

ATHERSYS, INC / NEW

FORM 8-K (Current report filing)

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Address	3201 CARNEGIE AVENUE CLEVELAND, OH, 44115-2634
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Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): May 10, 2018

Athersys, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33876
(Commission
File No.)

20-4864095
(I.R.S. Employer
Identification Number)

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 or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition.

On May 10, 2018, Athersys, Inc. issued a press release announcing financial results for its first quarter ended March 31, 2018. A copy of this press release is attached hereto as Exhibit 99.1.

The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished to the Securities and Exchange Commission and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. Furthermore, the information contained in Item 2.02 of this Current Report on Form 8-K shall not be deemed to be incorporated by reference into any registration statement or other document filed pursuant to the Securities Act of 1933.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 10, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 10, 2018

ATHERSYS, INC.

By: /s/ Laura K. Campbell

Name: Laura K. Campbell

Title: Senior Vice President of Finance

PRESS RELEASE



ATHERSYS REPORTS FIRST QUARTER 2018 RESULTS

Management to host conference call at 4:30 pm EDT today

CLEVELAND, Ohio, May 10, 2018 – Athersys, Inc. (NASDAQ: ATHX) announced today its financial results for the three months ended March 31, 2018.

Highlights of the first quarter of 2018 and recent events include:

- Completed a \$21.1 million equity investment and announced plans to expand the HEALIOS K.K. (“Healios”) collaboration by June 1, 2018. This proposed expansion includes a \$10 million license fee funded in an escrow account and a potential additional \$25 million of committed payments over time, as well as possible payments including milestones and royalties, if the collaboration is fully expanded in accordance with the letter of intent disclosed in March 2018;
- Advanced our preparations for the MASTERS-2 Phase 3 registration study for ischemic stroke to enable initiation of this important study in the near-term, and supported the continued enrollment of Healios’ TREASURE study;
- Progressed Phase 1/2 study evaluating MultiStem therapy in acute respiratory distress syndrome (ARDS) patients;
- Announced plans with The University of Texas Health Science Center at Houston to conduct a Phase 2 clinical trial evaluating MultiStem cell therapy for early treatment and prevention of complications after severe traumatic injury;
- Established a new equity facility with Aspire Capital Fund LLC as a follow-on to a prior facility, providing the Company with access to additional capital as needed to support its ongoing operations;
- Recognized revenues of \$1.1 million for the quarter ended March 31, 2018 and a net loss of \$10.2 million, or \$(0.08) per share; and
- Ended the 2018 first quarter with \$49.7 million of cash and cash equivalents, excluding the \$10 million in escrow from Healios related to the proposed collaboration expansion.

“We finished the first quarter in a strong financial position, with approximately \$50 million on the balance sheet and look forward to building on that as we work to complete the expansion of our partnership with Healios,” commented Dr. Gil Van Bokkelen, Chairman & CEO at Athersys. “As we and Healios recently disclosed, we have extended the timeline to complete the agreements to expand our collaboration until the end of May, and we are working together to achieve that goal.

“We are also focused on preparing for the upcoming initiation of our MASTERS-2 trial, while we continue to support the ongoing TREASURE trial in Japan,” added Dr. Van Bokkelen. “In addition, we have been advancing our other clinical programs and broadening our portfolio of new opportunities, as evidenced by the recent announcement related to a clinical study in trauma. This represents another significant area of unmet clinical need that we are now well-positioned to pursue with funding support from the Medical Technology Enterprise Consortium and our collaborator, UTHealth,” concluded Dr. Van Bokkelen.

