August 6, 2015

Athersys Reports Second Quarter 2015 Results

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

CLEVELAND, Aug. 06, 2015 (GLOBE NEWSWIRE) -- Athersys, Inc. (NASDAQ:ATHX) today announced its financial and operating results for the three months ended June 30, 2015.

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

- Completed additional analyses of data from Phase 2 clinical study of MultiStem® therapy to treat ischemic stroke further demonstrating the potential benefit to patients who receive MultiStem treatment within 36 hours of stroke, as described below;
- Advanced launch activities for grant-supported Phase 2 clinical study to evaluate the administration of MultiStem cells to patients who have suffered a severe, non-ST-elevated acute myocardial infarction;
- Received FDA authorization for grant-supported clinical study exploring MultiStem treatment of acute respiratory distress syndrome ("ARDS") patients and preparing to begin trial in the United Kingdom and United States;
- Received grant awards from the National Institutes of Health totaling approximately $800,000 for non-clinical research in areas of acute central nervous system trauma;
- Reported revenues of $0.2 million for quarter ended June 30, 2015 and net loss of $1.0 million for the period, which includes non-cash income of $6.0 million related to the change in fair value of our warrant liabilities and non-cash expense of $0.7 million related to stock-based compensation;
- Recorded net loss per share of $0.01 for the quarter ended June 30, 2015, which reflects the non-cash income impact of $0.06 per share from the $5.3 million in aggregate, net non-cash items noted above; and
- Ended the quarter with $32.3 million in cash and cash equivalents, and expecting $2 million Japanese tax withholding refund.

"We have continued to analyze the initial results from our Phase 2 trial for treating ischemic stroke, which provide a strong foundation for an exciting path forward," said Dr. Gil Van Bokkelen, Chairman and CEO of Athersys, Inc. "In short, the clinical and emerging biomarker data support the view that MultiStem treatment within 36 hours following the stroke provides substantial benefits to patients who have suffered moderate to severe disability. In particular, our analysis demonstrates that a much higher proportion of patients receiving earlier MultiStem treatment achieve recovery as measured by improvement in all three clinical rating scales. These scales evaluate improvement in overall disability level, cognitive and motor skills, and the ability to engage in activities of daily living, and this broad-based improvement is very important to patients, clinicians and healthcare payors. These results also complement the data presented previously that indicates that MultiStem treatment is associated with lower infections, fewer serious adverse events and lower mortality, as well as reduced hospitalization and time in the intensive care unit. The data also provides further evidence that MultiStem cell therapy may meaningfully extend the treatment window for stroke patients, who currently must get to the hospital within a few hours to receive reperfusion therapy. We are actively planning for the next ischemic stroke study for potential initiation next year.

"We have also made progress in our Phase 2 acute myocardial infarction study and are working aggressively to bring additional sites on and drive enrollment. Though it is too early to make firm projections, our target remains to generate top-line data in 2016," added Dr. Van Bokkelen. "Also, with recent regulatory and operations progress, we expect to begin our exploratory study in the ARDS area in the next several months. We believe that MultiStem therapy has the potential to moderate the hyper-inflammation associated with ARDS and help patients regain lung function, alleviate the need for ventilator-assisted breathing, and enable faster and more effective recovery.

"We have maintained a good balance sheet to support our current activities. Additionally, we continue to focus on business development activities oriented to further improving the balance sheet, offsetting development costs and risks, and bringing partner capabilities to bear for various development programs," concluded Dr. Van Bokkelen.

Updated Phase 2 Ischemic Stroke Clinical Trial Results

As previously noted, the interim results following the 90-day patient evaluation demonstrated favorable safety and tolerability for MultiStem treatment, consistent with prior studies. With respect to the primary and component secondary endpoints for the intent-to-treat population, the cell therapy did not show a significant difference at 90 days compared to placebo. However, MultiStem treatment was associated with lower rates of mortality and life threatening adverse events, infections and pulmonary events, and also a reduction in hospitalization. Furthermore, a higher proportion of patients receiving MultiStem achieved an "Excellent Outcome," which is defined clinically as the patient achieving excellent recovery in each of the three clinical rating scales, as evidenced by patients achieving a score of mRS ≤1, NIHSS ≤1 and BI ≥95 (p=0.10).

