ATHERSYS, INC / NEW
Form 10-Q
August 10, 2011

Table of Contents

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

(Mark One)

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

For the quarterly period ended June 30, 2011

OR

o **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 þ No o
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 þ No o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company þ

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

The number of outstanding shares of the registrant s common stock, $0.001 par value, as of July 29, 2011 was 23,502,581.

ATHERSYS INC.
TABLE OF CONTENTS

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)

	June 30, 2011 (Unaudited)	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 4,719	$ 2,105
Available-for-sale securities	16,194	13,076
Accounts receivable	426	2,328
Receivable from Angiotech	175	106
Prepaid expenses and other	341	329
Total current assets	21,855	17,944
Equipment, net	1,205	955
Deposits and other	28	207
Total assets	$ 23,088	$ 19,106
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,978	$ 1,498
Accrued compensation and related benefits	590	580
Accrued clinical trial costs	842	207
Accrued expenses	784	1,012
Deferred revenue	4,178	5,541
Total current liabilities	8,372	8,838
Deferred revenue		1,263
Warrant liability	1,873	
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at June 30, 2011 and December 31, 2010		
Common stock, $0.001 par value; 100,000,000 shares authorized, and 23,502,581 and 18,930,678 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively	23	19
Additional paid-in capital	225,090	214,174
Accumulated other comprehensive income	97	26

Accumulated deficit	(212,367)	(205,214)
Total stockholders equity	12,843	9,005
Total liabilities and stockholders equity	$ 23,088	$ 19,106

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 June 30,		Six months ended June 30,	
	2011	**2010**	**2011**	**2010**
Revenues				
Contract revenue	$ 2,140	$ 1,519	$ 4,641	$ 2,914
Grant revenue	295	352	784	697
Total revenues	2,435	1,871	5,425	3,611
Costs and expenses				
Research and development	4,444	3,405	9,032	6,227
General and administrative	1,392	1,483	2,611	2,920
Depreciation	67	70	127	145
Total costs and expenses	5,903	4,958	11,770	9,292
Loss from operations	(3,468)	(3,087)	(6,345)	(5,681)
Interest income, net	33	57	66	118
Other income (expense), net	212	(47)	(874)	(75)
Net loss	$ (3,223)	$ (3,077)	$ (7,153)	$ (5,638)
Basic and diluted net loss per share	$ (0.14)	$ (0.16)	$ (0.32)	$ (0.30)
Weighted average shares outstanding, basic and diluted	23,502,581	18,929,333	22,693,155	18,929,333

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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

	Six months ended June 30,	
	2011	**2010**
Operating activities		
Net loss	$ (7,153)	$ (5,638)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	127	145
Stock-based compensation	266	1,044
Issuance of common stock to former lenders	607	
Change in fair value of warrant liability	78	
Amortization of premium on available-for-sale securities and other	41	147
Changes in operating assets and liabilities:		
Accounts receivable	1,902	85
Receivable from Angiotech	(69)	84
Prepaid expenses and other assets	84	(29)
Accounts payable and accrued expenses	897	(389)
Deferred revenue	(2,626)	(1,285)
Net cash used in operating activities	(5,846)	(5,836)
Investing activities		
Purchase of available-for-sale securities	(12,508)	(8,081)
Maturities of available-for-sale securities	9,503	5,500
Purchases of equipment	(377)	(323)
Net cash used in investing activities	(3,382)	(2,904)
Financing activities		
Proceeds from issuance of common stock and warrants, net of offering costs	11,842	
Net cash provided by financing activities	11,842	
Increase (decrease) in cash and cash equivalents	2,614	(8,740)
Cash and cash equivalents at beginning of the period	2,105	11,167
Cash and cash equivalents at end of the period	$ 4,719	$ 2,427

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Athersys, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
Three- and Six-Month Periods Ended June 30, 2011 and 2010

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, 2010. 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 change 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 was effective for us for new arrangements or modifications to existing arrangements entered into on or after January 1, 2011 and had no effect on our financial statements for the three and six months ended June 30, 2011. The adoption of this new guidance may have the potential effect of less future revenue deferral for new collaborations and bundled units of accounting being accounted for as separate units than we have historically experienced.

In March 2010, ASC 605-28, *Milestone Method of Revenue Recognition*, was amended (ASU No. 2010-17) 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 was effective for us for new arrangements entered into on or after January 1, 2011. The adoption of this guidance had no effect on our financial statements, since we have been historically recognizing milestone revenue consistent with this 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:

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Outstanding options	4,493,101	4,124,262	4,493,101	4,124,262
Restricted stock units	39,300		39,300	
Outstanding warrants	6,435,496	5,125,496	6,435,496	5,125,496
	10,967,897	9,249,758	10,967,897	9,249,758

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.

