

ATHERSYS, INC / NEW  
Form 10-Q  
May 06, 2010

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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, 2010

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**

**20-4864095**

(State or other jurisdiction  
of incorporation or organization)

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

**3201 Carnegie Avenue, Cleveland, Ohio**

**44115-2634**

(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 ☒ 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, 2010 was 18,929,333.

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**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)  
(Unaudited)

	<b>March 31, 2010</b>	<b>December 31, 2009</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,779	\$ 11,167
Available-for-sale securities	8,625	10,135
Accounts receivable	188	352
Receivable from Angiotech	244	229
Investment interest receivable	102	93
Prepaid expenses and other	189	173
 Total current assets	 14,127	 22,149
 Available-for-sale securities	 9,095	 5,080
Equipment, net	1,031	849
Deposits and other	253	253
 Total assets	 \$ 24,506	 \$ 28,331
 <b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,275	\$ 1,128
Accrued compensation and related benefits	197	667
Accrued clinical trial costs	115	83
Accrued expenses and other	798	857
Deferred revenue	2,372	3,123
 Total current liabilities	 4,757	 5,858
 Deferred revenue	 2,916	 3,516
 Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at March 31, 2010 and December 31, 2009		
Common stock, \$0.001 par value; 100,000,000 shares authorized, and 18,929,333 shares issued and outstanding at March 31, 2010 and December 31, 2009	19	19
Additional paid-in capital	213,154	212,704
Accumulated other comprehensive income	58	71
Accumulated deficit	(196,398)	(193,837)

Total stockholders' equity	16,833	18,957
Total liabilities and stockholders' equity	\$ 24,506	\$ 28,331

*See accompanying notes to unaudited condensed consolidated financial statements.*

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

	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Revenues</b>		
Contract revenue	\$ 1,395	\$ 188
Grant revenue	345	182
Total revenues	1,740	370
<b>Costs and expenses</b>		
Research and development	2,822	2,611
General and administrative	1,437	1,453
Depreciation	75	59
Total costs and expenses	4,334	4,123
Loss from operations	(2,594)	(3,753)
Interest income and other	33	128
<b>Net loss</b>	\$ (2,561)	\$ (3,625)
Basic and diluted net loss per share	\$ (0.14)	\$ (0.19)
Weighted average shares outstanding, basic and diluted	18,929,333	18,927,988
<i>See accompanying notes to unaudited condensed consolidated financial statements.</i>		

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

	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Operating activities</b>		
Net loss	\$ (2,561)	\$ (3,625)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	75	59
Stock-based compensation	450	513
Amortization of premium on available-for-sale securities and other	50	61
Changes in operating assets and liabilities:		
Accounts receivable	164	123
Receivable from Angiotech	(15)	(309)
Prepaid expenses and other assets	(25)	65
Accounts payable and accrued expenses	(350)	23
Deferred revenue	(1,351)	(53)
Net cash used in operating activities	(3,563)	(3,143)
<b>Investing activities</b>		
Purchase of available-for-sale securities	(6,068)	(4,073)
Maturities of available-for-sale securities	3,500	7,800
Purchases of equipment	(257)	(24)
Net cash (used in) provided by investing activities	(2,825)	3,703
<b>Financing activities</b>		
(Decrease) increase in cash and cash equivalents	(6,388)	560
Cash and cash equivalents at beginning of the period	11,167	12,552
Cash and cash equivalents at end of the period	\$ 4,779	\$ 13,112

*See accompanying notes to unaudited condensed consolidated financial statements.*



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**Athersys, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements**

Three-Month Periods Ended March 31, 2010 and 2009

**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, 2009. 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. Recently Issued Accounting Standards**

In September 2009, Accounting Standards Codification ( ASC ) 605-25, *Multiple-Element Arrangements*, was updated (Accounting Standards Update ( ASU ) No. 2009-13) related to revenue recognition for arrangements with multiple elements. The revised guidance provides for two significant changes to the existing guidance, the first relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting, which will likely result in the requirement to separate more deliverables within an arrangement leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Together, these changes are likely to result in earlier recognition of revenue for multiple-element arrangements than under previous guidance. The new guidance also significantly expands the disclosures required for multiple-element revenue arrangements. The new guidance is effective for our annual report on Form 10-K for the year ended December 31, 2010, however, early adoption is permitted provided that the new guidance is retroactively applied to the beginning of the year of adoption. We have not yet evaluated the potential effect of the future adoption of this new guidance.

