APPLIED GENETIC TECHNOLOGIES CORP
Form 8-K
December 13, 2018

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): December 7, 2018

APPLIED GENETIC TECHNOLOGIES CORPORATION

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36370**	**59-3553710**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

14193 NW 119th Terrace

Suite 10

Alachua, Florida, 32165

(Address of principal executive offices) (Zip Code)

(386) 462-2204

(Registrant s telephone number, including area code)

Not Applicable

(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 (see General Instruction A.2. below).

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 1.02. Termination of Material Definitive Agreement.

On December 7, 2018, we received written notice from Biogen MA Inc. (Biogen), a wholly owned subsidiary of Biogen Inc., that Biogen has elected to terminate the Collaboration and License Agreement (the Collaboration Agreement) between Biogen and us and dated as of July 1, 2015. The termination will become effective on March 8, 2019.

Under the terms of the Collaboration Agreement, we agreed to collaborate with Biogen to develop, seek regulatory approval for and commercialize gene therapy products to treat X-linked juvenile retinoschisis (XLRS) and X-linked retinitis pigmentosa (XLRP) based on our adeno-associated virus (AAV) vector technologies. The Collaboration Agreement also provided for discovery programs targeting three indications using our AAV technology whereby we would conduct discovery, research and development activities for those additional drug candidates through the stage of clinical candidate designation, after which, Biogen would have been eligible to exercise an option to continue to develop, seek regulatory approval for and commercialize the designated clinical candidate. Pursuant to the Collaboration Agreement, the Company has been eligible to receive certain milestone and sales based royalty payments. We also granted Biogen: (i) an exclusive, royalty-bearing license, with the right to grant sublicenses, to use adeno-associated virus vector technology and other technology controlled by us for the purpose of researching, developing, manufacturing and commercializing licensed products developed under the agreement and (ii) a non-exclusive, worldwide, royalty-free, fully paid license, with the right to grant sublicenses, of our interest in other intellectual property developed pursuant to the agreement.

Upon termination of the Collaboration Agreement, we will receive back the exclusive license rights to develop, manufacture or commercialize XLRP, XLRS and the three discovery programs.

Item 7.01. Regulation FD Disclosure.

On December 12, 2018, the Company issued a press release announcing the termination of the Collaboration Agreement and topline interim six-month data from our XLRS Phase 1/2 clinical trial. A copy of this press release is furnished as Exhibit 99.1 to this Report on Form 8-K. The press release contains forward-looking statements which involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Please refer to the cautionary note in the press release regarding these forward-looking statements.

The information in this Item 7.01 and Exhibit 99.1 attached hereto are intended to be furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

Item 8.01. Other Events.

On December 12, 2018, we announced topline interim six-month data from Phase 1/2 of our XLRS clinical trial of rAAV2tYF-CB-hRS1, an investigational AAV-based gene therapy delivered via intravitreal injection for XLRS due to mutations in the RS1 gene. Results from the study show that rAAV2tYF-CB-hRS1 is generally safe and well-tolerated, but no signs of clinical activity were observed at six-months. The primary endpoint of this study was designed to evaluate safety and tolerability, whereas secondary efficacy outcomes included changes in visual acuity, visual field, schisis (cystic) cavity size, and ERG b-wave amplitude, among others. A total of 27 subjects were treated and all subjects completed study visits through at least month six.

Key study findings include:

There were no signs of clinical activity over the 6-month interim analysis period.

There were no study discontinuations and no dose-related toxicities. Mild to moderate ocular inflammation resolved with and without steroid treatment.

Baseline patient demographics were relatively well-balanced.

AGTC will continue to monitor study participants as required in the study protocol.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated December 12, 2018, entitled AGTC Announces Topline Interim Six-Month Data from Phase 1/2 X-linked Retinoschisis Clinical Study; Termination of Biogen Collaboration

Forward Looking Statements

This current report on Form 8-K contains forward-looking statements that reflect AGTC s plans, estimates, assumptions and beliefs. Forward-looking statements include information concerning possible or assumed future results of operations, business strategies and operations, preclinical and clinical product development, including regarding which programs, if any, will be advanced in the future, and regulatory progress, potential growth opportunities, potential market opportunities and the effects of competition. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as anticipates, believes, could, seeks, estimates, expects, intends, may, plans, potential, predicts, projects, should, will, would or sim negatives of those terms. Actual results could differ materially from those discussed in the forward-looking statements, due to a number of important factors. Risks and uncertainties that may cause actual results to differ materially include, among others: gene therapy is still novel with only a few approved treatments so far; AGTC cannot predict when or if it will obtain regulatory approval to commercialize a product candidate or receive reasonable reimbursement; uncertainty inherent in clinical trials and the regulatory review process; risks and uncertainties associated with drug development and commercialization; factors that could cause actual results to differ materially from those described in the forward-looking statements are set forth under the heading Risk Factors in the Company s Annual Report on Form 10-K for the fiscal year ended June 30, 2018, as filed with the U.S. Securities and Exchange Commission. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent management s plans, estimates, assumptions and beliefs only as of the date of this release. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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 thereunto duly authorized.

APPLIED GENETIC TECHNOLOGIES CORPORATION

By: /s/ William A. Sullivan
William A. Sullivan
Chief Financial Officer

Date: December 13, 2018