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): September 28, 2016

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 8.01. Other Events.

On September 28, 2016, Athersys, Inc. ("Athersys") announced the agreement from the U.S. Food and Drug Administration under a Special Protocol Assessment (SPA) for the design and planned analysis of a Phase 3 clinical trial of Athersys' novel MultiStem ® cell therapy product for the treatment of ischemic stroke. A copy of the press release issued by Athersys announcing the SPA agreement is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Press Release dated September 28, 2016

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: September 28, 2016

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 September 28, 2016

Exhibit 99.1

PRESS RELEASE

ATHERSYS RECEIVES FDA AGREEMENT UNDER SPECIAL PROTOCOL ASSESSMENT FOR PHASE 3 STUDY OF MULTISTEM ® TREATMENT FOR ISCHEMIC STROKE

SPA for pivotal registration trial clarifies and de-risks development pathway for stem cell therapy

CLEVELAND, September 28, 2016 – Athersys, Inc. (NASDAQ: ATHX) announced today that it has received agreement from the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the design and planned analysis of a Phase 3 clinical trial of Athersys' novel MultiStem ® cell therapy product for the treatment of ischemic stroke. The SPA provides agreement from the FDA that the protocol design, clinical endpoints, planned conduct and statistical analyses encompassed in Athersys' planned Phase 3 study are acceptable to support a regulatory submission for approval of the MultiStem product for treating ischemic stroke patients. The results from the Phase 3 trial entitled, "MultiStem Administration for Stroke Treatment and Enhanced Recovery Study-2" (MASTERS-2), together with other available clinical data, would provide the foundation of the regulatory package to be submitted for marketing approval.

"This is a major accomplishment for Athersys, as it clearly defines the development and regulatory pathway for the approval of MultiStem cell therapy for the treatment of ischemic stroke," stated Dr. Gil Van Bokkelen, Chairman and Chief Executive Officer of Athersys. "We would like to thank the FDA for its engagement and guidance in this process, and the clinical investigators who have been critical to our development of this potential treatment for stroke.

"The SPA is important in clarifying and de-risking an accelerated development pathway for us because it means that the successful completion of the MASTERS-2 trial, together with other available clinical data, could enable us to apply for marketing approval in the United States," continued Dr. Van Bokkelen. "With this goal now achieved, we will continue the process of engagement with the FDA, European and Canadian regulators, as well as the many sites that have expressed an interest in participating in the study, to complete other necessary activities prior to trial initiation. We intend to be prepared to launch the trial in 2017 and will update our stockholders as we move forward with these plans."

The MASTERS-2 clinical trial will be a randomized, double-blind, placebo-controlled clinical trial designed to enroll 300 patients in North America and Europe who have suffered moderate to moderate-severe ischemic stroke. The enrolled subjects will receive either a single intravenous dose of MultiStem cell therapy or placebo, administered within 18-36 hours of the occurrence of the stroke, in addition to the standard of care. The primary endpoint will evaluate disability using modified Rankin Scale (mRS) scores at three months, comparing the distribution, or the "shift", between the MultiStem treatment and placebo groups. The mRS shift analysis considers disability across the full spectrum, enabling recognition of large and small improvements in disability and differences in mortality and other serious outcomes, among strokes of different severities. The study will also assess Excellent Outcome (mRS ≤ 1, NIHSS ≤ 1, and Barthel Index ≥ 95) at three months and one year as key secondary endpoints. Additionally, the study will consider other measures of functional recovery, biomarker data and clinical outcomes, including hospitalization, mortality and life-threatening adverse events, and post-stroke complications such as infection. Recently, Athersys' partner, HEALIOS KK, successfully completed a review from Japan's Pharmaceutical and Medical Devices Agency of its Clinical Trial Notification, allowing it to commence a clinical trial evaluating the safety and efficacy of the administration of Athersys' MultiStem cell therapy for the treatment of ischemic stroke in Japan.

Dr. David Hess, a lead clinical investigator in the planned MASTERS-2 trial, stroke specialist and Professor & Chairman of the Department of Neurology at the Medical College of Georgia at Augusta University, commented, "We were very encouraged by the results from the Phase 2 study, and we believe that MultiStem therapy has the potential to help many stroke patients who do not have access to or did not benefit from other therapies, such as tPA or mechanical thrombectomy. We are excited to be a lead site in the MASTERS-2 trial and look forward to getting started. If the trial is successful, then MultiStem could represent a major advancement in stroke clinical care."

About Special Protocol Assessments

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and planned analysis of proposed study that are intended to form the basis of efficacy claims for a new drug application or biologic license application. Final marketing approval depends on the results of the efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be modified through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on the SPA process, please visit:
http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm080571.pdf

About Ischemic Stroke

Stroke represents an area where the clinical need is particularly significant, since it is a leading cause of death and serious disability worldwide, with a substantially impaired quality of life for many stroke victims. Currently, there are nearly 17 million people that suffer a stroke globally and more than two million stroke victims each year in the United States, Europe and Japan, combined. Ischemic strokes, which represent the most common form of stroke, are caused by a blockage of blood flow in the brain that cuts off the supply of oxygen and nutrients and can result in long-term or permanent disability due to neurological damage. Unfortunately, current therapeutic options for ischemic stroke victims are limited, since the only available therapies, administration of the clot dissolving agent tPA, or "thrombolytic," or surgical intervention using mechanical reperfusion to remove the clot, must be conducted within several hours of the occurrence of the stroke. As a consequence of this limited time window, only a small percentage of stroke victims are treated with the currently available therapy—most simply receive supportive or "palliative" care. The long-term costs of stroke are substantial, with many patients requiring extended hospitalization, extended physical therapy or rehabilitation (for those patients that are capable of entering such programs), and many require long-term institutional or family care.

About MultiStem

MultiStem cell therapy is a patented regenerative medicine product that has shown the ability to promote tissue repair and healing in a variety of ways, such as through the production of therapeutic factors produced in response to signals of inflammation and tissue damage. MultiStem therapy's potential for multidimensional therapeutic impact distinguishes it from traditional biopharmaceutical therapies focused on a single mechanism of benefit. The product represents a unique "off-the-shelf" stem cell product that can be manufactured in a scalable manner, may be stored for years in frozen form, and is administered without tissue matching or the need for immune suppression. Based upon its efficacy profile, its novel mechanisms of action, and a favorable and consistent safety profile demonstrated in both preclinical and clinical settings, MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need. Athersys has forged strategic partnerships and a broad network of collaborations to develop MultiStem cell therapy for a variety of indications, with an initial focus in the neurological, cardiovascular and inflammatory and immune disorder areas.

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 cardiovascular, neurological, inflammatory and immune disease areas, 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.

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 clinical trials, including the MASTERS-2 Phase 3 clinical trial and the Healios 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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