

ATHERSYS, INC / NEW
Form 10-Q
November 09, 2016
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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 September 30, 2016

OR

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

For the transition period from _____ to _____.

Commission file number: 001-33876

Athersys, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

20-4864095
(I.R.S. Employer
Identification No.)

3201 Carnegie Avenue, Cleveland, Ohio
(Address of principal executive offices)

44115-2634
(Zip Code)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

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

The number of outstanding shares of the registrant's common stock, \$0.001 par value, as of November 1, 2016 was 85,498,369.

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ATHERSYS, INC.

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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)

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,309	\$ 23,027
Available-for-sale-securities	11,070	
Accounts receivable	298	361
Prepaid expenses and other	855	429
Total current assets	20,532	23,817
Equipment, net	2,597	1,135
Deferred tax assets	190	177
Total assets	\$ 23,319	\$ 25,129
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 3,603	\$ 2,702
Accrued compensation and related benefits	912	1,024
Accrued clinical trial costs	98	82
Accrued expenses	548	513
Deferred revenue		245
Note payable		190
Total current liabilities	5,161	4,756
Warrant liabilities	2,134	649
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at September 30, 2016 and December 31, 2015		
Common stock, \$0.001 par value; 150,000,000 shares authorized, and 85,498,369 and 83,720,154 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	85	84
Additional paid-in capital	327,092	322,582
Accumulated deficit	(311,153)	(302,942)

Total stockholders' equity	16,024	19,724
Total liabilities and stockholders' equity	\$ 23,319	\$ 25,129

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**Athersys, Inc.****Condensed Consolidated Statements of Operations and Comprehensive Loss**

(In thousands, except share and per share data)

(Unaudited)

	Three months ended		Nine months ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenues				
Contract revenue	\$ 150	\$ 39	\$ 15,410	\$ 194
Grant revenue	161	357	954	1,149
Total revenues	311	396	16,364	1,343
Costs and expenses				
Research and development	5,263	5,089	17,750	16,018
General and administrative	1,830	1,941	5,831	5,751
Depreciation	114	66	248	201
Total costs and expenses	7,207	7,096	23,829	21,970
Gain from insurance proceeds, net	682		682	
Loss from operations	(6,214)	(6,700)	(6,783)	(20,627)
Income (expense) from change in fair value of warrants, net	191	255	(1,689)	609
Other income (loss), net	7	(79)	228	(31)
Loss before income taxes	(6,016)	(6,524)	(8,244)	(20,049)
Income tax benefit	12	27	34	35
Net loss and comprehensive loss	\$ (6,004)	\$ (6,497)	\$ (8,210)	\$ (20,014)
Net loss per share, basic	\$ (0.07)	\$ (0.08)	\$ (0.10)	\$ (0.24)
Weighted average shares outstanding, basic	84,928,198	83,140,864	84,352,347	81,736,273
Net loss per share, diluted	\$ (0.07)	\$ (0.08)	\$ (0.10)	\$ (0.24)
Weighted average shares outstanding, diluted	85,896,993	83,425,669	84,352,347	82,572,984

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**Athersys, Inc.****Condensed Consolidated Statements of Cash Flows**

(In thousands)

(Unaudited)

	Nine months ended	
	September 30,	
	2016	2015
Operating activities		
Net loss	\$ (8,210)	\$ (20,014)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	248	201
Income from forgiveness of note payable	(190)	
Stock-based compensation	2,177	2,187
Gain from insurance proceeds, net	(682)	
Change in fair value of warrant liabilities	1,689	(609)
Changes in operating assets and liabilities:		
Accounts receivable	63	379
Prepaid expenses and other	(262)	55
Accounts payable and accrued expenses	765	(529)
Deferred revenue	(245)	9,925
Net cash used in operating activities	(4,647)	(8,405)
Investing activities		
Purchase of available-for-sale-securities	(15,903)	
Sales of available-for-sale-securities	4,830	
Purchases of equipment	(1,635)	(99)
Proceeds from insurance	507	
Net cash used in investing activities	(12,201)	(99)
Financing activities		
Proceeds from issuance of common stock, net	2,386	10,371
Purchase of treasury stock	(418)	(437)
Proceeds from exercise of warrants	162	976
Net cash provided by financing activities	2,130	10,910
(Decrease) increase in cash and cash equivalents	(14,718)	2,406
Cash and cash equivalents at beginning of the period	23,027	26,127
Cash and cash equivalents at end of the period	\$ 8,309	\$ 28,533

