ATHERSYS, INC / NEW
Form 10-Q
May 10, 2018
Table of Contents

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, 2018

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, a smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (do not check if a smaller reporting company) Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018 was 137,958,545.

Table of Contents

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)

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	**$ 49,673**	$ 29,316
Accounts receivable	**759**	586
Accounts receivable from Healios	**132**	153
Prepaid expenses and other	**1,020**	1,135
Contractual right to consideration from Healios	**1,538**	
Other asset related to Healios	**5,300**	
Total current assets	**58,422**	31,190
Equipment, net	**2,312**	2,206
Other	**200**	197
Total assets	**$ 60,934**	$ 33,593
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 8,092**	$ 4,469
Accrued compensation and related benefits	**743**	1,065
Accrued clinical trial costs	**430**	1,453
Accrued expenses	**389**	425
Accrued license fee expense	**1,665**	1,900
Deferred revenue	**250**	771
Total current liabilities	**11,569**	10,083
Advance from Healios	**1,833**	134
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at March 31, 2018 and December 31, 2017		
Common stock, $0.001 par value; 300,000,000 shares authorized, and 137,958,545 and 122,077,453 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	**138**	122

Additional paid-in capital	**406,308**	373,884
Accumulated deficit	**(358,914)**	(350,630)
Total stockholders equity	**47,532**	23,376
Total liabilities and stockholders equity	**$ 60,934**	$ 33,593

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 March 31,	
	2018	**2017**
Revenues		
Contract revenue from Healios	**$ 348**	$ 28
Royalty and contract revenue	**401**	1,232
Grant revenue	**317**	210
Total revenues	**1,066**	1,470
Costs and expenses		
Research and development	**8,850**	5,633
General and administrative	**2,655**	2,071
Depreciation	**186**	164
Total costs and expenses	**11,691**	7,868
Gain from insurance proceeds	**363**	
Loss from operations	**(10,262)**	(6,398)
Income from change in fair value of warrants		728
Other income, net	**107**	39
Net loss and comprehensive loss	**$ (10,155)**	$ (5,631)
Net loss per common share, basic and diluted	**$ (0.08)**	$ (0.06)
Weighted average shares outstanding, basic and diluted	**126,897,425**	102,047,062

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Athersys, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2018	**2017**
Operating activities		
Net loss	**$ (10,155)**	$ (5,631)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**186**	164
Stock-based compensation	**813**	689
Change in fair value of warrant liabilities		(728)
Changes in operating assets and liabilities:		
Accounts receivable	**(173)**	(1,168)
Accounts receivable from Healios	**(51)**	
Prepaid expenses and other	**127**	(231)
Accounts payable and accrued expenses	**1,992**	1,022
Advance from Healios	**1,583**	
Deferred revenue		503
Net cash used in operating activities	**(5,678)**	(5,380)
Investing activities		
Purchases of equipment	**(292)**	(134)
Net cash used in investing activities	**(292)**	(134)
Financing activities		
Proceeds from issuance of common stock, net	**26,411**	20,877
Shares retained for withholding tax payments on stock-based awards	**(84)**	(37)
Proceeds from exercise of warrants		1,861
Net cash provided by financing activities	**26,327**	22,701
Increase in cash and cash equivalents	**20,357**	17,187
Cash and cash equivalents at beginning of the period	**29,316**	14,753
Cash and cash equivalents at end of the period	**$ 49,673**	$ 31,940

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Athersys, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Three-Month Periods Ended March 31, 2018 and 2017

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 of research and later-stage product development activities.

We incurred losses since our inception in 1995 and had an accumulated deficit of $359 million at March 31, 2018. We will require substantial additional capital to continue our research and development programs, including progressing our clinical product candidates to commercialization and preparing for commercial-scale manufacturing. At March 31, 2018, we had available cash and cash equivalents of $49.7 million plus, under a proposed expansion to a collaboration discussed herein, our collaborator has funded $10 million as an expansion fee into an escrow account in March 2018 that is due to be released to us by June 1, 2018. We believe that these funds, used to execute our existing operating plans, are sufficient to meet our obligations as they come due at least for a period of twelve months from the date of the issuance of these unaudited condensed consolidated financial statements. In the longer term, we will make use of available cash, but will have to continue to generate additional capital to meet our needs through new and existing collaborations and related license fees and milestones, the sale of equity securities from time to time, including through our equity purchase agreement, grant-funding opportunities, deferring certain discretionary costs and staging certain development costs, as needed.

