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): March 9, 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))

Item 2.02. Results of Operations and Financial Condition.

On March 9, 2017, Athersys, Inc. issued a press release announcing financial results for its fourth quarter ended December 31, 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 March 9, 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: March 9, 2017

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 March 9, 2017

PRESS RELEASE

Athersys inc.

ATHERSYS REPORTS FINANCIAL RESULTS FOR FOURTH QUARTER, FULL YEAR 2016

Company also announces priority review designation obtained by Healios in Japan-accelerating potential approval pathway for MultiStem ® clinical program for ischemic stroke

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

CLEVELAND, Ohio, March 9, 2017 – Athersys, Inc. (Nasdaq: ATHX) today reported its fourth quarter of 2016 and annual 2016 financial results and highlights.

"In 2016, we made good headway in advancing our lead clinical program in ischemic stroke," said Gil Van Bokkelen, Chairman and Chief Executive Officer of Athersys. "We believe that the program is well-positioned for further development with a defined path to commercialization in a very large potential market segment. Furthermore, we have continued to make progress in our other programs, building out the underlying technology and science and strengthening our core capabilities in areas that will be important for supporting commercialization."

2016 Highlights

- Received agreement from the U.S. Food and Drug Administration under a Special Protocol Assessment for the design and planned analysis of our Phase 3 MASTERS-2 ischemic stroke clinical trial – providing the path and foundation for development of MultiStem ® to marketing approval submission for this indication;
- Announced positive results from analysis of one-year data from our Phase 2 study of MultiStem cell therapy to treat ischemic stroke. These results demonstrated progressive improvements and a statistically significant higher rate of excellent outcomes for MultiStem-treated subjects – with greater benefits for patients receiving treatment within 36 hours of the stroke;
- Established a collaboration with HEALIOS K.K. (Healios) to develop MultiStem cell therapy for stroke in Japan, positioning the program for Japanese development and to take advantage of Japan's progressive regenerative medicine regulatory framework and its potential for accelerated approval;
- Completed successful review from Japan's Pharmaceutical and Medical Devices Agency (PMDA) of the Clinical Trial Notification allowing Healios to commence its Phase 2/3 TREASURE study; and

Fourth Quarter 2016 Highlights and Recent Activities

- Healios' key investigator presented at the 2017 International Stroke Conference the design and commencement of Healios' TREASURE Phase 2/3 stroke study in Japan, which it expects to complete in the second half of 2018;
- Received public notification by the Ministry of Health Labor and Welfare (MHLW) in Japan of priority review designation of MultiStem for the treatment of ischemic stroke, enabling acceleration of the potential PMDA assessment time for approval to six months (under the recently implemented accelerated review pathway for innovative medicines, or Sakigake);
- Established in December 2016 a collaboration with a global leader in the animal health business segment to evaluate our stem cell technology for application in a specified animal health area – with successful results, the collaboration could expand into development and commercialization license;
- Supported preparations for launch of Healios' TREASURE study and advanced our preparations for the MASTERS-2 Phase 3 study – with a focus on European regulatory alignment with prior FDA discussions and actions, manufacturing and trial infrastructure;
- Published in March 2017 in the peer-reviewed journal, *Stem Cells* , an article that explains how MultiStem cell therapy could provide benefit to patients following an ischemic stroke based on preclinical study results;
- Progressed our Phase 1/2 study evaluating administration of MultiStem therapy to acute respiratory distress syndrome patients and our Phase 2 acute myocardial infarction study;
- Received milestone payment from our long-standing collaboration with Bristol-Myers Squibb Company related to advancement into Phase 2 development of a program using our RAGE ® technology;
- Recorded revenues of $1.0 million and a net loss of $7.1 million for the quarter ended December 31, 2016; and for year ended December 31, 2016, recorded revenues of $17.3 million and a net loss of $15.3 million, or $0.18 per share, which included the $15.0 million license fee from Healios; and
- Ended 2016 with $14.8 million in cash and cash equivalents, followed by an additional $20.9 million of net proceeds from a February 2017 common stock offering in support of ongoing and planned clinical and process development activities.

"Last year, we accomplished several very important objectives and over the course of the year, we worked closely with Healios on regulatory matters to support their efforts to obtain authorization from the PMDA to enable commencement of the TREASURE clinical study," stated Dr. Van Bokkelen. "As a result, we believe that Healios is well-positioned to take advantage of Japan's innovative regulatory framework for the development, assessment and efficient approval of MultiStem for the treatment of ischemic stroke. The recently obtained priority review designation under Sakigake reinforces the strength of this program and our shared commitment to successful development with Healios. This achievement is consistent with the Special Protocol Assessment recently obtained from the FDA for our planned international Phase 3 study. Both represent important milestones for this program and lay out an efficient potential path for development toward marketing approval."

