
**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): May 7, 2019**

APPLIED GENETIC TECHNOLOGIES CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36370
(Commission
File Number)

59-3553710
(IRS Employer
Identification Number)

14193 NW 119th Terrace, Suite 10, Alachua, Florida 32615
(Address of Principal Executive Offices, Including 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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value	AGTC	Nasdaq Global Market

Item 2.02. Results of Operations and Financial Condition

On May 7, 2019, Applied Genetic Technologies Corporation issued a press release entitled “AGTC Announces Financial Results and Business Update for the Quarter Ended March 31, 2019.” The earnings release is furnished herewith as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.**Description**

99.1

[Press release dated May 7, 2019, entitled “AGTC Announces Financial Results and Business Update for the Quarter Ended March 31, 2019”](#)

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

Date: May 7, 2019

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



AGTC Announces Financial Results and Business Update for the Quarter Ended March 31, 2019

GAINESVILLE, Fla., and CAMBRIDGE, Mass., May 7, 2019 – Applied Genetic Technologies Corporation (Nasdaq: AGTC), a biotechnology company conducting human clinical trials of adeno-associated virus (AAV)-based gene therapies for the treatment of rare diseases, today announced financial results for the quarter ended March 31, 2019.

“Completing enrollment in the dose escalation portion of our Phase 1/2 trial in patients with achromatopsia due to mutations in the CNGB3 gene and the expansion cohort of our Phase 1/2 trial in patients with X-linked retinitis pigmentosa demonstrates our clinical development progress and keeps us on track to report multiple data sets in the second half of 2019,” said Sue Washer, President and CEO of AGTC. “Achieving these clinical milestones reflects our continued progress and commitment to developing new approaches to treat inherited retinal diseases positioning AGTC well to create value for patients and shareholders.”

AGTC Clinical Program Update

AGTC remains on track to meet its current enrollment milestones across its three Phase 1/2 clinical programs:

X-linked Retinitis Pigmentosa (XLRP) Phase 1/2 Clinical Trial

To date, AGTC has completed enrollment of ten patients in the dose escalation portion of the XLRP trial and six patients in the expansion portion of the trial. The Company expects to:

- Provide interim six-month data for the dose escalation group in the third quarter of 2019; and
- Provide interim six-month data for the expansion group in the fourth quarter of 2019.

Achromatopsia (ACHM) Phase 1/2 Clinical Trials

The Company is enrolling patients in two parallel Phase 1/2 clinical trials of its product candidates for ACHM caused by mutations in the two most common ACHM genes, CNGB3 and CNGA3. To date, AGTC has enrolled twelve patients in the ACHM CNGB3 trial and seven patients in the ACHM CNGA3 trial. The Company expects to:

- Complete enrollment of the dose escalation portion of the CNGA3 trial in the second quarter of 2019;

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- Provide topline interim six-month data for the dose escalation portions of the CNGB3 and CNGA3 trials in the fourth quarter of 2019; and
 - Complete enrollment of the expansion groups of the CNGB3 and CNGA3 trials in the second half of 2019 and provide topline interim six-month data in the first half of 2020.

Optogenetic Program

Through the AGTC-Bionic Sight collaboration, the companies are pursuing the development of an innovative optogenetic therapy to treat patients with advanced retinal disease. This potential therapy utilizes AGTC's broad experience in gene therapy and ophthalmology and Bionic Sight's patented neural coding device. Bionic Sight filed an IND for the program in advance of completing the final formulation and testing of clinical trial material produced by their contract manufacturing organization. The U.S. Food and Drug Administration (FDA) has put the trial on hold pending full review of the final testing to assure comparability to the material in the toxicology study. Bionic Sight expects clearance of the IND and initiation of the Phase 1/2 clinical trial in the second half of 2019.

Financial Results for the Three and Nine Months Ended March 31, 2019

Revenue: Total revenue for the three and nine months ended March 31, 2019 were \$21.3 million and \$41.3 million, respectively, compared to \$3.6 million and \$18.8 million in the comparable periods in 2018. The increase of \$22.5 million for the nine-month period was primarily due to recognizing revenue of \$20.4 million as a result of the termination of the Collaboration Agreement with Biogen, and recognizing revenue of \$8.3 million associated with the receipt of a \$10.0 million milestone payment from Biogen during the first quarter of fiscal year 2019, partially offset by decreased license and related service revenue due to the Company's revised pattern of revenue recognition under ASC 606, Revenue from Contracts with Customers.

