



May 5, 2016

## Athersys Reports First Quarter 2016 Results

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

CLEVELAND, May 05, 2016 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) today announced its financial results for the three months ended March 31, 2016.

Highlights of the first quarter of 2016 and recent events include:

- | Announced positive one-year follow-up results from the Phase 2 study of MultiStem<sup>®</sup> cell therapy to treat ischemic stroke - demonstrating progressive improvements and significantly higher rate of excellent outcomes at one year for MultiStem-treated patients - with greater benefits for patients receiving MultiStem treatment within 36 hours of the stroke;
- | Established collaboration with HEALIOS K.K. ("Healios") to develop MultiStem cell therapy for stroke in Japan, which included an upfront payment of \$15 million, additional potential milestone payments aggregating up to \$225 million, double-digit royalties on product sales and an option for Healios to expand the collaboration to include acute respiratory distress syndrome ("ARDS") and another indication with a \$10 million expansion payment and additional associated milestone payments and royalties;
- | Advanced preparations for next stroke trials, including working with Healios to reach agreement with the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") on study design to potentially clear the way for a Japanese investigational new drug ("J-IND") filing and subsequent trial launch, and engaging with other regulators about requirements for the Company's planned international stroke study;
- | Continued enrollment of Phase 2a study evaluating administration of MultiStem therapy to ARDS patients, and Phase 2 acute myocardial infarction ("AMI") study, evaluating and taking measures to accelerate enrollment;
- | Recorded revenues of \$15.5 million for quarter ended March 31, 2016, reflecting the recognition of the \$15.0 million license fee payment from Healios, and net income of \$4.8 million; and
- | Ended the quarter with \$30.4 million in cash and cash equivalents.

"We remain very excited about our ischemic stroke program," stated Dr. Gil Van Bokkelen, Chairman & CEO at Athersys.

"As we have presented at several conferences, we have seen that MultiStem<sup>®</sup> treatment has the potential to help ischemic stroke victims, especially those who can be treated within 36 hours following the stroke. We were especially pleased with the one-year follow-up results, which showed continued and significant functional improvement with MultiStem treatment. As a result, we are moving forward diligently with clinical development in Japan with our partner Healios, and with planning for a corresponding study in the United States and Europe, focused on MultiStem treatment within 36 hours of the stroke.

"Our partnership with Healios is off to a strong start," continued Dr. Van Bokkelen. "Building from our previous engagement with the PMDA and with our support, Healios has reached general agreement with the PMDA about trial design and requirements. Healios is preparing its J-IND filing and planning for the subsequent launch of its planned study, and we are engaged in manufacturing to support their clinical product requirements. Based on discussions with the PMDA, we believe that a successful trial in Japan could make contingent, or even full, approval possible, utilizing Japan's progressive regulations for the development and approval of regenerative medicine products.

"We are also fully engaged in planning and preparing for an international ischemic stroke study focused in the United States and several European countries. Upcoming discussions with the U.S. Food and Drug Administration and other regulators will help us refine and finalize the trial design and complete trial preparations," noted Dr. Van Bokkelen.

"We are also enrolling our two grant-supported Phase 2 trials, in AMI and ARDS, although progress has been slower than we have anticipated," commented Dr. Van Bokkelen. "We have undertaken a number of actions to accelerate enrollment, including adding clinical sites. We believe that MultiStem cell therapy is well-suited to treat these acute conditions based on our preclinical and clinical experience to date, and we are motivated to move these studies forward expeditiously.

"We continue to focus on other important areas, including actively exploring partnering opportunities around multiple programs. Finally, we have a substantial effort underway in manufacturing and process development focused, first, on supplying our planned clinical studies, and second, on advancing our manufacturing platform and related capabilities to support high-volume, low-cost production important to commercialization," concluded Dr. Van Bokkelen.

## First Quarter Results

For the three months ended March 31, 2016, total revenues were \$15.5 million compared to \$0.7 million in the same period in 2015, reflecting the recognition of \$15.0 million in contract revenue from our Healios collaboration in the first quarter of 2016. Grant revenue was \$0.3 million less in the first quarter of 2016 compared to the same period in 2015, and grant revenues may fluctuate from period to period based on the timing of grant-related activities and the award and expiration of new grants.

