March 10, 2016

Athersys Reports Fourth Quarter and 2015 Annual Results

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

CLEVELAND, March 10, 2016 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) today announced its financial results for the fourth quarter and year ended December 31, 2015.

"Overall, we have made substantial progress over the past twelve months," said Gil Van Bokkelen, Chairman and Chief Executive Officer of Athersys. "We have seen that MultiStem® treatment has the potential to help ischemic stroke victims, especially those who can be treated within 36 hours following the stroke. We have identified a promising path forward for continued development through a new partnership in Japan that is well positioned to take advantage of Japan's progressive regulations for the development and approval of regenerative medicine products. Furthermore, we have continued to make progress in our other programs, strengthening the underlying science and our core capabilities, including manufacturing."

Highlights of the fourth quarter of 2015 and recent events include:

- Announced in February at the 2016 International Stroke Conference positive results from analysis of one-year follow-up data from the Phase 2 study of MultiStem cell therapy to treat ischemic stroke - demonstrating progressive improvements and significantly higher rate of excellent outcomes at one year for MultiStem-treated patients;
- Established a collaboration with HEALIOS K.K. ("Healios") in January 2016 to develop MultiStem cell therapy for stroke in Japan, receiving an upfront license fee of $15 million. Collaboration includes potential for development and commercialization milestones aggregating $215 million and royalties on product sales. Healios may expand the collaboration to include acute respiratory distress syndrome ("ARDS") and another indication with a $10 million expansion payment and associated milestone payments and royalties;
- Initiated enrollment in a Phase 2a study evaluating administration of MultiStem therapy to ARDS patients, and continued enrollment of a Phase 2 acute myocardial infarction ("AMI") study;
- Published the results of a preclinical study in the *Journal of Neuroinflammation* demonstrating that MultiStem therapy provides significant benefit in a large animal model of hypoxic-ischemia, and providing further evidence in support of MultiStem treatment for acute neurological injuries;
- Published in *Nature*'s Scientific Reports the results of a preclinical acute spinal cord injury study demonstrating that MultiStem therapy promoted improved walking and urinary function, preserved at-risk neuronal tissue, and modulated inflammation following the injury;
- Received Special Protocol Assessment designation from the Food and Drug Administration and positive opinion from European Medicines Agency through its Scientific Advice procedure regarding the registration study design for Phase 2/3 trial of MultiStem cell therapy to prevent or reduce graft-versus-host disease and other complications for patients undergoing a hematopoietic stem cell transplant to treat leukemia or related conditions;
- For quarter ended December 31, 2015, recorded revenues of $10.6 million, reflecting the recognition of $10 million license fee payment upon termination of the collaboration with Chugai Pharmaceutical Co, Ltd. ("Chugai"), and net income of $3.6 million; and for year ended December 31, 2015, recorded revenues of $11.9 million and net loss of $16.4 million; and
- Ended year with $23.0 million in cash and cash equivalents, and received $15 million in January 2016 in connection with our Healios collaboration.

"We are very pleased with the ischemic stroke study's one-year follow-up results for all subjects, which show that MultiStem treatment can significantly increase the number of patients who have an Excellent Outcome, meaning complete or nearly full recovery, when compared to standard of care," stated Dr. Gil Van Bokkelen, Chairman & CEO at Athersys. "MultiStem treatment was also associated with improvement in other measures of function through one year, and as we expected, patients who received MultiStem treatment within 36 hours of the stroke did substantially better than placebo patients and subjects receiving later treatment with MultiStem. Based on our interim 90-day data and these one-year results, we are excited to move forward with clinical development focused on MultiStem treatment within 36 hours of the stroke, and we believe that such treatment has the potential to substantially improve patient outcomes following ischemic stroke."

"We are actively working with Healios in Japan on the development of MultiStem therapy for treatment of ischemic stroke, and we are both very engaged on planning for a trial in Japan," continued Dr. Van Bokkelen. "The company has an accomplished leadership team, an excellent network of institutional partners and collaborators, and is focused on the regenerative medicine field. They are committed to rapid and efficient development under the new regulatory framework in Japan, which has the potential to provide the fastest path to market for our MultiStem stroke program."

"Since last year, we have initiated two grant-supported Phase 2 trials, in AMI and ARDS, both of which represent areas of unmet need," commented Dr. Van Bokkelen. "We believe that MultiStem cell therapy is well-suited to treat these acute conditions, based on our preclinical and clinical experience to date. Additionally, we have been focused on advancing our manufacturing platform and related capabilities to support late stage clinical development and, eventually, commercialization."