R&D Expenses: Research and development expenses for the three and nine months ended March 31, 2019 were \$7.2 million and \$24.9 million, respectively, compared to \$7.4 million and \$23.4 million in the comparable periods in 2018. The increase of \$1.5 million for the nine-month period was primarily due to incurring sublicense expense of \$2.3 million associated with receiving a milestone payment from Biogen and increased employee-related costs, partially offset by decreased pre-clinical R&D spending.

G&A Expenses: General and administrative expenses for the three and nine months ended March 31, 2019 were \$3.1 million and \$9.3 million, respectively, compared to \$3.9 million and \$11.0 million for comparable periods in 2018. The decrease was primarily driven by decreased employee-related and share-based compensation expenses.

Net Income: Net income for the three and nine months ended March 31, 2019 was \$11.5 million and \$8.5 million, respectively, compared to a net loss of \$8.1 million and \$14.7 million in the comparable periods in 2018.

Financial Guidance: As of March 31, 2019, the Company's cash, cash equivalents, and investments amounted to \$89.2 million. The Company believes these funds will be sufficient to allow AGTC to generate data from its ongoing clinical programs, to move the pre-clinical optogenetic program in collaboration with Bionic Sight into the clinic and fund the currently planned research and discovery programs for approximately two years. The Company expects total cash, cash equivalents and investments as of June 30, 2019 to be between \$75 and \$80 million.

Conference Call and Webcast

AGTC will host a conference call and webcast to discuss financial results for the third fiscal quarter ended March 31, 2019 today at 8:00am ET. To access the call, dial 877-407-6184 (US) or 201-389-0877 (outside of the US). A live webcast will be available in the Events and Presentations section of AGTC's Investor Relations site at <http://ir.agtc.com/events-and-presentations>. Please log in approximately 10 minutes prior to the scheduled start time.

The archived webcast will be available in the Events and Presentations section of the Company's website.

About AGTC

AGTC is a clinical-stage biotechnology company that uses a proprietary gene therapy platform to develop transformational genetic therapies for patients suffering from rare and debilitating diseases. Its initial focus is in the field of ophthalmology, where it has active clinical trials in X-linked retinitis pigmentosa (XLRP), achromatopsia (ACHM CNGB3 & ACHM CNGA3) and X-linked retinoschisis (XLRS). In addition to its clinical trials, AGTC has preclinical programs in optogenetics, adrenoleukodystrophy (ALD), which is a disease of the central nervous system (CNS), and other ophthalmology and otology indications. The optogenetics program is being developed in collaboration with Bionic Sight. In addition to its product pipeline, AGTC has a significant intellectual property portfolio and extensive expertise in the design of gene therapy products including capsids, promoters and expression cassettes, as well as expertise in the formulation, manufacture and physical delivery of gene therapy products.

About Achromatopsia (ACHM)

Achromatopsia is an inherited retinal disease, which is present from birth and is characterized by the lack of cone photoreceptor function. The condition results in markedly reduced visual acuity, extreme light sensitivity causing day blindness, and complete loss of color discrimination. Best-corrected visual acuity in persons affected by achromatopsia, even under subdued light conditions, is usually about 20/200, a level at which people are considered legally blind.

About X-linked Retinitis Pigmentosa (XLRP)

XLRP is an inherited condition that causes progressive vision loss in boys and young men. Characteristics of the disease include night blindness in early childhood and progressive constriction of the visual field. In general, XLRP patients experience a gradual decline in visual acuity over the disease course, which results in legal blindness around the 4th decade of life. AGTC was granted FDA orphan drug designation in 2017, as well as European Commission orphan medicinal product designation in 2016, for its gene therapy product candidate to treat XLRP caused by mutations in the RPGR gene.

