APPLIED GENETIC TECHNOLOGIES CORP
Form 8-K
July 06, 2015

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): July 1, 2015

APPLIED GENETIC TECHNOLOGIES CORPORATION

(Exact name of Registrant as Specified in Its Charter)

Delaware	001-36370	59-3553710
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
11801 Research Drive Suite D		
Alachua, Florida		32615
(Address of Principal Executive Offices)		(Zip Code)

Registrant’s Telephone Number, Including Area Code: (386) 462-2204

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:

¨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 1.01. Entry into a Material Definitive Agreement.

On July 1, 2015, we entered into a Collaboration and License Agreement, which we refer to as the collaboration agreement with Biogen MA Inc., a wholly owned subsidiary of Biogen Inc. ("Biogen"), pursuant to which we and Biogen will collaborate to develop, seek regulatory approval for and commercialize gene therapy products to treat X-linked juvenile retinoschisis ("XLRS"), X-linked retinitis pigmentosa ("XLRP") and discovery programs targeting three indications based on our adeno-associated virus vector technologies.

The collaboration agreement and the related agreements described below will become effective upon the satisfaction of customary conditions, including the expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, which we currently expect to occur during our first fiscal quarter ending September 30, 2015. Biogen has a right to terminate the collaboration agreement upon the occurrence of a material adverse event affecting us during such waiting period.

Under the collaboration agreement, we will conduct all development activities through regulatory approval in the United States for the XLRS program, and all development activities through the completion of the first in human clinical trial for the XLRP program.

Budgeted development expenses for the programs are funded by Biogen, through an allocation of the upfront license fee described below, subject to cost sharing for budget overruns and additional clinical trials that may be required prior to a pivotal trial for each of the XLRS and XLRP programs. During our development of the XLRS and XLRP products, Biogen retains the right to step in and take over the remaining development activities under specified circumstances. When Biogen assumes development responsibility, budgeted development expenses are paid by Biogen, subject to cost sharing for additional development activities. For each of the XLRS and XLRP programs, we have an option to share in development costs and resulting profits as well as an option to co-promote the second product approved in the United States.

The collaboration agreement also provides for discovery programs targeting three indications whereby we will conduct discovery, research and development activities for those additional drug candidates through the stage of clinical candidate designation, after which, Biogen may exercise an option to continue to develop, seek regulatory approval for and commercialize the designated clinical candidate.

We and Biogen will form a joint development committee, consisting of an equal number of representatives of us and of Biogen, to oversee the XLRS and XLRP research programs. We will also form a joint commercialization committee to oversee the commercialization of any product for which we elect to share in development costs and profits.

Under the collaboration agreement, we will be eligible to receive upfront payments, option exercise fees and milestone payments aggregating over $1 billion, including an upfront license fee of $94.0 million, a portion of which will be allocated to fund our costs incurred in connection with budgeted research and development activities for the XLRS and XLRP programs as well as the discovery programs. Payment of the upfront license fee is expected to occur during our first fiscal quarter ending September 30, 2015. In the event that Biogen exercises its option to obtain an exclusive commercial license for one or more discovery products that are designated as clinical candidates, we are eligible to receive an option exercise fee for each drug candidate.

In addition, we are eligible to receive development milestone payments upon the achievement of specified regulatory, clinical development and commercialization milestones of up to $472.5 million collectively for the two lead programs and, together with option exercise fees, up to $592.5 million across the discovery programs. Biogen also has the right to substitute up to two discovery programs, with a limited ability to reinstate such substituted programs within six months. In the event Biogen elects to reinstate such substituted programs, we are eligible to receive additional option exercise fees and potential development, regulatory and sales milestone payments.

Under the collaboration agreement, we will grant Biogen 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. We also grant Biogen 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. Biogen will pay royalties for each licensed product at tiered rates ranging from high single digit to mid-teen percentages of annual net sales of the XLRS or XLRP products and rates ranging from mid-single digit to low-teen percentages of annual net sales for the discovery products.

