NEWS RELEASE

Athersys Reports First Quarter 2023 Financial Results and Business Highlights

5/18/2023

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc. (NASDAQ: ATHX), a regenerative medicine company developing MultiStem® (invimestrocel) cell therapy for critical care indications, announced on Monday, May 15th financial results for the three months ended March 31, 2023 and provided a business update.

First Quarter 2023 and Recent Corporate and Operational Highlights

- Continued reducing expenses to conserve cash and heightened focus on MASTERS-2 trial, thereby making Athersys more attractive to potential financial and strategic partners
- Maintained operating expenses below $2.5 million per month
- Raised $3.7 million through a registered direct offering with institutional investors
- Appointed biotechnology and pharmaceutical executive Joseph Nolan to the Board of Directors
- Participated in Request for Proposal (RFP) process with the Biomedical Advanced Research and Development Authority (BARDA) for a proposed clinical trial with MultiStem for acute respiratory distress syndrome (ARDS) and other COVID-19 co-morbidities
- Completed DSMB review of cohort 1 & 2 of MATRICS trauma trial using both cell factory and bioreactor manufactured clinical product

- Awarded a U.S. patent for the novel SIFU® cryogenic storage system, the Company's user-friendly system to improve storage and handling of cryogenic products in hospital settings

MASTERS-2

- Amended the clinical trial protocol reflecting modifications proposed during a Type B meeting with the U.S. FDA that best reflect the potential benefits of MultiStem in treating acute, moderate-to-severe, ischemic stroke; protocol modifications include:
    - Primary endpoint assessed by shift analysis in modified Rankin Scale (mRS) score was changed to Day 365, from Day 90 previously
    - Shift analysis in mRS score at Day 90 is retained as a key secondary endpoint
    - Eligibility caps on concomitant reperfusion therapy (e.g., tPA, MR or tPA+MR) were removed to ensure the study population appropriately reflects the evolving standard of care in ischemic stroke treatment
    - Added the option to conduct an interim analysis for powering to confirm 300 patient sample size is adequate to achieve statistical significance with new primary endpoint

Medical Affairs

- Athersys executives participated in several industry conferences to build awareness of Athersys and share clinical and manufacturing progress achieved with MultiStem, including:
    - Advanced Therapies Week presented by Phacilitate
    - 2nd Allogeneic Cell Therapies Summit Europe
    - International Stroke Conference 2023
    - BioProcess International US West
    - The American Society for Neural Therapy and Repair Annual Conference
    - Cellular Therapies and Transfusion Medicine in Trauma and Critical Care Conference

Management Commentary

"We entered 2023 with greater clarity and confidence on our path forward with MultiStem, having largely completed a significant restructuring in the second half of last year that reduced our operating expenses below $2.5 million per month. In addition, achieving a successful Type B meeting with the FDA on proposed MASTERS-2 trial modifications will now more appropriately represent the regenerative benefits of MultiStem over a longer period and reflect changes we've observed in ischemic stroke standard of care. We've also made meaningful progress with trial enrollment and advanced conversations with multiple parties exploring business development opportunities with MultiStem as well as our animal health franchise and SIFU," said Dan Camardo, Chief Executive Officer of Athersys. "We have more work to do, but I'm encouraged by the progress we've made and the catalysts we are working toward in the coming year."

First Quarter Results

There was no revenue for the first quarter of 2023 compared with $2.9 million for the first quarter of 2022, which included the delivery of services under the arrangement with Healios. As of September 30, 2022, services under this arrangement were largely complete and were limited to close-out activities.

Research and development expenses were $4.5 million for the first quarter of 2023 compared with $20.9 million for the comparable period in 2022. The decrease reflects our restructuring plan which resulted in reduced clinical trial expenses which includes personnel, manufacturing and other costs.

General and administrative expenses were $2.8 million for the first quarter of 2023 compared with $4.1 million for the comparable period in 2022, with the decrease primarily due to the restructuring. The Company expects further decreases in general and administrative expenses.

Net loss for the first quarter of 2023 was $7.8 million, or $0.43 per share, compared with a net loss of $22.2 million, or $2.27 per share, for the comparable period in 2022.

Cash and cash equivalents were $3.1 million as of March 31, 2023 compared with $9.0 million as of December 31, 2022.

About MultiStem®

MultiStem® (invimestrocel) cell therapy is a patented regenerative medicine product in clinical development that has shown the ability to promote tissue repair and healing in a variety of ways, such as through the production of therapeutic factors in response to signals of inflammation and tissue damage. MultiStem therapy’s potential for multidimensional therapeutic impact distinguishes it from traditional biopharmaceutical therapies focused on a single mechanism of benefit. The therapy represents a unique "off-the-shelf" stem cell product that can be manufactured in a scalable manner, may be stored for years in frozen form, and is administered without tissue matching or the need for immune suppression. Based upon its efficacy profile, its novel mechanisms of action, and a favorable and consistent tolerability demonstrated in clinical studies, we believe that MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need.

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** 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** and on our social media accounts. Follow Athersys on Twitter at **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; 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, 2021 under Item 1A, "Risk Factors" and our other lings 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
(In thousands)

	March 31, 2023 (Unaudited)	December 31, 2022 (Note)
Assets		
Cash and cash equivalents	$ 3,121	$ 9,038
Accounts receivable from Healios, billed and unbilled	716	716
Prepaid expenses, deposits and other	3,999	3,781
Operating right-of-use assets, net	7,591	7,846
Property and equipment, net	4,079	4,214
Deposits and other	2,126	2,136
Total assets	$ 21,632	$ 27,731
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other current liabilities	$ 37,844	$ 37,164
Operating lease liabilities	8,437	8,685
Warrant liability	1,163	534
Advance from Healios	5,199	5,199
Other long-term liabilities	—	—
Total stockholders' equity	(31,011)	(23,851)
Total liabilities and stockholders' equity	$ 21,632	$ 27,731

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 March 31,	
	2023	2022
Revenues		
Contract revenue from Healios	$ —	$ 2,912
Total revenues	—	2,912
Costs and expenses		
Research and development	4,467	20,944
General and administrative	2,815	4,099
Depreciation	52	247
Total costs and expenses	7,334	25,290
Loss from operations	(7,334)	(22,378)
Other income, net	(477)	162
Net loss and comprehensive loss	$ (7,811)	$ (22,216)
Net loss per share, basic and diluted	$ (0.43)	$ (2.27)
Weighted average shares outstanding, basic and diluted	18,292	9,768

Athersys

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Source: Athersys, Inc.