About X-linked Retinoschisis (XLRS)

XLRS is an inherited retinal disease caused by mutations in the RS1 gene, which encodes the retinoschisin protein. It is characterized by abnormal splitting of the layers of the retina, resulting in poor visual acuity in young boys, which can progress to legal blindness in adult men.

In December 2018, AGTC reported topline interim six-month data from its Phase 1/2 clinical trial in patients with XLRS. Results from the XLRS study supported general safety and tolerability of AGTC's gene delivery platform but did not demonstrate signs of clinical activity at six-months. A total of 27 subjects were treated and all subjects completed study visits through at least month six. The Company will complete patient monitoring activities on the XLRS program according to the clinical protocol.

Forward Looking Statements

This release 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, financial guidance, business strategies and operations, preclinical and clinical product development 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 similar expressions and the 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 and in Quarterly Reports in Form 10-Q for subsequent periods, filed with the SEC. 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.

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Financial tables follow

APPLIED GENETIC TECHNOLOGIES CORPORATION
BALANCE SHEETS
(Unaudited)

In thousands, except per share data	March 31,	June 30,
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 21,570	\$ 31,065
Investments	67,665	73,840
Grants receivable	26	210
Prepaid and other current assets	2,948	4,009
Total current assets	<u>92,209</u>	<u>109,124</u>
Property and equipment, net	4,500	5,254
Intangible assets, net	994	968
Investment in Bionic Sight	1,952	1,980
Other assets	1,260	1,206
Total assets	<u>\$ 100,915</u>	<u>\$ 118,532</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,450	\$ 945
Accrued and other liabilities	7,024	7,155
Deferred revenue	—	6,295
Total current liabilities	<u>8,474</u>	<u>14,395</u>
Deferred revenue, net of current portion	—	610
Other liabilities	4,139	4,345
Total liabilities	<u>12,613</u>	<u>19,350</u>
Stockholders' equity:		
Common stock, par value \$.001 per share, 150,000 shares authorized; 18,185 and 18,137 shares issued; 18,168 and 18,126 shares outstanding at March 31, 2019 and June 30, 2018, respectively	18	18
Additional paid-in capital	213,395	210,139
Shares held in treasury of 17 and 11 at March 31, 2019 and June 30, 2018, respectively	(77)	(49)
Accumulated deficit	(125,034)	(110,926)
Total stockholders' equity	<u>88,302</u>	<u>99,182</u>
Total liabilities and stockholders' equity	<u>\$ 100,915</u>	<u>\$ 118,532</u>

APPLIED GENETIC TECHNOLOGIES CORPORATION
STATEMENTS OF OPERATIONS
(Unaudited)

In thousands, except per share amounts	Three Months Ended March 31,		Nine Months Ended March 31,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	\$21,207	\$ 3,588	\$ 41,128	\$ 18,727
Grant and other revenue	111	15	158	43
Total revenue	21,318	3,603	41,286	18,770
Operating expenses:				
Research and development	7,203	7,353	24,851	23,355
General and administrative and other	3,110	3,946	9,345	11,020
Total operating expenses	10,313	11,299	34,196	34,375
Income/(loss) from operations	11,005	(7,696)	7,090	(15,605)
Other income:				
Investment income, net	512	325	1,504	866
Other expense	—	—	—	(10)
Total other income, net	512	325	1,504	856
Income/(loss) before provision for income taxes	11,517	(7,371)	8,594	(14,749)
Provision/(benefit) for income taxes	19	725	57	(66)
Income/(loss) before equity in net losses of affiliate	11,498	(8,096)	8,537	(14,683)
Equity in net losses of affiliate	(9)	(5)	(29)	(5)
Net income/(loss)	\$11,489	\$ (8,101)	\$ 8,508	\$ (14,688)
Weighted Average Shares Outstanding				
Weighted average shares outstanding—basic	18,166	18,112	18,149	18,098
Weighted average shares outstanding—diluted	18,324	18,112	18,322	18,098
Net earnings/(loss) per common share				
Net earnings/(loss) per share, basic	\$ 0.63	\$ (0.45)	\$ 0.47	\$ (0.81)
Net earnings/(loss) per share, diluted	\$ 0.63	\$ (0.45)	\$ 0.46	\$ (0.81)

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