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, 2017. 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 February 2016, the Financial Accounting Standards Board (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

Table of Contents

amount, adjusted for lease prepayments, lease incentives received and the lessee s initial direct costs. The guidance is effective for the annual and interim periods beginning after December 15, 2018, with early adoption permitted. We plan to adopt Topic 842 effective January 1, 2019 and are in the process of evaluating the impact the new guidance will have on our consolidated financial statements upon adoption. We currently have operating leases for two facilities that will need to be evaluated under this new guidance.

In May 2017, the FASB issued ASU 2017-09, Compensation Stock Compensation (Topic 718): Scope of Modification Accounting. This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The ASU is effective for the annual periods beginning after December 15, 2017 and interim periods within those annual periods. Effective January 1, 2018, we adopted this standard. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

3. Revenue Recognition and Adoption of New Accounting Pronouncement

Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, product supply revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). Topic 606 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, we apply the five steps under Topic 606 that an entity should apply when recognizing revenue.

We adopted this guidance as of January 1, 2018, utilizing the modified retrospective transition method applied to contracts that were not complete as of January 1, 2018. We evaluated all of our collaborative agreements on a contract-by-contract basis, identifying all of the performance obligations, including those that are contingent. For our contracts with customers that contain multiple performance obligations, we account for the individual performance obligations separately when they are both capable of being distinct, whereby the customer can benefit from the service either on its own or together with other resources that are readily available from third parties or from us, and are distinct in the context of the contract, whereby the transfer of the services is separately identifiable from other promises in the contract. Under the new standard, we assessed whether licenses granted under our collaboration and license agreements are distinct in the context of the agreement from other performance obligations and functional when granted. After considering the relative selling prices of the contract elements and the allocation of revenue thereto, we recognized a cumulative effect adjustment of $1.9 million as an adjustment to the opening balance of our accumulated deficit primarily related to a contract asset since the revenue permitted to be recognized at inception was not limited to the cash proceeds received as of that time, which was a requirement of the previous guidance. We also concluded that the new guidance resulted in revisions to accounting for our arrangement with Healios K.K. (Healios) only, since our other collaborations had no remaining performance obligations and potential contingent receipts would be constrained.

Milestone Payments

Topic 606 does not contain guidance specific to milestone payments, but rather requires potential milestone payments to be considered in accordance with the overall model of Topic 606. As a result, revenues from contingent milestone payments is recognized based on an assessment of the probability of

7

Table of Contents

milestone achievement and the likelihood of a significant reversal of such milestone revenue at each reporting date. This assessment may result in recognizing milestone revenue before the milestone event has been achieved. Since the milestones in the Healios arrangement are generally related to development and commercial milestone achievement by Healios, we have not included any of the Healios milestones in the estimated transaction price of the Healios arrangement, since they would be constrained, as a significant reversal of revenue could result in future periods.

Other than for our collaboration with Healios that has remaining deliverables, we had recognized the full amount of license fees under our collaboration agreements as contract revenue under the prior guidance associated with multiple-element arrangements, since the performance periods for our multiple element arrangements have concluded. The events triggering any future contingent milestone payments from these arrangements were determined to be non-substantive and revenue is recognized in the period that the triggering event occurs, and the remaining potential commercial milestones are recognized when earned.

Grant revenue

Grant revenue, which is not within the scope of Topic 606, consists of funding under cost reimbursement programs primarily from federal and non-profit foundation 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 and recorded as revenue as grant-funded activities are performed.

Royalty Revenue

We recognize royalty revenue relating to the sale by a licensee of our licensed products. Royalty revenue is recognized upon the later to occur of (i) achievement of the collaborator s underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the license to our intellectual property is deemed to be the predominant item to which the sales-based royalties relate.

Deferred Revenue

Amounts received from customers or collaborators in advance of our performance of services or other deliverables is included in deferred revenue. For product supply, we typically invoice our customers a portion of the purchase order in advance, followed by invoices as product is released and available for pick-up. The amount paid in advance by the customer is applied to the last deliveries under the purchase order. Similarly, any grant proceeds received in advance of our performance under the grant is included in deferred revenue. Generally, deferred revenue is a current obligation, as opposed to non-current. During the three-month period ended March 31, 2018, we did not recognize any revenues that were deferred as of January 1, 2018.

Advance from Healios

As further described in Note 6, proceeds from Healios that relate specifically to the cost-sharing arrangement for Healios stroke study in Japan that may result in a net reduction in the proceeds we receive from Healios upon the achievement of future milestones are recognized as non-current advances from Healios until the related milestones are achieved or such amounts are repaid to Healios at our election. During the three-month period ended March 31, 2018, no revenue was recognized that was included in the advance from Healios as of January 1, 2018.

