

# ATHERSYS, INC / NEW

## **FORM 8-K** (Current report filing)

Filed 03/13/18 for the Period Ending 03/13/18

Address	3201 CARNEGIE AVENUE CLEVELAND, OH, 44115-2634
Telephone	216-431-9900
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SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 8-K**

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

**Date of report (Date of earliest event reported): March 13, 2018**

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

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**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)

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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.

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**Item 2.02. Results of Operations and Financial Condition.**

On March 13, 2018, Athersys, Inc. issued a press release announcing financial results for its fourth quarter ended December 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>Description</u>
99.1	<a href="#">Press Release dated March 13, 2018</a>

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**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: March 13, 2018

ATHERSYS, INC.

By: /s/ Laura K. Campbell

Name: Laura K. Campbell

Title: Senior Vice President of Finance

# PRESS RELEASE



**ATHERSYS REPORTS FINANCIAL RESULTS FOR  
FOURTH QUARTER, FULL YEAR 2017**

**Company also announces equity investment and binding letter of intent to expand  
HEALIOS K.K. collaboration, covered in a separate release**

**Management to host conference call at 4:30 PM EST today**

**CLEVELAND, Ohio, March 13, 2018** – Athersys, Inc. (NASDAQ: ATHX) announced today its fourth quarter 2017 and annual 2017 financial results and highlights.

“As we announced today in a separate press release, we have entered a letter of intent to expand our collaboration with Healios, and we are actively working with them with to complete the broader collaboration expansion by April 30, 2018, as we disclosed earlier today. In doing so, this would result in committed capital in the amount of \$56.1 million, of which \$31.1 million is already committed, in the form of the initial equity investment and license fee payments. Importantly, the broadened collaboration would lead to increased development of MultiStem treatment in Asia and provide us with capital to support our pivotal registration study for ischemic stroke, MASTERS-2, in the United States and Europe, as well as other important activities,” commented Dr. Gil Van Bokkelen, CEO of Athersys.

**Fourth Quarter 2017 and Recent Highlights:**

- Announced today plans to significantly expand our existing HEALIOS K.K. (“Healios”) collaboration, including a \$21.1 million equity investment and \$10 million in guaranteed license fees, and, if the expansion is consummated, would also further provide an additional \$25 million in committed payments over time. As part of the expansion, Healios would receive a license to MultiStem® products for acute respiratory distress syndrome (“ARDS”) and trauma in Japan, and Healios’ organ bud technology and certain ophthalmological indications globally. Also, Healios would receive an exclusive option to license MultiStem products for ischemic stroke, ARDS and trauma in China, and Athersys would be entitled to license fees, milestone payments and escalating royalties for the licensed indications;
- Advanced our preparations for the MASTERS-2 Phase 3 registration study for ischemic stroke, to enable initiation of this important study;
- Entered into a new equity facility in February 2018 as follow-on to current facility, with right to sell up to \$100 million of common stock to Aspire Capital, LLC over three-year period, providing access to capital as needed to support our operations;
- Recorded revenues of \$1.2 million and a net loss of \$13.1 million for the quarter ended December 31, 2017, noting that included in the net loss for the quarter was a \$4.7 million non-recurring charge (\$3.2 million of which was non-cash) related to a settlement and license agreement to resolve a long-standing intellectual property dispute; and
- Ended 2017 with \$29.3 million in cash and cash equivalents.

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**Other 2017 Highlights:**

- Received multiple special designations from regulators for our stroke program this year, including Regenerative Medicine Advanced Therapy designation and Fast Track designation from U.S. Food and Drug Administration, as well as a Final Scientific Advice positive opinion from European Medicines Device Agency;
- Expanded manufacturing and process development collaborative relationships, including Nikon CeLL innovation Co., Ltd., and progressed key manufacturing campaigns and process development projects; and
- Recorded revenues of \$3.7 million and a net loss of \$32.2 million, or \$0.29 net loss per share, for the year ended December 31, 2017, again, factoring in the 2017 charge of \$4.7 million for the intellectual property settlement and license.

“Over the course of 2017 and into 2018, we have undertaken and completed multiple initiatives that are intended to advance MultiStem therapy into registrational studies and ultimately to commercialization,” stated Dr. Van Bokkelen. “We plan to launch our MASTERS-2 study in the second quarter, and continue to advance our manufacturing platform and capabilities. Importantly, through these activities and our collaboration expansion with Healios, we have further strengthened our financial position, while retaining North American and European rights for MultiStem therapy in ischemic stroke and other indications, while we continue to evaluate additional collaborative opportunities.”

**Fourth Quarter 2017 Financial Results**

Total revenues for the fourth quarter of 2017 were \$1.2 million compared to \$1.0 million in the same period in the prior year, reflecting a combination of contract revenues and grant revenues.

Research and development expenses increased to \$12.1 million in the 2017 fourth quarter from \$7.1 million in the same period in the prior year. In 2017, approximately \$4.7 million of license fees were expensed (of which \$3.2 million was non-cash) related to a settlement and license agreement to resolve a long-standing intellectual property dispute. After factoring in this one-time charge, the remaining difference of \$0.3 million from year-to-year was primarily due to increased clinical and preclinical development costs, which vary based on trials underway, clinical manufacturing and process development activities.

General and administrative expenses remained relatively consistent at \$2.1 million and \$2.0 million in the 2017 and 2016 fourth quarters, respectively.