In addition, analyses show that patients who received MultiStem treatment earlier (24-36 hours post-stroke) in the study's treatment window had better recovery in comparison to placebo, and this treatment effect appeared to be more pronounced the earlier the MultiStem administration within this timeframe. For example, at 90 days post-stroke, patients who were treated with MultiStem within 24-36 hours of the stroke (i.e. consistent with our original study design) had much better outcomes compared to placebo patients as measured by the proportion of patients who achieved good or excellent recovery in each of the key secondary endpoints (i.e. Global Recovery), defined as: mRS ≤ 2, NIHSS Δ ≥75% and BI ≥95, with 41.9% of MultiStem-treated patients achieving recovery in all three categories versus only 24.6% of placebo patients, a difference of 17.3% (p=0.08).

Furthermore, additional analyses demonstrate that patients who received treatment with MultiStem within 24-36 hours post-stroke versus patients receiving placebo exhibited even stronger recovery when considering all patients except those that received both tPA and mechanical reperfusion (and who were excluded in the original trial design). Among these patients, 44.4% of MultiStem-treated subjects achieved good or excellent recovery in all three clinical rating scales, whereas only 17.3% of subjects receiving placebo achieved this level of recovery, a difference of 27.1% (p < 0.01), representing a greater than 2.5 fold increase in the number of patients achieving robust recovery.

Comparison of MultiStem (MS) and Placebo (P) Treatments			
At 90 days	**Intent-to-Treat** 65 MS v 61 P	**Early MS treatment** 31 MS v 61 P	**Post-hoc (excludes tPA + MR)** 27 MS v 52 P
Global Recovery (patients achieving mRS≤2, NIHSSΔ≥75% and BI≥95)	MS: 30.8% vs P: 24.6% Δ = 6.2%	MS: 41.9% vs P: 24.6% Δ = 17.3%*	MS: 44.4% vs P: 17.3% Δ = 27.1%**
Excellent Outcome (mRS≤1, NIHSS≤1 and BI≥95)	MS: 15.4% vs P: 6.6% Δ = 8.8%*	MS: 16.1% vs P: 6.6% Δ = 9.5%	MS: 18.5% vs P: 3.8% Δ = 14.7%**
Life threatening AEs / death	MS: 10.8% vs P: 24.6% Δ = (13.8%)	MS: 9.7% vs P: 24.6% Δ = (14.9%)	MS: 11.1% vs P: 26.9% Δ = (15.8%)
Secondary infections	MS: 36.9% vs P: 47.5% Δ = (10.6%)	MS: 16.1% vs P: 47.5% Δ = (31.4%)	MS: 14.8% vs P: 53.8% Δ = (39.0%)
Hospitalization days	MS: 7.9 d vs P: 9.8 d Δ = (1.9 d, 19.4%)	MS: 6.8 d vs P: 9.8 d Δ = (3.0 d, 30.6%)**	MS: 6.7 d vs P: 10.3 d Δ = (3.6 d, 35.0%)**

* p-value ≤ 0.10; ** p-value ≤ 0.05

mRS = modified Rankin Scale; NIHSS = NIH Stroke Scale; and BI = Barthel Index

The MultiStem group also demonstrated substantially better performance in each of the three key individual recovery endpoints, exhibited accelerated improvement (i.e. recovery by 7 and 30 days) in comparison to patients receiving placebo, and were more likely to achieve recovery based on the Global Test Statistic - the primary endpoint (p=0.06). Additionally, as described previously, these MultiStem patients achieved significantly higher rates of Excellent Outcome (p=0.03), and the MultiStem group showed better improvement on the Cochran-Mantel-Haenszel "shift" analysis (p=0.03), which compares performance for the patient groups across the spectrum of mRS outcomes. Hospitalization duration was significantly reduced for the MultiStem-treated patients (35% lower than the average for placebo patients), and the average intensive care unit stay was also meaningfully reduced.

Preliminary analysis of biomarker data obtained from samples of study subjects indicates that MultiStem treatment reduces post-stroke inflammation compared to placebo as evidenced by substantially reduced levels of multiple inflammatory cytokines, including IL-6, IL-12, TNFa and others. Furthermore, results suggest these effects are more pronounced for subjects receiving MultiStem administration within 36 hours. This effect is consistent with the hypothesized mechanisms of action and related preclinical data, and with the clinical data suggesting faster recovery for MultiStem-treated patients. Further analyses of biomarker and clinical data are ongoing.

