ATHERSYS, INC / NEW
Form 10-Q
August 09, 2018

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 June 30, 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.

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 August 1, 2018 was 138,583,673.

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)

	June 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 53,353	$ 29,316
Accounts receivable	545	586
Accounts receivable from Healios	552	153
Unbilled accounts receivable from Healios	8,280	
Prepaid expenses and other	2,480	1,135
Contractual right to consideration from Healios	34	
Other asset related to Healios	4,220	
Total current assets	69,464	31,190
Equipment, net	2,578	2,206
Deposits and other	866	197
Total assets	$ 72,908	$ 33,593
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 10,918	$ 4,469
Accrued compensation and related benefits	946	1,065
Accrued clinical trial costs	1,674	1,453
Accrued expenses	640	425
Accrued license fee expense	500	1,900
Deferred revenue		771
Total current liabilities	14,678	10,083
Advances from Healios	1,981	134
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at June 30, 2018 and December 31, 2017		
Common stock, $0.001 par value; 300,000,000 shares authorized, and 138,583,673 and 122,077,453 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	139	122
Additional paid-in capital	408,091	373,884

Accumulated deficit		**(351,981)**		(350,630)
Total stockholders equity		**56,249**		23,376
Total liabilities and stockholders equity	**$**	**72,908**	$	33,593

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Athersys, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except per share data)

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	**2018**	2017
Revenues				
Contract revenue from Healios	**$ 18,755**	$ 239	**$ 19,103**	$ 267
Royalty and other contract revenue	**591**	210	**992**	1,442
Grant revenue	**45**	220	**362**	430
Total revenues	**19,391**	669	**20,457**	2,139
Costs and expenses				
Research and development	**10,093**	4,633	**18,943**	10,266
General and administrative	**2,382**	2,207	**5,038**	4,278
Depreciation	**191**	167	**376**	331
Total costs and expenses	**12,666**	7,007	**24,357**	14,875
Gain from insurance proceeds	**20**		**383**	
Income (loss) from operations	**6,745**	(6,338)	**(3,517)**	(12,736)
Income from change in fair value of warrants				728
Other income, net	**188**	71	**295**	110
Net income (loss) and comprehensive income (loss)	**$ 6,933**	$ (6,267)	**$ (3,222)**	$ (11,898)
Net income (loss) per share, basic	**$ 0.05**	$ (0.06)	**$ (0.02)**	$ (0.11)
Weighted average shares outstanding, basic	**138,225**	111,820	**132,592**	106,960
Net income (loss) per share, diluted	**$ 0.05**	$ (0.06)	**$ (0.02)**	$ (0.11)
Weighted average shares outstanding, diluted	**139,375**	111,820	**132,592**	106,960

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, 2018	2017
Operating activities		
Net loss	**$ (3,222)**	$ (11,898)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**376**	331
Stock-based patent license and settlement expense	**315**	
Stock-based compensation	**1,637**	1,418
Discount on revenue from issuance of warrant	**1,080**	
Deferred revenue from prior period	**(250)**	
Change in fair value of warrant liabilities		(728)
Changes in operating assets and liabilities:		
Accounts receivable	**41**	68
Accounts receivable from Healios - billed and unbilled	**(8,649)**	(78)
Prepaid expenses, deposits and other	**(2,014)**	(7)
Contractual right to consideration from Healios	**1,402**	
Accounts payable and accrued expenses	**6,267**	(670)
Deferred revenue		503
Advances from Healios	**1,731**	
Net cash used in operating activities	**(1,286)**	(11,061)
Investing activities		
Purchases of equipment	**(749)**	(136)
Net cash used in investing activities	**(749)**	(136)
Financing activities		
Proceeds from issuance of common stock, net	**26,263**	23,270
Shares retained for withholding tax payments on stock-based awards	**(191)**	(93)
Proceeds from exercise of warrants		1,861
Net cash provided by financing activities	**26,072**	25,038
Increase in cash and cash equivalents	**24,037**	13,841
Cash and cash equivalents at beginning of the period	**29,316**	14,753
Cash and cash equivalents at end of the period	**$ 53,353**	$ 28,594

See accompanying notes to unaudited condensed consolidated financial statements.

Athersys, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Three- and Six-Month Periods Ended June 30, 2018 and 2017

1. Background and Basis of Presentation

Background: 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 clinical-stage product development activities.