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, 2016 and 2015

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, 2015. 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 Standards

In November 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2015-17, *Balance Sheet Classification of Deferred Taxes*, which amends the existing guidance to require that deferred income tax liabilities and assets be classified as noncurrent in a classified balance sheet and eliminates the prior guidance, which required an entity to separate deferred tax liabilities and assets into a current amount and a noncurrent amount in a classified balance sheet. The amendments in this ASU are effective for financial statements for annual periods and interim periods within those annual periods beginning after December 15, 2016, with early adoption permitted, and the new guidance can be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. We have adopted this ASU in the first quarter of 2016 on a prospective basis and, therefore, the adoption did not impact prior period financial statements.

In May 2014, the 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 2-09 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, i.e., for year-end 2016 and interim periods thereafter, with early adoption permitted. We will adopt ASU 2014-15 as required and are evaluating the impact the new guidance will have on our year-end disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to put most leases on their balance sheets, but recognize expenses on their income statements in a manner similar to current accounting practice. Under the guidance, lessees initially recognize a lease liability for the obligation to make lease payments and a right-of-use (ROU) asset for the right to use the underlying asset for the lease term. The lease liability is measured at the present value of the lease payments over the lease term. The ROU asset is measured at the lease liability amount, adjusted for lease prepayments, lease incentives received and the lessee's initial direct costs. The guidance is effective for the annual periods beginning after December 15, 2018 and interim periods thereafter, with early adoption permitted. We are in the process of evaluating the impact the new guidance will have on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation - Improvements to Employee Share-Based Payment Accounting*, which involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Under the new standard, income tax benefits and deficiencies are to be recognized as income tax expense or benefit in the income statement and the tax effects of exercised or vested awards should be treated as discrete items in the reporting period in which they occur. An entity should also recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Excess tax benefits should be classified along with other income tax cash flows as an operating activity. In regards to forfeitures, the entity may make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures when they occur. This ASU is effective for fiscal years beginning after December 15, 2016 including interim periods within that reporting period, with early adoption permitted, provided that all amendments are adopted in the same period. We are currently evaluating the impact the adoption of ASU 2016-09 will have on our consolidated financial statements.

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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, 2016 and 2015, in thousands, except per share data.

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Numerator:				
Net loss attributable to common stockholders - Basic	\$ (6,004)	\$ (6,497)	\$ (8,210)	\$ (20,014)
Less: income from change in fair value of warrants	(191)	(220)		(196)
Net loss attributable to common stockholders used to calculate diluted net loss per share	\$ (6,195)	\$ (6,717)	\$ (8,210)	\$ (20,210)
Denominator:				
Weighted-average shares outstanding - Basic	84,928	83,141	84,352	81,736
Potentially dilutive common shares outstanding:				
Warrants	969	285		837
Weighted-average shares used to calculate diluted net loss per share	85,897	83,426	84,352	82,573
Basic earnings per share	\$ (0.07)	\$ (0.08)	\$ (0.10)	\$ (0.24)
Dilutive earnings per share	\$ (0.07)	\$ (0.08)	\$ (0.10)	\$ (0.24)

We have outstanding stock-based awards 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,	
	2016	2015	2016	2015
Stock - based awards	10,840,306	8,455,885	10,840,306	8,455,885
Warrants		2,810,000	1,893,527	2,810,000
Total	10,840,306	11,265,885	12,733,833	11,265,885

4. 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.

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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 September 30, 2016 (in thousands):

Description	Fair Value Measurements at September 30, 2016 Using			
	Balance as of September 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Other Significant Inputs (Level 3) Unobservable
Assets:				
Available-for-sale securities:				