



Athersys Reports Second Quarter 2018 Results

August 7, 2018

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

CLEVELAND, Aug. 07, 2018 (GLOBE NEWSWIRE) -- Athersys, Inc. (NASDAQ: ATHX) announced today its financial results for the three months ended June 30, 2018.

Highlights of the second quarter of 2018 and recent events include:

- Announced the completion of an expansion of our collaboration with HEALIOS K.K. ("Healios") in June 2018 to develop and commercialize additional indications for \$20 million in license fees, plus potential payments and royalties, which followed a \$21.1 million investment by Healios in the Company's common stock in March 2018;
- Granted to Healios a time-limited first right of negotiation for an exclusive option for a license to develop and commercialize MultiStem® therapy in China for several indications;
- Launched the MASTERS-2 Phase 3 registration study for ischemic stroke and enrolled initial patients into the study;
- Continued to support the enrollment of Healios' ongoing TREASURE study for ischemic stroke in Japan by providing clinical product;
- Made several strategic hires, including Greg Liposky as Senior Vice President of Commercial Manufacturing to lead the execution of our manufacturing strategy;
- Progressed Phase 1/2 study evaluating MultiStem therapy in acute respiratory distress syndrome (ARDS) patients, nearing enrollment completion;
- Announced the award of a grant from the Medical Technology Enterprise Consortium (funded through the Department of Defense) to The University of Texas Health Science Center at Houston and Hermann Memorial Trauma Center to conduct a Phase 2 clinical trial evaluating MultiStem cell therapy for early treatment and prevention of complications after severe traumatic injury;
- Recognized revenues of \$19.4 million for the quarter ended June 30, 2018 and net income of \$6.9 million, or \$0.05 per diluted share; and
- Ended the second quarter with \$53.4 million of cash and cash equivalents.

"We finished the second quarter in a strong financial position, following the successful recent expansion of our partnership with Healios. We continue to explore additional partnering opportunities," commented Dr. Gil Van Bokkelen, Chairman & CEO at Athersys. "Just as importantly, we have achieved the goal of initiating our Phase 3 MASTERS-2 trial evaluating the treatment of patients that have suffered a debilitating ischemic stroke, and we are pleased to report the trial is off to a strong start.

"The recent addition of key members to the organization underscores our commitment to systematically establishing the capabilities necessary to enable us to fulfill our vision of becoming a leading biopharma company. We're very pleased with the talented individuals and leadership that have joined the company, and we look forward to working together to achieve our goals," concluded Dr. Van Bokkelen.

Second Quarter Results

Revenues increased by \$18.7 million to \$19.4 million for the three months ended June 30, 2018 compared to \$0.7 million for the three months ended June 30, 2017. Our revenues are derived from license fees, manufacturing-related activities for Healios, royalty and other contract revenue, and grant revenue. Our revenue from Healios increased during the second quarter of 2018 compared to the prior year second quarter by approximately \$18.5 million due to the collaboration expansion in June 2018, which included several additional licensed indications.

Research and development expenses increased to \$10.1 million for the three months ended June 30, 2018 from \$4.6 million in the comparable period in 2017. The \$5.5 million increase is primarily comprised of an increase in preclinical and clinical development costs of \$4.4 million, an increase in license fees of \$0.6 million, an increase in personnel costs of \$0.2 million, and an increase in internal research supplies and other research costs of \$0.3 million. The increase in our clinical and preclinical costs during the period is primarily a result of increased clinical product manufacturing costs, a portion of which are invoiced to Healios, technology transfer services performed on Healios' behalf in Japan that are reimbursed to us by Healios, start-up contractual costs related to our MASTERS-2 clinical trial, and process development activities to support large-scale manufacturing.

General and administrative expenses increased to \$2.4 million for the three months ended June 30, 2018 from \$2.2 million in the comparable period in 2017. The \$0.2 million increase was due primarily to increases in professional fees, consulting services, personnel costs and other administrative costs compared to the same period last year.

Net income for the second quarter was \$6.9 million in 2018 compared to a net loss of \$6.3 million in 2017. The difference of \$13.2 million reflects the

above variances, as well as an increase of \$0.2 million in other items.

