



NEWS RELEASE

Athersys Reports First Quarter 2020 Results

5/7/2020

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

CLEVELAND, May, 07, 2020 (BUSINESSWIRE) -- Athersys, Inc. (NASDAQ: ATHX) announced today its financial results for the three months ended March 31, 2020.

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

- Received authorization from the U.S. Food and Drug Administration (FDA) to initiate a Phase 2/3 COVID-19 induced acute respiratory distress syndrome (ARDS) clinical trial; completed site initiation and began enrolling patients in this trial referred to as the MACOVIA study;
- Received FDA authorization to initiate a Phase 2 clinical trial with The University of Texas Health Science Center at Houston (UTHealth) titled MultiStem[®] Administration for Trauma Related Inflammation and Complications (MATRICS-1); funded by a grant from the Medical Technology Enterprise Consortium (MTEC) and the Memorial Hermann Foundation;
- Announced positive one-year results from our exploratory clinical study of MultiStem cell therapy for ARDS; MultiStem treated patients reported consistent improvement in quality of life over the one-year evaluation period and showed marked improvements in key clinical metrics, including intensive care unit-free days, ventilator-free days and mortality compared to placebo, especially in patients with pneumonia-induced ARDS;
- Furthered discussions with the Biomedical Advanced Research and Development Authority (BARDA) to establish a collaboration to advance our MultiStem program;

- Appointed Mr. Ivor Macleod as our Chief Financial Officer and Ms. Maia Hansen as Senior Vice President, Operations and Supply Chain, adding their expertise to our leadership team to help plan and execute our strategy as we approach potential product commercialization;
- Initiated new sites for the MASTERS-2 ischemic stroke study while continuing to enroll new patients into the trial;
- Advanced through our Japanese partner, HEALIOS K.K. (Healios), its ARDS and ischemic stroke programs, with Healios disclosing its intent to finish enrollment of both its ONE-BRIDGE ARDS study and its TREASURE stroke study this year;
- Engaged in partnering discussions with companies interested in MultiStem commercialization rights in Europe and other regions;
- Received an additional \$7.0 million investment from Healios resulting from its exercise in full of a warrant to purchase additional shares of Athersys common stock;
- Raised gross proceeds of approximately \$57.6 million, before deducting the underwriting discount and offering expenses, through an underwritten public offering of 25,587,500 shares of common stock, providing additional working capital for general corporate purposes, including the initiation of the MACOVIA trial, further advancement of process development and manufacturing projects, and other key initiatives;
- Recognized net loss of \$15.6 million, or \$0.10 net loss per share, for the quarter ended March 31, 2020; and
- Ended the first quarter with \$32.7 million of cash and cash equivalents, which excludes the impact of the Healios warrant exercise and proceeds from the recent underwritten public offering.

“We have achieved a number of important milestones recently, including obtaining FDA authorization to move two important trials forward. The first of these, the MACOVIA study for treating patients suffering from COVID-19 induced ARDS and related complications, represents our second pivotal trial, alongside our ongoing MASTERS-2 trial evaluating the administration of MultiStem for treating ischemic stroke. Working in collaboration with the FDA and our clinical partners, we were able to get the MACOVIA trial designed, authorized and up and running very quickly, and we thank everyone for their tremendous commitment and effort over the past several months,” commented Dr. Gil Van Bokkelen, Chairman and CEO of Athersys. “In addition, we recently announced authorization to initiate the MATRICS-1 trial for evaluating administration of MultiStem to patients suffering from serious traumatic injury, which is being supported by MTEC, the funding arm of the Department of Defense, and UTHealth. We thank the FDA, MTEC and our clinical collaborators for their support in these advancements.

“Following the successful completion of the recent fundraising and the full exercise of the outstanding warrant by our partner, Healios, we have strengthened our financial position, and are focused on making further progress in our important programs and core capabilities. Despite the

challenging and chaotic environment created by the COVID-19 pandemic, we have maintained our commitment to the advancement of our portfolio of critical care programs and to helping patients in areas of significant unmet clinical need. I'd like to thank each of our employees for their dedication, determination and extraordinary effort," concluded Dr. Van Bokkelen.

First Quarter Results

There were no revenues for the three months ended March 31, 2020 compared to \$1.4 million for the three months ended March 31, 2019. The revenues in the prior period were generated from our collaboration with Healios related to manufacturing services performed. 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 \$12.1 million for the three months ended March 31, 2020 from \$11.4 million for the comparable period in 2019. The \$0.7 million net increase is associated with increases in research supplies of \$0.7 million, personnel costs of \$0.3 million, outside services of \$0.2 million, consulting costs of \$0.1 million, stock compensation costs of \$0.1 million and other research and development costs of \$0.2 million with such increases partially offset by decreases in clinical trial and manufacturing process development 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 \$3.5 million for the three months ended March 31, 2020 compared to \$3.1 million in the comparable period in 2019. The \$0.4 million increase was primarily due to increased personnel costs, outside services and stock compensation costs.

Net loss for the first quarter of 2020 was \$15.6 million compared to a net loss of \$13.0 million in the first quarter of 2019. The difference primarily results from the above variances.

During the three months ended March 31, 2020, net cash used in operating activities was \$12.1 million compared to \$5.5 million in the three months ended March 31, 2019. At March 31, 2020, we had \$32.7 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	May 7, 2020
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	(877) 396-3286
Telephone access: International	(647) 689-5528
Access code	6575418
Live webcast	Webcast link

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 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 May 14, 2020 by dialing (800) 585-8367 or (416) 621-4642 and entering Encore passcode 6575418.

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; our ability to successfully finalize and implement an alliance with BARDA, and the terms of any such alliance, including the amount, if any, of funding that we might receive; the success of our MACOVIA study and MATRICS-1 clinical trial; the timing and nature of results from MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial, the Phase 2 clinical trial conducted by The University of Texas Health Science Center at Houston at the Memorial Hermann-Texas Medical Center evaluating MultiStem cell therapy for the early treatment of traumatic injuries, and the HEALIOS K.K. (Healios) TREASURE and ONE-BRIDGE clinical trials in Japan; 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 possibility of delays, work stoppages or interruptions in manufacturing by third parties or 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 ischemic stroke, ARDS, 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 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 Securities and Exchange Commission. 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)

	March 31, 2020	December 31, 2019
	(Unaudited)	(Note)
Assets		
Cash and cash equivalents	\$ 32,692	\$ 35,041
Accounts receivable	17	17
Accounts receivable from Healios	259	945
Prepaid expenses, deposits and other	3,061	2,781
Equipment, net	3,039	2,882
Total assets	\$ 39,068	\$ 41,666
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other	\$ 13,589	\$ 11,924
Accounts payable to Healios	1,068	1,068
Deferred revenue - Healios	65	65
Advance from Healios	5,338	5,338
Total stockholders' equity	19,008	23,271
Total liabilities and stockholders' equity	\$ 39,068	\$ 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) Income
(Unaudited)
(In Thousands, Except Per Share Amounts)

	Three months ended March 31,	
	2020	2019
Revenues		
Contract revenue from Healios	\$ -	\$ 1,441
Grant revenue	-	4
Total revenues	-	1,445
Costs and expenses		
Research and development	12,095	11,415
General and administrative	3,474	3,106
Depreciation	190	184
Total costs and expenses	15,759	14,705
Loss from operations	(15,759)	(13,260)
Other income, net	115	304
Net loss and comprehensive loss	\$ (15,644)	\$ (12,956)
Net loss per share, basic and diluted	\$ (0.10)	\$ (0.09)
Weighted average shares outstanding, basic and diluted	162,715	145,964

Source: Athersys, Inc.