First Quarter Results

Revenues decreased to \$1.1 million for the three months ended March 31, 2018 compared to \$1.5 million for the three months ended March 31, 2017. Our revenues are comprised of revenue from manufacturing-related activities for Healios, royalty and related contract revenue from our collaboration with RTI Surgical, Inc. and grant revenue. Our revenue from Healios increased during the first quarter of 2018 compared to the prior year first quarter by approximately \$0.3 million as we continue to supply clinical product to Healios and provide other manufacturing-related services, and we expect these revenues will be higher for the 2018 annual period as compared to the 2017 year. Regarding our royalty revenue, excluding a \$1.0 million milestone payment from RTI in the 2017 first quarter, royalty revenues increased by approximately \$0.2 million in the first quarter of 2018 as a result of an increase in the royalty rate that became effective late 2017 associated with our technology license to RTI. Grant revenue varies from period-to-period with new and completed grants, and the timing of grant-funded activities. Absent new grant awards, we expect our annual grant revenue to decline in 2018 from 2017 with the expiration of certain grant-funded programs.

Research and development expenses increased to \$8.9 million for the three months ended March 31, 2018 from \$5.6 million in the comparable period in 2017. The \$3.3 million increase is primarily comprised of an increase in preclinical and clinical development costs of \$2.7 million, an increase in personnel costs of \$0.3 million, and an increase in internal research supplies and other research costs of \$0.3 million. The increase in our clinical and preclinical costs is primarily a result of increased process development activities to support large-scale manufacturing and clinical product manufacturing costs during the period.

General and administrative expenses increased to \$2.7 million for the three months ended March 31, 2018 from \$2.1 million in the comparable period in 2017. The \$0.6 million increase was due primarily to an increase of \$0.3 million in professional fees and increases in personnel costs, stock-based compensation costs and other administrative costs compared to the same period last year.

Net loss was \$10.2 million in 2018 compared to \$5.6 million in 2017. The difference of \$4.6 million reflects the above variances, as well as \$0.4 million in insurance proceeds that we received this quarter, which were offset by a \$0.7 million non-cash gain related to the fair value of our warrant liabilities recorded in the first quarter of 2017 for warrants that expired in 2017. The warrant issued in March 2018 to Healios in connection with its equity investment was treated as equity with its value recorded as additional paid-in capital with an offset in other current assets.

Net cash used in operating activities was \$5.7 million for the three months ended March 31, 2018 and \$5.4 million for the three months ended March 31, 2017, reflecting the increased net loss in the first quarter of 2018 (i.e., cash used to fund preclinical and clinical development activities) compared to the prior year period, as offset in part by proceeds received from Healios for our cost-share arrangement for clinical product supply and an increase in accounts payable due to

service providers, such as contract manufacturers, under longer-term contracts. As of March 31, 2018, we had \$49.7 million in cash and cash equivalents, compared to \$29.3 million at December 31, 2017, which includes, among other things, the investment made by Healios in March 2018 and excludes the \$10 million that Healios has funded into an escrow account to be released to us upon execution of the expansion agreements.

Conference Call

Gil Van Bokkelen, Chairman and Chief Executive Officer, and William (BJ) Lehmann, President and Chief Operating Officer, will host a conference call today to review the results as follows:

Date	Thursday, May 10, 2018
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	800-273-1254
Telephone access: International	973-638-3440
Access code	1189915
Live webcast	www.athersys.com , under the Investors section

A replay will be available for on-demand listening shortly after the completion of the call until 11:59 PM Eastern Time on May 24, 2018 at the aforementioned URL, or by dialing (800) 585-8367 or (855) 859-2056 in the U.S. and Canada, or from abroad (404) 537-3406, and entering access code 1189915.

About MultiStem[®]

MultiStem[®] cell therapy is a patented regenerative medicine product in clinical development that has shown the ability to promote tissue repair and healing in a variety of ways, such as through the production of therapeutic factors produced in response to signals of inflammation and tissue damage. MultiStem therapy's potential for multidimensional therapeutic impact distinguishes it from traditional biopharmaceutical therapies focused on a single mechanism of benefit. The therapy represents a unique "off-the-shelf" stem cell product that can be manufactured in a scalable manner, may be stored for years in frozen form, and is administered without tissue matching or the need for immune suppression. Based upon its efficacy profile, its novel mechanisms of action, and a favorable and consistent safety profile demonstrated in clinical studies, MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need.