Second Quarter Financial Results

For the three months ended June 30, 2015, total revenues were $0.2 million compared to $0.4 million in the comparable period in 2014, reflecting a decrease in grant 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 and new business collaborations. The $10 million up-front payment from Chugai is recorded as deferred revenue at June 30, 2015, in accordance with our accounting policy for recognizing revenue for multiple element arrangements. Under the terms of the agreement with Chugai, we may terminate the collaboration in the event that Chugai does not pay us a $7 million milestone payment following its review of the interim results from our Phase 2 ischemic stroke study. This payment is due during the third quarter of 2015, since Chugai was provided with several months to review the study results.

Research and development expenses were $5.3 million for the second quarter of 2015 compared to $5.8 million for the second quarter of 2014. The decrease is comprised of lower clinical and preclinical development costs and sponsored research costs, which were partially offset by higher patent legal fees. General and administrative expenses were relatively consistent at $1.9 million in the second quarter of 2015 compared to $1.8 million in the same period of 2014. The non-cash income from the change in the fair value of our warrant liabilities was $6.0 million in the second quarter of 2015 and $7.9 million in the prior-year period.

Net loss for the three months ended June 30, 2015 was $1.0 million, which included non-cash income of $6.0 million from the warrant valuation and non-cash expense of $0.7 million from stock-based compensation, compared to net income of $0.7 million for the three months ended June 30, 2014, which included non-cash income of $7.9 million from the warrant valuation and non-cash expense of $0.6 million from stock-based compensation.

As of June 30, 2015, we had $32.3 million in cash and cash equivalents and are expecting a $2 million Japanese tax withholding refund, compared to $26.1 million at December 31, 2014. Cash used in operating activities during the second quarter of 2015 was $5.8 million compared to $6.1 million cash used in the second quarter of 2014.

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 6, 2015
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	800-273-1254
Telephone access: International	973-638-3440
Access code	22710390
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 20, 2015 by dialing 800-585-8367 or 855-859-2056 (U.S. and Canada), or 404-537-3406, and entering access code 22710390. 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, including Chugai electing to retain its license by making the required milestone payment to continue our ischemic stroke collaboration in Japan; 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.

(Financial Tables Follow)

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

	June 30, 2015	December 31, 2014
	(Unaudited)	(Note)
Assets		
Cash and cash equivalents	$ 32,346	$ 26,127
Accounts and other receivables	2,382	694
Other current assets	341	427
Equipment, net	1,207	1,270
Other noncurrent assets	203	200
Total assets	**$ 36,479**	**$ 28,718**
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 3,848	$ 4,617
Deferred revenue	10,000	75
Note payable	187	183
Warrant liabilities	1,068	2,948
Total stockholders' equity	21,376	20,895
Total liabilities and stockholders' equity	**$ 36,479**	**$ 28,718**

Note: The Condensed Consolidated Balance Sheet Data at December 31, 2014 has been derived from the audited financial statements as of that date.

Athersys, Inc.
Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income
(In Thousands, Except Per Share Amounts)

	Three Months ended June 30,	
	2015	2014
	(Unaudited)	
Revenues		
Contract revenue	$ 49	$ 36
Grant revenue	167	352
Total revenues	216	388

Costs and Expenses		
Research and development	5,261	5,754
General and administrative	1,924	1,827
Depreciation	65	93
Total costs and expenses	7,250	7,674
Loss from operations	(7,034)	(7,286)
Other income, net	42	42
Income from change in fair value of warrants	5,957	7,919
Net (loss) income and comprehensive (loss) income	**$ (1,035)**	**$ 675**
Net (loss) income per share - Basic	$ (0.01)	$ 0.01
Weighted average shares outstanding- Basic	82,844	77,077
Net loss per share - Diluted	$ (0.05)	$ (0.04)
Weighted average shares outstanding- Diluted	83,562	78,778

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

President and Chief Operating Officer

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Primary Logo

Source: Athersys, Inc.

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