

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
Fiscal Year	12/31

**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): August 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 August 9, 2017, Athersys, Inc. issued a press release announcing financial results for its second quarter ended June 30, 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 August 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: August 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 August 9, 2017

PRESS RELEASE



ATHERSYS REPORTS SECOND QUARTER 2017 RESULTS

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

CLEVELAND, August 9, 2017 – Athersys, Inc. (Nasdaq: ATHX) today announced its financial results for the three months ended June 30, 2017.

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

- Clinical program for stroke received Final Scientific Advice positive opinion from the European Medicines Device Agency (“EMA”) – establishing alignment between European and U.S. regulators about the potential for approval based on the success of the planned MASTERS-2 study;
- Stroke program awarded Fast Track Designation by U.S. Food & Drug Administration (“FDA”) – meaning that the program is eligible for accelerated approval, priority review and rolling submission of the biologics license application, facilitating timely regulatory review;
- Provided initial shipment of clinical product to HEALIOS K.K. (“Healios”), our partner for stroke in Japan, for its TREASURE study;
- Continued discussions, diligence activities and evaluation of potential partnering opportunities for ischemic stroke and other programs;
- Revenues of \$0.7 million recognized for quarter ended June 30, 2017 and net loss of \$6.3 million, or \$0.06 net loss per share; and
- Cash and cash equivalents balance of \$28.6 million at the end of the second quarter.

“We are pleased to have received the EMA positive opinion for our pivotal MASTERS-2 stroke study and the Fast Track Designation from the FDA earlier in the quarter,” commented Dr. Gil Van Bokkelen, Chairman & CEO at Athersys. “As a result, we have now successfully established regulatory alignment and clarity with respect to the development and approval path for MultiStem[®] therapy for ischemic stroke for three major pharmaceutical markets – the U.S., Europe and Japan.

“We have continued to advance our preparations for the MASTERS-2 study and intend to be ready for launch later this year, and in parallel, we are pursuing business development and other initiatives to provide adequate funding for this pivotal trial, as well as advancement of our other core programs. Our partnering discussions continue to progress in stroke and other areas and remain an important priority for the company, and the regulatory clarity we have successfully established reinforces our strong development position,” concluded Dr. Van Bokkelen.

Second Quarter Results

Revenues increased to \$0.7 million for the three months ended June 30, 2017 from \$0.6 million in the comparable period in 2016 due to an increase of \$0.3 million in contract revenue primarily from our collaboration with Healios, partially offset by a \$0.2 million decrease in grant revenue. Research and development expenses decreased to \$4.6 million for the three months ended June 30, 2017 from \$5.8 million for the comparable period in 2016. The \$1.2 million decrease is primarily associated with decreased clinical and preclinical development costs of \$0.9, decreased sponsored research costs of \$0.2 million and decreased internal research supplies of \$0.2 million, partially offset by a \$0.1 million increase in legal and professional fees.

General and administrative expenses increased to \$2.2 million for the three months ended June 30, 2017 compared to \$2.0 million in 2016. The \$0.2 million increase was primarily due to increased legal and professional fees, salaries and benefits, and other contracted services.

Net loss was \$6.3 million in 2017, compared to net loss of \$7.0 million in 2016. The difference of \$0.7 million reflects the above variances, as well as a \$0.3 million non-cash decrease in the gain related to the fair value of our warrant liabilities. All outstanding warrants were either exercised or expired as of March 31, 2017.

Cash used in operating activities was \$5.7 million during the 2017 second quarter, compared to cash used of \$6.5 million in the 2016 second quarter. As of June 30, 2017, we had \$28.6 million in cash and cash equivalents, compared to \$14.8 million at December 31, 2016, which includes, among other things, the impact 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	Wednesday, August 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	51542352
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 August 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 51542352.

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 regulatory approvals 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: 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)

	June 30, 2017	December 31, 2016
	(Unaudited)	(Note)
Assets		
Cash and cash equivalents	\$ 28,594	\$ 14,753
Other current assets	1,528	1,527
Equipment, net	2,410	2,605
Deferred tax assets	191	175
Total assets	\$ 32,723	\$ 19,060
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	\$ 6,205	\$ 6,875
Deferred revenue	503	—
Warrant liabilities	—	1,004
Total stockholders' equity	26,015	11,181
Total liabilities and stockholders' equity	\$ 32,723	\$ 19,060

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 June 30,	
	2017	2016
Revenues		
Contract revenue	\$ 449	\$ 136
Grant revenue	220	459
Total revenues	<u>669</u>	<u>595</u>
Costs and expenses		
Research and development	4,633	5,824
General and administrative	2,207	1,985
Depreciation	167	67
Total costs and expenses	<u>7,007</u>	<u>7,876</u>
Loss from operations	<u>(6,338)</u>	<u>(7,281)</u>
Income from change in fair value of warrants	—	301
Other income, net	58	11
Loss before income taxes	<u>(6,280)</u>	<u>(6,969)</u>
Income tax benefit	13	13
Net loss and comprehensive loss	<u>\$ (6,267)</u>	<u>\$ (6,956)</u>
Net loss per share – Basic and Diluted	<u>\$ (0.06)</u>	<u>\$ (0.08)</u>
Weighted average shares outstanding – Basic	111,819,655	84,341,401
Weighted average shares outstanding – Diluted	111,819,655	85,416,506