ATHERSYS, INC / NEW
Form 10-Q
November 05, 2015
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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, 2015

OR

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

For the transition period from __________ to __________.

Commission file number: 001-33876

Athersys, Inc.

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of** **incorporation or organization)**	**20-4864095** **(I.R.S. Employer** **Identification No.)**
3201 Carnegie Avenue, Cleveland, Ohio **(Address of principal executive offices)**	**44115-2634** **(Zip Code)**

Registrant s telephone number, including area code: (216) 431-9900

Former name, former address and former fiscal year, if changed since last report: Not Applicable

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes 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, 2015 was 83,285,747.

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, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 28,533	$ 26,127
Accounts and other receivables	315	694
Prepaid expenses and other	383	427
Total current assets	29,231	27,248
Equipment, net	1,167	1,270
Deferred tax assets	195	200
Total assets	$ 30,593	$ 28,718
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,639	$ 2,767
Accrued compensation and related benefits	795	1,060
Accrued clinical trial costs	179	126
Accrued expenses	475	664
Deferred revenue	10,000	75
Note payable	189	
Total current liabilities	14,277	4,692
Note payable		183
Warrant liabilities	813	2,948
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at September 30, 2015 and December 31, 2014		
Common stock, $0.001 par value; 150,000,000 shares authorized, and 83,285,747 and 77,706,816 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	83	78
Additional paid-in capital	321,954	307,337
Accumulated deficit	(306,534)	(286,520)

Total stockholders equity		**15,503**		20,895
Total liabilities and stockholders equity	**$**	**30,593**	$	28,718

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three months ended September 30, 2015	Three months ended September 30, 2014	Nine months ended September 30, 2015	Nine months ended September 30, 2014
Revenues				
Contract revenue	**$ 39**	$ 75	**$ 194**	$ 155
Grant revenue	**357**	218	**1,149**	1,233
Total revenues	**396**	293	**1,343**	1,388
Costs and expenses				
Research and development	**5,089**	5,775	**16,018**	17,756
General and administrative	**1,941**	1,695	**5,751**	5,303
Depreciation	**66**	91	**201**	272
Total costs and expenses	**7,096**	7,561	**21,970**	23,331
Loss from operations	**(6,700)**	(7,268)	**(20,627)**	(21,943)
Other (expense) income, net	**(79)**	8	**(31)**	62
Income from change in fair value of warrants, net	**255**	2,540	**609**	6,335
Loss before taxes	**(6,524)**	(4,720)	**(20,049)**	(15,546)
Tax benefit	**27**	1	**35**	18
Net loss and comprehensive loss	**$ (6,497)**	$ (4,719)	**$ (20,014)**	$ (15,528)
Net loss per share - Basic	**$ (0.08)**	$ (0.06)	**$ (0.24)**	$ (0.20)
Weighted average shares outstanding - Basic	**83,140,864**	77,320,425	**81,736,273**	76,755,599
Net loss per share - Diluted	**$ (0.08)**	$ (0.08)	**$ (0.24)**	$ (0.23)
Weighted average shares outstanding - Diluted	**83,425,669**	78,349,840	**82,572,984**	78,495,281

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, 2015	Nine months ended September 30, 2014
Operating activities		
Net loss	**$ (20,014)**	$ (15,528)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**201**	272
Stock-based compensation	**2,187**	1,894
Change in fair value of warrant liabilities	**(609)**	(6,335)
Changes in operating assets and liabilities:		
Accounts receivable	**379**	(145)
Prepaid expenses and other	**55**	(29)
Accounts payable and accrued expenses	**(529)**	295
Deferred revenue	**9,925**	(81)
Net cash used in operating activities	**(8,405)**	(19,657)
Investing activities		
Purchases of equipment	**(99)**	(270)
Net cash used in investing activities	**(99)**	(270)
Financing activities		
Proceeds from issuance of common stock and warrants, net	**10,371**	19,701
Purchase of treasury stock	**(437)**	(292)
Proceeds from exercise of warrants	**976**	938
Net cash provided by financing activities	**10,910**	20,347
Increase in cash and cash equivalents	**2,406**	420
Cash and cash equivalents at beginning of the period	**26,127**	31,948
Cash and cash equivalents at end of the period	**$ 28,533**	$ 32,368

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, 2015 and 2014

1. Background and Basis of Presentation

We are an international biotechnology company that is focused primarily in 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, 2014. 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 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. In August 2015, the FASB issued ASU 2015-14, which delays the effective date by one year, making the new standard effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early adoption is permitted for annual reporting periods beginning after December 15, 2016. 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.

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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 it has plans to 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 will adopt ASU 2014-15 as required.

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, 2015 and 2014, in thousands.

