



Athersys Reports Third Quarter 2018 Results

November 6, 2018

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

CLEVELAND, Nov. 06, 2018 (GLOBE NEWSWIRE) -- Athersys, Inc. (NASDAQ: ATHX) announced today its financial results for the period ended September 30, 2018.

Highlights of the third quarter of 2018 and recent events include:

- Completed enrollment of our Phase 1/2 study evaluating MultiStem[®] therapy in acute respiratory distress syndrome (ARDS) patients;
- Commenced enrollment of patients in the MASTERS-2 Phase 3 registration study for ischemic stroke;
- Continued to support Healios' ongoing TREASURE study for ischemic stroke in Japan by providing clinical product;
- Extended to December 6, 2018, Healios' option and negotiation period for further expansion of the collaboration, including an exclusive option for a license to develop and commercialize MultiStem therapy in China for certain indications;
- Recognized revenues of \$2.3 million and net loss of \$9.7 million, or \$0.07 net loss per share, for the quarter ended September 30, 2018; and
- Cash and cash equivalents were \$48.0 million at the end of the third quarter.

"We had another solid quarter in the third quarter of 2018 as we advanced key initiatives, reflected by the completion of enrollment in our exploratory clinical trial evaluating administration of MultiStem to patients suffering from ARDS and the initiation of enrollment in the Phase 3 MASTERS-2 study for treating ischemic stroke," commented Dr. Gil Van Bokkelen, Chairman & CEO at Athersys. "We are working collaboratively with Healios in multiple areas, and we further strengthened our core capabilities.

"In addition, we have maintained a solid balance sheet as we continue to implement our strategic plan, working toward the achievement of our key goals on behalf of our shareholders and the patients we are committed to helping," concluded Dr. Van Bokkelen.

Third Quarter Results

Revenues increased to \$2.3 million for the three months ended September 30, 2018 compared to \$0.4 million for the three months ended September 30, 2017. Our revenues are generally derived from license fees, manufacturing-related activities for Healios, royalty and related contract revenue from our collaborations, and grant revenue.

Research and development expenses increased to \$9.5 million for the three months ended September 30, 2018 from \$5.4 million for the comparable period in 2017. The \$4.1 million increase is primarily associated with increased clinical development costs of \$3.0 million, increased personnel costs of \$0.6 million, increased license fees of \$0.2 million and increased internal research supplies and other of \$0.3 million. The \$3.0 million increase in our clinical costs during the period is primarily a result of increased clinical product manufacturing costs, covered in part by Healios, technology transfer services associated with planned Japan manufacturing for Healios, process development activities to support large-scale manufacturing, and costs related to our MASTERS-2 clinical trial that began enrolling patients in the third quarter of 2018.

General and administrative expenses increased to \$2.6 million for the three months ended September 30, 2018 from \$2.1 million in the comparable period in 2017. The \$0.5 million increase was due primarily to increases in professional fees, consulting services, personnel costs and other administrative costs compared to the same period last year.

Net loss for the third quarter was \$9.7 million in 2018 compared to a net loss of \$7.2 million in 2017. The difference of \$2.5 million reflects the above variances, as well as an increase of \$0.2 million in other income.

In the nine months ended September 30, 2018, net cash used in operating activities was \$8.8 million compared to \$17.9 million in the nine months ended September 30, 2017. The difference reflects in part \$15.0 million in license fees paid by Healios in connection with the collaboration expansion and an increase in clinical development activity in 2018. Healios is obligated to make two more license fee payments of \$2.5 million each in December 2018 and March 2019. At September 30, 2018, we had \$48.0 million in cash and cash equivalents, compared to \$29.3 million at December 31, 2017.

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 | Tuesday, November 6th, 2018 |
| Time | 4:30 p.m. (Eastern Time) |

| | |
|-----------------------------------|--|
| Telephone access: U.S. and Canada | 800-273-1254 |
| Telephone access: International | 973-638-3440 |
| Access code | 7396506 |
| 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 November 20, 2018 at the aforementioned URL, or by dialing (800) 585-8367 or (855) 859-2056 in the U.S. and Canada, or from abroad (404) 537-3406, and entering access code 7396506.

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

(In thousands)

| | September 30, 2018 (Unaudited) | December 31, 2017 (Note) |
|--|---|---|
| Assets | | |
| Cash and cash equivalents | \$ 47,967 | \$ 29,316 |
| Accounts receivable | 573 | 586 |
| Accounts receivable – Healios, billed and unbilled | 7,252 | 153 |
| Contractual right to consideration from Healios | 440 | -- |
| Other asset related to Healios | 4,220 | -- |
| Prepaid expenses and other | 2,183 | 1,135 |
| Equipment, net | 3,002 | 2,206 |
| Deposits and other | 892 | 197 |
| Total assets | \$ 66,529 | \$ 33,593 |
| Liabilities and stockholders' equity | | |
| Accounts payable and accrued expenses | \$ 13,747 | \$ 9,312 |
| Deferred revenue | -- | 771 |
| Advances from Healios | 2,445 | 134 |
| Total stockholders' equity | 50,337 | 23,376 |
| Total liabilities and stockholders' equity | \$ 66,529 | \$ 33,593 |

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 (Unaudited)

(In Thousands, Except Per Share Amounts)

| | Three months ended September 30, | |
|---|---|--------------------|
| | 2018 | 2017 |
| Revenues | | |
| Contract revenue from Healios | \$ 1,906 | \$ -- |
| Royalty and other contract revenue | 312 | 179 |
| Grant revenue | 103 | 220 |
| Total revenues | 2,321 | 399 |
| Costs and expenses | | |
| Research and development | 9,545 | 5,441 |
| General and administrative | 2,556 | 2,113 |
| Depreciation | 196 | 177 |
| Total costs and expenses | 12,297 | 7,731 |
| Loss from operations | (9,976 |) (7,332 |
| Other income, net | 236 | 89 |
| Net loss and comprehensive loss | \$ (9,740 |) \$ (7,243 |
| Net loss per share – basic and diluted | \$ (0.07 |) \$ (0.06 |
| Weighted average shares outstanding – basic and diluted | 138,930 | 114,515 |



Source: Athersys, Inc.