



NEWS RELEASE

## Athersys Reports Second Quarter 2021 Results

Announced promising topline ARDS results reported by Athersys partner, HEALIOS K.K., from its ONE-BRIDGE study

Advanced partnership with Healios to enhance commercial readiness preparations for MultiStem in Japan

Made continued progress in establishing manufacturing and other capabilities for commercial success

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

CLEVELAND, Ohio, August 9, 2021 (BUSINESSWIRE) -- Athersys, Inc. (NASDAQ: ATHX) announced today its financial results for the three months ended June 30, 2021 and provided a corporate update.

"We are happy about the positive topline results for the ONE-BRIDGE ARDS study in Japan reported by Healios last week," stated Mr. William (B.J.) Lehmann, Jr., Interim Chief Executive Officer of Athersys. "The results are consistent with results from our previous MUST-ARDS trial in the United States and the United Kingdom and provide further support for the potential therapeutic benefit for ARDS patients treated with MultiStem® cell therapy."

"Additionally, we were pleased to announce new agreements with Healios to improve our collaboration as the MultiStem therapy approaches commercialization following potential regulatory approvals in Japan," added Mr. Lehmann. "Healios will take on greater responsibility and investment with respect to product supply in Japan, which we will continue to support, while we deepen our focus on advanced manufacturing technologies and higher volume manufacturing. In

addition, by expanding the scope of the license in Japan, we have created opportunities for both parties to realize additional returns on their investments in this innovative therapy.”

**Highlights of the first quarter of 2021 and recent events include:**

- Partner HEALIOS K.K. (Healios) announced positive topline data from its ONE-BRIDGE clinical trial in Japan evaluating the safety and efficacy of MultiStem cell therapy (HLCM051; invimestrocel) in patients with pneumonia-induced and COVID-induced acute respiratory distress syndrome (ARDS);
- Expanded our partnership with Healios to optimize and better align the collaboration structure to drive the commercial success and therapeutic reach for MultiStem therapy in Japan;
- Published in *Scientific Reports* important new data about the relevance of MultiStem’s mechanism of action in critical care applications – specifically, the role of these cells in promoting regulatory T cell (Treg) differentiation and proliferation and modulation of immune response;
- Advanced our large-scale bioreactor manufacturing platform and initiated efforts to establish GMP production capacity including necessary supply chain and support capabilities;
- Continued to build an experienced, world-class team with important hires in regulatory, supply chain, and operations, including the addition of Mr. James Glover as Senior Vice President of Commercial Manufacturing;
- Recognized net loss of \$22.6 million, or \$0.10 net loss per share, for the quarter ended June 30, 2021; and
- Ended the second quarter with \$56.7 million of cash and cash equivalents.

“We continue to advance our clinical programs with a priority focus on our MASTERS-2 ischemic stroke trial and on the establishment of core capabilities and partnerships necessary for driving commercial success following approval. With important read-outs ahead of us, including Healios’ TREASURE stroke study and our MASTERS-2 study, we are planning and preparing for success,” concluded Mr. Lehmann.

**Second Quarter Results**

There were no revenues for the three months ended June 30, 2021 compared to \$0.1 million for the three months ended June 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 increased to \$17.7 million for the three months ended June 30, 2021 from \$13.8 million for the comparable period in 2020. The \$3.9 million increase is associated with increases in clinical trial and manufacturing process development costs of \$2.6 million, personnel costs of \$0.8 million, facilities costs of \$0.3 million and other costs of \$0.2 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 slightly to \$4.2 million for the three months ended June 30, 2021 from \$4.4 million in the comparable period in 2020. The \$0.2 million decrease was primarily related to decreased stock compensation expense.

Net loss for the second quarter of 2021 was \$22.6 million compared to a net loss of \$18.4 million in the second quarter of 2020. The difference primarily results from the above variances.

During the six months ended June 30, 2021, net cash used in operating activities was \$37.2 million compared to \$24.9 million in the six months ended June 30, 2020. At June 30, 2021, we had \$56.7 million in cash and cash equivalents, compared to \$51.5 million at December 31, 2020.

## Conference Call

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

Date	August 9, 2021
Time	4:30 p.m. (Eastern Time)
Live webcast registration	<a href="#">Webcast Link</a>
Phone registration	<a href="http://www.directeventreg.com/registration/event/5972392">http://www.directeventreg.com/registration/event/5972392</a>

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](http://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 August 16, 2021, by dialing (800) 585-8367 or (416) 621-4642 and entering the conference code 5972392.

## **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<sup>®</sup> 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. More information is available at [www.athersys.com](http://www.athersys.com). Follow Athersys on Twitter at [www.twitter.com/ather](http://www.twitter.com/ather)

## **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, 2020 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.*

**Contacts:**

Ivor Macleod  
Chief Financial Officer  
Tel: (216) 431-9900  
[ir@athersys.com](mailto:ir@athersys.com)

Karen Hunady  
Director of Corporate Communications & Investor Relations  
Tel: (216) 431-9900  
[khunady@athersys.com](mailto:khunady@athersys.com)

David Schull  
Russo Partners, LLC  
Tel: (212) 845-4271 or (858) 717-2310  
[David.schull@russopartnersllc.com](mailto:David.schull@russopartnersllc.com)

(Tables Follow)

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

	<b>June 30, 2021</b>	<b>December 31, 2020</b>
	(Unaudited)	(Note)
<b>Assets</b>		
Cash and cash equivalents	\$ 56,654	\$ 51,546
Accounts receivable from Healios	89	89
Prepaid expenses, deposits and other	4,164	4,276
Operating right-of-use assets, net	9,447	648
Property and equipment, net	2,946	3,155
<b>Total assets</b>	<b>\$ 73,300</b>	<b>\$ 59,714</b>
<b>Liabilities and stockholders' equity</b>		
Accounts payable, accrued expenses and other	\$ 26,091	\$ 20,704
Accounts payable to Healios	1,205	1,705
Deferred revenue - Healios	65	65
Operating Lease Liabilities	9,692	677
Advance from Healios	5,201	5,201
Total stockholders' equity	31,046	31,362
<b>Total liabilities and stockholders' equity</b>	<b>\$ 73,300</b>	<b>\$ 59,714</b>

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)*

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Revenues</b>		
Contract revenue from Healios	-	77
Grant revenue	-	7
Total revenues	-	84
<b>Costs and expenses</b>		
Research and development	17,691	13,767
General and administrative	4,158	4,432
Depreciation	723	222
Total costs and expenses	22,572	18,421
Loss from operations	(22,572)	(18,337)
Other (expense) income, net	(27)	(35)
<b>Net loss and comprehensive loss</b>	<b>\$ (22,599)</b>	<b>\$ (18,372)</b>
Net loss per share, basic and diluted	<b>\$ (0.10)</b>	<b>\$ (0.10)</b>
Weighted average shares outstanding, basic and diluted	<b>222,436</b>	<b>191,317</b>

Source: Athersys, Inc.