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APPLIED GENETIC TECHNOLOGIES CORP

FORM 8-K
(Current report filing)

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Address	14193 NW 119TH TERRACE
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Telephone	386-462-2204
CIK	0001273636
Symbol	AGTC
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Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	06/30

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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): September 13, 2017

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 119 th 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 2.02. Results of Operations and Financial Condition

On September 13, 2017, Applied Genetic Technologies Corporation issued a press release entitled "AGTC Announces Financial Results and Business Update for the Quarter and Fiscal Year Ended June 30, 2017." The press release is furnished as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated September 13, 2017, entitled "AGTC Announces Financial Results and Business Update for the Quarter and Fiscal Year Ended June 30, 2017"

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: September 13, 2017

Exhibit Index

Exhibit No.	Description
99.1	Press release dated September 13, 2017, entitled "AGTC Announces Financial Results and Business Update for the Quarter and Fiscal Year Ended June 30, 2017"

AGTC Announces Financial Results and Business Update for the Quarter and Fiscal Year Ended June 30, 2017

GAINESVILLE, Fla., and CAMBRIDGE, Mass., September 13, 2017 – Applied Genetic Technologies Corporation (NASDAQ: AGTC), a clinical-stage biotechnology company that uses its proprietary gene therapy platform to develop transformational genetic therapies for patients suffering from rare and debilitating diseases, today announced financial results for the quarter and fiscal year ended June 30, 2017.

AGTC's lead product candidates are designed to treat inherited orphan diseases of the eye, caused by mutations in single genes that significantly affect visual function and currently lack effective medical treatments. AGTC's pipeline includes clinical-stage ophthalmology programs in X-linked retinoschisis (XLRS), achromatopsia (ACHM) caused by mutations in the CNGB3 and CNGA3 genes, and X-linked retinitis pigmentosa (XLRP) as well as a preclinical optogenetics program.

Recent Highlights

- In June, the company announced topline safety data for the dose escalation phase of the company's Phase 1/2 XLRS clinical trial.
- Also in June, Investigational New Drug application (IND)-enabling preclinical data for the company's gene therapy product candidate to treat ACHM due to mutations in the CNGA3 gene was published in *Human Gene Therapy Clinical Development* .
- In August, the U.S. Food and Drug Administration (FDA) granted orphan drug designation for AGTC's gene therapy product candidate for the treatment of XLRP.
- Also in August, the company filed an IND with the FDA to support initiation of a Phase 1/2 clinical trial of the company's gene therapy product candidate for XLRP.
- The company appointed William Sullivan as Chief Financial Officer and Andrew Ashe as General Counsel. Both Mr. Sullivan and Mr. Ashe are industry veterans with more than 20 years of financial and life sciences leadership experience.
- AGTC and the Foundation Fighting Blindness (FFB) announced a partnership agreement to support the organizations' shared mission to advance gene therapy research to treat inherited retinal diseases through expanded patient genotyping and registry efforts.

"We remain focused on the ongoing clinical advancement of our XLRS and ACHM studies. Completing the dose escalation phase of our Phase 1/2 trial in XLRS and continuing site initiation and patient enrollment in the Phase 1/2 trials of our ACHM programs demonstrate our commitment to accelerate the clinical development of our product candidates," said Sue Washer, President and CEO of AGTC. "This is further demonstrated by the progress of our XLRP program, where we have received orphan drug designation from the FDA, published important work on the design of the product and recently filed an IND application. Now that our IND has been filed and cleared by the FDA, we expect to initiate patient enrollment in the XLRP program in the first quarter of 2018 and look forward to expanding our clinical pipeline."

XLRS Phase 1/2 Clinical Trial

AGTC is currently enrolling patients in a Phase 1/2 clinical trial for its XLRS product candidate as part of the company's collaboration with Biogen. The primary endpoint of this clinical trial is safety.

To date, the company has completed enrollment of 12 patients in the first four groups which completes the dose escalation phase of the trial. The company is also enrolling adult patients in the expansion group at the highest dose level and three children between the ages of 6 and 18 at the mid-dose level. As of September 13, 2017, a total of 17 adults and one child have been enrolled in the trial across all groups.

In June 2017, Mark Pennesi, M.D., Ph.D., one of the XLRS trial investigators, presented safety data at the Macula Society Annual Meeting from the first twelve patients in the XLRS trial, some of which have been followed for more than one year. The data demonstrates that the company's XLRS product candidate has been generally safe and well tolerated. No treatment related serious adverse events have been reported.

