Athersys Announces Financial Results for Fourth Quarter and Full Year 2018

March 14, 2019

Substantial progress over the year, advancing programs and expanding collaboration with HEALIOS K.K.

Management to host conference call at 4:30 PM EST today

CLEVELAND, March 14, 2019 (GLOBE NEWSWIRE) -- Athersys, Inc. (NASDAQ: ATHX) announced today its fourth quarter 2018 and annual 2018 financial results and recent highlights.

“As we have announced previously, we had a number of important accomplishments in 2018, including the initiation of our Phase 3 MASTERS-2 study and the expansion of our partnership with Healios. Additionally, we completed enrollment of, and recently announced positive results for, our exploratory clinical study of MultiStem® treatment of acute respiratory distress syndrome patients,” commented Dr. Gil Van Bokkelen, Chairman and Chief Executive Officer of Athersys. “We also finished the year in a meaningfully stronger financial position, which was an important objective.”

Fourth Quarter 2018 and Recent Highlights:

- Announced positive results from our exploratory clinical study of MultiStem cell therapy for treatment of acute respiratory distress syndrome (ARDS), further confirming the tolerability and safety profile of MultiStem treatment and demonstrating trends of lower mortality and greater ventilator-free and ICU-free days; the study has been selected for presentation at the American Thoracic Society International Conference in May 2019;
- Our partner, HEALIOS K.K. (Healios), announced plans to initiate an ARDS trial using MultiStem therapy for patients in Japan, which, if successful could lead to registration under Japan’s regenerative medicine regulatory framework;
- Advanced our ischemic stroke program through continued support of Healios’ Japan TREASURE trial and enrollment of our MASTERS-2 Phase 3 registration study for ischemic stroke;
- Received a $2.0 million payment from Healios for a right of first negotiation through June 2019 for an option to develop and commercialize MultiStem therapy for certain indications in China; Healios may extend the negotiation period through December 2019 with an additional payment of $3.0 million;
- Recognized revenues of $1.5 million and net loss of $11.3 million, or $0.08 net loss per share, for the quarter ended December 31, 2018; and
- Ended 2018 with $51.1 million in cash and cash equivalents and February 28, 2019 with $51.5 million in cash and cash equivalents, reflecting a solid financial foundation.

Other 2018 Highlights:

- Expanded our collaboration with Healios in June 2018 to include additional areas - such as development for the treatment of ARDS in Japan, iPSC and MultiStem cells in combination to treat dysfunction in certain organs in Japan, and potential use of MultiStem cells alone or with RPE cells for certain ophthalmological indications globally - for $20 million in license fees, plus potential milestone payments and royalties; this followed a $21.1 million investment by Healios through the purchase of our common stock in March 2018;
- Commenced the MASTERS-2 Phase 3 registration study for ischemic stroke and started enrolling patients;
- Completed the enrollment of our exploratory clinical study of MultiStem cell therapy treatment for ARDS, and announced positive results soon thereafter as noted above;
- Announced grant funding and began preparations to conduct a Phase 2 clinical trial evaluating MultiStem cell therapy for early treatment and prevention of complications after severe traumatic injury, in collaboration with The University of Texas Health Science Center at Houston and Hermann Memorial Trauma Center;
- Expanded our process development and manufacturing efforts, including strategic leadership hires and diversification in our manufacturing networks; and
- Entered into a new equity facility during the first quarter of 2018 as a follow-on to the existing facility, giving us the right to sell up to $100 million of common stock over a three-year period, providing access to capital, as needed, to support operations.

“We believe we are well-positioned to capitalize on our innovative MultiStem product platform and to develop and deliver highly effective new

treatments to patients in areas of substantial unmet medical need, particularly in the critical care area. The Healios' TREASURE trial and our MASTERS-2 trial are making continued progress, and the results from our exploratory ARDS trial illustrate the potential of MultiStem therapy in other acute care settings. We continue to work toward the scale-up of our manufacturing capabilities and to focus on the further development of other core capabilities and programs, while we continue to explore additional partnering opportunities," concluded Dr. Van Bokkelen.

Fourth Quarter 2018 Financial Results

Revenues increased to $1.5 million for the three months ended December 31, 2018 compared to $1.2 million for the three months ended December 31, 2017. Our revenues are generally derived from license fees, manufacturing-related services for Healios, royalty and related contract revenue from our collaborations, and grant revenue.

Research and development expenses decreased to $10.2 million for the three months ended December 31, 2018 from $12.1 million for the comparable period in 2017. In 2017, approximately $4.7 million of license fees were expensed (of which $3.2 million was non-cash) related to a settlement and license agreement. After factoring in this one-time charge, the net $2.8 million increase is associated with increased clinical development costs of $1.6 million, personnel costs of $0.6 million, internal research supplies of $0.2 million and other expenses of $0.4 million. The $1.6 million increase in our clinical costs during the period is primarily related to clinical product manufacturing, covered in part by Healios, technology transfer services associated with planned Japan manufacturing for Healios, process development activities to support large-scale manufacturing, and our MASTERS-2 clinical trial that began enrolling patients in the third quarter of 2018.