In March 2010, ASC 605-28, Milestone Method of Revenue Recognition, was amended (ASU No. 2009-13) related to the ratification of the application of the proportional performance model of revenue recognition when applied to milestones in research and development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The new guidance is effective for fiscal years beginning on or after June 15, 2010, and may be applied prospectively or retrospectively. Early adoption is permitted provided that the new guidance is retrospectively applied to the beginning of the year of adoption. We have not yet evaluated the potential effect of the future adoption of this new guidance.

**Table of Contents****3. Net Loss per Share**

Basic and diluted net loss per share has been computed using the weighted-average number of shares 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 antidilutive. 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 4,026,149 and 3,745,149 shares of common stock for the three-month periods ended March 31, 2010 and 2009, respectively; and
- 2) Warrants to purchase 5,125,496 shares of common stock for each of the three-month periods ended March 31, 2010 and 2009.

**4. 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.

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Net loss	\$ (2,561)	\$ (3,625)
Unrealized loss on available-for-sale securities	(13)	(53)
Comprehensive loss	\$ (2,574)	\$ (3,678)

**5. Fair Value of Financial Instruments**

Our available-for-sale securities include U.S. government obligations and corporate debt securities. As of March 31, 2010, approximately 85% of our investments were in U.S. government obligations, including government-backed agencies.

The inputs used to measure fair value are classified 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.

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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, 2010 (in thousands):

Description	Balance as of March 31, 2010	Fair Value Measurements at March 31, 2010 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	\$ 17,720	\$ 17,720	\$	\$
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Fair value is based upon quoted market prices in active markets. We had no level 2 or level 3 assets at March 31, 2010. 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.

The following is a summary of available-for-sale securities (in thousands) at March 31, 2010 and December 31, 2009, respectively:

	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Estimated Fair Value
March 31, 2010:				
U.S. government obligations, which included government-backed agencies	\$ 15,108	\$ (2)	\$ 37	\$ 15,143
Corporate debt securities	2,554	(1)	24	2,577
	<b>\$ 17,662</b>	<b>\$ (3)</b>	<b>\$ 61</b>	<b>\$ 17,720</b>
December 31, 2009:				
U.S. government obligations, which included government-backed agencies	\$ 12,613	\$ (12)	\$ 52	\$ 12,653
Corporate debt securities	2,531		31	2,562
	<b>\$ 15,144</b>	<b>\$ (12)</b>	<b>\$ 83</b>	<b>\$ 15,215</b>

We had no realized gains or losses on the sale of available-for-sale securities for any of the periods presented.

Unrealized gains and losses on our available-for-sale securities are excluded from earnings and are reported as a separate component of stockholders' equity within accumulated other comprehensive income until realized. When available-for-sale securities are sold in the future, the cost of the securities will be specifically identified and used to determine any realized gain or loss. The net unrealized gain on available-for-sale securities was \$58,000 and \$71,000 as of March 31, 2010 and December 31, 2009, respectively.

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The amortized cost of and estimated fair value of available-for-sale securities at March 31, 2010 by contractual maturity are shown below (in thousands). Actual maturities may differ from contractual maturities because the issuers of the securities may have the right to repay the obligations without prepayment penalties. Although the investments are available-for-sale, it is our intention to hold the investments classified as long-term for more than a year from March 31, 2010.

