August 11, 2014

Athersys Reports Second Quarter 2014 Results

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

CLEVELAND, Aug. 11, 2014 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) today announced its financial results for the three months ended June 30, 2014. Highlights of the second quarter of 2014 and recent events include:

- Advanced enrollment of Phase 2 clinical trial of MultiStem® cell therapy for treatment of ischemic stroke, expecting to complete enrollment in the next several months with initial top-line results following analysis of patient data collected through 90 days after treatment;
- Progressed preparations for Phase 2 acute myocardial infarction (AMI) study targeted to be launched later this year;
- Continued interactions with Pfizer regarding the collection and analysis of additional patient information from Phase 2 clinical study of MultiStem cell therapy to treat refractory ulcerative colitis (UC) being conducted by Pfizer, to better understand and characterize previously reported clinical results;
- Successfully advanced regulatory discussions with U.S. Food and Drug Administration (FDA) regarding study design and potential accelerated approval path for Phase 2/3 graft-versus-host disease prophylaxis study, and with Japan's Pharmaceutical and Medical Devices Agency (PMDA) concerning the execution of clinical trial activity in Japan with the potential for accelerated development;
- Reported revenues of $0.4 million and net income of $0.7 million, which includes non-cash income of $7.9 million related to the change in fair value of warrant liabilities and non-cash expense of $0.6 million in stock-based compensation, for quarter ended June 30, 2014;
- Recorded net income per share of $0.01 for the quarter ended June 30, 2014, which reflects the benefit of $0.09 per share from the $7.3 million in aggregate non-cash items noted above; and
- Ended the quarter with $38.8 million in cash and cash equivalents.

"We believe that MultiStem cell therapy and our related technologies have great potential to help patients by improving clinical outcomes and quality of life, and reduce related healthcare costs in multiple disease areas," said Gil Van Bokkelen, Chairman and Chief Executive Officer of Athersys. "By advancing multiple programs in parallel, we position ourselves well for success even if, as we have seen from the UC clinical study, one of our therapeutic applications is not successful the first time through.

"We are pleased with the enrollment progress of our Phase 2 ischemic stroke study through the second quarter. Though rates have slowed over the last several weeks during the summer holiday period, we expect to complete enrollment within the next several months, with top-line data available three to four months after the last patient is enrolled. We believe that MultiStem therapy has the potential to greatly improve treatment outcomes for more severe stroke patients, and we look forward to the results from this trial.

"Meanwhile, we are excited about the planned initiation of our Phase 2 acute myocardial infarction study later this year and are well-along in preparation for this trial," added Dr. Van Bokkelen. "We are eager to commence this study to further evaluate MultiStem for AMI patients, especially given our promising Phase 1 clinical and supporting non-clinical data, much of which has been published. This body of data demonstrates the consistent safety of the product and the delivery approach, and provides meaningful evidence of therapeutic effectiveness as well as a thorough understanding of key mechanisms of action."

"As we have previously noted, Pfizer will continue to generate information through the end of the year from the ongoing Phase 2 UC study, including additional clinical data and biomarker analyses. We look forward to receiving and evaluating this information to better understand the previously reported clinical results and the potential relevance for MultiStem therapy in this and related therapeutic areas.

"On the regulatory front, we are actively engaged in interactions to advance clinical development in several areas, including with the FDA regarding the study design for a Phase 2/3 graft-versus-host disease prophylaxis trial and with the PMDA to support Japanese clinical development activities. Both of these efforts are intended to lay the groundwork for accelerated development paths for MultiStem therapy," concluded Dr. Van Bokkelen.

Second Quarter Results

For the three months ended June 30, 2014, total revenues were $0.4 million compared to $0.6 million in the comparable period in 2013, reflecting decreases in both grant and contract revenues. Grant revenues 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 or new business collaborations.

Research and development expenses were $5.8 million for the second quarter of 2014 compared to $5.1 million for the second quarter of 2013. The difference reflects increases in personnel costs, research supplies, stock-based compensation and sponsored research, which were partially offset by a decrease in clinical and preclinical costs. General and administrative expenses increased to $1.8 million during the second quarter of 2014 compared to $1.6 million in the same period of 2013 due to increases in personnel costs and stock-based compensation.

Net income for the three months ended June 30, 2014 was $0.7 million compared to a net loss of $5.9 million for the three months ended June 30, 2013. The difference reflects the impact of a $7.7 million increase in non-cash income as a result of the change in the fair value of our warrant liabilities, less the $0.2 million decrease in revenues and the $0.9 million increase in research and development and general and administrative expenses (of which $0.4 million is related to an increase in non-cash stock-based compensation expense).

As of June 30, 2014, we had $38.8 million in cash and cash equivalents, compared to $31.9 million at December 31, 2013. During the second quarter of 2014, cash used in operating activities was $6.1 million compared to $6.4 million in the second quarter 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	August 11, 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	74126643
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 25, 2014 by dialing 800-585-8367 or 855-859-2056 (U.S. and Canada), or 404-537-3406, and entering access code 74126643. 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® 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.

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; 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)

	June 30, 2014 (Unaudited)	December 31, 2013 (Note)
Assets		
Cash, cash equivalents	$38,750	$31,948
Other current assets	1,025	907
Equipment, net	1,343	1,333
Total assets	$41,118	$34,188
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and deferred revenue	$4,317	$4,368
Warrant liabilities and note payable	5,923	9,999
Total stockholders' equity	30,878	19,821
Total liabilities and stockholders' equity	$41,118	$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)

	Three Months ended June 30,	
	2014	2013
	(Unaudited)	
Revenues		

Contract revenue	$36	$194
Grant revenue	352	377
Total revenues	388	571
Costs and Expenses		
Research and development	5,754	5,107
General and administrative	1,827	1,555
Depreciation	93	86
Total costs and expenses	7,674	6,748
Loss from operations	(7,286)	(6,177)
Other income, net	42	15
Income from change in fair value of warrants	7,919	216
Net income (loss) and comprehensive income (loss)	$675	$ (5,946)
Net income (loss) per share - Basic	$0.01	$ (0.11)
Weighted average shares outstanding, basic	77,077,492	56,028,461
Net loss per share - Diluted	$ (0.04)	$ (0.11)
Weighted average shares outstanding, diluted	78,778,181	57,841,167

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Source: Athersys, Inc.