MultiStem for other indication areas, including oncology treatment support, neurological indications, autoimmune disease, and other areas. Although early in 2009 we suspended the further development of our ATHX-105 obesity product candidate, we are continuing to develop next generation 5HT_{2c} agonist compounds while we explore potential partnerships for the program. We are also developing a different class of novel, orally active pharmaceutical compounds for the treatment of certain central nervous system disorders, including disorders affecting attention, cognition or wakefulness. Our collaboration agreement with Bristol-Myers Squibb, which was initially established in 2001 to provide cell lines expressing well validated drug targets produced using our RAGE technology, is now in its final phase. In April 2009, we executed an agreement with Bristol-Myers Squibb extending through 2009 our collaboration to prepare and deliver validated drug targets for use by Bristol-Myers Squibb in its drug discovery efforts and to provide for the possibility of delivering targets in the future. We remain entitled to receive license fees for targets delivered to Bristol-Myers Squibb, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology.

Table of Contents*Financial*

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of \$182 million at March 31, 2009. 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, to discover and develop therapeutic product candidates and to acquire certain technologies and assets. We have also built drug development capabilities that have enabled us to advance product candidates into clinical trials. We have established strategic collaborations that have provided revenues and capabilities to help 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 and milestone payments from our collaborators, and grant proceeds primarily 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 external clinical and preclinical study fees, manufacturing costs for clinical and preclinical product, salaries and related personnel costs, legal expenses resulting from intellectual property application processes, facility costs 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 product and manufacture our product candidates. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees and other corporate expenses. 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.

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

Revenues

	Three months ended March 31,	
	2009	2008
License fees	\$ 188	\$ 390
Grant revenue	182	402
	\$ 370	\$ 792

Table of Contents**Research and development expenses**

<i>Type of expense</i>	Three months ended March 31,	
	2009	2008
Personnel costs	\$ 823	\$ 765
Research supplies	253	183
Facilities	208	211
Clinical and preclinical development costs	509	2,298
Sponsored research	130	105
Patent legal fees	267	230
Other	207	333
Stock-based compensation	214	190
	\$ 2,611	\$ 4,315

General and administrative expenses

<i>Type of expense</i>	Three months ended March 31,	
	2009	2008
Personnel costs	\$ 499	\$ 489
Facilities	82	87
Legal and professional fees	324	296
Other	249	335
Stock-based compensation	299	274
	\$ 1,453	\$ 1,481

Three Months Ended March 31, 2009 and 2008

Revenues. Revenues decreased to \$370,000 for the three months ended March 31, 2009 from \$792,000 in the comparable period in 2008. Grant revenue decreased \$220,000 for the three months ended March 31, 2009 compared to the three months ended March 31, 2008 primarily due to the completion late in 2008 of a three-year state grant, and to the timing of expenditures that are reimbursed with grant proceeds. License fee revenues decreased \$202,000 for the three months ended March 31, 2009 compared to the three months ended March 31, 2008 as a result of the nature and timing of target acceptances under our collaboration agreement with Bristol-Myers Squibb. During 2009, our revenues may fluctuate compared to 2008 as a result of differences in demand for targets and the achievement and timing of Bristol-Myers Squibb milestones, if any. Beyond 2009, we anticipate that Bristol-Myers Squibb's demand for new targets will be reduced, or cease altogether. Additionally, our grant revenues could fluctuate during the year based on the timing of grant-related activities and the award of new grants.

