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 8, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 8, 2017, Athersys, Inc. issued a press release announcing financial results for its third quarter ended September 30, 2017. 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.	Description
99.1	Press Release dated November 8, 2017

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 8, 2017

ATHERSYS, INC.

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

PRESS RELEASE

ATHERSYS REPORTS THIRD QUARTER 2017 RESULTS

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

CLEVELAND, November 8, 2017 – Athersys, Inc. (Nasdaq: ATHX) today announced its financial results for the three months ended September 30, 2017.

Highlights of the third quarter of 2017 and recent events include:

- Our partner in Japan, HEALIOS K.K. (Healios), resumed enrollment in the TREASURE stroke clinical trial, following a temporary suspension related to placebo product;
- Entered into agreement with Nikon CeLL innovation Co., Ltd. (Nikon) to prepare for manufacturing of MultiStem ® cell therapy for future commercialization in Japan by Healios;
- Awarded Regenerative Medicine Advanced Therapy designation (RMAT) from U.S. Food and Drug Administration (FDA) for MultiStem ischemic stroke program under the landmark 21st Century Cures Legislation, which is intended to expedite the development and regulatory review process and lead to accelerated U.S. approval;
- Received Final Scientific Advice positive opinion for stroke program from European Medicines Device Agency (EMA), establishing alignment between European and U.S. regulators about potential for product approval following a successful MASTERS-2 study;
- Progressed discussions with multiple parties regarding collaboration and business opportunities associated with stroke program;
- Included in Deloitte's Technology Fast 500 ™ , a ranking of the 500 fastest growing technology, media, telecommunications, life sciences and energy tech companies in North America;
- Recognized revenues of $0.4 million for quarter ended September 30, 2017 and net loss of $7.2 million, or $0.06 net loss per share; and
- Maintained a stable balance sheet with cash and cash equivalents of $28.2 million at the end of the third quarter.

"Over the past year, we have submitted extensive data and information to the FDA, EMA and other regulators who have conducted a rigorous review of the results from the MASTERS-1 trial and the other information we have provided for their consideration," commented Dr. Gil Van Bokkelen, Chairman & CEO at Athersys. "In response, we have received multiple important regulatory designations, including the Fast Track designation from the FDA earlier this year and, more recently, the RMAT designation, as well as the positive opinion from EMA. These actions provide tangible evidence of the support we have received from regulators following their careful review of the clinical data and information, and the potential this program has for redefining clinical care for patients that have suffered a debilitating ischemic stroke.

“We are pleased that Healios’ stroke study has resumed, following the resupply of placebo. In addition to our support for the ongoing TREASURE study and continued preparations for the MASTERS-2 study, we are laying the groundwork for commercialization in anticipation of clinical success. An important recent step was the establishment of a collaboration with Nikon to prepare for commercial manufacturing to support initial commercialization of MultiStem therapy for stroke in Japan. We are also engaged in related activities to support manufacturing scale-up and commercial supply.”

Dr. Van Bokkelen continued, “We have also advanced our discussions with potential business partners to support development and commercialization activities, particularly related to our lead stroke program, and we are currently engaged in active negotiations, discussions and other activities regarding specific proposals with certain companies. As we have conveyed previously, we are intent on establishing one or more partnerships that balance our partner’s contribution of capabilities and resources, commitment to the program, and appropriate recognition of the value of the commercial opportunity. Though we are currently focused on several possible options, we cannot provide guidance about the precise nature, scope and size of any potential partnership while this process is ongoing. Needless to say, this remains an important priority and objective for the company and our shareholders.”

Third Quarter Results

Revenues increased to $0.4 million for the three months ended September 30, 2017, compared to $0.3 million for the three months ended September 30, 2016, due to an increase of $0.1 million in grant revenues. Our grant revenues fluctuate from period to period based on the timing of grant-related activities and the award and expiration of new grants. Research and development expenses increased to $5.4 million for the three months ended September 30, 2017 from $5.3 million in the comparable period in 2016. The $0.1 million increase is primarily comprised of an increase in preclinical and clinical development costs of $0.8 million partially offset by decreases in internal research supplies of $0.4 million, sponsored research costs of $0.2 million and travel costs of $0.1 million.