As previously disclosed, mild to moderate ocular inflammation was observed in the majority of patients, which resolved either without treatment or after treatment with topical or oral corticosteroids.

The company has observed variability in the visual function of the 56 patients in its XLRS natural history study, as well as those dosed in its Phase 1/2 trial. The company believes that in addition to the three patients initially enrolled in the high-dose group, the full group of patients in the expansion group needs to be enrolled and followed for at least six months before meaningful conclusions can be drawn regarding biological activity. It expects to fully enroll this expansion group by the first quarter of 2018 and will present complete data after the last patient has been followed for six months. To date, no evidence of biological activity has been seen in the group of treated patients, which is not unexpected given the small patient pool, the relatively short period of observation in the high-dose group and the variability in the patient population.

ACHM CNGB3 Phase 1/2 Clinical Trial

A Phase 1/2 clinical trial evaluating the company's ACHM CNGB3 product candidate is currently enrolling patients. The company has completed enrollment of four patients in the low-dose group. An additional patient will be treated at the low-dose to bring the total number of patients in that group to five; three of which will be patients treated by a single surgeon to minimize differences in surgical technique. The company is collecting the data from the patients in the low-dose group to present to the Data Safety and Monitoring Committee (DSMC) prior to enrollment of patients in the mid-dose group.

ACHM A3 Phase 1/2 Clinical Trial

The company is currently conducting site initiation activities and screening patients for enrollment in a Phase 1/2 clinical trial evaluating the company's ACHM CNGA3 product candidate.

XLRP Clinical Trial

In early August of this year, the company filed an IND with the FDA to support the initiation of a Phase 1/2 clinical trial of the company's gene therapy product candidate for the treatment of XLRP caused by mutations in the RPGR gene. The company is currently conducting site initiation activities at four clinical sites and plans to initiate a clinical study in the United States in the first quarter of 2018.

Preclinical Optogenetic Program

In February, 2017, the company entered into a collaboration agreement with Bionic Sight to develop an optogenetic product candidate for patients with advanced retinal disease. This product would introduce genes for light-sensitive proteins into ocular cells in order to monitor and control their activity using light signals and thus potentially allow patients without functional photoreceptors to regain visual function. Through the AGTC-Bionic Sight collaboration, the companies will seek to develop a new optogenetic therapy that leverages AGTC's deep experience in gene therapy and ophthalmology and Bionic Sight's innovative neuro-prosthetic device and algorithm for retinal coding. AGTC is working with Bionic Sight to file their IND for this product candidate, which the company expects to occur in 2018.

Financial Results for the Quarter Ended and Fiscal Year Ended June 30, 2017

- **Revenue:** Revenue was $8.3 million for the fourth quarter of 2017 and $39.5 million for the year ended June 30, 2017, compared to $12.1 million and $47.4 million in the comparable periods in fiscal year 2016. The decrease for the full year is primarily due to recognizing $5.0 million of milestone revenue in fiscal year 2016 associated with achieving an XLRS patient enrollment milestone under the company's collaboration arrangement with Biogen, and to a lesser extent due to reduced revenue associated with the amortization of upfront fees associated with the Biogen collaboration.
- **R&D Expenses:** Research and development expenses were $8.3 million for the fourth quarter of 2017 and $26.2 million for the year ended June 30, 2017, compared to $6.8 million and $39.4 million in the comparable periods in fiscal year 2016. The decrease in research and development expenses for the full year was primarily attributable to a $12.0 million reduction in sublicense expenses associated with the company's collaboration arrangement with Biogen on the XLRS and XLRP programs and a $3 million reduction in licensing and milestones fees paid to collaborators associated with the company's early stage discovery and research programs. These decreases were partially offset by increased employee-related expenses associated with the hiring of additional employees to support clinical trial execution and research and development activity.
- **G&A Expenses:** General and administrative expenses were $2.8 million for the fourth quarter of 2017 and $11.4 million for the fiscal year ended June 30 2017, compared to $2.9 million and $10.1 million in the comparable periods in fiscal year 2016. The increase in general and administrative expenses was primarily driven by increased headcount which resulted in higher share-based compensation and other employee-related costs.

