

ATHERSYS, INC / NEW
Form 8-K
June 01, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): May 31, 2018

Athersys, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33876
(Commission
File Number)

20-4864095
(IRS 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 7.01. Regulation FD Disclosure.

As previously announced, on May 1, 2018, Athersys, Inc. (the Company) and HEALIOS K.K. (Healios) agreed to extend the period from April 30, 2018 to May 31, 2018 to complete their proposed collaboration expansion, as contemplated by the binding letter of intent (the LOI) entered into by the parties on March 13, 2018. On May 31, 2018, the Company and Healios agreed to further extend the period for negotiating the collaboration expansion to June 4, 2018. A license fee payment of \$10 million held in escrow will be released to the Company today in accordance with the terms of the LOI, which will result in an expansion of the parties' current license agreement to include acute respiratory distress syndrome (ARDS) and ophthalmological indications in Japan and organ bud therapies worldwide, as previously disclosed. The Company and Healios are continuing negotiations related to the scope of the collaboration expansion, including the financial terms thereof.

Forward-Looking Statements

This Current Report on Form 8-K 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, 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: our ability to work with Healios under the terms of the LOI to successfully negotiate the terms of and execute, the agreements necessary to expand the existing collaboration; 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 clinical trials, including the MASTERS-2 Phase 3 clinical trial and the TREASURE 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 Current Report on Form 8-K, and we undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

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.

ATHERYS, INC.

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

Date: June 1, 2018