

ATHERSYS, INC / NEW

FORM 8-K (Current report filing)

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Address	3201 CARNEGIE AVENUE CLEVELAND, OH 44115-2634
Telephone	216-431-9900
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Industry	Biotechnology & Medical Research
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 9, 2017

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33876
(Commission
File Number)

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 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 9, 2017, Athersys, Inc. issued a press release announcing financial results for its first quarter ended March 31, 2017. 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>Exhibit Description</u>
99.1	Press Release dated May 9, 2017

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 9, 2017

ATHERSYS, INC.

By: /s/ Laura K. Campbell

Name: Laura K. Campbell

Title: Senior Vice President of Finance

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	Press Release dated May 9, 2017

PRESS RELEASE



ATHERSYS REPORTS FIRST QUARTER 2017 RESULTS

Company announces Fast Track Designation by FDA for Stroke Program and other progress

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

CLEVELAND, May 9, 2017 – Athersys, Inc. (Nasdaq: ATHX) today announced its financial results for the three months ended March 31, 2017.

Highlights of the first quarter of 2017 and recent events include:

- Clinical program for stroke awarded Fast Track Designation by U.S. Food & Drug Administration (“FDA”) – designation means that the program becomes eligible for Rolling Submission, Accelerated Approval and Priority Review of the biologics license application, facilitating timely regulatory review;
- Clinical investigators published two articles in March 2017 in peer-reviewed journals, *Stem Cells* and *Lancet Neurology*, respectively, with the first article describing preclinical results showing how MultiStem[®] cell therapy could provide benefit to patients following ischemic stroke and the second article describing results from Phase 2 trial of MultiStem cell therapy for treating ischemic stroke patients (the “MASTERS” trial);
- Following completion of an assessment of operational issues related to a recent FDA inspection at our contract manufacturer, Lonza, investigational product is now being released, and our partner, HEALIOS K.K., is preparing for patient enrollment of the TREASURE study in Japan;
- Commercial milestone payment of \$1.0 million received from collaboration with RTI Surgical, Inc. (“RTI”);
- Net proceeds of \$20.9 million received in February 2017 from common stock offering in support of ongoing and planned clinical and process development activities;
- Proceeds from warrant exercises of \$1.9 million received in first quarter of 2017, resulting in the issuance of approximately 1.8 million shares of common stock, and no warrants remain outstanding;
- Revenues of \$1.5 million recognized for quarter ended March 31, 2017 and net loss of \$5.6 million, or \$0.06 loss per share; and
- Cash and cash equivalents balance of \$31.9 million at first quarter-end.

“We are excited about receiving Fast Track designation for our clinical stroke program, and we thank the FDA for its continued support of our efforts to develop and provide an important new treatment option for patients in this area of unmet medical need,” commented Dr. Gil Van

Bokkelen, Chairman & CEO at Athersys. “Recent publications and presentations continue to illustrate how we might be able to extend the treatment window for stroke patients out to 36 hours with MultiStem, beyond the narrow window for treatment that exists today, and also the important biological mechanisms that our cell therapy may provide to help patients recover from a debilitating stroke event. Stroke remains the leading cause of serious disability, yet many people are still unaware of the signs and symptoms of stroke, or the need to take action right away, and we are committed to building public awareness in this area.

“We are pleased that the Healios TREASURE trial in Japan is now getting underway,” added Dr. Van Bokkelen. “Additionally, we are actively engaged with the FDA, European Medicines Agency and other regulators to obtain regulatory alignment for our planned Phase 3 clinical trial for stroke, MASTERS-2, and we anticipate completing the key regulatory activities for our study sometime this summer. In parallel, we are advancing our partnering discussions in stroke and other areas, which represent an important priority for the company,” concluded Dr. Van Bokkelen.