	Three months ended September 30,		Nine months ended September 30,	
	2015	**2014**	**2015**	**2014**
Numerator:				
Net loss attributable to common stockholders - Basic	**$ (6,497)**	$ (4,719)	**$ (20,014)**	$ (15,528)
Less: income from change in fair value of warrants	**(220)**	(1,160)	**(196)**	(2,504)
Net loss attributable to common stockholders used to calculate diluted net loss per share	**$ (6,717)**	$ (5,879)	**$ (20,210)**	$ (18,032)
Denominator:				
Weighted-average shares outstanding - Basic	**83,141**	77,320	**81,736**	76,756
Potentially dilutive common shares outstanding:				
Warrants	**285**	1,030	**837**	1,739
Weighted-average shares used to calculate diluted net loss per share	**83,426**	78,350	**82,573**	78,495
Basic earnings per share	**$ (0.08)**	$ (0.06)	**$ (0.24)**	$ (0.20)
Dilutive earnings per share	**$ (0.08)**	$ (0.08)	**$ (0.24)**	$ (0.23)

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,	
	2015	**2014**	**2015**	**2014**
Stock options	**7,151,392**	6,261,164	**7,151,392**	6,261,164

Restricted stock units	**1,304,493**	2,142,779	**1,304,493**	2,142,779
Warrants	**2,810,000**	6,310,000	**2,810,000**	6,310,000
Total	**11,265,885**	14,713,943	**11,265,885**	14,713,943

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

Level 3 Unobservable inputs for the asset or liability.

The following table provides a summary of the fair values of our assets and liabilities measured at fair value on a recurring basis as of September 30, 2015 (in thousands):

		Fair Value Measurements at September 30, 2015 Using		
Description	**Balance as of September 30, 2015**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Warrant liabilities	$ 813	$	$	$ 813

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, 2015:

	Expected Volatility	Risk-Free Interest Rate	Expected Life
Warrants with one year or less remaining term	61.59% - 84.39%	0.01% 0.33%	0.34 0.79 year
Warrants with greater than one year remaining term	67.55%	0.33%	1.45 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, 2015		Nine months ended September 30, 2015
Balance July 1, 2015	**$ 1,068**	**Balance January 1, 2015**	**$ 2,948**
Settlements from exercise		Settlements from exercise	(1,526)
Income for the period	(255)	Income for the period	(609)
Balance September 30, 2015	**$ 813**	**Balance September 30, 2015**	**$ 813**

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5. Collaborative Arrangements and Revenue Recognition

Chugai

On October 20, 2015, we and Chugai Pharmaceutical Co. Ltd. (Chugai) agreed to terminate the License Agreement (the Agreement), dated February 28, 2015, between the parties, as a result of an inability to reach an agreement on the modification of the financial terms of the agreement and on the development strategy of our MultiStem® cell therapy for the treatment of ischemic stroke in Japan. Pursuant to the terms of the Agreement, upon termination, we regained all rights for developing our stem cell technologies and products for ischemic stroke in Japan, and Chugai no longer has any license rights or options with respect to our technologies and products. Neither we nor Chugai have any further obligations to each other, and the licenses granted to Chugai to develop and commercialize MultiStem for ischemic stroke in Japan terminate.

Under the agreement, we received a non-refundable, up-front cash payment of $10 million from Chugai, of which approximately $2.0 million was temporarily withheld by Japan taxing authorities and was refunded in September 2015. The $10 million upfront payment from Chugai was recorded as deferred revenue at September 30, 2015 since we had concluded that the license grant did not have standalone value (as defined in ASC 605-25) at the inception of the arrangement. In connection with the termination and the parties having no further obligations under the Agreement, we will recognize the $10 million upfront payment from Chugai as revenue in October 2015.

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 for the worldwide market on an exclusive basis. In addition, Pfizer conducted a Phase 2 clinical study exploring the potential of MultiStem cell therapy to treat advanced and severe ulcerative colitis, and would be responsible for any subsequent development. Overall, the study results were disappointing, even though a single administration of the cell therapy may have had some short-term beneficial effects. Taking these results into account, following an internal portfolio review, Pfizer determined that it would not invest further in this program, as would be required by the collaboration, and notified us of this decision to terminate the license agreement effective in the third quarter of 2015. In connection with the termination, all rights that Pfizer had to the program reverted to us, and intellectual property generated through the collaboration is owned by us.

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. Under the terms of the agreement, we received a non-refundable license fee in installments and performed certain services that were concluded in 2012, and 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 began receiving in 2014 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.

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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 September 30, 2015, a total of 2,426,442 shares of common stock have been issued under our equity incentive plans.

As of September 30, 2015, a total of 617,673 shares were available for issuance under our equity compensation plans and stock-based awards to purchase 8,455,885 shares of common stock were outstanding. For the three-month periods ended September 30, 2015 and 2014, stock-based compensation expense was approximately $730,000 and $714,000, respectively. At September 30, 2015, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately $4.4 million, which is expected to be recognized by the end of 2019 using the straight-line method.

7. Issuance of Common Stock and Warrants

In January 2014, we completed a registered direct offering generating net proceeds of approximately $18.8 million through the issuance of 5,000,000 shares of common stock and immediately exercisable warrants to purchase 1,500,000 shares of common stock with an exercise price of $4.50 per share that expire on July 15, 2016. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.30 shares of common stock at an offering price of $4.10 per fixed combination.

During the quarter ended September 30, 2015, we did not sell any shares under the equity purchase agreement with Aspire Capital, and during the nine-month period ended September 30, 2015, we sold 4,023,719 shares of common stock at an average price of $2.58 per share.

As of September 30, 2015, we had the following outstanding warrants to purchase shares of common stock:

Number of Underlying Shares	Exercise Price	Expiration