	<b>March 31, 2010</b>	
	<b>Amortized Cost</b>	<b>Estimated Fair Value</b>
Due in one year or less	\$ 8,568	\$ 8,625
Due after one year through two years	9,094	9,095
	<b>\$ 17,662</b>	<b>\$ 17,720</b>

**6. Collaborative Arrangements and Revenue Recognition****Collaborative Arrangements**

Collaborative arrangements that involve cost or future profit 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. The accounting may be susceptible to change if the nature of a collaborator's business changes. Currently, our only collaboration accounted for on a net basis is our cost-sharing collaboration with Angiotech Pharmaceuticals, Inc. ( "Angiotech" ), since the responsibilities under this collaboration are shared with no principal party.

**Revenue Recognition**

Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, manufacturing revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under ASC 605-25, *Multiple-Element Arrangements*, (which originated primarily from the guidance in EITF 00-21) to assess whether they have standalone value and objective and reliable evidence of fair value, and if so, are accounted for as a single unit. We then recognize revenue for each unit based on the culmination of the earnings process under ASC 605-S25 (issued as SAB Topic 13) and our estimated performance period for the single units of accounting based on the specific terms of each collaborative agreement. We subsequently adjust the estimated performance periods, if appropriate, on a prospective basis based upon available facts and circumstances. Future changes in estimates of the performance period may materially impact the timing of future revenue recognized. Amounts received prior to satisfying the revenue recognition criteria for contract revenues are recorded as deferred revenue in the accompanying balance sheets. Reimbursement amounts (other than those accounted for using collaboration accounting) paid to us are recorded on a gross basis in the statements of operations as contract revenues. We entered into a collaboration agreement with Pfizer Inc. ( "Pfizer" ) in December 2009 that contains multiple elements and deliverables, as described below.

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Also included in contract revenue are license fees received from Bristol-Myers Squibb, which are specifically set forth in the license and collaboration agreement as amounts due to us based on our completion of certain tasks (e.g., delivery and acceptance of a cell line) and development milestones (e.g., clinical trial phases), and as such, are not based on estimates that are susceptible to change. Such amounts are invoiced and recorded as revenue as tasks are completed and as milestones are achieved.

Similarly, grant revenue consists of funding under cost reimbursement programs primarily from federal and state sources for qualified research and development activities performed by us, and as such, are not based on estimates that are susceptible to change. Such amounts are invoiced (unless prepaid) and recorded as revenue as tasks are completed.

*Angiotech*

In our co-development collaboration with Angiotech, we bear all preclinical costs and the parties jointly fund clinical development activity. We have primary responsibility for preclinical and early clinical development and clinical manufacturing, and Angiotech will take the lead on pivotal and later clinical trials and commercialization. The parties will share net profits from the future sale of approved products and we may receive equity investments and cash payments based on the successful achievement of specified clinical development and commercialization milestones. We continue to jointly fund clinical development activities with Angiotech in accordance with our co-development collaboration, and \$244,000 was due from Angiotech as of March 31, 2010. Our clinical costs for the three months ended March 31, 2010 and 2009 are reflected net of Angiotech's cost-sharing amount of \$244,000 and \$309,000, respectively.

*Pfizer*

In December 2009, we entered into a collaboration with Pfizer to develop and commercialize MultiStem to treat inflammatory bowel disease ( IBD ) for the worldwide market. Under the terms of the agreement, we received an up-front license and technology access payment of \$6.0 million from Pfizer and receive research funding and support. In addition, we are also eligible to receive milestone payments upon the successful achievement of certain development, regulatory and commercial milestones, for which we evaluated the nature of the events triggering these contingent payments and concluded that these events constituted substantive milestones that will be recognized as revenue in the period in which the underlying triggering event occurs.

Pfizer will pay us for manufacturing product for clinical development and commercialization purposes. Pfizer will have responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at phase III clinical development.

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We evaluated the facts and circumstances of the agreement to determine whether the Pfizer agreement has obligations constituting deliverables and concluded that it has multiple deliverables, including deliverables relating to the grant of a license and access to our technology, performance of research and development services and performance of certain manufacturing services, and concluded that these deliverables should be combined into a single unit of accounting. We recognize the license and technology access fee and research and development funding ratably on a straight-line basis over the estimated performance period, which began in December 2009 and is estimated to be completed in 2012, and recognize manufacturing revenue when services are performed. Prepaid license and technology access fee and prepaid research and development funding are recorded as deferred revenue and are amortized on a straight-line basis over the research period.

