



November 10, 2014

## **Athersys Reports Third Quarter 2014 Results**

### **Management to Host Conference Call at 4:30pm EST Today**

CLEVELAND, Nov. 10, 2014 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) today announced its financial results for the three months ended September 30, 2014. Highlights of the third quarter of 2014 and recent events include:

- Enrollment nearly complete in Phase 2 clinical trial of MultiStem<sup>®</sup> cell therapy for treatment of ischemic stroke;
- Confirmation by the Japanese Pharmaceutical and Medical Devices Agency (PMDA) that MultiStem product manufacturing is suitable for clinical development - an important regulatory milestone;
- Preparations for Phase 2 acute myocardial infarction (AMI) study nearing completion, with several clinical sites progressing toward site initiation;
- Multiple grants awarded in the United States and Europe directed at process development and non-clinical and clinical development in central nervous system and pulmonary areas;
- Third quarter 2014 revenues of \$0.3 million and net loss of \$4.7 million, which includes non-cash income of \$2.5 million related to the change in fair value of warrant liabilities and non-cash expense of \$0.7 million in stock-based compensation for quarter ended September 30, 2014; and
- Ended the quarter with \$32.4 million in cash and cash equivalents.

"We have focused in the past several months on completing enrollment of our ongoing Phase 2 study of MultiStem cell therapy as a treatment for ischemic stroke," said Gil Van Bokkelen, Chairman and Chief Executive Officer of Athersys. "Enrollment is nearly completed and we anticipate having data from the trial around the end of the first quarter of 2015, several weeks after our last patient completes the ninety-day follow-up visit. We believe that MultiStem therapy has the potential to greatly improve outcomes for stroke patients and represents a substantial market opportunity given the limited treatment options available today, and we eagerly await the results of this study.

"In Japan, we continue to build relationships with the PMDA and potential Japanese collaborators to better position Athersys in this important market," added Dr. Van Bokkelen. "We are pleased that the PMDA recently confirmed that our manufacturing is suitable for Japanese clinical development, which represents an important regulatory milestone that helps facilitate our development efforts there. Importantly, the new regulations regarding the accelerated regulatory pathway are expected to be implemented in Japan by the end of this year, paving the way for accelerated development and commercialization of regenerative medicines, such as MultiStem therapy.

"We have also made great strides in preparing for our Phase 2 clinical trial of MultiStem to treat acute myocardial infarction," added Dr. Van Bokkelen. "This study builds on promising Phase 1 clinical and supporting non-clinical data that suggests MultiStem could provide a meaningful benefit to patients that have suffered serious damage from a heart attack. Our first study sites are expected to be ready to go by the end of this year, and we look forward to substantial clinical study activity in 2015.

"Additionally, we are engaged in preparation activities for clinical work in other targeted areas where we believe MultiStem therapy may be well-suited. Finally, we continue to have discussions with potential partners focused on several areas, driven both by the strength of our programs and technology, as well as promising trends in the regulatory area," concluded Dr. Van Bokkelen.

### **Third Quarter Results**

For the three months ended September 30, 2014, total revenues were \$0.3 million compared to \$0.6 million in the comparable period in 2013, reflecting primarily a decrease in grant revenue. Grant revenue may fluctuate from period to period due to the timing of grant-related activities and the award and expiration of grants, while contract revenues will be driven by license, royalty and milestone payments from existing and possibly new business collaborations.

Research and development expenses were \$5.8 million for the third quarter of 2014 compared to \$4.7 million for the third quarter of 2013. The difference reflects increases in preclinical and clinical development costs, personnel costs, research

supplies, and stock-based compensation. General and administrative expenses increased to \$1.7 million during the third quarter of 2014 compared to \$1.5 million in the same period of 2013 due to increases in personnel costs and legal and professional fees.

