August 9, 2016

Athersys Reports Second Quarter 2016 Results

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

CLEVELAND, Aug. 09, 2016 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) today announced its financial results for the three months ended June 30, 2016.

Highlights of the second quarter of 2016 include:

- Successful discussions with the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") on ischemic stroke study design and requirements, led by HEALIOS K.K. ("Healios") with Athersys support, laying the groundwork for study initiation later this year;
- Productive discussions with U.S. Food and Drug Administration ("FDA") about the design of our planned international Phase 3 study of MultiStem® treatment for ischemic stroke, and ongoing engagement with European regulators;
- Inclusion of our common stock in the broad-market Russell 3000® Index as part of the Russell U.S. Indices annual reconstitution, which became effective in June 2016;
- Recorded revenues of $0.6 million and net loss of $7.0 million for quarter ended June 30, 2016; and
- Ended the quarter with $24.0 million in cash and cash equivalents and available-for-sale securities.

"Along with our partner, Healios, we are focused on completing the preparations and activities related to the initiation of the confirmatory clinical trial in Japan, and continue to make steady progress toward that goal. In addition, we are engaged in discussions with FDA and other regulators regarding our larger, Phase 3 international clinical trial for stroke," stated Dr. Gil Van Bokkelen, Chairman & CEO at Athersys. "We have had productive and successful engagement with the regulators, including completing an End of Phase 2 meeting with the FDA, and have advanced our operational preparations to support both studies. As we have described previously, the studies will be focused on ischemic stroke patients that have suffered meaningful disability and who can be treated within 36 hours of the event, which would represent a significant expansion of the treatment window for these patients, which is currently limited to several hours. This would overcome a key limitation of current standard of care, enable many more stroke victims to be treated, and could redefine stroke therapy as we know it. It also represents a substantial clinical and commercial opportunity.

"We believe that we could have a favorable path forward for the continued development of MultiStem for the treatment of ischemic stroke, which represents one of the greatest areas of unmet clinical need in medicine, and an urgent priority in many countries due to the growing impact of an expanding elderly population that is more susceptible to stroke," continued Dr. Van Bokkelen. "Based on discussions with the PMDA and recent precedents, we believe that a successful trial in Japan with positive results could make conditional, or even full, approval possible, utilizing Japan's progressive regulations for the development and approval of regenerative medicine products. Moreover, our engagement so far with the FDA suggests that the data from this Japan study, together with data from our Phase 3 international study, could provide the basis for a Biologics License application ("BLA") for registration, meaning that we would have an accelerated path to commercialization in the United States, as well as potentially other regions.

"We continue to enroll our two grant-supported Phase 2 trials, in AMI and ARDS, although progress is slower than we would like," 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.

"We continue to focus on other important areas, including actively exploring partnering opportunities. We also have a substantial manufacturing and process development efforts underway focused, first, on supplying our planned clinical studies, and second, on advancing our manufacturing platform and related capabilities to support eventual commercialization," concluded Dr. Van Bokkelen.

Second Quarter Results

For the three months ended June 30, 2016, total revenues were $0.6 million compared to $0.2 million in the same period in 2015, due to an increase of $0.1 million in contract revenues from royalties and a $0.3 million increase in grant revenue. Grant revenues relate to both clinical and preclinical studies.

Research and development expenses increased to $5.8 million in the 2016 second quarter from $5.3 million in the 2015 second quarter, primarily due to increased clinical and preclinical development. Our clinical and preclinical costs increased during the period as a result of our process development activities to support large-scale manufacturing, and clinical product manufacturing costs during the period, with such increases partially offset by a decrease in costs for our stroke B01-02 study that concluded this spring. General and administrative expenses were $2.0 million and $1.9 million for the three months ended June 30, 2016 and 2015, respectively.

We recognized net loss for the three months ended June 30, 2016 of $7.0 million compared to net loss of $1.0 million for the same period in 2015. The $6.0 million net variance is due primarily to a $5.7 million decrease in non-cash income from the change in the fair value of our warrant liabilities, combined with the net impact of the $0.4 million increase in revenues and the $0.7 million increase in operating expenses for the three-month period ended June 30, 2016. Cash used in operating activities was $6.5 million during the 2016 second quarter compared to $5.8 million in the 2015 second quarter. As of June 30, 2016, we had $24.0 million in cash and cash equivalents and available-for-sale securities, 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	Tuesday, August 9, 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	45914024
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, 2016, by dialing 800-585-8367 or 855-859-2056 (U.S. and Canada), or 404-537-3406, and entering access code 45914024. 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.

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, 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)

	June 30, 2016	December 31, 2015
	(Unaudited)	(Note)
Assets		
Cash and cash equivalents	$ 13,837	$ 23,027
Available-for-sale securities	10,187	--
Other current assets	1,647	790
Equipment, net	2,028	1,135
Deferred tax assets	187	177
Total assets	**$ 27,886**	**$ 25,129**
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 5,745	$ 4,321
Deferred revenue	--	245
Warrant liabilities and note payable	2,369	839
Total stockholders' equity	19,772	19,724
Total liabilities and stockholders' equity	**$ 27,886**	**$ 25,129**

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)
(Unaudited)

	Three months ended June 30,	
	2016	2015
Revenues		
Contract revenue	**$ 136**	$ 49
Grant revenue	**459**	167
Total revenues	**595**	216
Costs and expenses		

Research and development	**5,824**		5,261
General and administrative	**1,985**		1,924
Depreciation	**67**		65
Total costs and expenses	**7,876**		7,250
Loss from operations	**(7,281)**		(7,034)
Income from change in fair value of warrants, net	**301**		5,957
Other income, net	**11**		25
Loss before income taxes	**(6,969)**		(1,052)
Income tax benefit	**13**		17
Net loss and comprehensive loss	**$ (6,956)**	$	(1,035)
Net loss per share, basic	**$ (0.08)**	$	(0.01)
Weighted average shares outstanding, basic	**84,341**		82,844
Net loss per share, diluted	**$ (0.08)**	$	(0.05)
Weighted average shares outstanding, diluted	**85,417**		83,562

Contact:

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President and Chief Operating Officer

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Primary Logo

Source: Athersys, Inc.

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