**7. Stock-based Compensation**

Our equity incentive plans authorize an aggregate of 4,500,000 shares of common stock for awards to employees, directors and consultants. These 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, 2010, a total of 476,000 shares were available for issuance under our equity compensation plans and options to purchase 4,026,149 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, 2010, stock-based compensation expense was approximately \$450,000. At March 31, 2010, total unrecognized estimated compensation cost related to unvested stock options was approximately \$1,024,000, which is expected to be recognized by the middle of 2013 using the straight-line method.

**8. Warrants**

As of March 31, 2010, we had the following outstanding warrants to purchase shares of common stock:

<b>Number of underlying shares</b>	<b>Exercise Price</b>	<b>Expiration</b>
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. Our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses.

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**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, 2009. 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 clinical trials. In addition, we are developing novel pharmaceuticals to treat indications such as obesity and for certain cognitive, attention and wakefulness disorders.

*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, or AMI) 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 AMI clinical trial with our partner Angiotech Pharmaceuticals, Inc., and we completed phase I enrollment in the first quarter of 2010. We intend to utilize the phase I results, combined with information from our extensive development efforts, to design a robust AMI phase II efficacy trial. In our GvHD trial, we have now successfully completed dosing patients at the first two dosing levels and are currently dosing patients at the third dose level. In the first quarter of 2010, we received authorization from the independent safety committee to commence the multi-dose arm of the GvHD trial and are currently dosing patients.

In addition to these two MultiStem clinical studies, we have authorization from the Food and Drug Administration, or FDA, to initiate a third clinical study administering MultiStem to patients for the treatment of ischemic stroke, a leading cause of death and disability. In 2009, we took a cautious approach to initiating this clinical study in light of the volatile and uncertain capital markets. While we continue our preparations to initiate this phase I trial, we also have been furthering our research efforts designed to deepen our understanding of the ways in which MultiStem promotes healing and repair in the wake of an ischemic stroke or other neurological injury.

In December 2009, we entered into a collaboration agreement with Pfizer Inc. to develop and commercialize MultiStem for the treatment of inflammatory bowel disease, or IBD, for the worldwide market. We are currently planning and preparing for a phase I clinical study in IBD and plan to initiate the study as soon as possible after regulatory approval.

We are also independently developing novel orally active pharmaceutical products for the treatment of obesity and for certain cognitive, attention and wakefulness disorders. We are actively evaluating these compounds, as we seek to identify candidates to advance further into development while we pursue collaboration partners who could work with us to develop these promising candidate compounds.

**Table of Contents***Financial*

We have incurred losses since inception of operations in 1995 and had an accumulated deficit of \$196 million at March 31, 2010. 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 contract revenues 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, 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. 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 and amounts are stated in thousands.

**Revenues**

	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Contract revenue	\$ 1,395	\$ 188
Grant revenue	345	182
	<b>\$ 1,740</b>	<b>\$ 370</b>

**Research and development expenses**

	<b>Three months ended March 31,</b>	
<i>Type of expense</i>	<b>2010</b>	<b>2009</b>
Personnel costs	\$ 952	\$ 823
Research supplies	262	253
Facilities	219	208
Clinical and preclinical development costs	478	509
Sponsored research	205	130
Patent legal fees	301	267
Other	252	207
Stock-based compensation	153	214
	<b>\$ 2,822</b>	<b>\$ 2,611</b>





**Table of Contents****General and administrative expenses**

<i>Type of expense</i>	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Personnel costs	\$ 480	\$ 499
Facilities	67	82
Legal and professional fees	282	324
Other	311	249
Stock-based compensation	297	299
	<b>\$ 1,437</b>	<b>\$ 1,453</b>

