



NEWS RELEASE

Athersys Reports Third Quarter 2020 Results and Provides Corporate Update

11/9/2020

Company announces initiation of MultiStem[®] Phase 2 study led by UTHealth in patients with trauma related inflammation and complications at Memorial Hermann-Texas Medical Center

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

CLEVELAND, Ohio, Nov. 9, 2020 (BUSINESSWIRE) -- Athersys, Inc. (NASDAQ: ATHX) announced today its financial results for the three months ended September 30, 2020 and provided a corporate update.

Highlights of the third quarter of 2020 and recent events include:

- Received Regenerative Medicine Advanced Therapy (RMAT) designation for MultiStem[®] from the U.S. Food and Drug Administration (FDA) for the treatment of acute respiratory distress syndrome (ARDS), a designation enabling additional interactions with the FDA that are focused on expediting development;
- Commenced patient screening for the Phase 2 clinical trial led by The University of Texas Health Science Center at Houston (UTHealth) evaluating MultiStem Administration for Trauma Related Inflammation and Complications (MATRICS-1) in patients at Memorial Hermann-Texas Medical Center, a leading Level 1 Trauma center;

- Further advanced the MACOVIA Phase 2/3 trial evaluating MultiStem administration to patients with COVID-19 induced ARDS and advanced preparations to potentially expand the study to include a broader range of patients with ARDS, including from influenza and other pathogens;
- Advanced the MASTERS-2 ischemic stroke study, reactivating all clinical sites previously impacted by COVID-19 operational disruptions, and adding new sites to the study;
- Received notification that HEALIOS K.K. (Healios), our Japanese partner, completed enrollment of its COVID-19 induced ARDS patient cohort in its ONE-BRIDGE study. Healios has previously stated it intends to complete enrollment of the entire ONE-BRIDGE study and the TREASURE ischemic stroke study by around the end of the year;
- Advanced our partnering negotiations regarding MultiStem for potential commercialization in Europe and other regions of interest;
- Continued key initiatives for establishing commercialization readiness, including supply chain and logistics, process development, manufacturing, branding and other key areas;
- Recognized net loss of \$22.5 million, or \$0.11 net loss per share, for the quarter ended September 30, 2020; and
- Ended the third quarter with \$61.7 million of cash and cash equivalents.

“Despite the continuing chaos created by the ongoing COVID-19 pandemic, we made excellent progress this quarter. Our clinical programs and ongoing partnering negotiations continue to advance, and our efforts to establish commercial readiness in several key areas have also made good progress,” commented Dr. Gil Van Bokkelen, Chairman and CEO of Athersys. “We have maintained a strong financial position while also continuing to build key capabilities that would support our planned transition into commercialization following regulatory approval of our innovative therapies.

“Completing a high value partnership for Europe and potentially other geographies is an important near-term priority, and we are focused on achieving that goal, which will be a key event in the continued evolution of the company,” concluded Dr. Van Bokkelen.

Third Quarter Results

There were revenues of \$0.1 million for the three months ended September 30, 2020 compared to revenues of negative \$0.4 million for the three months ended September 30, 2019, primarily related to our collaboration with Healios. 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 increased to \$18.5 million for the three months ended September 30, 2020 from \$8.9 million for the comparable period in 2019. The \$9.6 million net increase is primarily associated with increases in clinical trial and manufacturing process development costs of \$6.9 million, research supplies of \$1.4 million, and personnel and stock compensation costs of \$0.9 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 increased to \$3.7 million for the three months ended September 30, 2020 compared to \$3.0 million in the comparable period in 2019. The \$0.7 million increase was primarily due to increased personnel and stock compensation costs, outside services and consulting costs.

Net loss for the third quarter of 2020 was \$22.5 million compared to a net loss of \$12.0 million in the third quarter of 2019. The difference primarily results from the above variances.

During the nine months ended September 30, 2020, net cash used in operating activities was \$44.5 million compared to \$25.2 million in the nine months ended September 30, 2019. At September 30, 2020, we had \$61.7 million in cash and cash equivalents, compared to \$35.0 million at December 31, 2019.

Conference Call

Gil Van Bokkelen, Chairman and Chief Executive Officer, Ivor Macleod, Chief Financial Officer, and Karen Hunady, Director of Corporate Communications and Investor Relations will host a conference call today to review the results as follows:

Date	November 9, 2020
Time	4:30 p.m. (Eastern Time)
Live webcast registration	Webcast Link
Phone registration	http://www.directeventreg.com/registration/event/8465606

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.

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 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, our ability to access our traditional financing sources on the same or reasonably similar terms as were available to us before the COVID-19 pandemic; 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; 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 potential receipt of regulatory approvals, payments 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, 2019 under Item 1A, "Risk Factors" and our other filings with the SEC. 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, 2020	December 31, 2019
	(Unaudited)	(Note)
Assets		
Cash and cash equivalents	\$ 61,711	\$ 35,041
Accounts receivable	-	17
Accounts receivable from Healios	141	945
Prepaid expenses, deposits and other	3,942	2,781
Equipment, net	3,069	2,882
Total assets	\$ 68,863	\$ 41,666
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other	\$ 18,230	\$ 11,924
Accounts payable to Healios	1,205	1,068
Deferred revenue - Healios	65	65
Advance from Healios	5,201	5,338
Total stockholders' equity	44,162	23,271
Total liabilities and stockholders' equity	\$ 68,863	\$ 41,666

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,	
	2020	2019
Revenues		
Contract revenue from Healios	\$ 85	\$ (368)
Grant revenue	1	7
Total revenues	<u>86</u>	<u>(361)</u>
Costs and expenses		
Research and development	18,471	8,856
General and administrative	3,700	2,958
Depreciation	233	167
Total costs and expenses	<u>22,404</u>	<u>11,981</u>
Loss from operations	(22,318)	(12,342)
Other (expense) income, net	(225)	327
Net loss and comprehensive loss	<u>\$ (22,543)</u>	<u>\$ (12,015)</u>
Net loss per share, basic and diluted	\$ (0.11)	\$ (0.08)
Weighted average shares outstanding, basic and diluted	197,343	153,096

Source: Athersys, Inc.