Research and development expenses increased to \$6.7 million in the 2016 first quarter from \$5.7 million in the 2015 first quarter, primarily due to increased clinical and preclinical development costs, including process development activities to support manufacturing. General and administrative expenses were relatively consistent at \$2.0 million and \$1.9 million for the three months ended March 31, 2016 and 2015, respectively.

We recognized net income for the three months ended March 31, 2016 of \$4.8 million compared to net loss of \$12.5 million for the same period in 2015. The \$17.2 million net variance includes the impact of the \$15.0 million Healios license revenue, the \$0.3 million decrease in grant revenues, the \$1.1 million increase in combined R&D and G&A expenses, a \$3.4 million decrease in non-cash expense from the change in the fair value of our warrant liabilities, and a \$0.2 million increase in net other income. Cash provided in operating activities was \$7.3 million during the 2016 first quarter (reflecting \$14.8 million of cash received from Healios), compared to \$1.1 million in the 2015 first quarter (including \$8.0 million of cash received from our former collaborator, Chugai Pharmaceutical Co., Ltd). As of March 31, 2016, we had \$30.4 million in cash and cash equivalents, compared to \$23.0 million at December 31, 2015.

## 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 5, 2016
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	800-273-1254
Telephone access: International	973-638-3440
Access code	22710393
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 May 19, 2016, by dialing 800-585-8367 or 855-859-2056 (U.S. and Canada), or 404-537-3406, and entering access code 22710393. The archived webcast will be available for one year at the aforementioned URL.

## 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 cardiovascular, neurological, 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](http://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 our 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, our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; the success of our collaborations, including our ability to reach milestones and receive milestone payments, including in connection with our collaboration with Healios, and whether any products are successfully developed and sold so that we earn royalty payments; 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; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials; 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.

(Tables Follow)

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

	March 31, 2016 (Unaudited)	December 31, 2015 (Note)
<b>Assets</b>		
Cash and cash equivalents	\$ 30,414	\$ 23,027
Other current assets	1,132	790
Equipment, net	1,253	1,135
Deferred tax assets	184	177
<b>Total assets</b>	<b>\$ 32,983</b>	<b>\$ 25,129</b>
<b>Liabilities and stockholders' equity</b>		
Accounts payable and accrued expenses	\$ 4,721	\$ 4,321
Deferred revenue	0	245
Warrant liabilities and note payable	2,830	839
Total stockholders' equity	25,432	19,724
<b>Total liabilities and stockholders' equity</b>	<b>\$ 32,983</b>	<b>\$ 25,129</b>

**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 Income (Loss)**  
*(In Thousands, Except Per Share Amounts)*

	Three months ended March 31,	
	2016	2015
<b>Revenues</b>		
Contract revenue	\$ 15,124	\$ 106
Grant revenue	334	625

Total revenues	15,458		731
<b>Costs and expenses</b>			
Research and development	6,664		5,668
General and administrative	2,014		1,886
Depreciation	68		70
Total costs and expenses	8,746		7,624
Income (loss) from operations	6,712		(6,893)
Expense from change in fair value of warrants	(2,181)		(5,604)
Other income, net	210		15
<b>Income (loss) before income taxes</b>	4,741		(12,482)
Income tax benefit	9		--
<b>Net income (loss) and comprehensive income (loss)</b>	<b>\$ 4,750</b>	<b>\$</b>	<b>(12,482)</b>
Net income (loss) per share - Basic and Diluted	<b>\$ 0.06</b>	<b>\$</b>	<b>(0.16)</b>
Weighted average shares outstanding - Basic	<b>83,781</b>		79,181
Weighted average shares outstanding - Diluted	<b>83,866</b>		79,181

Contact:

William (B.J.) Lehmann, J.D.

President and Chief Operating Officer

Tel: (216) 431-9900

[bjlehmann@athersys.com](mailto:bjlehmann@athersys.com)

 Primary Logo

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