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Net loss	$ (3,223)	$ (3,077)	$ (7,153)	$ (5,638)
Unrealized gain (loss) on available-for-sale securities	19	(6)	40	(19)
Proportionate share of comprehensive income for equity method investment	19		31	
Comprehensive loss	$ (3,185)	$ (3,083)	$ (7,082)	$ (5,657)

5. Fair Value of Financial Instruments

Our available-for-sale securities include U.S. government obligations, corporate debt securities, a fixed income mutual fund, and a corporate equity security that we received in a settlement in 2003, for which the corporation completed an initial public offering in 2011. As of June 30, 2011, approximately 80% of our investments were in U.S. government obligations, including government-backed agencies, and 12% of our investments were in a fixed-income mutual fund. 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 Adjusted 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 significant inputs other than quoted prices that are observable for the asset or liability.

Level 3 Unobservable inputs for the asset or liability.

Table of Contents

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 June 30, 2011 (in thousands):

		Fair Value Measurements at June 30, 2011 Using		
Description	**Balance as of June 30, 2011**	**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	$ 16,194	$ 16,019	$ 175	$
Warrant liability	$ 1,873	$	$	$ 1,873

Fair value is based upon quoted market prices in active markets for our level 1 investments and quoted market prices for similar assets for our level 2 investments. The estimated fair value of warrants accounted for as liabilities, representing a level 3 fair value measure, was determined on the issuance date and subsequently adjusted to its fair value at each financial reporting date. The fair value of the warrants is estimated using the expected volatility based on the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization, using a Black-Scholes valuation model with the following inputs at June 30, 2011:

Exercise price	$ 3.55
Market value of stock at end of period	$ 2.71
Expected volatility	73.42%
Risk-free interest rate	1.76%
Expected life (in years)	4.59

A rollforward of fair value measurements using significant unobservable inputs (Level 3) for the warrants is as follows (in thousands):

	Three months ended June 30, 2011	Six months ended June 30, 2011
Balance January 1, 2011		$
Issuance of warrants February 2011		1,795
Balance April 1, 2011 (for three-month period, only)	$ 2,070	
(Gain) loss included in other expense for the period	(197)	78
Balance June 30, 2011	$ 1,873	$ 1,873

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 in a fair value measurement may result in a reclassification between fair value hierarchy levels.

The following is a summary of available-for-sale securities (in thousands) at June 30, 2011 and December 31, 2010, respectively:

	Amortized	**Gross Unrealized**	**Gross Unrealized**	**Estimated Fair**

	Cost	Losses	Gains	Value
June 30, 2011:				
U.S. government obligations, which included government-backed agencies	$ 13,010	$	$ 8	$ 13,018
Corporate debt securities	1,004	(1)		1,003
Fixed income mutual fund	2,000	(2)		1,998
Corporate equity security, with restrictions	114		61	175
	$ 16,128	**$ (3)**	**$ 69**	**$ 16,194**
December 31, 2010:				
U.S. government obligations, which included government-backed agencies	$ 11,034	$	$ 23	$ 11,057
Corporate debt securities	2,016		3	2,019
	$ 15,144	**$**	**$ 26**	**$ 13,076**

Table of Contents

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 and if 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 $66,000 and $26,000 as of June 30, 2011 and December 31, 2010, respectively.

The amortized cost of and estimated fair value of available-for-sale securities at June 30, 2011 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.

	June 30, 2011	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 14,014	$ 14,021
Mutual fund and an equity security	2,114	2,173
	$ 16,128	**$ 16,194**

6. Collaborative Arrangements and Revenue Recognition

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 a non-refundable up-front payment from Pfizer and receive research funding and support. In addition, we are 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 pays us for manufacturing product for clinical development and commercialization purposes. Pfizer has 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.

We evaluated the facts and circumstances of the agreement and determined the Pfizer agreement has multiple deliverables that should be combined into a single unit of accounting. We are recognizing the license and technology access fee and research and development funding ratably on a straight-line basis over the estimated performance period, which is estimated to be completed in 2012. Further, we are measuring manufacturing revenue beginning upon the culmination of the earnings process and recognizing it over the remainder of the performance period of the bundled unit of accounting. Prepaid license and technology access fee and prepaid research and development funding are recorded as deferred revenue and amortized on a straight-line basis over the performance period.

Angiotech

In our 2006 co-development collaboration with Angiotech to develop and commercialize MultiStem to treat acute myocardial infarction (AMI) for the worldwide market, we received initial equity investments and may also receive cash payments and an equity investment based on the successful achievement of specified clinical development and commercialization milestones. 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. The parties jointly fund clinical development activity and will share net profits from the future sale of approved products.