Table of Contents

Research and Development Expenses. Research and development expenses decreased to \$2.6 million for the three months ended March 31, 2009 from \$4.3 million in the comparable period in 2008. The decrease of approximately \$1.7 million related primarily to a decrease in clinical and preclinical development costs of \$1.8 million, \$1.5 million of which was related to costs associated with the completion of an ATHX-105 phase I clinical trial in the first quarter of 2008 and preparations for a phase II clinical trial of ATHX-105 in 2008, which included several preclinical studies and manufacturing costs. The ATHX-105 program was suspended early in 2009, meaning there will be no future costs incurred for the program. The remaining \$0.3 million decrease in clinical and preclinical development costs was related to manufacturing costs in the first quarter of 2008 for our MultiStem clinical trials, which were not incurred in the first quarter of 2009. Our clinical costs for the three months ended March 31, 2009 and 2008 are reflected net of Angiotech's cost-sharing amount related to our MultiStem acute myocardial infarction collaboration in the amount of \$309,000 and \$192,000, respectively. The decrease in other expenses of approximately \$126,000 for the three months ended March 31, 2009 from the comparable period in 2008 was primarily a result of reduced license fees and outside service costs in the first quarter of 2009. Our research and development costs may fluctuate as we advance the clinical development of our product candidates and enroll subjects in clinical trials. Other than external expenses for our clinical and preclinical programs, 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 remained consistent at approximately \$1.5 million for both the three months ended March 31, 2009 and 2008. We expect our general and administrative expenses to continue at similar levels during 2009.

Depreciation. Depreciation expense remained consistent at approximately \$60,000 for both the three months ended March 31, 2009 and the comparable period in 2008.

Interest Income and Other. Interest income represents interest income earned on our cash and available-for-sale securities and other income includes foreign currency gains and losses, if any, related to our activities in Europe and certain contracts denominated in foreign currencies. Interest income and other decreased to \$128,000 for the three months ended March 31, 2009 from \$459,000 for the comparable period in 2008 due to the decline in our investment balances as they are used to fund our operations, and we expect our 2009 interest income to continue to decline during 2009.

Interest Expense. Interest expense was \$62,000 in the three-month period ended in 2008, which related to interest on our senior loan that was repaid in June 2008. We do not expect any significant interest expense in 2009 unless we incur new debt.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and available-for-sale securities. At March 31, 2009, we had \$13.1 million in cash and cash equivalents and \$15.2 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.

Our collaboration agreement with Bristol-Myers Squibb, which was initially established in 2001 to provide cell lines expressing well validated drug targets produced using our RAGE technology, is now in its final phase. In April 2009, we executed an agreement with Bristol-Myers Squibb extending through 2009 our collaboration to prepare and deliver validated drug targets for use by Bristol-Myers Squibb in its drug discovery efforts and to provide for the possibility of delivering targets in the future. We remain entitled to receive license fees for targets delivered to Bristol-Myers Squibb, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology.

Our available-for-sale securities typically include United States government obligations, corporate debt securities and commercial paper. As of March 31, 2009, approximately 77% of our investments were in United States government obligations. We have been investing conservatively due to the current economic conditions, including the current credit crisis, and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments and have held our investments until maturity. Also, although these unfavorable market and economic conditions have resulted in a decrease to our market capitalization, there has been no impairment to the value of our assets. Our fixed assets are used for internal research

and development and, therefore, are not impacted by these external factors.

Table of Contents

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 expect to have available cash to fund our operations through 2011 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 or competition from other companies. 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, particularly in light of the current credit crisis. Any shortfall in funding could result in, among other things, 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 \$3.1 million for the three months ended March 31, 2009 and \$4.0 million for the three months ended March 31, 2008, representing the use of cash in funding preclinical and clinical development initiatives and administrative costs, and may fluctuate as we advance the clinical development of our product candidates and enroll subjects in clinical trials.

Net cash provided by investing activities was \$3.7 million for the three months ended March 31, 2009 and \$9.1 million for the three months ended March 31, 2008. The fluctuations from period to period are due to the timing of purchases and maturity dates of investments and the purchase of equipment.

Financing activities provided no cash for the three months ended March 31, 2009 and used cash of \$782,000 for the three months ended March 31, 2008 related to the repayment of our senior loan in June 2008.

Investors in the 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 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 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. The exercise of such warrants could provide us with cash proceeds. No warrants have been exercised at March 31, 2009.

Our senior loan was repaid in full in June 2008. The senior lenders retain a right to receive a milestone payment of \$2.25 million upon the occurrence of certain events 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, or (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 have occurred as of March 31, 2009. 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. The exercise of such warrants could provide us with cash proceeds. No warrants were exercised at March 31, 2009.

