NEWS RELEASE

Athersys Reports Third Quarter 2021 Results and Provides Corporate Update

11/15/2021

Positive topline data for ARDS study and completion of enrollment in Japan ischemic stroke study are important milestones for development and potential commercialization of MultiStem® cell therapy

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

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc. (NASDAQ: ATHX) announced today its financial results for the three months ended September 30, 2021 and provided a corporate update.

“The third quarter brought several important milestones in the development and potential commercialization of MultiStem® cell therapy,” stated Mr. William (B.J.) Lehmann, Jr., Interim Chief Executive Officer of Athersys. “First, our partner Healios announced positive topline data from its ONE-BRIDGE acute respiratory distress syndrome (ARDS) study, giving us further confidence in the potential of our cell therapy for the treatment of ARDS and critical care more generally. Second, enrollment has been completed for the Japan TREASURE study of MultiStem treatment for ischemic stroke patients, starting the countdown to the release of pivotal study data in this area. And third, we realigned our collaboration with Healios to put us in the best position to prepare together for commercialization in Japan.

“Additionally, we demonstrated steady progress in our MASTERS-2 study as well as in the steps necessary to establish commercial manufacturing capability,” added Mr. Lehmann. “We look forward to important data readouts ahead of us, our partner’s progress in Japan in the application process for marketing approval, and further development of our commercial capabilities.”

Highlights of the third quarter of 2021 and recent events include:

- Positive topline results from the ONE-BRIDGE study announced by HEALIOS K.K. (Healios). The ONE-BRIDGE study evaluated the Company’s proprietary cell therapy, MultiStem® (HLCM051; invimestrocel), for the treatment of pneumonia-induced and COVID-induced acute respiratory distress syndrome (ARDS) in Japan. Data from the study are consistent with the Company’s MUST-ARDS study results, and analyses of the pooled data of both studies reflect positive benefit trends;
- Completion of TREASURE study enrollment announced by Healios. The TREASURE study is evaluating MultiStem for the treatment of ischemic stroke patients in Japan. Based on the advice from the Pharmaceuticals and Medical Devices Agency (PMDA), in order to avoid any potential bias to the 365-day data (and related secondary endpoints) that could result from unblinding and disclosure of 90-day data (primary endpoint) the decision was made that the 90-day unblinding, data analysis and release would take place after the 365-day data is locked. This will follow the last patient’s one-year follow up visit which Healios expects to occur in March of 2022;
- Improved our collaboration with Healios and optimized the structure of the relationship to help drive commercial success for MultiStem therapy in Japan;
- Steadily progressed our MASTERS-2 study, including the initiation of new sites, including our first sites outside of the U.S.;
- Published additional important research findings covering Multipotent Adult Progenitor Cells (MAPC®) and Treg biology and MAPC mechanisms of action, with references available on the Company’s website;
- Achieved a "Prime" corporate rating from Institutional Shareholder Services Environmental, Social and Governance (ISS ESG) for fulfilling the requirements regarding sustainability performance in the Pharmaceuticals & Biotechnology sector;
- Recognized net loss of $16.2 million, or $0.07 net loss per share, for the quarter ended September 30, 2021; and
- Ended the third quarter with $49.7 million of cash and cash equivalents.

Third Quarter Results

Revenues increased to $4.8 million for the three months ended September 30, 2021 compared to $0.1 million for the three months ended September 30, 2020. Our collaboration revenues currently fluctuate from period to period

based on the delivery of goods and services under our arrangement with Healios.

Research and development expenses decreased to $17.2 million for the three months ended September 30, 2021 from $18.5 million for the comparable period in 2020. The $1.3 million decrease is associated with decreases in clinical trial and manufacturing process development costs of $2.0 million and internal research supplies of $0.6 million. These decreases were partially offset by increases in personnel costs of $0.5 million, facilities costs of $0.4 million and outside service costs of $0.4 million. Our clinical development, clinical manufacturing and manufacturing process development expenses vary over time based on the timing and stage of clinical trials underway, manufacturing campaigns for clinical trials and manufacturing process development projects.

General and administrative expenses decreased to $3.6 million for the three months ended September 30, 2021 from $3.7 million for the comparable period in 2020.

Net loss for the third quarter of 2021 was $16.2 million compared to a net loss of $22.5 million in the third quarter of 2020. The difference primarily results from the above variances.

During the nine months ended September 30, 2021, net cash used in operating activities was $56.9 million compared to $44.5 million in the nine months ended September 30, 2020. At September 30, 2021, we had $49.7 million in cash and cash equivalents, compared to $51.5 million at December 31, 2020.

