ATHERSYS, INC / NEW
Form 10-Q
November 10, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

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 x 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 x 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 x
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 x

The number of outstanding shares of the registrant s common stock, $0.001 par value, as of November 1, 2014 was 77,515,339.

ATHERSYS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

Athersys, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 32,368	$ 31,948
Accounts receivable	665	520
Prepaid expenses and other	416	387
Total current assets	33,449	32,855
Equipment, net	1,331	1,333
Total assets	$ 34,780	$ 34,188
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,891	$ 2,243
Accrued compensation and related benefits	909	1,067
Accrued clinical trial costs	85	88
Accrued expenses	692	884
Deferred revenue		86
Note payable	181	
Total current liabilities	4,758	4,368
Note payable		176
Warrant liabilities	3,204	9,823
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at September 30, 2014 and December 31, 2013		
Common stock, $0.001 par value; 150,000,000 shares authorized, and 77,515,339 and 70,749,212 shares issued at September 30, 2014 and December 31, 2013, respectively, and 77,515,339 and 70,683,480 shares outstanding at September 30, 2014 and December 31, 2013, respectively	78	71
Additional paid-in capital	306,706	284,323
Treasury stock, at cost; 65,732 shares at December 31, 2013		(135)

Accumulated deficit		**(279,966)**		(264,438)
Total stockholders equity		**26,818**		19,821
Total liabilities and stockholders equity	**$**	**34,780**	$	34,188

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except share and per share data)

(Unaudited)

	Three months ended September 30, 2014	Three months ended September 30, 2013	Nine months ended September 30, 2014	Nine months ended September 30, 2013
Revenues				
Contract revenue	**$ 75**	$ 87	**$ 155**	$ 365
Grant revenue	**218**	534	**1,233**	1,153
Total revenues	**293**	621	**1,388**	1,518
Costs and expenses				
Research and development	**5,775**	4,689	**17,756**	15,372
General and administrative	**1,695**	1,450	**5,303**	4,512
Depreciation	**91**	86	**272**	257
Total costs and expenses	**7,561**	6,225	**23,331**	20,141
Loss from operations	**(7,268)**	(5,604)	**(21,943)**	(18,623)
Other income (expense), net	**9**	(4)	**80**	28
Income (expense) from change in fair value of warrants, net	**2,540**	(6)	**6,335**	(2,353)
Net loss and comprehensive loss	**$ (4,719)**	$ (5,614)	**$ (15,528)**	$ (20,948)
Net loss per share - Basic	**$ (0.06)**	$ (0.10)	**$ (0.20)**	$ (0.38)
Weighted average shares outstanding - Basic	**77,320,425**	57,646,306	**76,755,599**	55,722,235
Net loss per share - Diluted	**$ (0.08)**	$ (0.10)	**$ (0.23)**	$ (0.38)
Weighted average shares outstanding - Diluted	**78,349,840**	59,248,031	**78,495,281**	55,722,235

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine months ended September 30, 2014	Nine months ended September 30, 2013
Operating activities		
Net loss	**$ (15,528)**	$ (20,948)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**272**	257
Stock-based compensation	**1,894**	918
Change in fair value of warrant liabilities	**(6,335)**	2,353
Changes in operating assets and liabilities:		
Accounts receivable	**(145)**	37
Prepaid expenses and other assets	**(29)**	3
Accounts payable and accrued expenses	**295**	(890)
Deferred revenue and other	**(81)**	
Net cash used in operating activities	**(19,657)**	(18,270)
Investing activities		
Purchases of equipment	**(270)**	(331)
Net cash used in investing activities	**(270)**	(331)
Financing activities		
Proceeds from issuance of common stock and warrants, net	**19,701**	10,617
Purchase of treasury stock	**(292)**	(137)
Proceeds from exercise of warrants	**938**	402
Net cash provided by financing activities	**20,347**	10,882
Increase (decrease) in cash and cash equivalents	**420**	(7,719)
Cash and cash equivalents at beginning of the period	**31,948**	25,533
Cash and cash equivalents at end of the period	**$ 32,368**	$ 17,814

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Three- and Nine-Month Periods Ended September 30, 2014 and 2013

1. Background and Basis of Presentation

We are an international biopharmaceutical company that is focused primarily on the field of regenerative medicine and operate 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, 2013. 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.

2. Recently Issued Accounting Standard

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 requires an entity to recognize revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, the amendment provides five steps that an entity should apply when recognizing revenue. The amendment also specifies the accounting of some costs to obtain or fulfill a contract with a customer and expands the disclosure requirements around contracts with customers. An entity can either adopt this amendment retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the update recognized at the date of initial application. The amendment is effective for annual reporting periods beginning after December 15, 2016. Early adoption is not permitted. We are in the process of evaluating, but have not determined, the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern, which establishes management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and, if so, to provide related footnote disclosures. ASU 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued or available to be issued. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The guidance is effective for the annual periods ending after December 15, 2016 and interim periods thereafter with early adoption permitted. We are in the process of evaluating the impact the new guidance will have on our disclosures.