Table of Contents

In connection with our MultiStem collaboration with Angiotech, upon the successful achievement of specified clinical development and commercialization milestones, we may 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. We continue to jointly fund clinical development activities with Angiotech in accordance with our collaboration, and, as of March 31, 2009, \$543,000 was due from Angiotech. Of this amount, \$236,000 was repaid in April 2009 representing its share of fourth quarter 2008 costs, and we expect the balance to be paid on a timely basis. 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, 2008. There have been no material changes in our accounting policies and estimates as described in our Annual Report. For additional information regarding 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, 2008.

New Accounting Standards

In December 2007, the Financial Accounting Standards Board (FASB) ratified the consensus reached in EITF Issue No. 07-1 (EITF 07-0), *Accounting for Collaborative Arrangements*. The effective date of EITF 07-1 is January 1, 2009 for calendar year companies with retrospective application required for all periods presented for collaborative arrangements existing as of the effective date. EITF 07-1 requires certain disclosures related to collaborative arrangements where parties are active participants and exposed to significant risks and rewards dependent on the commercial success of the activity. The adoption of EITF 07-1 did not have a material impact on our financial statements since our accounting for our collaborative agreement was consistent with the provisions of EITF 07-1. In May 2008, the FASB issued FASB Staff Position APB 14-1 (FSP 14-1), *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. FSP 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash on conversion to separately account for the liability and equity components in a manner that reflects the issuer's nonconvertible debt borrowing rate. We have no current convertible debt instruments, and concluded that all of our prior instruments were not within the scope of FSP 14-1; and therefore, there was no retrospective effect from the adoption of FSP 14-1 on our financial statements.

Table of Contents

In December 2007, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 141R, *Business Combinations*. This statement, which addresses the accounting for business acquisitions, is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited, and generally applies to business acquisitions completed after December 31, 2008. Among other things, SFAS No. 141R requires that all acquisition-related costs be expensed as incurred and that all restructuring costs related to acquired operations be expensed as incurred. SFAS No. 141R also addresses the current and subsequent accounting for assets and liabilities arising from contingencies acquired or assumed. The adoption of SFAS No. 141R had no impact on our financial statements. SFAS No. 141R could have a material impact on our financial statements in future periods if we complete a significant acquisition in the future.

In June 2008, the FASB issued EITF Issue No. 07-5 (EITF 07-5), *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*. EITF 07-5 clarifies the determination of whether certain instruments or features were indexed to an entity's own stock under EITF Issue No. 01-6. The statement is effective for fiscal years beginning after December 15, 2008. The adoption of the statement had no impact on our financial statements.

In April 2009, the FASB issued FASB Staff Position FAS 115-2 (FSP 115-2), *Recognition and Presentation of Other-Than-Temporary Impairments*. FSP 115-2 requires, among other things, that other-than-temporary impairments be separated into the amount recognized in earnings and the amount recognized in other comprehensive income. The statement is effective for periods ending after June 15, 2009, with early adoption permitted. We are evaluating the impact the adoption of this statement will have on our financial statements.

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 similar words. 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 initiate or 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;

Table of Contents

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, including the current economic crisis;

our ability to obtain capital in difficult market conditions;

changes in financial stability of collaborators;

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 United States government and its agencies, corporate debt securities and A1+/P1 commercial paper. As of March 31, 2009, approximately 77% of our investments were in United States government obligations. We have been investing conservatively due to the current economic conditions, including the current credit crisis, and have prioritized liquidity and the preservation of principal in lieu of potentially higher returns. As a result, we have experienced no losses on the principal of our investments.

We enter into loan arrangements with financial institutions when needed and when available to us. At March 31, 2009, we had no borrowings outstanding.

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, 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.

Table of Contents

Changes in internal control over financial reporting

During the first quarter of 2009, 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
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.

Table of Contents

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 7, 2009

/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)

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
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.