Conference Call

Members of the management team will host the call as follows:

Date	November 15, 2021
Time	4:30 p.m. EST
Live webcast registration	**Webcast link**
Phone registration	**http://www.directeventreg.com/registration/event/6652068**

We encourage shareholders to listen using the webcast link above. If you would like to dial in using the phone to ask a question, please register for the conference call ahead of time using the call registration link above. Once registered, you will receive the toll-free number, a direct entry passcode and a registrant ID.

A replay of the event will be available on the webcast link 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 approximately three hours after the completion of the call until 11:59 PM EST on November 22, 2021, by dialing (800) 585-8367 or (416) 621-4642 and entering the conference code 6652068.

About Athersys

Athersys is a 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 MultiStem cell therapy toward commercialization. Investors and others should note that we may post information about the Company on our website at **www.athersys.com** and/or on our accounts on Twitter, Facebook, LinkedIn or other social media platforms. It is possible that the postings could include information deemed to be material information. Therefore, we encourage investors, the media and others interested in the Company to review the information we post on our website at **www.athersys.com** and on our social media accounts. 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 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. The following 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: our ability to raise capital to fund our operations, including but not limited to, the timing and nature of results from MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial evaluating the administration of MultiStem for the treatment of ischemic stroke, and the Healios TREASURE and ONE-BRIDGE clinical trials in Japan evaluating the treatment in stroke and ARDS patients, respectively, including the timing of the release of data by Healios from its clinical trials, which could be delayed by, among other things, the regulatory process with the PMDA; the success of our MACOVIA clinical trial evaluating the administration of MultiStem for the treatment of COVID-19 induced ARDS, and the MATRICS-1 clinical

trial being conducted with The University of Texas Health Science Center at Houston evaluating the treatment of patients with serious traumatic injuries; the impact of the COVID-19 pandemic on our ability to complete planned or ongoing clinical trials; the possibility that the COVID-19 pandemic could delay clinical site initiation, clinical trial enrollment, regulatory review and the potential receipt of regulatory approvals, payment of milestones under our license agreements and commercialization of one or more of our product candidates, if approved; the availability of product sufficient to meet commercial demand shortly following any approval, such as in the case of accelerated approval for the treatment of COVID-19 induced ARDS; the impact on our business, results of operations and financial condition from the ongoing and global COVID-19 pandemic, or any other pandemic, epidemic or outbreak of infectious disease in the United States; 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 impact of the COVID-19 pandemic on the production capabilities of our contract manufacturing partners and our MultiStem trial supply chain; the possibility of delays, work stoppages or interruptions in manufacturing by third parties or us, such as due to material supply constraints, contamination, operational restrictions due to COVID-19 or other public health emergencies, labor constraints, regulatory issues or other factors 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 neurological, inflammatory and immune, cardiovascular and other critical care 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; the success of our competitors and the emergence of new competitors; and the risks mentioned elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2020 under Item 1A, "Risk Factors" and our other filings with the SEC. You should not place undue reliance on forward-looking statements contained on our website and/or on our accounts on Twitter, Facebook, LinkedIn or other social media platforms, and we undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2021 (Unaudited)	December 31, 2020 (Note)
Assets		
Cash and cash equivalents	$ 49,671	$ 51,546
Accounts receivable from Healios, billed and unbilled	6,400	89
Prepaid expenses, deposits and other	3,577	4,276
Operating right-of-use assets, net	8,828	648
Property and equipment, net	3,613	3,155
Total assets	$ 72,089	$ 59,714
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other current liabilities	$ 24,751	$ 20,704
Deferred revenue - Healios	2,094	65
Operating lease liabilities	9,579	677
Accounts payable to Healios	1,119	1,705
Advance from Healios	5,199	5,201
Total stockholders' equity	29,347	31,362
Total liabilities and stockholders' equity	$ 72,089	$ 59,714

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,	
	2021	2020
Revenues		
Contract revenue from Healios	$ 4,792	$ 85
Grant revenue	—	1
Total revenues	4,792	86
Costs and expenses		
Research and development	17,162	18,471
General and administrative	3,632	3,700
Depreciation	220	233
Total costs and expenses	21,014	22,404
Loss from operations	(16,222)	(22,318)
Other income (expense), net	45	(225)
Net loss and comprehensive loss	$ (16,177)	$ (22,543)
Net loss per share, basic and diluted	$ (0.07)	$ (0.11)
Weighted average shares outstanding, basic and diluted	229,218	197,343

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