



NEWS RELEASE

Athersys Reports Second Quarter 2019 Results

8/7/2019

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

CLEVELAND, Aug. 07, 2019 (GLOBE NEWSWIRE) -- Athersys, Inc. (NASDAQ: ATHX) announced today its financial results for the three months ended June 30, 2019.

Highlights of the second quarter of 2019 and recent events include:

- Received Fast Track designation from the FDA for our clinical development program involving administration of MultiStem[®] cell therapy for treatment of acute respiratory distress syndrome ("ARDS");
- Presented positive results from the MUST-ARDS study at the American Thoracic Society International Conference in May 2019;
- Announced first patient enrolled in the ONE-BRIDGE study in Japan being conducted by our partner in Japan, HEALIOS K.K. ("Healios"), evaluating MultiStem cell therapy treatment of patients suffering from pneumonia-induced ARDS;
- Advanced our ischemic stroke program, both through support of Healios' TREASURE study in Japan and increased enrollment in our MASTERS-2 Phase 3 registrational study;
- Entered into an open market sales agreement with Jefferies LLC, i.e., an 'at-the-market' equity program, providing additional flexibility and capital markets access as we progress to important milestones;
- Hosted a successful investor day in New York City in May 2019 highlighting our capabilities and technologies, as well as progress made developing the MultiStem product platform;

- Increased our media exposure as we were featured in video, podcasts and articles in the major publications *Fortune* and *Forbes*;
- Participated in several events at the International Society of Cell and Gene Therapy Conference in June 2019, including podium presentations, a panel participation and chairing a session, further establishing the Company as a leader and significant contributor in the field of cell therapy;
- Recognized revenues of \$4.3 million and net loss of \$9.7 million, or \$0.06 net loss per share, for the quarter ended June 30, 2019; and
- Ended the 2019 second quarter with \$44.2 million of cash and cash equivalents.

“We continue to make steady progress in key areas, including advancing our Phase 3 clinical program for treating ischemic stroke, while supporting Healios in the advancement of its TREASURE study for stroke patients and ONE-BRIDGE study for ARDS patients in Japan,” commented Dr. Gil Van Bokkelen, Chairman & CEO at Athersys. “Given our progress in multiple areas, including the recently announced Fast Track designation and promising results from our ARDS clinical program, we are exploring partnering opportunities in several important geographic areas, while we continue to advance our key initiatives and expand core capabilities. This includes continuing to advance our manufacturing activities and initiatives, that we believe will represent a significant competitive advantage as we move into commercialization.

“While we advance our programs through clinical development and toward commercialization, we have also taken prudent and appropriate steps to maintain a solid balance sheet, ensuring we have access to additional capital while we continue to maintain a long-term focus on creating value for our shareholders,” concluded Dr. Van Bokkelen.

Second Quarter Results

Revenues were \$4.3 million for the three months ended June 30, 2019 compared to \$19.4 million for the three months ended June 30, 2018. Revenues from our collaboration with Healios were \$4.2 million in the second quarter of 2019 compared to \$18.8 million for the same period last year, which included the impact of the June 2018 collaboration expansion. Royalty revenue from RTI Surgical, Inc. ceased late in 2018 upon its decision to discontinue distribution of the licensed product. Our revenues are generally derived from license fees, manufacturing-related activities for Healios, other contract revenue from our collaborations and grant revenue.

Research and development expenses increased to \$11.1 million for the three months ended June 30, 2019 from \$10.1 million for the comparable period in 2018. The \$1.0 million net increase is associated with increases in clinical trial and manufacturing process development costs of \$0.7 million, personnel costs of \$0.4 million, internal research supplies of \$0.3 million and stock compensation costs of \$0.2 million, with such increases partially offset by a decrease in license fees of \$0.6 million. Included in our clinical expenses are costs associated with providing manufacturing services to Healios, which are invoiced to Healios in accordance with our collaboration agreements.

General and administrative expenses increased to \$2.9 million for the three months ended June 30, 2019 from \$2.4 million in the comparable period in 2018. The \$0.5 million increase was due primarily to increased personnel costs, legal and professional fees, travel costs and stock compensation costs compared to the same period last year.

Net loss for the second quarter of 2019 was \$9.7 million compared to net income of \$6.9 million in the second quarter of 2018. The variance of \$16.6 million is primarily attributable to the June 2018 expansion of the Healios collaboration.