About Athersys

Athersys is an international biotechnology company engaged in the development of therapeutic products designed to extend and enhance the quality of human life. The Company is developing its MultiStem[®] cell therapy product, a patented, adult-derived "off-the-shelf" stem cell product, initially for disease indications in the neurological, cardiovascular, and inflammatory and immune disease areas, and has several ongoing clinical trials evaluating this potential regenerative medicine product. Athersys has forged strategic partnerships and a broad network of collaborations to further advance MultiStem cell therapy toward commercialization. More information is available at www.athersys.com. Follow Athersys on Twitter at [www.twitter.com/athersys](https://twitter.com/athersys).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. These forward-looking statements relate to, among other things, the expected timetable for development of our product candidates, our growth strategy, and our future financial performance, including our operations, economic performance, financial condition, prospects, and other future events. We have attempted to identify forward-looking statements by using such words as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “suggest,” “will,” or other similar expressions. These forward-looking statements are only predictions and are largely based on our current expectations. A number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. Some of the more significant known risks that we face that could cause actual results to differ materially from those implied by forward-looking statements are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as human therapeutics, such as the uncertainty regarding regulatory approval and market acceptance of our product candidates and our ability to generate revenues, including MultiStem for the treatment of ischemic stroke, acute myocardial infarction, spinal cord injury and acute respiratory distress syndrome and other disease indications, including graft-versus-host disease. These risks may cause our actual results, levels of activity, performance, or achievements to differ materially from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements. Other important factors to consider in evaluating our forward-looking statements include: our ability to work with Healios under our letter of intent to successfully negotiate the terms of and execute the documents necessary to expand our existing collaboration; the success of our collaboration with Healios and others, including our ability to reach milestones and receive milestone payments, and whether any products are successfully developed and sold so that we earn royalty payments; our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our collaborators’ ability to continue to fulfill their obligations under the terms of our collaboration agreements; the success of our efforts to enter into new strategic partnerships or collaborations and advance our programs; our ability to raise additional capital; results from our MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial and the TREASURE trial in Japan; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials within the expected time frame or at all; changes in external market factors; changes in our industry’s overall performance; changes in our business strategy; our ability to protect our intellectual property portfolio; our possible inability to execute our strategy due to changes in our industry or the economy generally; changes in productivity and reliability of suppliers; and the success of our competitors and the emergence of new competitors. You should not place undue reliance on forward-looking statements contained in this press release, and we undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

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(Tables Follow)

Athersys, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2018	December 31, 2017
	(Unaudited)	(Note)
Assets		
Cash and cash equivalents	\$ 49,673	\$ 29,316
Contractual right to consideration from Healios	1,538	
Other asset related to Healios	5,300	—
Other current assets	1,911	1,874
Equipment, net	2,312	2,206
Other assets	200	197
Total assets	\$ 60,934	\$ 33,593
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	\$ 11,319	\$ 9,312
Deferred revenue and other	2,083	905
Total stockholders' equity	47,532	23,376
Total liabilities and stockholders' equity	\$ 60,934	\$ 33,593

Note: The Condensed Consolidated Balance Sheet Data has been derived from the audited financial statements as of that date.

Athersys, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In Thousands, Except Per Share Amounts)

	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	<u>1,066</u>	<u>1,470</u>
Costs and expenses		
Research and development	8,850	5,633
General and administrative	2,655	2,071
Depreciation	186	164
Total costs and expenses	<u>11,691</u>	<u>7,868</u>
Gain from insurance proceeds	363	—
Loss from operations	<u>(10,262)</u>	<u>(6,398)</u>
Income from change in fair value of warrants	—	728
Other income, net	107	39
Net loss and comprehensive loss	<u>\$ (10,155)</u>	<u>\$ (5,631)</u>
Net loss per share — Basic and Diluted	<u>\$ (0.08)</u>	<u>\$ (0.06)</u>
Weighted average shares outstanding — Basic and Diluted	126,897	102,047