First Quarter Results

For the three months ended March 31, 2017, revenues were \$1.5 million compared to \$15.5 million in the same period in 2016, reflecting the recognition of a \$1.0 million commercial milestone in the first quarter of 2017 from our RTI collaboration and a \$15.0 million license fee from our Healios collaboration in the first quarter of 2016. Grant revenue remained consistent between the two quarters ended March 31. We expect our future contract revenues to be comprised primarily of revenues associated with our Healios collaboration, royalty payments and potential commercial milestone payments from RTI, and proceeds from potential new collaborations. Grant revenues continue to vary from period-to-period with new and completed grants, and with the timing of grant-funded projects.

Research and development expenses decreased to \$5.6 million in the 2017 first quarter from \$6.7 million in the 2016 first quarter primarily due to decreased clinical and preclinical development costs, decreased internal research supplies, decreased license fees and decreased travel costs. General and administrative expenses were relatively consistent at \$2.1 million and \$2.0 million for the three months ended March 31, 2017 and 2016, respectively.

Net loss was \$5.6 million in 2017, compared to net income of \$4.8 million in 2016. The difference of \$10.4 million reflects the above variances, as well as a \$2.9 million non-cash increase in the gain related to the fair value of our warrant liabilities. All outstanding warrants had either been exercised or expired as of March 31, 2017.

Cash used in operating activities was \$5.4 million during the 2017 first quarter, compared to cash provided of \$7.3 million in the 2016 first quarter, with the change of \$12.7 million driven primarily from collaborative payments in the three-month periods ending March 31, 2017 and 2016, respectively. As of March 31, 2017, we had \$31.9 million in cash and cash equivalents, compared to \$14.8 million at December 31, 2016, which includes, among other things, the net proceeds of the common stock offering in February 2017.

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	Tuesday, May 9, 2017
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	800-273-1254
Telephone access: International	973-638-3440
Access code	5869094
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 23, 2017 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 5869094.

About Athersys

Athersys is an international biotechnology company engaged in the discovery and development of therapeutic product candidates 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 collaborations with leading pharmaceutical and biotechnology companies, as well as world-renowned research institutions to further develop its platform and products. More information is available at www.athersys.com.

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 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: 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 ongoing and planned clinical trials, including the MASTERS-2 Phase 3 clinical trial and the Healios TREASURE clinical 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)

	<u>March 31,</u> <u>2017</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2016</u> <u>(Note)</u>
Assets		
Cash and cash equivalents	\$ 31,940	\$ 14,753
Other current assets	2,922	1,527
Equipment, net	2,576	2,605
Deferred tax assets	178	175
Total assets	<u>\$ 37,616</u>	<u>\$ 19,060</u>
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	\$ 7,897	\$ 6,875
Deferred revenue	503	—
Warrant liabilities	—	1,004
Total stockholders' equity	29,216	11,181
Total liabilities and stockholders' equity	<u>\$ 37,616</u>	<u>\$ 19,060</u>

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) Income
(In Thousands, Except Per Share Amounts)

	Three months ended March 31,	
	2017	2016
Revenues		
Contract revenue	\$ 1,260	\$15,124
Grant revenue	210	334
Total revenues	<u>1,470</u>	<u>15,458</u>
Costs and expenses		
Research and development	5,633	6,664
General and administrative	2,071	2,014
Depreciation	164	68
Total costs and expenses	<u>7,868</u>	<u>8,746</u>
(Loss) income from operations	(6,398)	6,712
Income (expense) from change in fair value of warrants	728	(2,181)
Other income, net	26	210
(Loss) income before income taxes	<u>(5,644)</u>	<u>4,741</u>
Income tax benefit	13	9
Net (loss) income and comprehensive (loss) income	<u>\$ (5,631)</u>	<u>\$ 4,750</u>
Net (loss) income per share – Basic and Diluted	\$ (0.06)	\$ 0.06
Weighted average shares outstanding – Basic	102,047	83,781
Weighted average shares outstanding – Diluted	102,047	83,866