



NEWS RELEASE

Athersys Reports Second Quarter 2020 Results

8/10/2020

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

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc. (NASDAQ: ATHX) announced today its financial results for the three months ended June 30, 2020.

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

- Initiated and advanced enrollment in the Phase 2/3 COVID-19 induced acute respiratory distress syndrome (ARDS) clinical trial (the MACOVIA study) and currently evaluating the safety, tolerability and dose levels of MultiStem® cell therapy in this indication;
- Continued interactions with the Biomedical Advanced Research and Development Authority (BARDA) regarding a potential collaboration;
- HEALIOS K.K. (Healios), our Japanese partner, enrolled the first COVID-19 induced ARDS patient in its ONE-BRIDGE arm and continues to advance this study and the TREASURE stroke study, both studies expected to complete enrollment in Q4 of 2020;
- Following the authorization from the Food and Drug Administration (FDA) and the Institutional Review Board (IRB) approval, The University of Texas Health Science Center at Houston (UTHealth) submitted the protocol for the Phase 2 clinical trial evaluating MultiStem Administration for Trauma Related Inflammation and

Complications (MATRICS-1) to the Human Research Protection Office (HRPO) for approval to initiate this important trial;

- Advanced our partnering discussions with companies interested in MultiStem commercialization rights in Europe and other regions;
- Participated in several events throughout the second quarter, including the Bank of America Healthcare Conference, the Alliance for Regenerative Medicine webinar, the International Society of Cell & Gene Therapy, and a CEO round table at LifeScience Leader, and participated in several media interviews and podcasts;
- Continued to advance the enrollment of the MASTERS-2 ischemic stroke study despite the impacts of COVID-19;
- New research coverage initiated by covering analysts at Bank of America and SMBC Nikko Securities;
- Advanced manufacturing technical transfer operations and bioreactor scaling to prepare for commercial readiness;
- Successfully attracted new talent and added new employees to the dedicated staff to help meet the corporate goals; including Mr. Ivor Macleod as Chief Financial Officer and Ms. Maia Hansen as Senior Vice President and Head of Operations and Supply Chain;
- 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 \$18.4 million, or \$0.10 net loss per share, for the quarter ended June 30, 2020; and
- Ended the second quarter with \$80.7 million of cash and cash equivalents.

“Over the past quarter, we have made additional progress in our key clinical programs, partnering discussions and efforts regarding the establishment of key infrastructure to support our planned transition to becoming a commercial stage company. While the COVID-19 pandemic continues to have a global impact and has impacted many patients and their families, as well as disrupted operations and clinical trials for many companies, we have continued to move forward and are in the strongest financial position in the history of the Company,” commented Dr. Gil Van Bokkelen, Chairman and CEO of Athersys. “We remain focused on supporting our partner Healios while it approaches completion of enrollment in both the TREASURE and ONE-BRIDGE trials in Japan, while we advance towards the establishment of new alliances in other key geographies, including Europe.

“A major focus for the Company in 2020 has been to advance our planning and preparation related to the establishment of infrastructure that will support our commercialization objectives, as well as the addition and integration of personnel and capabilities that will support the evolution. Despite the challenges posed by the COVID-19 pandemic, we are on track to achieve our core objectives in the second half of the year,” concluded Dr. Van Bokkelen.

Second Quarter Results

Revenues were \$0.1 million for the three months ended June 30, 2020 compared to \$4.3 million for the three months ended June 30, 2019. The revenues in both periods were primarily 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 \$13.8 million for the three months ended June 30, 2020 from \$11.1 million for the comparable period in 2019. The \$2.7 million net increase is associated with increases in clinical trial and manufacturing process development costs of \$0.8 million, research supplies of \$0.5 million, stock compensation costs of \$0.5 million, personnel costs of \$0.3 million, outside services of \$0.3 million and other research and development costs of \$0.3 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 \$4.4 million for the three months ended June 30, 2020 compared to \$2.9 million in the comparable period in 2019. The \$1.5 million increase was primarily due to increased personnel costs, outside services, professional fees, consulting costs and stock compensation costs.

Net loss for the second quarter of 2020 was \$18.4 million compared to a net loss of \$9.7 million in the second quarter of 2019. The difference primarily results from the above variances.

During the six months ended June 30, 2020, net cash used in operating activities was \$24.8 million compared to \$17.0 million in the six months ended June 30, 2019. At June 30, 2020, we had \$80.7 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	August 10, 2020
Time	4:30 p.m. (Eastern Time)
Live webcast registration	Webcast Link
Phone registration	Call Registration Link

We encourage shareholders to listen using the webcast link above, also available on www.athersys.com under the Investors section. 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 be provided the call details and a registrant ID.

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, 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; 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 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
(In thousands)

	June 30, 2020 (Unaudited)	December 31, 2019 (Note)
Assets		
Cash and cash equivalents	\$ 80,707	\$ 35,041
Accounts receivable	24	17
Accounts receivable from Healios	96	945
Prepaid expenses, deposits and other	2,446	2,781
Equipment, net	3,163	2,882
Total assets	\$ 86,436	\$ 41,666
Liabilities and stockholders' equity		
Accounts payable, accrued expenses and other	\$ 15,787	\$ 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	64,178	23,271
Total liabilities and stockholders' equity	\$ 86,436	\$ 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
(Unaudited)
(In Thousands, Except Per Share Amounts)

	Three months ended June 30,	
	2020	2019
Revenues		
Contract revenue from Healios	\$ 77	\$ 4,193
Grant revenue	7	69
Total revenues	84	4,262
Costs and expenses		
Research and development	13,767	11,139
General and administrative	4,432	2,867
Depreciation	222	157
Total costs and expenses	18,421	14,163
Loss from operations	(18,337)	(9,901)
Other income (expense), net	(35)	213
Net loss and comprehensive loss	\$ (18,372)	\$ (9,688)
Net loss per share, basic and diluted	\$ (0.10)	\$ (0.06)
Weighted average shares outstanding, basic and diluted	191,317	150,163

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200810005662/en/): <https://www.businesswire.com/news/home/20200810005662/en/>

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Source: Athersys, Inc.