Fourth Quarter Results

For the three months ended December 31, 2015, total revenues were $10.6 million compared to $0.2 million in the same period in 2014, reflecting the recognition of the full $10 million license fee that we received in 2015 from Chugai upon the termination of the collaboration in October 2015 and an increase in grant revenue.

Research and development expenses decreased to $5.3 million in the fourth quarter of 2015 from $5.6 million in the 2014 fourth quarter, primarily due to reduced clinical and preclinical development costs, which vary based on trials underway and clinical manufacturing campaigns. General and administrative expenses were $1.8 million in the fourth quarter of 2015 compared to $1.6 million in the corresponding 2014 period, reflecting increases in legal and professional fees, personnel costs and stock-based compensation.

We recognized net income for the three months ended December 31, 2015 of $3.6 million, compared to net loss of $6.6 million for the same period of 2014. The $10.2 million net variance includes the impact of the $10 million Chugai license fee, the $0.4 million increase in grant revenues, the $0.3 million decrease in research and development expenses, the $0.2 million increase in general and administrative costs, and an increase in net other expenses.

2015 Annual Financial Results

For the year ended December 31, 2015, total revenues were $11.9 million compared to $1.6 million for 2014, reflecting the $10 million Chugai license fee and an increase in grant revenue.

Research and development expenses decreased to $21.3 million in 2015 from $23.4 million in 2014 related primarily to decreases in clinical and preclinical development costs, sponsored research costs, legal and professional fees and travel costs, with such decreases partially offset increases in license fees and personnel costs. General and administrative expenses were $7.5 million in 2015 compared to $6.9 million in 2014, reflecting increases in stock-based compensation, professional fees and consulting costs.

Net loss for the year ended December 31, 2015 was $16.4 million, compared to $22.1 million in 2014. The difference of $5.7 million reflects the $10.3 million increase in revenues, the $2.1 million decrease in research and development expenses, the $0.6 million increase in general and administrative costs, a $5.8 million non-cash decrease in the change in the fair value of our warrant liabilities, and an increase in net other expenses. Cash used in operating activities was $13.8 million and $25.8 million in 2015 and 2014, respectively. As of December 31, 2015, we had $23.0 million in cash and cash equivalents.

Conference Call

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

Date	Thursday, March 10, 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	22710392
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 March 24, 2016, by dialing 800-585-8367 or 855-859-2056 (U.S. and Canada), or 404-537-3406, and entering access code 22710392. 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.

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 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, 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)

	December 31, 2015	December 31, 2014
	(Unaudited)	(Unaudited)
Assets		
Cash and cash equivalents	$ 23,027	$ 26,127
Other current assets	790	1,121
Equipment, net	1,135	1,270
Deferred tax assets	177	200

Total assets	**$ 25,129**	**$ 28,718**
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 4,321	$ 4,617
Deferred revenue	245	75
Warrant liabilities and note payable	839	3,131
Total stockholders' equity	19,724	20,895
Total liabilities and stockholders' equity	**$ 25,129**	**$ 28,718**

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 data)

(Unaudited)

	Three months ended December 31,		Twelve months ended December 31,	
	2015	**2014**	**2015**	**2014**
Revenues				
Contract revenue	**$ 10,104**	$ 131	**$ 10,298**	$ 286
Grant revenue	**501**	104	**1,650**	1,337
Total revenues	**10,605**	235	**11,948**	1,623
Costs and expenses				
Research and development	**5,298**	5,610	**21,316**	23,366
General and administrative	**1,785**	1,606	**7,536**	6,909
Depreciation	**66**	88	**267**	360
Total costs and expenses	**7,149**	7,304	**29,119**	30,635
Income (loss) from operations	**3,456**	(7,069)	**(17,171)**	(29,012)
Income from change in fair value of warrants	**164**	256	**772**	6,591
Other (expense) income, net	**(31)**	25	**(61)**	86
Income (loss) before income taxes	**3,589**	(6,788)	**(16,460)**	(22,335)
Income tax benefit	**3**	234	**38**	253
Net income (loss) and comprehensive loss	**$ 3,592**	$ (6,554)	**$ (16,422)**	$ (22,082)
Basic net income (loss) per share	**$ 0.04**	$ (0.08)	**$ (0.20)**	$ (0.29)
Weighted average shares outstanding, basic	**83,352**	77,545	**82,144**	76,955
Diluted net income (loss) per share	**$ 0.04**	$ (0.08)	**$ (0.20)**	$ (0.31)
Weighted average shares outstanding, diluted	**83,451**	77,545	**82,851**	78,541

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Source: Athersys, Inc.