ATHERSYS, INC / NEW
Form 8-K
June 10, 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): June 10, 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 June 10, 2011, Athersys, Inc. (the "Company") announced positive results from the analysis of one-year follow-up data from its Phase I clinical trial of MultiStem®, its allogeneic adult stem cell product, administered to individuals following acute myocardial infarction (AMI), more commonly referred to as a heart attack. Dr. Marc Penn, M.D., Ph.D., co-principal investigator of this study and Director of Cardiovascular Cell Therapy at the Cleveland Clinic, and Director of the Skirball Laboratory for Cardiovascular Cellular Therapeutics, presented the results on June 10, 2011 at the Eighth International Symposium on Stem Cell Therapy and Cardiovascular Innovations in Madrid, Spain. The long-term follow-up, based on one year of patient data, suggest that trends observed at four months – indicating a benefit in heart function from MultiStem treatment – were continued through twelve months.

Dr. Penn presented new information from the one-year follow-up data collected from patients in the Phase I clinical trial, showing benefit in heart function through twelve months in patients treated with MultiStem. Highlights from the new data include:

- The mean left ventricular ejection fraction (LVEF) of the treated patients was substantially higher at twelve months than at baseline, with an increase of 11.3% (4.6 absolute percentage points) from baseline over the twelve-month period for all treated patients pooled, compared to 3.2% (1.3 absolute percentage points) for the registry group.

- Treated patients' stroke volume and wall motion, two additional parameters of heart function, were substantially better than baseline at twelve months and also improved from the four-month evaluation. Mean stroke volume and wall motion improved 24.3% and 10.2%, respectively, from baseline over the twelve-month period, while registry patients improved only 7.7% and 5.8% over the period.

- Among those patients with more severe heart attacks (i.e. LVEF ≤ 45%) where twelve-month data were available, the MultiStem treated patients demonstrated a 19.9% improvement in mean LVEF over the period, compared to 6.2% for the registry patients. Treated patients showed a statistically significant improvement in mean stroke volume relative to baseline with a 27.7% improvement ($p<0.01$), compared to a decline of 8.8% for the registry group. Mean wall motion improved 11.9% for the treatment group, while declining by 0.4% in the registry group.

- Additionally, analysis of data from Holter monitoring in the first month demonstrated a trend for lower incidence of tachycardia in the treated patients compared to the registry patients and no significant difference in arrhythmias between the groups.

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,"

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"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 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 heart attack patients; 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.

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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: June 10, 2011

ATHERSYS, INC.

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