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3. Net Loss per Share

Basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during the period. The table below reconciles the net loss and the number of shares used to calculate basic and diluted net loss per share for the three and nine month periods ended September 30, 2014 and 2013, in thousands.

	Three months ended September 30,		Nine months ended September 30,	
	2014	**2013**	**2014**	**2013**
Numerator:				
Net loss attributable to common stockholders - Basic	**$ (4,719)**	$ (5,614)	**$ (15,528)**	$ (20,948)
Less: income from change in fair value of warrants	**(1,160)**	(33)	**(2,504)**	
Net loss attributable to common stockholders used to calculate diluted net loss per share	**$ (5,879)**	$ (5,647)	**$ (18,032)**	$ (20,948)
Denominator:				
Weighted-average shares outstanding - Basic	**77,320**	57,646	**76,756**	55,722
Potentially dilutive common shares outstanding:				
Warrants	**1,030**	1,602	**1,739**	
Weighted-average shares used to calculate diluted net loss per share	**78,350**	59,248	**78,495**	55,722
Basic earnings per share	**$ (0.06)**	$ (0.10)	**$ (0.20)**	$ (0.38)
Dilutive earnings per share	**$ (0.08)**	$ (0.10)	**$ (0.23)**	$ (0.38)

We have outstanding options, restricted stock units 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 September 30,		Nine months ended September 30,	
	2014	**2013**	**2014**	**2013**
Stock options	**6,261,164**	5,130,329	**6,261,164**	5,130,329
Restricted stock units	**2,142,779**	2,674,348	**2,142,779**	2,674,348
Warrants	**6,310,000**	1,459,026	**6,310,000**	5,409,027
Total	**14,713,943**	9,263,703	**14,713,943**	13,213,704

4. Fair Value of Financial Instruments

Fair Value Measurements

We classify the inputs used to measure fair value into the following hierarchy:

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

Level 2 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.

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 September 30, 2014 (in thousands):

		Fair Value Measurements at September 30, 2014 Using		
Description	**Balance as of September 30, 2014**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Warrant liabilities	$ 3,204	$	$	$ 3,204

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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. There were no reclassifications for all periods presented.

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 marked to market at each financial reporting date. We use the Black-Scholes valuation model to value the warrant liabilities at fair value. The fair value is estimated using the expected volatility based on our historical volatility for warrants issued after January 1, 2013, or for warrants issued prior to 2013, using the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization. The fair value of the warrants is determined using probability weighted-average assumptions, when appropriate. The following inputs were used at September 30, 2014:

	Expected Volatility	Risk-Free Interest Rate	Expected Life
Warrants with one year or less remaining term	114.77%	0.13%	0.50 year
Warrants with greater than one year remaining term	67.59% - 78.63%	0.13% - 0.58%	1.34 - 2.46 years

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

	Three months ended September 30, 2014		Nine months ended September 30, 2014
Balance July 1, 2014	**$ 5,744**	**Balance January 1, 2014**	**$ 9,823**
Issuance of warrants		Issuance of warrants January 2014	2,012
Exercise of warrants		Exercise of warrants	(2,296)
Gain included in income from change in fair value of warrants for the period	(2,540)	Gain included in income from change in fair value of warrants for the period	(6,335)
Balance September 30, 2014	**$ 3,204**	**Balance September 30, 2014**	**$ 3,204**

5. Collaborative Arrangements and Revenue Recognition

Pfizer

In 2009, we entered into a collaboration with Pfizer Inc. (Pfizer) to develop and commercialize our MultiStem® product candidate to treat inflammatory bowel disease (IBD) for the worldwide market on an exclusive basis. 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. No significant milestone revenue has been recognized to date.

Pfizer pays us for manufacturing product for clinical development and commercialization purposes, which is recognized in the period that the manufacturing services are performed. Pfizer has responsibility for development and regulatory, including decision-making regarding the advancement or cessation of further development under the collaboration. If the product is successfully developed, Pfizer would also have sole responsibility for commercialization. We may elect to co-develop with Pfizer, in which case, the parties would share development and commercialization expenses and profits (if any) on an agreed basis beginning at Phase 3 clinical development. Alternatively, we may elect to not co-develop with Pfizer, in which case Pfizer will pay us tiered single-digit royalties on worldwide commercial sales of MultiStem IBD products. Any royalties may be subject to certain reductions related to market exclusivity, patent claims and credits from sales milestone payments. In the event that Pfizer does not move the program forward, the development and commercialization rights would revert to us.

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RTI Surgical, Inc.

In 2010, we entered into an agreement with RTI Surgical, Inc. (RTI) to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market on an exclusive basis. We are eligible to receive cash payments upon the successful achievement of certain commercial milestones. We evaluated the nature of the events triggering these contingent payments and concluded that these events are substantive and that revenue will be recognized in the period in which each underlying triggering event occurs. No milestone revenue has been recognized to date. In addition, we are entitled to receive tiered royalties on worldwide commercial sales of implants using our technologies based on a royalty rate starting in the mid-single digits and increasing into the mid-teens. Any royalties may be subject to a reduction if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product.

6. Stock-based Compensation

We have two incentive plans that authorized an aggregate of 11,500,000 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. As of Septe