We continue to jointly fund clinical development activities with Angiotech in accordance with our co-development collaboration, and $175,000 was due from Angiotech as of June 30, 2011. Our clinical costs for the six months ended

June 30, 2011 and 2010 are reflected net of Angiotech s cost-sharing amount of $152,000 and $389,000, respectively. Included in the $152,000 cost share for the six months ended June 30, 2011 was a write down of $114,000 from the final court settlement of our prepetition claims in connection with Angiotech s bankruptcy proceedings, which are now concluded. Angiotech assumed our collaboration agreement in the bankruptcy proceedings and following the bankruptcy, has made payments to us in accordance with our agreement.

Table of Contents

RTI Biologics, Inc.

In September 2010, we entered into an agreement with RTI, a provider of orthopedic and other biologic implants, under which we provided RTI a license to one of our technologies to enable RTI to develop and commercialize biologic implants exclusively for certain orthopedic applications in the bone graft substitutes market. Under the terms of the agreement, we received $3.0 million of guaranteed license fee payments and are entitled to receive $2.0 million of license fee payments contingent on future milestone events. We are also eligible to receive milestone payments upon the successful achievement of certain development and commercial milestones, including the $2.0 million contingent license fee payments mentioned above. We evaluated the nature of the events triggering these contingent license payments and concluded that these events are substantive and that revenue will be recognized in the period in which the underlying triggering event occurs. In addition, we will receive tiered royalties on worldwide commercial sales, if any, of implants using our technologies.

We evaluated the facts and circumstances and determined the RTI agreement has multiple deliverables that should be combined into a single unit of accounting. We recognize the $3.0 million guaranteed license fee ratably on a straight-line basis over the estimated performance period, which is estimated to be completed in the fourth quarter of 2011.

7. Stock-based Compensation

Our equity incentive plans authorize an aggregate of 5,500,000 shares of common stock for awards to employees, directors and consultants, which includes an increase of 1,000,000 authorized shares that was approved by stockholders in June 2011. Our 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 June 30, 2011, a total of 968,674 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 4,532,401 shares of common stock were outstanding (which includes options to purchase 1,075 shares of common stock related to our old option plans prior to our merger in June 2007). During the three-month period ended June 30, 2011, we granted 195,900 stock options and 39,300 restricted stock units. For the three-month periods ended June 30, 2011 and 2010, stock-based compensation expense was approximately $147,000 and $594,000, respectively. At June 30, 2011, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately $1,065,000, which is expected to be recognized by the first quarter of 2015 using the straight-line method.

8. Issuance of Common Stock and Warrants

In February 2011, we completed a registered direct offering of 4,366,667 shares of common stock and five-year warrants to purchase 1,310,000 shares of common stock with an exercise price of $3.55 per share, generating net proceeds of $11.9 million. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.3 of a share of common stock at an offering price of $3.00 per fixed combination.

In connection with the offering in February 2011, our former lenders were entitled to a milestone payment in the amount of $810,000, of which $202,500 was paid in cash and $607,500 was paid through the issuance of our common stock to the former lenders at $2.96 per share in February 2011. This milestone payment is included in other expense in the consolidated statement of operations.

9. Warrant Liability

We account for common stock warrants as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. Registered common stock warrants that could require cash settlement are accounted for as liabilities. We classify these warrant liabilities on the consolidated balance sheet as a non-current liability, which is revalued to fair value at each reporting date subsequent to the initial issuance. We use a Black-Scholes valuation model to value the warrant liability at its fair value (See Note 5). Changes in the fair market value of the warrant are reflected in the consolidated statement of operations as other income (expense).

Table of Contents

The warrants issued in the February 2011 registered direct offering contain a provision for net cash settlement in the event that there is a fundamental transaction (e.g., merger, sale of substantially all assets, tender offer, or share exchange). If a fundamental transaction occurs in which the consideration issued consists of all cash or stock in a non-public company, then the warrant holder has the option to receive cash equal to the fair value of the remaining unexercised portion of the warrant. Also, the warrants generally provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, the warrant agreements do not expressly state that a net cash settlement is prohibited. Therefore, even though a cashless exercise feature is available to the holder, in the absence of an express prohibition on net cash settlement, the warrants may be subject to cash settlement, as it is not within the absolute control of the Company to provide freely-tradable shares in all circumstances.

The warrants issued in February 2011 have been classified as liabilities, as opposed to equity, due to the potential cash settlement upon the occurrence of certain events as described above, and are recorded at a fair value of $1,873,000 at June 30, 2011.

As of June 30, 2011, 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
1,310,000	$ 3.55	February 2, 2016
6,435,496		

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.

Table of Contents

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, 2010. 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, related metabolic conditions such as diabetes, and certain neurological conditions.

Current Programs

By applying our proprietary cell therapy platform, MultiStem, we have established therapeutic product development programs in the areas of treating cardiovascular disease, neurological conditions, inflammatory and immune system disorders, and certain other conditions. To date, we have advanced four programs to clinical development stage, including:

An ongoing Phase II clinical study involving administration of MultiStem to patients suffering from