

ATHERSYS, INC / NEW
Form 8-K
June 08, 2018

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 6, 2018

Athersys, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction

of incorporation)

3201 Carnegie Avenue,

001-33876
(Commission

File Number)

20-4864095
(IRS Employer

Identification No.)

44115-2634

Cleveland, Ohio

(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))

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 1.01. Entry into a Material Definitive Agreement.

As more fully described in our Current Report on Form 8-K filed on January 13, 2016, on January 8, 2016, Athersys, Inc. (we or the Company), through its wholly-owned subsidiary, ABT Holding Company (together with the Company, Athersys), entered into a License Agreement (the First License Agreement) with HEALIOS K.K. (Healios) to develop and commercialize MultiStem[®] cell therapy for ischemic stroke in Japan, and to provide Healios with access to Athersys proprietary multipotent adult progenitor cell technology for use in Healios organ bud program, initially for transplantation to treat liver disease or dysfunction. Pursuant to the First License Agreement, Healios also obtained a right to expand the scope of the Agreement to include the exclusive rights to develop and commercialize MultiStem for the treatment of two additional indications in Japan, which at that time included acute respiratory distress syndrome (ARDS) and another indication in the orthopedic area, and to include all indications for the organ bud program (such expansion right, the Expansion Option). Pursuant to the First License Agreement, Healios will develop and commercialize the product in Japan, and Athersys will provide the manufactured product to Healios.

As more fully described in our Current Report on Form 8-K filed on March 16, 2018, Athersys entered into a Letter of Intent for Collaboration Expansion with Healios on March 13, 2018 outlining the terms for a potential expansion of the relationship with Healios beyond that contemplated by the First License Agreement. The original deadline for accomplishing such broader expansion was April 30, 2018, and that deadline was extended twice by mutual agreement of the parties. On June 6, 2018, the parties agreed to such expansion by entering into a Collaboration Expansion Agreement. The key elements of the Collaboration Expansion Agreement are summarized below. For the rights granted to Healios under the Collaboration Expansion Agreement, including entry into the agreements described below, Healios has paid to Athersys \$10 million by release from an escrow account on June 1, 2018, and has agreed to pay another \$10 million in four equal quarterly installments starting on June 7, 2018. These quarterly installment payments are creditable against milestone payments that may become due under the First License Agreement.

Under the terms of the Collaboration Expansion Agreement, the First License Agreement was expanded to include MultiStem products for use in treatment of ARDS and Athersys cell technology for uses with organ buds in any and all indications, and the ability to add MultiStem products for use in the previously designated indication in the orthopedic area under the First License Agreement was terminated. As a result of adding ARDS to the licensed field, in addition to the financial compensation previously disclosed with respect to use of MultiStem products for the treatment of ischemic stroke, Athersys will be entitled to receive additional success-based filing and regulatory approval milestones for ARDS aggregating up to \$50 million, as well as potential sales milestones of up to \$175 million. Athersys will also be entitled to receive tiered royalties on the aggregate product sales for stroke and ARDS, starting in the low double digits and increasing incrementally into the high teens depending upon net sales levels.

In addition, a new license agreement (Ophth License Agreement) was entered into, granting Healios worldwide, exclusive rights to treat certain ophthalmological diseases, by using either MultiStem products in combination with retinal pigment epithelium cells derived from either induced pluripotent stem cells (iPSC) or embryonic stem cells, or MultiStem products on a standalone basis. For the standalone products, Athersys will be entitled to receive success-based regulatory filing and approval milestones aggregating up to \$48.1 million, potential sales milestones of up to \$87.5 million, and tiered royalties on product sales in the single digits depending upon net sales levels. For the combination products, Athersys will be entitled to receive a low single-digit royalty, but no milestone payments.

A second new license agreement (Combination Product License Agreement) was also entered into granting Healios exclusive rights in Japan to treat diseases of the liver, kidney, pancreas and intestinal tissue through local administration of MultiStem products in combination with iPSC-derived cells through certain delivery methods. Athersys will be entitled to receive a low single-digit royalty on net sales of the combination product treatments, but no milestone payments.

The Ophth License Agreement and Combination Product License Agreement will expire with respect to each licensed product in each country upon the later of four events: (i) expiration of Athersys applicable pre-existing patents, (ii) expiration of Athersys applicable patents filed after the effective date, (iii) loss of all data or other regulatory exclusivity, and (iv) 10 years after first commercial sale. The agreement may expire earlier for products in territories upon certain defined conditions related to the availability of alternative products. Each agreement would terminate in its entirety when all such product terms for each territory have expired. After expiration of a product in a territory, or the agreement as a whole, Healios licenses remain in effect and Healios remains obligated to pay royalties at a reduced rate, and for a limited time, at which time the exclusive nature of the licenses convert to non-exclusive. Additionally, Healios may terminate the agreements under certain circumstances, including for material breach and without cause upon advance written notice (in which case Healios licenses do not survive). Athersys may terminate either of these agreements if there is an uncured material breach of an agreement by Healios (in which case Healios licenses would not survive).

In addition, under the Collaboration Expansion Agreement, Athersys granted to Healios an exclusive right of first negotiation for six months to expand the territory or field in the Combination Product License Agreement. If the parties do not agree to expand the scope of the Combination Product License Agreement during such period, they have agreed to negotiate in good faith with respect to adding another indication under the First License Agreement. The parties have also agreed to discuss the appropriate time and content of a separate agreement regarding the transfer of certain manufacturing technology from Athersys to a contract manufacturer located in Japan.

Under the Collaboration Expansion Agreement, Athersys also grants to Healios an exclusive right of first negotiation through September 1, 2018 (the ROFN Period) with respect to (i) an option for an exclusive license in China (the China Option Agreement) to use MultiStem products for the treatment of one or more of ischemic stroke, ARDS, and either trauma or an alternative mutually agreed-upon indication and (ii) an exclusive license for Healios to use certain other Athersys technology for non-therapeutic applications. If the parties agree to the terms of the China Option Agreement and the additional non-therapeutic technology license, Healios would be required to pay to Athersys an upfront fee of \$15 million in six equal installments, which payments would be capable of being applied as credits towards payments due under the First License Agreement.

On March 14, 2018, the Company issued a warrant (the Warrant) to purchase up to 20,000,000 shares of its common stock (the Warrant Shares). In connection with the entry into the Collaboration Expansion Agreement, the Company and Healios amended the terms of the Warrant such that (i) the Warrant will not be exercisable with respect to 16,000,000 Warrant Shares unless during the ROFN Period, Athersys and the Holder have entered into the China Option Agreement or a license for MultiStem products in China and (ii) the Warrant will only be exercisable with respect to 4,000,000 Warrant Shares at an exercise price equal to the Reference Price (which is generally 110% of the average closing price per share of the Company's common stock for the ten trading days ending on the trading day immediately preceding (and not including) the date the Warrant is exercised), but no less than \$1.76 per share, if Healios has satisfied its initial \$2.5 million payment obligation under the Collaboration Expansion Agreement.

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.

ATHERYS, INC.

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

Date: June 8, 2018