



**Athersys**  
i n c. ®

NEWS RELEASE

# Athersys Reports Fourth Quarter and Full Year 2022 Financial Results and Business Highlights

3/31/2023

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc. (NASDAQ: ATNX) today announced financial results for the three and 12 months ended December 31, 2022, and provided a business update.

## Fourth Quarter 2022 and Recent Corporate and Operational Highlights

- Largely completed the company's restructuring initiative with the goal of significantly reducing expenses, conserving cash, improving focus and making Athersys more attractive to potential financial and strategic partners
  - Reduced operating expenses below \$3 million per month, compared with \$7 million per month a year ago
  - Reduced headcount by 70% to 20 FTEs currently
  - Closed ReGenesys, Athersys' animal health-focused division based in Belgium, and sold all related equipment
  - Initiated efforts to sublet the Stow, Ohio facility
  - Reduced and streamlined internal research functions to focus on the pivotal Phase 3 MASTERS-2 clinical trial in ischemic stroke

- Appointed experienced biotechnology and pharmaceutical executive Joseph Nolan to the Board of Directors
- Raised gross proceeds of \$5.5 million in a public offering
- Completed enrollment in cohorts 1 and 2 of MATRICS-1, the investigator-initiated Phase 2 trial evaluating MultiStem in patients following resuscitation from hemorrhagic trauma
- Announced participation in a Request for Proposal process with the Biomedical Advanced Research and Development Authority (BARDA) to explore the use of MultiStem for acute respiratory distress syndrome (ARDS) and other COVID-19 co-morbidities
- Healios announced regulatory agreement on the outline for a clinical trial in Japan with HLCM051 (MultiStem) in patients with pneumonia-induced ARDS, including in patients with COVID-19
- Granted first U.S. patent for the SIFU® ultracold storage technology

## MASTERS-2

- Announced planned amendments to MASTERS-2 clinical trial protocol following a successful Type B meeting with the U.S. Food & Drug Administration (FDA)
  - Proposed modifications establish primary and secondary endpoints that best reflect the full potential benefit of MultiStem treatment for patients with acute, moderate-to-severe ischemic stroke as well as the evolving standard of care
  - Primary endpoint will become mRS shift analysis at Day 365
- Convened a meeting of stroke Key Opinion Leaders (KOLs) to discuss potential changes to the MASTERS-2 trial design, given clinical findings from Healios' TREASURE trial in Japan and comparing data results from our Phase 2 MASTERS-1 study
- Exceeded 50% enrollment in MASTERS-2 and significantly increased the rate of patient enrollment due in part to increased trial site engagement and opening new sites across more geographies, with more sites expected to be activated throughout 2023
  - Three sites in the U.S. and eight or nine sites in Europe are expected to be activated in the first half of 2023

## Management Commentary

"Last year was a transformative year for Athersys that required us to evaluate every aspect of our business," said Dan Camardo, Chief Executive Officer of Athersys. "We have worked diligently to reduce the company's historically large cash burn while prioritizing areas where we can deliver the highest value to patients and shareholders. With a leaner organization, key management and board appointments, and reduced expenses, we entered 2023 in a far stronger position."

"We remain focused on advancing MASTERS-2 in ischemic stroke and look forward to meeting with FDA and EMA

regulators later this month to discuss insights gained from the TREASURE trial conducted in Japan. We also continue to engage with potential global and regional partners to advance MultiStem in ischemic stroke and other potential early-stage indications," he added. "We look forward to updating shareholders throughout the year via public disclosures and periodic business update calls."

## Fourth Quarter 2022 Financial Results

Revenues for the fourth quarter of 2022 were approximately \$0.1 million compared to \$0.7 million for the fourth quarter of 2021. Collaboration revenues fluctuate from period to period based on the delivery of services under the arrangement with Healios. As of September 30, 2022, services under the Healios arrangement were largely complete and were limited to close-out activities.

Research and development expenses were \$10.9 million for the fourth quarter of 2022 compared with \$18.7 million for the comparable period in 2021. The decrease is due to our restructuring efforts which caused a decrease in clinical trial expenses of \$4.2 million, personnel costs of \$2.8 million, legal costs of \$0.04 million and \$0.4 million of other costs.

General and administrative expenses were \$2.8 million for the fourth quarter of 2022, compared with \$3.4 million for the comparable period in 2021. The decrease is primarily related to our restructuring efforts which caused a decrease in personal costs of \$0.8 million. This decrease was partially offset by an increase in legal and professional fees of \$0.3 million.

Net loss for the fourth quarter of 2022 was \$13.0 million, or \$0.83 per share, compared with a net loss of \$21.7 million, or \$2.29 per share, for the comparable period in 2021.

## Full Year 2022 Financial Results

Revenues were \$5.3 million and \$5.5 million for 2022 and 2021, respectively, a decrease of \$0.2 million, or 3.6%, reflecting the completion of services under the Healios arrangement.