Table of Contents

Effect of Adoption of Topic 606

Our arrangement with Healios was the only collaboration that was impacted by the adoption of Topic 606. Notes 6 and 8 further describe our arrangement with Healios, including modifications that have resulted. We have applied the practical expedient under Topic 606 and have reflected the aggregate effect of all modifications at January 1, 2018. The components of the cumulative effect of the changes made to our consolidated January 1, 2018 balance sheet for the adoption of Topic 606 were as follows (in thousands):

	As of December 31, 2017	Adjustments Due to Topic 606	As of January 1, 2018
Assets			
Accounts receivable - Healios	$ 153	$ 30	$ 183
Contractual right to consideration from Healios	$	$ 1,436	$ 1,436
Liabilities			
Deferred revenue - Healios	$ (521)	$ 521	$
Advance from Healios	$ (134)	$ (116)	$ (250)
Equity			
Accumulated deficit	$ 350,630	$ (1,871)	$ 348,759

In accordance with the new revenue recognition requirements, the disclosure of the impact of adoption on our condensed consolidated balance sheet and statement of operations for the three months ended March 31, 2018 was as follows (in thousands, except per share data):

	As Reported	As of March 31, 2018 Balances without Adoption of Topic 606	Effect of Change
Assets			
Contractual right to consideration from Healios	$ 1,538	$	$ 1,538
Liabilities			
Deferred revenue - Healios	$	$ (259)	$ 259
Equity			
Accumulated deficit	$ 358,914	$ 360,711	$ (1,797)

	Three months ended March 31, 2018		
	As Reported	Balances without Adoption of Topic 606	Effect of Change
Revenues			
Contract revenues - Healios	$ 348	$ 422	$ (74)
Net loss	$ (10,155)	$ (10,081)	$ 74
Net loss per common share			

Basic and diluted	$ (0.08)	$ (0.08)	$

The adoption of Topic 606 had no impact on our total cash flows from operations.

Table of Contents

Disaggregation of Revenues

We recognize license-related amounts, including upfront payments, exclusivity fees, additional disease indication fees, and development, regulatory and sales-based milestones at a point in time when earned. Similarly, product supply revenue is recognized at a point in time, while service revenue is recognized when earned over time. The following table presents our contract revenues from Healios disaggregated by recognition at a point in time and over time (in thousands).

	Three months ended March 31, 2018		
	Recognized at Point in Time	Recognized Over Time	Total
Contract Revenues - Healios			
Product supply revenue	$ 227	$	227
Service revenue		121	121
Total	**$ 227**	**$ 121**	**$ 348**

4. 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. We have outstanding stock-based awards that are not used in the calculation of diluted net loss per share because to do so would be antidilutive. We have one warrant outstanding that was issued to Healios in March 2018, but Healios is not yet permitted to exercise any of the shares underlying the warrant. Refer to Note 8 for additional details. The following instruments were excluded from the calculation of diluted net loss per share because their effects would be antidilutive:

	Three months ended March 31,	
	2018	2017
Stock-based awards	**10,294,613**	10,091,837
Warrants see Note 8	**20,000,000**	
Total	**30,294,613**	10,091,837

5. Proceeds from Insurance

In 2016, our facility sustained flood damage representing both an unusual and infrequent event. Insurance proceeds are recorded to the extent of the losses and then, only if recovery is realized or probable. Any gains in excess of losses are recognized only when the contingencies regarding the recovery are resolved, and the amount is fixed or determinable. We recognized an insurance recovery gain of $0.4 million in the first quarter of 2018 as additional insurance proceeds were received.

6. Collaborative Arrangements and Revenue Recognition

Healios

2016 Inception of License Arrangement

In 2016, we entered into a license agreement (Healios Agreement) with Healios to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan and to provide Healios with access to our proprietary MAPC technology for use in its organ bud program, initially for transplantation to treat liver disease or dysfunction. Under the Healios Agreement, Healios obtained a right to expand the scope of the collaboration to include the exclusive rights to develop and commercialize MultiStem for the treatment of certain additional indications in Japan, which include acute respiratory distress syndrome (ARDS), and, as addressed herein, plans for an expansion of the collaboration are underway.

Table of Contents

Under the terms of the Healios Agreement, we received a nonrefundable, up-front cash payment of $15 million. Healios is responsible for the costs of clinical development in Japan. Athersys is providing manufacturing services to Healios, currently comprising the supply of product for its clinical trial and preparations for commercial manufacturing, and we receive payments for product supplied to Healios. We also receive financial support from Healios for services we perform to establish a contract manufacturer in Japan to produce product for Healios. The costs of the services are reimbursed by Healios at our cost.

For the ischemic stroke indication, we may also receive additional success-based development, regulatory approval and sales milestones, which are non-refundable and non-creditable towards future royalties or any other payment due from Healios. We may also receive tiered royalties on net product sales, starting in the low double-digits and increasing increm