ATHERSYS, INC / NEW

FORM 8-K
(Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 9, 2016

Athersys, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-33876	20-4864095
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3201 Carnegie Avenue, Cleveland, Ohio	44115-2634
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (216) 431-9900

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On November 9, 2016, Athersys, Inc. issued a press release announcing financial results for its third quarter ended September 30, 2016. A copy of this press release is attached hereto as Exhibit 99.1.

The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished to the Securities and Exchange Commission and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. Furthermore, the information contained in Item 2.02 of this Current Report on Form 8-K shall not be deemed to be incorporated by reference into any registration statement or other document filed pursuant to the Securities Act of 1933.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Press Release dated November 9, 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 9, 2016

ATHERSYS, INC.

By: /s/ Laura K. Campbell
Name: Laura K. Campbell
Title: Senior Vice President of Finance

EXHIBIT INDEX

Exhibit No.	Exhibit Description
99.1	Press Release dated November 9, 2016

Exhibit 99.1

PRESS RELEASE

ATHERSYS REPORTS THIRD QUARTER 2016 RESULTS

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

CLEVELAND, November 9, 2016 – Athersys, Inc. (NASDAQ: ATHX) today announced its financial results for the three months ended September 30, 2016.

Highlights of the third quarter of 2016 and recent events include:

- Announced agreement with U.S. Food and Drug Administration (FDA) under Special Protocol Assessment (SPA) for design and planned analysis of pivotal Phase 3 clinical trial of MultiStem ® cell therapy for treatment of ischemic stroke – "MultiStem Administration for Stroke Treatment and Enhanced Recovery Study-2" (MASTERS-2) – which would provide foundation for regulatory submission for marketing approval, if successful;
- Announced successful completion of Japan's Pharmaceutical and Medical Devices Agency (PMDA) review of Clinical Trial Notification (equivalent to Investigational New Drug application in U.S.), allowing HEALIOS K.K. (Healios) to commence confirmatory trial of MultiStem treatment of ischemic stroke, to be evaluated under new Japan regenerative medicine regulatory framework;
- Initiated discussions with European regulators and advanced preparations for planned stroke studies;
- Continued advancement of acute myocardial infarction study and acute respiratory distress syndrome study – implementing protocol amendments to improve enrollment;
- In fourth quarter 2016, received $0.6 million development milestone from Bristol-Myers Squibb related to legacy drug target program;
- Recorded revenues of $0.3 million and net loss of $6.0 million for quarter ended September 30, 2016; and
- Ended quarter with $19.4 million in cash and cash equivalents and available-for-sale securities.

"During the third quarter, we achieved two very important regulatory milestones that support our progression into late stage clinical development and towards commercialization. Most notably, the agreement with the FDA on the conduct of a pivotal study under a SPA is a significant achievement, since it defines a clear and efficient path forward for the development of MultiStem for the treatment of ischemic stroke patients. We remain actively engaged with international regulators, as well as focused on other important activities in anticipation of this important study," said Dr. Gil Van Bokkelen, Chairman & CEO of Athersys, Inc. "We believe that success in this next development phase will put us in a position to deliver a safe, effective and practical therapy for stroke victims, with the potential to advance and redefine stroke care as we know it.

“In addition, over the past few months, we have worked closely with our partner in Japan to obtain acceptance from the PMDA for the conduct in Japan of a confirmatory clinical trial under the new accelerated regulatory framework for regenerative medicine therapies, and we are pleased that Healios is now in a position to move forward with that important study. Stroke is an urgent and growing public health threat in Japan, which is experiencing one of the most challenging demographic transitions of any developed country due to the unprecedented expansion of the elderly segment of the population,” he continued.

“In addition to the important progress on our stroke program, we continue to focus on the achievement of our other goals, including exploring additional partnering opportunities, advancing our process development and manufacturing related activities, and advancing our portfolio of other programs,” concluded Dr. Van Bokkelen.

Our MASTERS-2 clinical trial will be a randomized, double-blind, placebo-controlled clinical trial designed to enroll 300 patients in North America and Europe who have suffered moderate to moderate-severe ischemic stroke. The enrolled subjects will receive either a single intravenous dose of MultiStem cell therapy or placebo, administered within 18-36 hours of the occurrence of the stroke, in addition to the standard of care. The primary endpoint will evaluate disability using modified Rankin Scale (mRS) scores at three months, comparing the distribution, or the “shift,” between the MultiStem treatment and placebo groups. The mRS shift analysis evaluates patient improvement across the full disability spectrum, enabling recognition of improvements in disability and differences in mortality and other serious outcomes, among strokes of different severities. The study will also assess Excellent Outcome (the achievement of mRS ≤ 1, NIHSS ≤ 1, and Barthel Index ≥ 95, representing the three major indices of functional assessments for stroke patients) at three months and one year as key secondary endpoints. Additionally, the study will consider other measures of functional recovery, biomarker data and clinical outcomes, including hospitalization, mortality and life-threatening adverse events, and post-stroke complications such as infection.

Healios’ planned study in Japan will be a randomized, double-blind, placebo-controlled clinical trial designed to enroll 220 patients and conducted at hospitals in Japan that have extensive experience at providing care for stroke victims. Based on the experience from our B01-02 study, subjects enrolled in the trial will receive either a single intravenous dose of MultiStem or placebo, administered within 18–36 hours of the occurrence of the stroke, in addition to standard of care. The primary endpoint will be the proportion of patients with an Excellent Outcome functional assessment at 90 days.