Net loss for the three months ended September 30, 2014 was \$4.7 million compared to a net loss of \$5.6 million for the three months ended September 30, 2013. The difference reflects the impact of a \$2.5 million increase in non-cash income from the change in the fair value of our warrant liabilities, less the \$1.3 million aggregate increase in research and development and general and administrative expenses, and the \$0.3 million decrease in revenues.

As of September 30, 2014, we had \$32.4 million in cash and cash equivalents, compared to \$31.9 million at December 31, 2013. During the nine-month period ended September 30, 2014, cash used in operating activities was \$19.7 million and was \$18.3 million in the comparable period of 2013.

## Conference Call

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

Date	November 10, 2014
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	800-273-1254
Telephone access: International	973-638-3440
Access code	22692627
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 November 24, 2014 by dialing 800-585-8367 or 855-859-2056 (U.S. and Canada), or 404-537-3406, and entering access code 22692627. The archived webcast will be available for one year at the aforementioned URL.

## About Athersys

Athersys is a clinical stage 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<sup>®</sup> cell therapy product, a patented, adult-derived "off-the-shelf" stem cell product platform for disease indications in the cardiovascular, neurological, inflammatory and immune disease areas. The Company currently has several clinical stage programs involving MultiStem, including for treating inflammatory bowel disease, ischemic stroke, damage caused by myocardial infarction, and for the prevention of graft-versus-host disease. Athersys has also developed a diverse portfolio that includes other technologies and product development opportunities, and has forged strategic partnerships and collaborations with leading pharmaceutical and biotechnology companies, as well as world-renowned research institutions in the United States and Europe to further develop its platform and products. More information is available at [www.athersys.com](http://www.athersys.com).

The Athersys, Inc. logo is available at: <http://www.globenewswire.com/newsroom/prs/?pkgid=4548>.

## 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 inflammatory bowel disease, acute myocardial infarction, stroke and other potential indications, including lysosomal storage disorders and the prevention of graft-versus-host disease. These risks and*

uncertainties 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 raise additional capital; final 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 and obtain all necessary regulatory approvals; our ability to successfully initiate clinical development of MultiStem in Japan; 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 realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our ability to meet milestones under our collaboration agreements; 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 and advance our programs; 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)*

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
	<b>(Unaudited)</b>	<b>(Note)</b>
<b>Assets</b>		
Cash, cash equivalents	\$32,368	\$31,948
Other current assets	1,081	907
Equipment, net	1,331	1,333
Total assets	\$34,780	\$34,188
<b>Liabilities and stockholders' equity</b>		
Accounts payable, accrued expenses and deferred revenue	\$4,577	\$4,368
Warrant liabilities and note payable	3,385	9,999
Total stockholders' equity	26,818	19,821
Total liabilities and stockholders' equity	\$34,780	\$34,188

**Note:** The Condensed Consolidated Balance Sheet Data at December 31, 2013 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 Share and Per Share Amounts)*

	<b>Three Months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(Unaudited)</b>	
<b>Revenues</b>		
Contract revenue	\$75	\$87
Grant revenue	218	534
Total revenues	293	621

**Costs and Expenses**

Research and development	5,775	4,689
General and administrative	1,695	1,450
Depreciation	<u>91</u>	<u>86</u>
Total costs and expenses	<u>7,561</u>	<u>6,225</u>
Loss from operations	(7,268)	(5,604)
Other income (expense), net	9	(4)
Income (expense) from change in fair value of warrants	<u>2,540</u>	<u>(6)</u>
<b>Net loss and comprehensive loss</b>	<b><u><u>\$ (4,719)</u></u></b>	<b><u><u>\$ (5,614)</u></u></b>
Net loss per share - Basic	\$ (0.06)	\$ (0.10)
Weighted average shares outstanding - Basic	77,320,425	57,646,306
Net loss per share - Diluted	\$ (0.08)	\$ (0.10)
Weighted average shares outstanding - Diluted	78,349,840	59,248,031

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Source: Athersys, Inc.

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