***Three Months Ended March 31, 2010 and 2009***

**Revenues.** Revenues increased to \$1.7 million for the three months ended March 31, 2010 from \$370,000 in the comparable period in 2009. Contract revenue increased \$1.2 million for the three months ended March 31, 2010 compared to the three months ended March 31, 2009, primarily as a result of our collaboration with Pfizer that we entered into in December 2009, partially offset by less revenues from our collaboration with Bristol-Myers Squibb due to a decline in activity. We expect our contract revenues related to the Pfizer collaboration in the next few years to reflect the amortization of the \$6.0 million up-front license fee over the estimated performance period, research and development funding, and the performance of manufacturing services. Our collaboration with Bristol-Myers Squibb is now in its final phase since the requirement for Bristol-Myers Squibb to nominate new targets ended in 2009, and we anticipate that Bristol-Myers Squibb's demand for new targets will be substantially reduced or cease altogether. However, we intend to continue to prepare and deliver validated drug targets as needed by Bristol-Myers Squibb for use in its drug discovery efforts and will remain entitled to receive license fees, milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology. Grant revenue increased \$163,000 for the three months ended March 31, 2010 compared to the three months ended March 31, 2009 primarily due to new grants that started late in 2009. Our grant revenues could fluctuate from period to period based on the timing of grant-related activities and the award of new grants.

**Research and Development Expenses.** Research and development expenses increased to \$2.8 million for the three months ended March 31, 2010 from \$2.6 million in the comparable period in 2009. The increase of approximately \$200,000 related primarily to an increase in personnel costs of \$129,000, an increase in sponsored research of \$75,000, an increase in other research and development expenses of \$45,000 and an increase in patent legal fee expense of \$34,000 for the three months ended March 31, 2010 from the comparable period in 2009. These increases were partially offset by a decrease in stock compensation expense of \$61,000 and a decrease in clinical and preclinical development costs of \$31,000 for the three months ended March 31, 2010 from the comparable period in 2009. The increase in personnel costs related to the addition of personnel in support of our preclinical and clinical programs and regulatory affairs. Sponsored research costs increased primarily due to an increase in grant-funded programs that require collaboration with certain academic research institutions. Patent legal fees vary from period to period while we further develop and maintain our portfolio of patent applications. Our clinical costs for the three months ended March 31, 2010 and 2009 are reflected net of Angiotech's cost-sharing amount of \$244,000 and \$309,000, respectively. We expect our research and development expenses in 2010 to be higher than in 2009, though this impact will be largely offset by increased revenues. 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.

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*General and Administrative Expenses.* General and administrative expenses remained consistent at approximately \$1.5 million for both the three months ended March 31, 2010 and 2009. We expect our general and administrative expenses to continue at similar levels during 2010.

*Depreciation.* Depreciation expense increased to \$75,000 for the three months ended March 31, 2010 from \$59,000 in the comparable period in 2009. The increase in depreciation expense was due to depreciation on capital purchases made in 2009 and 2010.

*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 \$33,000 for the three months ended March 31, 2010 from \$128,000 for the comparable period in 2009 due to the decline in our investment balances as they are used to fund our operations and foreign currency losses related to our European subsidiary. Due to low interest rates and declining cash balances as a result of our ongoing and planned clinical and preclinical development, we expect our 2010 interest income to be less than 2009 absent any new financings or business transactions.

### **Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and available-for-sale securities. At March 31, 2010, we had \$4.8 million in cash and cash equivalents and \$17.7 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.

In December 2009, we entered into a collaboration agreement with Pfizer to develop and commercialize MultiStem for the treatment of IBD for the worldwide market. Under the terms of the agreement, we received an up-front cash payment of \$6 million from Pfizer and will receive research funding and support. In addition, we are also eligible to receive milestone payments of up to \$105 million upon the successful achievement of certain development, regulatory and commercial milestones, though there can be no assurance that we will achieve any milestones. Pfizer will pay us for manufacturing product for clinical development and commercialization purposes. Pfizer will have responsibility for development, regulatory and commercialization and will pay us tiered royalties on worldwide commercial sales of MultiStem IBD products. Alternatively, in lieu of royalties and certain commercialization milestones, we may elect to co-develop with Pfizer and the parties will share development and commercialization expenses and profits/losses on an agreed basis beginning at phase III clinical development.