General and administrative expenses increased to $2.1 million for the three months ended September 30, 2017 from $1.8 million in the comparable period in 2016. The $0.3 million increase was due primarily to increases in personnel costs of $0.1 million, stock-based compensation of $0.1 million and other administrative costs of $0.1 million.

Net loss was $7.2 million in the 2017 third quarter, compared to net loss of $6.0 million in the comparable period in 2016. The difference of $1.2 million reflects the above variances, as well as a non-recurring $0.2 million gain on the fair value of warrant liabilities and a non-recurring $0.7 million net gain from insurance proceeds related to flood damage, both of which were recognized in the third quarter of 2016.

Cash used in operating activities was $6.8 million during the 2017 third quarter, compared to cash used of $5.5 million in the 2016 third quarter. As of September 30, 2017, we had $28.2 million in cash and cash equivalents, compared to $14.8 million at December 31, 2016, which includes, among other things, the impact of the common stock offering in February 2017, the exercise of warrants to purchase common stock and proceeds from the issuance of common stock under our equity purchase facility.

Conference Call

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

Date	Wednesday, November 8, 2017
Time	4:30 p.m. (Eastern Time)
Telephone access: U.S. and Canada	800-273-1254
Telephone access: International	973-638-3440
Access code	96178367
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 22, 2017 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 96178367.

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, 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 the MultiStem cell therapy toward commercialization. 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 regulatory approval and market acceptance of our product candidates and our ability to generate revenues, including MultiStem for the treatment of ischemic stroke, acute myocardial infarction, spinal cord injury and 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 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; the success of our efforts to enter into new strategic partnerships or collaborations and advance our programs; our ability to raise additional capital; results from our MultiStem ongoing and planned 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 within the expected time frame or at all; changes in external market factors; changes in our industry's overall performance; changes in our business strategy; our ability to protect our intellectual property portfolio; 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.

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(Tables Follow)

Athersys, Inc.

Condensed Consolidated Balance Sheets

(In thousands)

	September 30, 2017 (Unaudited)	December 31, 2016 (Note)
Assets		
Cash and cash equivalents	**$ 28,234**	$ 14,753
Other current assets	**1,738**	1,527
Equipment, net	**2,265**	2,605
Deferred tax assets	**198**	175
Total assets	**$ 32,435**	$ 19,060
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	**$ 5,860**	$ 6,875
Deferred revenue	**503**	—
Warrant liabilities	**—**	1,004
Total stockholders' equity	**26,072**	11,181
Total liabilities and stockholders' equity	**$ 32,435**	$ 19,060

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
(In Thousands, Except Per Share Amounts)

	Three months ended September 30,	
	2017	**2016**
Revenues		
Contract revenue	**$ 179**	$ 150
Grant revenue	**220**	161
Total revenues	**399**	311
Costs and expenses		
Research and development	**5,441**	5,263
General and administrative	**2,113**	1,830
Depreciation	**177**	114
Total costs and expenses	**7,731**	7,207
Gain from insurance proceeds, net	**—**	682
Loss from operations	**(7,332)**	(6,214)
Income from change in fair value of warrants	**—**	191
Other income, net	**71**	7
Loss before income taxes	**(7,261)**	(6,016)
Income tax benefit	**18**	12
Net loss and comprehensive loss	**$ (7,243)**	$ (6,004)
Net loss per share – Basic and Diluted	**$ (0.06)**	$ (0.07)
Weighted average shares outstanding – Basic	**114,515,405**	84,928,198
Weighted average shares outstanding – Diluted	**114,515,405**	85,896,993