In the six months ended June 30, 2019, net cash used in operating activities was \$17.0 million compared to \$1.3 million in the six months ended June 30, 2018, with 2018 being impacted by proceeds from the Healios collaboration expansion. At June 30, 2019, we had \$44.2 million in cash and cash equivalents, compared to \$51.1 million at December 31, 2018.

Conference Call

William (B.J.) Lehmann, President and Chief Operating Officer, and Laura Campbell, Senior Vice President of Finance, will host a conference call today to review the results as follows:

Date	August 7, 2019
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	(877) 396-3286
Telephone access: International	(647) 689-5528
Access code	5087881
Live webcast	www.athersys.com , under the Investors section

We encourage shareholders to listen using the webcast link and to use the phone line if you intend to ask a question. A replay will be available at www.athersys.com under the Investors section approximately two hours after the call has ended. Shareholders may also call in for on-demand listening shortly after the completion of the call until 11:59 PM Eastern Time on August 14, 2019 by dialing (800) 585-8367 or (416) 621-4642 and entering Encore passcode 5087881.

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 neurological, inflammatory and immune, cardiovascular, and other critical care indications and has several ongoing clinical trials evaluating this potential regenerative medicine product. Athersys has forged strategic partnerships and a broad network of collaborations to further advance the MultiStem cell therapy toward commercialization. More information is available at www.athersys.com. Follow Athersys on Twitter at www.twitter.com/athersys.

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 therapeutics, including the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues. 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: our ability to raise capital to fund our operations; the timing and nature of results from our MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial and Healios' TREASURE and ONE-BRIDGE clinical trials in Japan; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials of our product candidates; the possibility of delays, work stoppages or interruptions in manufacturing by third parties to us, such as due to material supply constraints, contaminations, or regulatory issues, which could negatively impact our trials and the trials of our collaborators; uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the treatment of stroke, acute respiratory distress syndrome, acute myocardial infarction and trauma, and the prevention of graft-versus-host disease and other disease indications; changes in external market factors; changes in our industry's overall performance; changes in our business strategy; our ability to protect and defend our intellectual property and related business operations, including the successful prosecution of our patent applications and enforcement of our patent rights, and operate our business in an environment of rapid

technology and intellectual property development; our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our ability to meet milestones and earn royalties under our collaboration agreements, including the success of our collaboration with Healios; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements and generate sales related to our technologies; the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in North America, Europe and Japan; 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.

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(Tables Follow)

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

	June 30, 2019	December 31, 2018
	<u>(Unaudited)</u>	<u>(Note)</u>
Assets		
Cash and cash equivalents	\$ 44,237	\$ 51,059
Accounts receivable	80	262
Accounts receivable from Healios, billed and unbilled	2,908	4,728
Prepaid expenses, deposits and other	2,960	2,679
Equipment, net	3,062	3,002
Total assets	<u>\$ 53,247</u>	<u>\$ 61,730</u>
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other	\$ 14,952	\$ 12,801
Deferred revenue and deposits from Healios	2	2,674
Advance from Healios	5,042	3,139
Total stockholders' equity	33,251	43,116
Total liabilities and stockholders' equity	<u>\$ 53,247</u>	<u>\$ 61,730</u>

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) Income
(Unaudited)

(In Thousands, Except Per Share Amounts)

	Three months ended June 30,	
	2019	2018
Revenues		
Contract revenue from Healios	\$ 4,193	\$ 18,755
Royalty and other contract revenue	—	591
Grant revenue	69	45
Total revenues	<u>4,262</u>	<u>19,391</u>
Costs and expenses		
Research and development	11,139	10,093
General and administrative	2,867	2,382
Depreciation	157	191
Total costs and expenses	<u>14,163</u>	<u>12,666</u>
Gain from insurance proceeds	—	20
(Loss) income from operations	<u>(9,901)</u>	<u>6,745</u>
Other income, net	213	188
Net (loss) income and comprehensive (loss) income	<u>\$ (9,688)</u>	<u>\$ 6,933</u>
Net (loss) income per share, basic	\$ (0.06)	\$ 0.05
Weighted average shares outstanding, basic	150,163	138,225
Net (loss) income per share - diluted	\$ (0.06)	\$ 0.05
Weighted average shares outstanding - diluted	150,163	139,375

Source: Athersys, Inc.