Research and development expenses decreased to \$65.0 million for the year ended December 31, 2022 from \$71.1 million for the year ended December 31, 2021. The decrease in research and development expenses year-over-year of \$6.1 million is related primarily to our restructuring plan which resulted in decreased clinical trial costs of \$1.9 million, legal costs of \$1.0 million, and personnel costs of \$3.0 million, including stock-based compensation expense, and other expense of \$0.2 million. Based on our current restructuring plans, we expect our 2023 annual research and development expenses to be lower compared to 2022, and such costs will vary over time based on clinical manufacturing campaigns, the timing and stage of clinical trials underway, manufacturing process

development projects and regulatory initiatives. These variations in activity level may also impact our accounts payable, accrued expenses and prepaid expenses balances from period-to-period. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

General and administrative expenses decreased to \$15.9 million in 2022 from \$20.1 million in 2021. The \$4.2 million decrease year-over-year is related primarily to our restructuring plan which resulted in decreased personnel costs of \$3.3 million. Additionally, legal costs of \$2.3 million decreased due to the legal costs around the Comprehensive Framework that occurred in 2021 but not in 2022. These decreases were partially offset by increases in outside service and consulting expenses of \$1.1 million and facility expense of \$0.3 million.

Net loss was \$72.5 million, or \$6.07 per share, and \$87.0 million, or \$9.69 per share, for 2022 and 2021, respectively.

Net cash used in operating activities was \$59.0 million in 2022 compared to \$76.2 million in 2021. As of December 31, 2022, Athersys had \$9.0 million in cash and cash equivalents, compared to \$37.4 million as of December 31, 2021.

In lieu of a fourth quarter earnings conference call, we will hold a business update call in late April. Details for this call will be announced separately at a later date.

## 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, 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](http://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](http://www.athersys.com) and on our social media accounts. Follow Athersys on Twitter at [www.twitter.com/athersys](http://www.twitter.com/athersys). Information that we may post about the Company on our website and/or on our accounts on Twitter, Facebook, LinkedIn or other social media platforms may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. 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.

## 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. In addition, 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 risk that we will be unable to raise capital to fund our operations in the near term and long term, including our ability to obtain funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, on terms acceptable to us or at all, and to continue as a going concern and our ability to successfully resolve the payment issues with our primary contract manufacturer and gain access to our clinical product. 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 in the near term and long term, including our ability to obtain funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, on terms acceptable to us or at all, and to continue as a going concern; our ability to successfully license our SIFU technology; our ability to successfully resolve the payment issues with our primary contract manufacturer and gain access to our clinical product our collaborators' ability and willingness to continue to fulfill their obligations under the terms of our collaboration agreements and generate sales related to our technologies; the possibility of unfavorable results from ongoing and additional clinical trials involving MultiStem; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in an early stage clinical trial may not be predictive of results in later stage or large scale clinical trials; our ability to regain compliance with the Nasdaq continued listing requirements; 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 effect of amendments to its clinical trial protocol; our ability to meet milestones and earn royalties under our collaboration agreements, including the success of our collaboration with Healios; the success of our MACOVIA clinical trial evaluating the administration of MultiStem for the treatment of ARDS induced by COVID-19 and other pathogens, 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 availability of product sufficient to meet our clinical needs and potential commercial demand following any approval; 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, contamination, operational restrictions due to COVID-19 or other public health emergencies, labor constraints, regulatory issues or other factors that 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; the success of our efforts to enter into new strategic partnerships and advance our programs; 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, 2022 under Item 1A, "Risk Factors" and our other filings with the SEC. You should not place undue reliance on forward-looking statements, 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,	
	2022	2021
<b>Assets</b>		
Cash and cash equivalents	\$ 9,038	\$ 37,407
Accounts receivable from Healios, billed and unbilled	716	4,414
Prepaid expenses, deposits and other	5,917	5,711
Operating right-of-use assets, net	7,846	8,960
Property and equipment, net	4,214	3,692
<b>Total assets</b>	<b>\$ 27,731</b>	<b>\$ 60,184</b>
<b>Liabilities and stockholders' equity</b>		
Accounts payable, accrued expenses and other current liabilities	\$ 37,164	\$ 24,391
Deferred revenue - Healios	—	3,340
Operating lease liabilities	8,685	9,766

Warrant liabilities	534	—	—
Accounts payable to Healios	—	1,119	—
Advance from Healios	5,199	5,199	—
Total stockholders' equity	(23,851)	16,369	—
Total liabilities and stockholders' equity	<u>\$ 27,731</u>	<u>\$ 60,184</u>	—

---

**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,	
	2022	2021	2022	2021
<b>Revenues</b>				
Contract revenue from Healios	\$ 32	\$ 722	\$ 5,325	\$ 5,514
Grant revenue	—	—	—	—
Total revenues	32	722	5,325	5,514
<b>Costs and expenses</b>				
Research and development	10,869	18,719	65,031	71,080
General and administrative	2,885	3,438	15,883	20,065
Depreciation	(62)	240	1,420	1,427
Total costs and expenses	13,692	22,397	82,335	92,572
Loss from operations	(13,660)	(21,675)	(77,010)	(87,058)
Other income (expense), net	659	(36)	4,475	103
Net loss and comprehensive loss	<u>\$ (13,001)</u>	<u>\$ (21,711)</u>	<u>\$ (72,535)</u>	<u>\$ (86,955)</u>
Net loss per common share — basic and diluted	\$ (0.83)	\$ (2.29)	\$ (6.07)	\$ (9.69)
Weighted average shares outstanding — basic and diluted	15,709	9,475	11,945	8,971

Athersys

Ellen Gurley

Manager of Corporate Communications and Investor Relations

[ir@athersys.com](mailto:ir@athersys.com)

LHA Investor Relations

Tirth T. Patel

212-201-6614

[tpatel@lhai.com](mailto:tpatel@lhai.com)

Source: Athersys, Inc.