NEWS RELEASE

Athersys Announces Financial Results for Fourth Quarter and Full Year 2020

3/25/2021

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

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc. (NASDAQ: ATHX) announced today its fourth quarter 2020 and annual 2020 financial results and recent highlights.

"Despite a difficult operating environment, Athersys has made meaningful progress over the past year," commented Mr. William (B.J.) Lehmann, Interim Chief Executive Officer of Athersys. "We made considerable progress in developing our large-scale manufacturing processes. On the clinical front, we took advantage of the opportunity, with the onset of the COVID-19 pandemic, to accelerate the development of our MultiStem® therapy for ARDS with the launch of the MACOVIA study. The MASTERS-2 study moved forward but at a slower pace than expected. Importantly, we entered into a cooperation agreement with our partner, Healios, to put us on a better path to jointly prepare for potential commercialization of the MultiStem therapy in Japan.

"In 2021, we expect to see the top-line results from both the TREASURE and ONE-BRIDGE studies, the TREASURE study giving us the first look at late-stage clinical trial data for MultiStem treatment of ischemic stroke. We are also working to achieve proof-of-principle for our large-scale manufacturing processes, an important milestone on the way to establishing the capability to serve large potential markets such as ischemic stroke," added Mr. Lehmann.

Fourth Quarter, 2020 and Recent Highlights:

- Assisted HEALIOS K.K. (Healios), our partner in Japan, in its regulatory preparations as it advanced enrollment to near completion in its TREASURE ischemic stroke and ONE-BRIDGE acute respiratory distress syndrome (ARDS) studies;
- Reached a cooperation agreement with Healios to resolve the legal matter between its CEO and Athersys Board member, Dr. Kagimoto, and the Company, and to set the stage for addressing open matters important to continued development, regulatory progress and successful commercialization in Japan following approval;
- Received INN designation for "invimestrocel" as the non-proprietary name for the MultiStem cell therapy and made progress in registering our proprietary brand name for the product candidate;
- Received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA) for MultiStem therapy for the treatment of ARDS;
- Initiated and conducting the MACOVIA study for the treatment of ARDS in COVID-19 patients, and amended the protocol with the FDA to include other pathogen-induced ARDS patients;
- Launched the MATRICS-1 study evaluating MultiStem treatment in severe trauma patients, with the first patient enrolled in the fourth quarter;
- Made important leadership hires in key areas, including Mr. Ivor Macleod as Chief Financial Officer and Ms. Maia Hansen as Senior Vice President, Operations and Supply Chain;
- Appointed four new directors to our board, adding experience and diversity, to help the Company achieve its growth objectives and success;
- Raised gross proceeds of approximately $57.6 million, before deducting the underwriting discount and offering expenses, through an underwritten public offering of 25.6 million shares of common stock, providing additional working capital for key initiatives;
- Recognized revenues of $1.3 million and net loss of $22.2 million, or $0.11 net loss per share, for the quarter ended December 31, 2020; and
- Had $51.5 million in cash and cash equivalents as of December 31, 2020, $61.5 million in cash and cash equivalents as of March 19, 2021.

"We believe deeply in the quality and distinctiveness of our science and technology and the potential to help patients in important critical care areas. Though there are risks ahead of us, we believe we are well-situated to advance our programs and Company over the course of this year," concluded Mr. Lehmann.

Fourth Quarter 2020 Financial Results

Revenues increased to $1.3 million for the three months ended December 31, 2020 compared to $0.3 million for the three months ended December 31, 2019. Our collaboration revenues are primarily derived from our Healios

arrangement. We expect our collaboration revenues to vary over time as we contract with Healios to perform manufacturing services and as we potentially enter into new collaborations.

Research and development expenses increased to $18.7 million for the three months ended December 31, 2020 from $7.6 million for the comparable period in 2019. The $11.1 million increase is primarily associated with clinical trial and manufacturing process development costs, timing of reagent purchases used for our internal process development activities, and personnel costs, including stock compensation expense.