Net loss was \$13.1 million in the fourth quarter of 2017, compared to net loss of \$7.1 million for the same period of 2016. The increase in net loss was primarily due to the variances outlined above (e.g., settlement and license fees) and a \$1.1 million gain in the fourth quarter of 2016 related to the fair value of our warrant liabilities (non-cash), with no corresponding warrant activity in the 2017 fourth quarter, since all of our warrants were either exercised or expired early in 2017.

**Full Year 2017 Financial Results**

Revenues decreased to \$3.7 million for the year ended December 31, 2017 from \$17.3 million in 2016, related to a \$15.0 million payment received and recognized as revenue for the Healios collaboration entered into in January 2016, partially offset by 2017 increases in other contract revenues, including a \$1.0 million milestone payment from our collaboration with RTI Surgical, Inc. and manufacturing and service proceeds from Healios.

Research and development expenses increased to \$27.8 million for the year ended December 31, 2017 from \$24.8 million for the year ended December 31, 2016. After factoring in the non-recurring charge of \$4.7 million for license fees referred to above, the decrease in research and development expenses year-over-year of \$1.7 million related primarily to reduced spending on research supplies of \$0.9 million and sponsored research of \$0.5 million.

General and administrative expenses increased to \$8.5 million in 2017 from \$7.8 million in 2016. The \$0.7 million increase was due primarily to increases in personnel costs and legal and professional services.

Net loss was \$32.2 million in 2017, compared to \$15.3 million in 2016. The difference of \$16.9 million reflects the variances above, particularly the \$15.0 million Healios revenue in 2016 and the \$4.7 million one-time license fee expense in 2017, as well as an increase in 2017 of \$1.3 million in the gain in the fair value of warrant liabilities, a decrease in 2017 of \$0.7 million in the gain from insurance proceeds, and overall variances in operational activities.

Cash used in operating activities was \$24.0 million and \$10.9 million for full year 2017 and full year 2016, respectively, which takes into account the \$15.0 million initial license fee revenue from Healios in 2016 and the other variances noted above.

As of December 31, 2017, we had \$29.3 million in cash and cash equivalents, compared to \$14.8 million at December 31, 2016.

### **Conference Call**

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

Date	Tuesday, March 13, 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	8898346
Live webcast	<a href="http://www.athersys.com">www.athersys.com</a> , 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 March 27, 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 8898346. The archived webcast will be available for one year at the aforementioned URL.

### **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<sup>®</sup> 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

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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](http://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 the terms of the letter of intent described elsewhere in the press release to successfully negotiate the terms of and execute, the agreements necessary to expand the 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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**Contact:**

William (B.J.) Lehmann  
President and Chief Operating Officer  
Tel: (216) 431-9900  
[bjlehmann@athersys.com](mailto:bjlehmann@athersys.com)

Karen Hunady  
Corporate Communications & Investor Relations  
Tel: (216) 431-9900  
[khunady@athersys.com](mailto:khunady@athersys.com)

David Schull  
Russo Partners, LLC  
Tel: (212) 845-4271 or (858) 717-2310  
[David.schull@russopartnersllc.com](mailto:David.schull@russopartnersllc.com)

(Tables Follow)

**Athersys, Inc.**  
**Condensed Consolidated Balance Sheets**

*(In thousands)*  
*(Unaudited)*

	<u>December 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
<b>Assets</b>		
Cash and cash equivalents	\$ 29,316	\$ 14,753
Other current assets	1,874	1,527
Equipment, net	2,206	2,605
Other assets	197	175
<b>Total assets</b>	<u>\$ 33,593</u>	<u>\$ 19,060</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable and accrued expenses	\$ 9,312	\$ 6,875
Deferred revenue and other	905	—
Warrant liabilities and note payable	—	1,004
Total stockholders' equity	<u>23,376</u>	<u>11,181</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 33,593</u>	<u>\$ 19,060</u>

**Athersys, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
*(In thousands, except per share data)*  
*(Unaudited)*

	Three months ended December 31,		Twelve months ended December 31,	
	2017	2016	2017	2016
<b>Revenues</b>				
Contract revenue	\$ 955	\$ 828	\$ 2,843	\$ 16,238
Grant revenue	215	155	865	1,109
Total revenues	<u>1,170</u>	<u>983</u>	<u>3,708</u>	<u>17,347</u>
<b>Costs and expenses</b>				
Research and development	12,134	7,088	27,841	24,838
General and administrative	2,075	2,004	8,466	7,835
Depreciation	176	134	684	382
Total costs and expenses	<u>14,385</u>	<u>9,226</u>	<u>36,991</u>	<u>33,055</u>
Gain from insurance proceeds, net	—	—	—	682
Loss from operations	<u>(13,215)</u>	<u>(8,243)</u>	<u>(33,283)</u>	<u>(15,026)</u>
Income (expense) from change in fair value of warrants	—	1,132	728	(557)
Other income (expense), net	<u>115</u>	<u>(19)</u>	<u>314</u>	<u>209</u>
<b>Loss before income taxes</b>	<u>(13,100)</u>	<u>(7,130)</u>	<u>(32,241)</u>	<u>(15,374)</u>
Income tax benefit	—	3	—	37
<b>Net loss and comprehensive loss</b>	<u>\$ (13,100)</u>	<u>\$ (7,127)</u>	<u>\$ (32,241)</u>	<u>\$ (15,337)</u>
Basic net loss per share	\$ (0.11)	\$ (0.08)	\$ (0.29)	\$ (0.18)
Weighted average shares outstanding, basic	119,611	85,797	112,053	84,715
Diluted net (loss) income per share	\$ (0.11)	\$ (0.10)	\$ (0.29)	\$ (0.18)
Weighted average shares outstanding, diluted	119,611	86,603	112,053	84,715