ATHERSYS, INC / NEW
Form 8-K
May 25, 2011

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 25, 2011

Athersys, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-33876**	**20-4864095**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(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:

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

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

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

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

Item 8.01 Other Events.

On May 25, 2011, Athersys, Inc. (the "Company") announced interim results from its ongoing Phase I study of the Company's MultiStem® for hematopoietic stem cell transplant (HSCT) support and graft-versus-host disease (GvHD). The study results for the single dose arm of this Phase I clinical trial demonstrate that MultiStem was well tolerated at all dose levels and also suggest that the product may reduce the incidence of severe GvHD, a complication of such transplants, as compared to historical clinical experience. The repeated dose administration arm of the clinical trial is ongoing with enrollment expected to be completed in 2011.

Interim data highlights from the single dose administration arm of the study included:

- No observations of infusional or product-related toxicities over 30 days following treatment, and no product-related serious adverse events (SAEs) over 100 days following treatment;
- No primary or secondary HSCT-graft failure through day 100;
- Overall, a low cumulative incidence of acute GvHD over the 100-day observation period for all subjects enrolled (28% grade II-IV, 6% grade III-IV), which compares favorably with expectations for this patient population based on historical experience;
- In the high dose group, no cases of grade III-IV GvHD, and only one case of grade II GvHD, which was subsequently resolved with treatment; and
- Other clinical parameters, such as infection and survival, were in line with or better than expectations for this patient population based on historical data.

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," "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 inflammatory bowel disease, acute myocardial infarction, stroke and other disease indications, and the prevention of 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: final results from the Phase I clinical trial of MultiStem for individuals undergoing allogeneic HSCTs; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials; 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 realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our ability to meet milestones under our collaboration agreements; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements; 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.

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: May 25, 2011

ATHERSYS, INC.

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