General and administrative expenses increased to $4.3 million for the three months ended December 31, 2020 from $2.4 million in the comparable period in 2019. The $1.9 million increase in the fourth quarter of 2020 over the same period of 2019 was due primarily to increased personnel costs, including stock compensation costs, as well as legal and professional services.

Net loss for the fourth quarter was $22.2 million in 2020 compared to a net loss of $9.9 million in the fourth quarter of 2019. The difference of $12.3 million reflects the above variances, as well as a decrease of $0.3 million in other income items.

Full Year 2020 Financial Results

Revenues decreased to $1.4 million for the year ended December 31, 2020 from $5.6 million in 2019. Our contract revenues from our collaboration with Healios decreased $4.1 million year over year. Our collaboration revenues fluctuate from period-to-period based on new licenses conferred and the delivery of goods and services under our arrangement with Healios.

Research and development expenses increased to $63.0 million for the year ended December 31, 2020 from $39.0 million for the year ended December 31, 2019. The $24.0 million increase in research and development expenses year-over-year was due primarily to increased clinical trial and manufacturing process development costs of $15.0 million, internal research supply costs of $4.2 million, personnel costs of $3.0 million, including stock-based compensation, outside service costs of $0.9 million, and other costs of $0.9 million.

General and administrative expenses increased to $15.9 million in 2020 from $11.4 million in 2019. The $4.5 million increase was due primarily to increases in personnel costs including stock-based compensation, legal and professional services, and other outside services.

Net loss was $78.8 million in 2020 compared to a net loss of $44.6 million in 2019. The difference of $34.2 million reflects the above variances, as well as an increase in other net expenses.

In the twelve months ended December 31, 2020, net cash used in operating activities was $61.8 million compared to $35.3 million in the twelve months ended December 31, 2019. The difference is primarily associated with overall increases in cash usage to fund our clinical development activity in 2020.

At December 31, 2020, we had $51.5 million in cash and cash equivalents, compared to $35.0 million at December 31, 2019.

Conference Call

Members of the management team will host a conference call today to review the results as follows:

Date	March 25, 2021
Time	4:30 p.m. (Eastern Time)
Live webcast registration	**Webcast link**
Phone registration	**http://www.directeventreg.com/registration/event/8674678**

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 an email containing 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 Eastern Time on April 5, 2021, by dialing (800) 585-8367 or (416) 621-4642 and entering the conference code 8674678.

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 the MultiStem cell therapy toward commercialization. More information is available at **http://www.athersys.com**. Follow Athersys on Twitter at **http://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; 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, 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.

(Tables Follow)

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

	December 31, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 51,546	$ 35,041
Accounts receivable from Healios	89	945
Prepaid expenses, deposits and other	4,924	2,798
Property and equipment, net	3,155	2,882
Total assets	$ 59,714	$ 41,666
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other	$ 21,381	$ 11,924
Accounts payable to Healios	1,705	1,068
Deferred revenue - Healios	65	65
Advance from Healios	5,201	5,338
Total stockholders' equity	31,362	23,271
Total liabilities and stockholders' equity	$ 59,714	$ 41,666

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,	
	2020	2019	2020	2019
Revenues				
Contract revenue from Healios	$ 1,270	$ 251	$ 1,432	$ 5,517
Grant revenue	—	36	8	116
Total revenues	1,270	287	1,440	5,633
Costs and expenses				
Research and development	18,661	7,634	62,994	39,045
General and administrative	4,282	2,448	15,888	11,378
Depreciation	245	190	890	698
Total costs and expenses	23,188	10,272	79,772	51,121
Loss from operations	(21,918)	(9,985)	(78,332)	(45,488)
Other (expense) income, net	(288)	62	(433)	906
Net loss and comprehensive loss	$ (22,206)	$ (9,923)	$ (78,765)	$ (44,582)
Net loss per common share — basic and diluted	$ (0.11)	$ (0.06)	$ (0.42)	$ (0.29)
Weighted average shares outstanding — basic and diluted	198,285	157,421	187,472	151,696

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Source: Athersys, Inc.