General and administrative expenses increased to $2.8 million for the three months ended December 31, 2018 from $2.1 million in the comparable period in 2017. The $0.7 million increase was due primarily to increases in personnel costs, professional fees, stock compensation costs and other administrative costs compared to the same period last year.

Net loss for the fourth quarter was $11.3 million in 2018 compared to a net loss of $13.1 million in the fourth quarter of 2017. The difference of $1.8 million reflects the above variances, as well as an increase of $0.3 million in other income items.

Full Year 2018 Financial Results

Revenues increased to $24.3 million for the year ended December 31, 2018 from $3.7 million in 2017. Our contract revenues from our collaboration with Healios increased $21.4 million year over year, reflecting the expansion of our collaboration in June 2018 to include additional licensed indications, among other things. Included in our 2018 revenues were royalties and other contract revenues of $1.5 million ($1.9 million in 2017) primarily related to our collaboration with RTI Surgical, Inc., which recently announced that it will cease distribution of its bone graft product that utilizes our technology.

Research and development expenses increased to $38.7 million for the year ended December 31, 2018 from $27.8 million for the year ended December 31, 2017. The increase in research and development expenses year-over-year of $10.9 million related to increases in clinical trial and manufacturing process development costs of $11.4 million, personnel costs of $1.6 million, and internal supply and other costs of $1.6 million. These increases were partially offset by a decrease in license fees of $3.7 million related to the settlement and license agreement in 2017 with one-time payments of cash and stock that concluded in 2018.

General and administrative expenses increased to $10.4 million in 2018 from $8.5 million in 2017. The $1.9 million increase was due primarily to increases in personnel costs, legal and professional services and stock compensation expense.

Net loss was $24.3 million in 2018 compared to a net loss of $32.2 million in 2017. The difference of $7.9 million reflects the above variances, as well as a decrease of $0.1 million in other net expenses.

In the twelve months ended December 31, 2018, net cash used in operating activities was $13.4 million compared to $24.0 million in the twelve months ended December 31, 2017. The difference reflects in part license fees paid by Healios in connection with the collaboration expansion being partially offset by an increase in clinical development activity in 2018.

At December 31, 2018, we had $51.1 million in cash and cash equivalents, compared to $29.3 million at December 31, 2017.

Conference Call

Gil Van Bokkelen, Chairman and Chief Executive Officer, 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	March 14, 2019
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	(877) 396-3286
Telephone access: International	(647) 689-5528
Encore Password (needed for the replay only)	7677927
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 on the webcast 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 March 21, 2019 by dialing (800) 585-8367 or (416) 621-4642 and entering Encore passcode 7677927. The archived webcast will be available for one year at the aforementioned URL.

About Athersys

Athersys is an international biotechnology company engaged in the development of therapeutic products 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, cardiovascular, and inflammatory and immune disease areas, 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

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 the Healios' TREASURE clinical trial 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 work with Healios to reach an agreement for an option in China; 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
(Unaudited)
(In thousands)

	December 31, 2018	2017
Assets		
Cash and cash equivalents	$ 51,059	$ 29,316
Accounts receivable	262	586
Accounts receivable from Healios, billed and unbilled	4,728	153
Prepaid expenses, deposits and other	2,679	1,332
Equipment, net	3,002	2,206
Total assets	**$ 61,730**	**$ 33,593**
Liabilities and stockholders' equity		

Accounts payable and accrued expenses	$ 12,801	$ 9,312
Deposit from Healios	2,000	—
Deferred revenue	674	771
Advance from Healios	3,139	134
Total stockholders' equity	43,116	23,376
Total liabilities and stockholders' equity	**$ 61,730**	**$ 33,593**

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

	Three months ended December 31,		Twelve months ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenues [(1)]				
Contract revenue from Healios	**$ 1,267**	$ 686	**$ 22,276**	$ 918
Royalty and other contract revenue	**158**	269	**1,461**	1,925
Grant revenue	**89**	215	**554**	865
Total revenues	**1,514**	1,170	**24,291**	3,708
Costs and expenses				
Research and development	**10,167**	12,134	**38,656**	27,841
General and administrative	**2,846**	2,075	**10,442**	8,466
Depreciation	**283**	176	**855**	684
Total costs and expenses	**13,296**	14,385	**49,953**	36,991
Gain from insurance proceeds, net	**234**	—	**617**	—
Loss from operations	**(11,548)**	(13,215)	**(25,045)**	(33,283)
Income from change in fair value of warrants	**—**	—	**—**	728
Other income, net	**227**	115	**762**	314
Net loss and comprehensive loss	**$ (11,321)**	$ (13,100)	**$ (24,283)**	$ (32,241)
Net loss per common share — basic and diluted	**$ (0.08)**	$ (0.11)	**$ (0.18)**	$ (0.29)
Weighted average shares outstanding — basic and diluted	**142,315**	119,611	**136,641**	112,053

(1) We adopted Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*, effective January 1, 2018. As a result, the recognized revenue in 2018 is not accounted for on the same basis as the prior years and is not comparable largely due to the timing of revenue recognition.

Source: Athersys, Inc.