Net cash provided by operating activities was \$4.4 million in the three months ended June 30, 2018 and net cash used by operating activities was \$5.7 million in the three months ended June 30, 2017, reflecting the receipt of \$12.5 million of license fees from our expansion with Healios, partially offset by an increase in the use of cash to fund preclinical and clinical development activities. Of the \$20 million of license fees related to the June 2018 expansion with Healios, we will receive the remaining \$7.5 million from Healios over the next three quarters. At June 30, 2018, we had \$53.4 million in cash and cash equivalents, compared to \$29.3 million at December 31, 2017.

Conference Call

Laura Campbell, Senior Vice President of Finance and William (B.J.) Lehmann, President and Chief Operating Officer, will host a conference call today to review the results as follows:

Date	Tuesday, August 7th, 2018
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	800-273-1254
Telephone access: International	973-638-3440
Access code	5144048
Live webcast	www.athersys.com , under the Investors section

A replay will be available for on-demand listening shortly after the completion of the call until 11:59 PM Eastern Time on August 21st, 2018 at the aforementioned URL, or by dialing (800) 585-8367 or (855) 859-2056 in the U.S. and Canada, or from abroad (404) 537-3406, and entering access code 5144048.

About MultiStem®

MultiStem® 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 produced 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 safety profile demonstrated in clinical studies, 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 an international biotechnology company engaged in the development of therapeutic products 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, cardiovascular, and inflammatory and immune disease areas, 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. Follow Athersys on Twitter at [www.twitter.com/athersys](https://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 that could cause actual results to differ materially from those implied by forward-looking statements 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. These risks 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. Other important factors to consider in evaluating our forward-looking statements include: our ability to raise capital to fund our operations; the timing and nature of results from our MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial and the Healios' TREASURE clinical trial in Japan; 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 to us, such as due to material supply constraints, contaminations, or regulatory issues; uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the treatment of stroke, acute respiratory distress syndrome, 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 work with Healios to reach an agreement for an option in China; 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; 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; and the success of our competitors and the emergence of new competitors. 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.

ATHX-G

Contact:

William (B.J.) Lehmann
President and Chief Operating Officer
Tel: (216) 431-9900
bilehmann@athersys.com

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

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

(Tables Follow)

Athersys, Inc.

Condensed Consolidated Balance Sheets

(In thousands)

	June 30, 2018 (Unaudited)	December 31, 2017 (Note)
Assets		
Cash and cash equivalents	\$ 53,353	\$ 29,316
Accounts receivable	545	586
Accounts receivable – Healios, billed and unbilled	8,832	153
Contract assets related to Healios	4,254	--
Prepaid expenses and other	2,480	1,135
Equipment, net	2,578	2,206
Other noncurrent assets	866	197
Total assets	\$ 72,908	\$ 33,593
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	\$ 14,678	\$ 9,312
Deferred revenue and other	--	771
Advances from Healios	1,981	134
Total stockholders' equity	56,249	23,376
Total liabilities and stockholders' equity	\$ 72,908	\$ 33,593

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 Income (Loss) (Unaudited)

(In Thousands, Except Per Share Amounts)

	Three months ended June 30, 2018	2017
Revenues		
Contract revenue from Healios	\$ 18,755	\$ 239
Royalty and other contract revenue	591	210
Grant revenue	45	220
Total revenues	19,391	669
Costs and expenses		
Research and development	10,093	4,633

General and administrative	2,382	2,207	
Depreciation	191	167	
Total costs and expenses	12,666	7,007	
Gain from insurance proceeds	20	--	
Income (loss) from operations	6,745	(6,338	)
Other income, net	188	71	
Net income (loss) and comprehensive income (loss)	\$ 6,933	\$ (6,267	)
Net income (loss) per share – Basic	0.05		
	\$	\$ (0.06	)
Weighted average shares outstanding – Basic	138,225	111,820	
Net income (loss) per share – Diluted			
	\$ 0.05	\$ (0.06	)
Weighted average shares outstanding – Diluted	139,375	111,820	

 [Primary Logo](#)

Source: Athersys, Inc.