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): April 15, 2020

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

Delaware	**001-33876**	**20-486095**
(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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**ATHX**	**NASDAQ Stock Market LLC**

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 8.01. Other Events.

Athersys, Inc. ("we," "our," "us," "Athersys" or the "Company") is filing this Current Report on Form 8-K to (1) provide certain updates regarding its operations and financial condition and (2) update Item 1. "Business" in its Annual Report on Form 10-K for the year ended December 31, 2019, filed on March 16, 2020 (the "2019 Form 10-K"), to correct a statement regarding the duration of coverage for its stem cell product candidates that could be provided by its current intellectual property estate made.

Phase 2/3 COVID-19 ARDS Study

On April 9, 2020, the U.S. Food and Drug Administration (the "FDA") authorized us to initiate a Phase 2/3 study, which will assess the safety and efficacy of MultiStem® therapy in subjects with moderate to severe acute respiratory distress syndrome ("ARDS") due to the novel strain of the coronavirus disease ("COVID-19"), which we refer to as our MACOVIA study. We plan to open the first clinical sites for recruitment of the MACOVIA study in the second quarter of 2020.

The trial will be a multicenter study featuring an open-label lead-in followed by a double-blind, randomized, placebo-controlled Phase 2/3 portion. The primary objectives of this study are to evaluate the safety and efficacy of MultiStem as a treatment for subjects with moderate to severe ARDS induced by COVID-19. The primary efficacy endpoint will be an analysis of ventilator-free days through day 28 as compared to placebo, a well-established endpoint for ARDS trials that evaluates an intervention's combined impact on survival and liberation from invasive mechanical ventilation. The secondary objectives of this study are to evaluate pulmonary function, all-cause mortality, tolerability and quality of life among survivors associated with MultiStem as a treatment for subjects with moderate to severe ARDS due to COVID-19. The study is designed to enroll up to 400 subjects and will be conducted at leading pulmonary critical care centers throughout the United States.

The first cohort of the study will be open-label, with a single active treatment arm to evaluate the safety of the MultiStem product candidate. The second cohort will be a double-blind, randomized, placebo-controlled run-in phase to evaluate the efficacy of MultiStem. The design of the third planned cohort will be based on analysis of the results of the second cohort. The intent-to-treat population will include all randomized subjects (i.e., subjects from the second and third cohorts).

Phase 2 Trauma Study

On April 15, 2020, the FDA authorized an Investigational New Drug ("IND") application to initiate a Phase 2 clinical trial evaluating MultiStem cell therapy for early treatment of traumatic injuries and the subsequent complications that result following severe trauma. The trial will be conducted by The University of Texas Health Science Center at Houston ("UTHealth") at Memorial Hermann-Texas Medical Center in Houston, Texas.

The objective of the clinical study is to evaluate the safety and effectiveness of MultiStem for the treatment of severely injured patients for the prevention and mitigation of complications that can result following severe traumatic injury. The proposed study will be a randomized, double-blind, placebo-controlled Phase 2 clinical trial estimated to enroll approximately 150 severely injured trauma patients following hospitalization, initial treatment and admission to the intensive care unit. These patients will be randomly assigned to receive MultiStem or placebo and both groups will receive the standard of care for their injuries.

As previously disclosed, this study is being supported under a grant awarded to McGovern Medical School at UTHealth from the Medical Technology Enterprise Consortium. Also, Memorial Hermann Foundation will provide additional funding. The study will be conducted under an Athersys IND, and Athersys will provide the investigational clinical product for the conduct of the trial, as well as regulatory and operational support. The trial protocol authorized by the FDA will be reviewed by the UTHealth Institutional Review Board to provide approval before trial initiation.

BARDA

As part of the U.S. Government's response to the outbreak of COVID-19 we have held discussions with and made presentations under the Medical Countermeasures TechWatch program to the Biomedical Advanced Research and Development Authority ("BARDA") and to the U.S. Government interagency COVID-19 Medical Countermeasures task force led by BARDA that also included other relevant governmental agencies and public health institutions (also referred to as the CoronaWatch task force). As a result of this review, our program involving administration of MultiStem for the treatment of ARDS was designated as highly relevant by the Medical Countermeasures TechWatch program. Following infection with COVID-19, or other viruses or pathogens that trigger severe pulmonary inflammation, ARDS can occur, resulting in significant morbidity or death.