In connection with our MultiStem collaboration with Angiotech, 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 are jointly funding clinical development activity, whereby preclinical costs are borne solely by us, costs for phase I and phase II clinical trials are borne 50% by us and 50% by Angiotech, costs for the first phase III clinical trial will be borne 33% by us and 67% by Angiotech, and costs for any phase III clinical trials subsequent to the first phase III clinical trial 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 has lead responsibility for later clinical trials and commercialization. Upon product commercialization, we will receive nearly half of the net profits from the sale of any jointly developed, approved products.

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Our collaboration agreement with Bristol-Myers Squibb, which was initially established in 2001, is now in its final phase since the requirement for Bristol-Myers Squibb to nominate new targets ended in 2009, and we anticipate that Bristol-Myers Squibb's demand for new targets will be substantially reduced or cease altogether. We intend to continue to prepare and deliver validated drug targets as needed by Bristol-Myers Squibb for use in its drug discovery efforts. We will remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb over the course of the collaboration, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology, though there can be no assurance that we will achieve any milestones or royalties. Our available-for-sale securities typically include U.S. government obligations, commercial paper and corporate debt securities. As of March 31, 2010, approximately 85% of our investments were in U.S. government obligations, including government-backed agencies. We have been investing conservatively due to the ongoing economic conditions 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.

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. 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. Any shortfall in funding could result in our having to curtail 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 \$3.6 million for the three months ended March 31, 2010 and \$3.1 million for the three months ended March 31, 2009, and represented the use of cash in funding preclinical and clinical product development activities.

Net cash used in investing activities was \$2.8 million for the three months ended March 31, 2010 and net cash provided by investing activities was \$3.7 million for the three months ended March 31, 2009. The fluctuations from period to period were due to the timing of purchases and maturity dates of investments and the purchase of equipment. Purchases of equipment were \$257,000 and \$24,000 in the first quarter of 2010 and 2009, respectively. We expect that our capital equipment expenditures will increase moderately in 2010 compared to 2009.

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 exercise of such warrants could provide us with cash proceeds. No warrants have been exercised as of March 31, 2010.

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Our senior loan was repaid in full in 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, 2010. 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 as of March 31, 2010.

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, or 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, 2009. 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, 2009.

### **Recently Issued Accounting Standards**

In September 2009, Accounting Standards Codification, or ASC, 605-25, *Multiple-Element Arrangements*, was updated (Accounting Standards Update, or ASU, No. 2009-13) related to revenue recognition for arrangements with multiple elements. The new guidance is effective for our annual report on Form 10-K for the year ended December 31, 2010, however, early adoption is permitted provided that the new guidance is retroactively applied to the beginning of the year of adoption. We have not yet evaluated the potential effect of the future adoption of this new guidance. In March 2010, ASC 605-28, *Milestone Method of Revenue Recognition*, was amended (ASU No. 2009-13) related to the ratification of the application of the proportional performance model of revenue recognition when applied to milestones in research and development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The new guidance is effective for our annual report on Form 10-K for the year ended December 31, 2010, and may be applied prospectively or retrospectively. Early adoption is permitted provided that the new guidance is retrospectively applied to the beginning of the year of adoption. We have not yet evaluated the potential effect of the future adoption of this new guidance.

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**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:

- the possibility of delays in, adverse results of and excessive costs of the development process;

- changes in external market factors;

- changes in our industry's overall performance;

- changes in our business strategy;

- our ability to protect our intellectual property portfolio;

- our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;

- our ability to meet milestones under our collaboration agreements;

- 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.

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**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, commercial paper and corporate debt securities. As of March 31, 2010, approximately 85% of our investments were in U.S. government obligations, including government-backed agencies. We have been investing conservatively due to the current economic conditions 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, 2010, 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, 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, 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 2010, 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.

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**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, 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, 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 6, 2010

/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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