"Achieving regulatory clarity and defining a clear efficient path forward is important for both our clinical development and ongoing partnering efforts," continued Dr. Van Bokkelen. "The recent addition of capital from the financing allows us to maintain a healthy balance sheet, while we continue our activities and discussions in these and other areas. We are excited about the continued progress and anticipate a productive 2017."

Fourth Quarter 2016 Financial Results

Total revenues for the fourth quarter of 2016 were $1.0 million compared to $10.6 million in the same period in the prior year, reflecting the recognition of the $10.0 million license fee that we received from Chugai Pharmaceutical Company, Ltd. ("Chugai") upon the termination of the collaboration in October 2015. This was partially offset by a $0.6 million milestone payment from Bristol-Myers Squibb Company in the fourth quarter of 2016.

Research and development expenses increased to $7.1 million in the 2016 fourth quarter from $5.3 million in the same period in the prior year, primarily due to increased clinical and preclinical development costs, which vary based on trials underway, clinical manufacturing and process development activities.

General and administrative expenses remained relatively consistent at $2.0 million in the 2016 fourth quarter, compared to $1.8 million in the corresponding 2015 period.

Net loss was $7.1 million in the fourth quarter of 2016, compared to net income of $3.6 million for the same period of 2015. The decrease was primarily due to the $10.0 million Chugai license fee in the fourth quarter 2015 revenue.

Full Year 2016 Financial Results

Total revenues were $17.3 million in 2016, compared to $11.9 million in 2015, reflecting the $15.0 million license fee from Healios in 2016 and the $10.0 million license fee from Chugai that was recognized in 2015.

Research and development expenses increased to $24.8 million in 2016 from $21.3 million in 2015. The increase related primarily to an increase in clinical and process development costs, an increase in personnel costs, an increase in legal and professional fees and an increase in research supplies related to internal process development research.

General and administrative expenses were $7.8 million in 2016 compared to $7.5 million in 2015, reflecting increases in personnel costs and other outside services.

Net loss was $15.3 million in 2016, compared to $16.4 million in 2015. The difference of $1.1 million reflects the variances above, as well as a $1.3 million non-cash change in the fair value of our warrant liabilities and a $0.7 million gain from insurance proceeds related to remediated flood damage.

Cash used in operating activities was $10.9 million and $13.8 million for full year 2016 and full year 2015, respectively.

As of December 31, 2016, we had $14.8 million in cash and cash equivalents, compared to $23.0 million at December 31, 2015. In February 2017, we sold an aggregate of 22,772,300 shares of common stock through an underwritten public offering. As a result of the offering, we received aggregate net proceeds of approximately $20.9 million.

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	Thursday, March 9, 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	73151585
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 March 23, 2017, by dialing 800-585-8367 or 855-859-2056 (U.S. and Canada), or 404-537-3406, and entering access code 22710392. 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 neurological, cardiovascular, inflammatory and immune disorders and certain pulmonary conditions, 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 . 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 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 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)

	December 31, 2016	December 31, 2015
Assets		
Cash and cash equivalents	$ 14,753	$ 23,027
Other current assets	1,527	790
Equipment, net	2,605	1,135
Deferred tax assets	175	177
Total assets	**$ 19,060**	**$ 25,129**
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 6,875	$ 4,321
Deferred revenue	—	245
Warrant liabilities and note payable	1,004	839
Total stockholders' equity	11,181	19,724
Total liabilities and stockholders' equity	**$ 19,060**	**$ 25,129**

Athersys, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except per share data)

(Unaudited)

	Three months ended December 31,		Twelve months ended December 31,	
	2016	2015	2016	2015
Revenues				
Contract revenue	**$ 828**	$10,104	**$ 16,238**	$ 10,298
Grant revenue	**155**	501	**1,109**	1,650
Total revenues	**983**	10,605	**17,347**	11,948
Costs and expenses				
Research and development	**7,088**	5,298	**24,838**	21,316
General and administrative	**2,004**	1,785	**7,835**	7,536
Depreciation	**134**	66	**382**	267
Total costs and expenses	**9,226**	7,149	**33,055**	29,119
Gain from insurance proceeds, net	**—**	—	**682**	—
(Loss) income from operations	**(8,243)**	3,456	**(15,026)**	(17,171)
Income (expense) from change in fair value of warrants	**1,132**	164	**(557)**	772
Other (expense) income, net	**(19)**	(31)	**209**	(61)
(Loss) income before income taxes	**(7,130)**	3,589	**(15,374)**	(16,460)
Income tax benefit	**3**	3	**37**	38
Net (loss) income and comprehensive (loss) income	**$ (7,127)**	**$ 3,592**	**$ (15,337)**	**$ (16,422)**
Basic net (loss) income per share	**$ (0.08)**	$ 0.04	**$ (0.18)**	$ (0.20)
Weighted average shares outstanding, basic	**85,797**	83,352	**84,715**	82,144
Diluted net (loss) income per share	**$ (0.10)**	$ 0.04	**$ (0.18)**	$ (0.20)
Weighted average shares outstanding, diluted	**86,603**	83,451	**84,715**	82,851