Third Quarter Financial Results

For the three months ended September 30, 2016, total revenues were $0.3 million compared to $0.4 million in the same period in 2015, reflecting a decrease in grant revenues related to clinical and preclinical studies.

Research and development expenses increased to $5.3 million in the 2016 third quarter from $5.1 million in the 2015 third quarter, with the variance primarily comprised of increases in personnel costs, sponsored research, research supplies and professional fees and a decrease in preclinical and clinical development costs of $0.3 million, which fluctuate from time-to-time. General and administrative expenses were $1.8 million and $1.9 million in the third quarter of 2016 and 2015, respectively. Non-cash expense from stock-based compensation was $0.7 million in both of the 2016 and 2015 third quarters.

In the quarter ended September 30, 2016, our operating loss included $0.7 million of a net gain from insurance proceeds related to storm-related damage at our primary facility. Non-cash income from the change in the fair value of our warrant liabilities was $0.2 million and $0.3 million in the third quarter of 2016 and 2015, respectively. Finally, net loss for the three-month periods ended September 30, 2016 and 2015 was $6.0 and $6.5 million, respectively, with the net gain from insurance proceeds being the primary variance between the periods.

As of September 30, 2016, we had $19.4 million in cash and cash equivalents and available-for-sale securities compared to $23.0 million at December 31, 2015. Cash used in operating activities during the third quarter of 2016 was $5.5 million compared to $3.7 million in the third quarter of 2015, with the 2015 third quarter including a $2.0 million refund related to Japan tax withholdings. Net loss per share was $(0.07) per share for the current three-month period ended September 31, 2016 and was $(0.08) per share for the prior three-month period ended September 31, 2015.

Conference Call

As previously announced, Gil Van Bokkelen, Chairman and Chief Executive Officer, and William (B.J.) Lehmann, President and Chief Operating Officer, will host a conference call today to review the results as follows:

Date	November 9, 2016
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	800-273-1254
Telephone access: International	973-638-3440
Access code	97839505
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 November 23, 2016 by dialing 800-585-8367 or 855-859-2056 (U.S. and Canada), or 404-537-3406, and entering access code 97839505. The archived webcast will be available for one year at the aforementioned URL.

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 cardiovascular, neurological, inflammatory and immune disease areas, and has several ongoing clinical trials evaluating this potential regenerative medicine product. Athersys has forged strategic partnerships and collaborations with leading pharmaceutical and biotechnology companies, as well as world-renowned research institutions to further develop its platform and products. More information is available at www.athersys.com.

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 human therapeutics, such as the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the treatment of ischemic stroke, acute myocardial infarction, acute respiratory distress syndrome and other disease indications, including graft-versus-host disease. 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: the timing and nature of results from our MultiStem cell therapy clinical trials, including the MASTERS-2 Phase 3 clinical trial and the Healios clinical trial in Japan; our ability to successfully initiate and complete clinical trials of our product candidates within an expected timeframe or at all; the possibility of delays in, adverse results of, and excessive costs of the development process; the productivity, reliability and availability of suppliers, including contract research and contract manufacturing organizations; our ability to raise capital to fund our operations; the success of our efforts to enter into new strategic partnerships or collaborations and advance our programs; the success of our collaboration with Healios and others, including our ability to reach milestones and receive milestone payments, and whether any products are successfully developed and sold so that we earn royalty payments; our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements; 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; changes in our business strategy; changes in external economic and market factors; changes in our industry's overall performance; 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.

Contact:

William (B.J.) Lehmann, J.D.
President and Chief Operating Officer
Tel: (216) 431-9900
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(Tables Follow)

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

	September 30, 2016 (Unaudited)	December 31, 2015 (Note)
Assets		
Cash and cash equivalents and available-for-sale securities	$ 19,379	$ 23,027
Receivables and other current assets	1,153	790
Equipment, net	2,597	1,135
Other noncurrent assets	190	177
Total assets	**$ 23,319**	**$ 25,129**
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 5,161	$ 4,321
Deferred revenue and note payable	—	435
Warrant liabilities	2,134	649
Total stockholders' equity	16,024	19,724
Total liabilities and stockholders' equity	**$ 23,319**	**$ 25,129**

Note: The Condensed Consolidated Balance Sheet Data at December 31, 2015 has been derived from the audited financial statements as of that date.

Athersys, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In Thousands, Except Per Share Amounts)

	Three Months ended September 30,	
	2016	2015
	(Unaudited)	
Revenues		
Contract revenue	$ 150	$ 39
Grant revenue	161	357
Total revenues	**311**	**396**
Costs and Expenses		
Research and development	5,263	5,089
General and administrative	1,830	1,941
Depreciation	114	66
Total costs and expenses	**7,207**	**7,096**
Gain from insurance proceeds, net	682	—
Loss from operations	**(6,214)**	**(6,700)**
Income from change in fair value of warrants, net	191	255
Other income (expense), net	7	(79)
Loss before income taxes	**(6,016)**	**(6,524)**
Tax benefit	12	27
Net loss and comprehensive loss	**$ (6,004)**	**$ (6,497)**
Net loss per share – Basic	$ (0.07)	$ (0.08)
Weighted average shares outstanding – Basic	84,928	83,141
Net loss per share – Diluted	$ (0.07)	$ (0.08)
Weighted average shares outstanding – Diluted	85,897	83,426