The entire agreement or the applicable program may be terminated by (i) either party, for the uncured material breach of the other party, (ii) either party, for the bankruptcy or other insolvency proceeding of the other party, (iii) us, in the event Biogen or any of its affiliates challenges a patent of ours or (iv) Biogen, for its convenience, in its sole discretion, upon advance written notice to us for the collaboration agreement, XLRS program or XLRP program and upon written notice to us for any of the discovery programs. If the agreement or applicable program is terminated for convenience by Biogen or terminated for Biogen's material breach by us, we receive exclusive rights to develop, manufacture or commercialize the XLRS or XLRP program that has been terminated. We are required to pay Biogen royalties following termination, at rates determined in a manner specified in the agreement. In the event Biogen terminates for a material breach by us, we will be restricted from competing with Biogen for two years in the terminated programs with Biogen having the right, in lieu of termination, to elect to maintain the license from us and reduce the royalties and milestones in a manner specified in the agreement.

Manufacturing Agreement

We also entered into a Manufacturing License and Technology Transfer Agreement, or manufacturing license, under which Biogen will receive an exclusive license to use AGTC's proprietary technology platform to make AAV vectors for up to six genes based on the selection process specified in the agreement. After Biogen selects three genes, the remaining three are subject to approval by AGTC. Biogen may develop, manufacture and commercialize products to deliver these selected genes using our HSV-assisted adeno-associated virus vector technologies. Under the manufacturing license, we agree to transfer to Biogen technology necessary or useful for such purpose. For each gene selected, we are eligible to receive a selection fee, clinical and regulatory development milestones, and commercial sales milestones. Biogen will pay us incremental royalties for each licensed product that are a low single digit percentage of annual net sales of each product containing a gene of interest.

Equity Agreement

We also entered into a Common Stock Purchase Agreement with Biogen, or equity agreement, pursuant to which Biogen will purchase 1,453,957 shares of our common stock, at a purchase price equal to $20.63 per share, for an aggregate purchase price in cash equal to $30 million. The share purchase is expected to occur contemporaneously with the effectiveness of the collaboration agreement, following the expiration or earlier termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended, assuming that other customary closing conditions are met. The shares issued to Biogen are expected to represent approximately 8.1% of our outstanding common stock post-issuance (based on 16,490,654 shares outstanding at June 30, 2015) and will constitute restricted securities that may not be resold by Biogen other than in a transaction registered under the Securities Act of 1933, as amended, or pursuant to an exemption from such registration requirement, and will bear a restrictive legend to such effect. We have not undertaken to register the resale of the shares to be issued to Biogen.

The equity agreement includes customary representations and warranties by us and by Biogen. The equity agreement also includes an 18 month "standstill" covenant by Biogen, pursuant to which it will not increase its ownership of our stock, announce an unsolicited proposal to acquire us, seek to control or influence our management, solicit proxies to vote our shares, or take similar actions, by itself or as part of a group. The standstill covenant does not prohibit Biogen from making any non-public offer or proposal to us or to our Board of Directors, and will lapse if a person not affiliated with Biogen announces an intention to offer to acquire a majority of our outstanding voting securities or publicly announces an intention to undertake a proxy contest with respect to the election of our directors.

Biogen also agreed that at any annual or special meeting of our stockholders held during the 18-month restricted period it will vote, or cause to be voted, all shares acquired pursuant to the equity agreement that are then owned of record or beneficially by Biogen in accordance with the recommendation of our Board of Directors and that it will, if so requested by us, deliver to us a duly executed proxy directing that such shares be voted in accordance with such recommendation.

Item 8.01. Other Events.

On July 2, 2015, we issued a press release announcing the Biogen collaboration. A copy of that press release is included as Exhibit 99.1 to this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Applied Genetic Technologies Corporation on July 2, 2015.

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.

APPLIED GENETIC
TECHNOLOGIES
CORPORATION

Date: July 6, 2015

By: /s/ Lawrence E. Bullock
Lawrence E. Bullock
Chief Financial Officer

EXHIBIT INDEX

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