

ATHERSYS, INC / NEW
Form 8-K
September 28, 2016

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
(State or Other Jurisdiction

of Incorporation)

3201 Carnegie Avenue, Cleveland, Ohio

001-33876
(Commission

File Number)

20-4864095
(I.R.S. Employer

Identification No.)

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 |