Discussions between Athersys and BARDA are continuing regarding a potential collaboration for which Athersys has submitted its formal proposal. However, there can be no assurance that BARDA will elect to pursue such collaboration with us, or as to the amount of funding, if any, that we might receive in connection with any such collaboration.

Financial Position

As of April 9, 2020, we had approximately $37.5 million of cash and cash equivalents, which gives effect to the receipt of approximately $7.0 million of proceeds from the issuance of 4,000,000 shares of common stock to HEALIOS K.K. upon its exercise in full of a warrant in March 2020 and the receipt of approximately $10.3 million of proceeds from the issuance of a total of 6,825,000 shares of common stock to Aspire Capital Fund, LLC ("Aspire Capital"), since December 31, 2019 pursuant to common stock purchase agreements that we previously entered into with Aspire Capital.

COVID-19

In December 2019, COVID-19 was identified in Wuhan, China, and has since spread to other countries, including the United States. In March 2020, the World Health Organization characterized COVID-19 as a pandemic. Several countries, including the United States, have taken steps to restrict travel, temporarily close businesses and issue quarantine orders, and it remains unclear how long such measures will remain in place.

As of the date of this Current Report on Form 8-K, the COVID-19 pandemic has not had a significant adverse effect on our business. However, it is possible that the COVID-19 pandemic could adversely affect our business, results of operations, financial condition or liquidity in the future. For example, it could impact the timing and enrollment of our or our collaborators' planned or ongoing clinical trials, delaying clinical site initiation, regulatory review and the potential receipt of regulatory approvals, payment of milestones under our license agreements and commercialization of one or more of our product candidates, if approved. The COVID-19 pandemic could also disrupt the production capabilities of our contract manufacturing partners and materially and adversely impact our MultiStem trial supply chain. Further, the outbreak of COVID-19 has heightened the risk that a significant portion of our workforce will suffer illness or otherwise be unable to work. The impact of the COVID-19 pandemic is fluid and continues to evolve, and therefore, we cannot currently predict the extent to which our business, clinical trials, results of operations, financial condition or liquidity will ultimately be impacted. We signed a promissory note that is in process as of April 15, 2020 for a $1.3 million forgivable loan under the Small Business Administration's Paycheck Protection Program established pursuant to the Coronavirus Aid, Relief and Economic Security Act. If funded, we will use the proceeds to help fund our payroll costs. While we anticipate that the loan will be funded within the next several days, there can be no assurance that we will receive the funding for the loan.

2019 Form 10-K

The second paragraph under "Intellectual Property" in Item 1. "Business" of the 2019 Form 10-K is hereby amended and restated in its entirety as follows:

> We have a broad patent estate with claims directed to compositions, methods of production, and methods of use of certain non-embryonic stem cells and related technologies. We developed, acquired and exclusively licensed intellectual property covering our cell therapy product candidates and other applications in the field. Our broad intellectual property portfolio consists of over 330 issued patents (of which 37 are United States patents) and more than 140 global patent applications around our stem cell technology and MultiStem® product platform. This includes 36 United States patents and more than 280 international patents that apply to our Multipotent Adult Progenitor Cell technology and related products, such as MultiStem. The current intellectual property estate, which incorporates additional filings and may broaden over time, could provide coverage for our stem cell product candidates, manufacturing processes or methods of use into 2035 based on the current portfolio. Furthermore, an extended period of market exclusivity may apply for certain products (e.g., exclusivity periods for orphan drug designation or biologics). We continue to develop new intellectual property for which we may seek patent protection.

No Items of the 2019 Form 10-K other than Item 1. "Business" are being updated by this filing. Information in the 2019 Form 10-K is generally stated as of December 31, 2019 and this filing does not modify or update in any way the disclosures made in the 2019 Form 10-K or reflect any subsequent information or events other than as described above. This Current Report on Form 8-K should be read in conjunction with the 2019 Form 10-K.

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.

ATHERSYS, INC.

Dated: April 15, 2020

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