We have incurred losses since our inception in 1995 and had an accumulated deficit of $352 million at June 30, 2018. We will require additional capital to continue our research and development programs, including progressing our clinical product candidates to commercialization and preparing for commercial-scale manufacturing. At June 30, 2018, we had available cash and cash equivalents of $53.4 million. 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.

Use of Estimates: 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.

Reclassifications: Certain reclassifications have been made to the 2017 condensed consolidated financial statements to separately disclose revenue and certain balance sheet accounts related to HEALIOS K.K., (Healios), to conform to the presentation in the current year.

2. Recently Issued Accounting Standards

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 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 are being 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, and its adoption 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.

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 arrangements 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 were 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 concluded that the new guidance resulted in revisions to accounting for our arrangement with Healios, only, since our other collaborations had no remaining performance obligations and potential contingent receipts would be constrained.

Our performance obligations and methods used for determining the relative selling prices and transaction prices of the Healios contract elements is further discussed in Note 6.

Table of Contents

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 are recognized based on an assessment of the probability of 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, as of the date of adoption of Topic 606 on January 1, 2018, 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 will be 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 and (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.

Unbilled Accounts Receivable

We record amounts that are due to us under contractual arrangements for which invoicing has not yet occurred if our performance has concluded for the billable activity, and we have the unconditional right to the consideration, but such amounts are not yet billable. At June 30, 2018, the unbilled accounts receivable from Healios was $8.3 million, which includes $7.5 million of license fees that are being paid to us by Healios in $2.5 million installments over the next several quarters related to the expansion described in Note 6.

Contractual Right to Consideration and Deferred Revenue

Amounts included in deferred revenue or contract assets are determined at the contract level, and for our Healios arrangement, such amounts are included in a contract asset. Amounts received from customers or collaborators in advance of our performance of services or other deliverables are included in deferred revenue, while amounts for performance of services or other deliverables before customer payment is received or due are included in contract assets, with those amounts that are unconditional being included in either accounts receivable or unbilled accounts receivable. Grant proceeds received in advance of our performance under the grant is included in deferred revenue. Generally, deferred revenue is classified as a current obligation, as opposed to non-current. During the three- and six-month periods ended June 30, 2018, we recognized $250,000 of revenue that was deferred as of January 1, 2018 since the associated agreement concluded in the second quarter of 2018.

Advances from Healios

The clinical trial supply agreement with Healios was amended in July 2017 to clarify a cost-sharing arrangement associated with our supply of clinical product for their ischemic stroke trial. The proceeds from Healios that relate specifically to the cost-sharing arrangement may result in a decrease in the amount of proceeds we receive from Healios upon the achievement of two future milestones, and an increase to a late-stage commercial milestone, if the cost-share amounts are not repaid at our election. While the amendment to the supply agreement resulted in a revision to the terms associated with the product supply, namely the cost of product supply, the revision did not affect any of the performance obligations under the overall arrangement. The proceeds from Healios that relate specifically to the cost-sharing arrangement for Healios stroke study in Japan 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- and six-month periods ended June 30, 2018, no revenue was recognized related to these advances.

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 subsequent modifications to the collaboration. For contracts that were modified prior to January 1, 2018, we aggregated the effect of those modifications when identifying the satisfied and unsatisfied performance obligations and determining the transaction price to be allocated. 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):

	Balance at December 31, 2017	**Adjustments Due to Topic 606**	**Balance at 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

Table of Contents

In accordance with the new revenue recognition requirements, the disclosure of the impact of adoption on our condensed consolidated balance sheet as of June 30, 2018 and statement of operations for the three- and six-month periods ended June 30, 2018 was as follows (in thousands, except per share data):

	As of June 30, 2018		
	As Reported	Balances without Adoption of Topic 606	Effect of Change
Assets			
Unbilled accounts receivable from Healios	$ 8,280	$ 780	$ 7,500
Contractual right to consideration from Healios	$ 34	$	$ 34
Liabilities			
Deferred revenue	$	$ (2,308)	$ 2,308
Equity			
Accumulated deficit	$ 351,981	$ 361,823	$ (9,842)

	Three Months ended June 30, 2018			Six months ended June 30, 2018		
	As Reported	Balances without Adoption of Topic 606	Effect of Change	As Reported	Balances without Adoption of Topic 606	Effect of Change
Revenues						