- **Tax Provision:** Income tax expense was $0.6 million for the fourth quarter of 2017 and $2.4 million for the year ended June 30, 2017 compared to no tax expense in fiscal year 2016. The fiscal year 2017 income tax expense results from the recognition of revenue related to the Biogen agreement for tax purposes, which is accelerated compared to the company's GAAP revenue, resulting in significantly more taxable income than GAAP net income. While the company's taxable income is largely offset by the use of NOLs, the company's income tax expense is primarily due to federal alternative minimum tax expense, the apportionment of income to certain state jurisdictions where the company does not have NOLs and the recognition of a reserve for uncertain tax positions.
- **Net Income or Loss:** Net loss was $3.2 million for the fourth quarter of 2017 and a net income of $0.4 million for the year ended June 30, 2017, compared to net income of $2.7 million and net loss of $1.4 million in the comparable periods in 2016.
- **Financial Guidance:** As of June 30, 2017, the company's cash, cash equivalents, and investments amounted to $138.4 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 at least the next two years.

Conference Call and Webcast

AGTC will host a conference call and webcast to discuss financial results for the fourth quarter and fiscal year 2017 today at 8:00 am ET. To access the call, dial 877-407-6184 (US) or 201-389-0877 (outside of the US). The passcode is 13669175. A live webcast will be available in the Events and Presentations section of AGTC's Investor Relations site at http://ir.agtc.com/events.cfm . 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 its proprietary gene therapy platform to develop transformational genetic therapies for patients suffering from rare and debilitating diseases, with an initial focus in ophthalmology. AGTC's product pipeline includes clinical-stage ophthalmology programs in X-linked retinoschisis (XLRS), X-linked retinitis pigmentosa (XLRP), achromatopsia (ACHM), as well as a preclinical optogenetics program. In addition to these ophthalmology programs, the company expects to advance one or more otology and/or adrenoleukodystrophy (ALD), which is a disease of the central nervous system (CNS) product candidates into clinical development in the next few years. Each of AGTC's XLRS, XLRP and ALD programs are part of its collaboration and license agreement with Biogen. AGTC employs a highly-targeted approach to selecting and designing its product candidates, choosing to develop therapies for indications having high unmet medical need that it

believes are clinically feasible and present commercial opportunities. 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 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.

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 boys to develop night blindness by the time they are ten and progresses to legal blindness by their early forties.

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, 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: no gene therapy products have been approved in the United States and only two such products have been approved in Europe; AGTC cannot predict when or if it will obtain regulatory approval to commercialize a product candidate; uncertainty inherent in 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, 2017, as 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.

###

Financial tables follow

APPLIED GENETIC TECHNOLOGIES CORPORATION

CONDENSED BALANCE SHEETS
(Unaudited)

In thousands, except per share data	At June 30, 2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,706	$ 28,868
Investments	95,994	69,664
Grants receivable	174	954
Prepaid and other current assets	3,361	3,089
Total current assets	130,235	102,575
Investments, net of current portion	11,749	74,183
Property and equipment, net	2,661	2,627
Intangible assets, net	1,219	1,321
Investment in Bionic Sight	2,000	—
Other assets	59	91
Total assets	$147,923	$180,797
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 998	$ 1,331
Accrued and other liabilities	6,162	6,514
Deferred revenue	20,996	46,898
Total current liabilities	28,156	54,743
Deferred revenue, net of current portion	4,438	16,766
Total liabilities	32,594	71,509
Stockholders' equity:		
Common stock, par value $.001 per share, 150,000 shares authorized; 18,088 and 18,053 shares issued and outstanding at June 30, 2017 and June 30, 2016, respectively	18	18
Additional paid-in capital	204,937	199,303
Accumulated deficit	(89,626)	(90,033)
Total stockholders' equity	115,329	109,288
Total liabilities and stockholders' equity	$147,923	$180,797

APPLIED GENETIC TECHNOLOGIES CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

In thousands, except per share amounts	For the Three Months Ended June 30, 2017	For the Three Months Ended June 30, 2016	For the Fiscal Year Ended June 30, 2017	For the Fiscal Year Ended June 30, 2016
Revenue:				
Collaboration revenue	$ 8,323	$12,043	$39,282	$46,751
Grant and other revenue	22	79	191	610
Total revenue	8,345	12,113	39,473	47,361
Operating expenses:				
Research and development	8,301	6,756	26,217	39,376
General and administrative	2,847	2,870	11,354	10,074
Total operating expenses	11,148	9,626	37,571	49,450
Income (loss) from operations	(2,803)	2,487	1,902	(2,089)
Other income (expense):				
Investment income, net	253	244	952	711
Other expense	(47)	(3)	(47)	(3)
Total other income (expense), net	206	241	905	708
Income (loss) before provision for income taxes	(2,597)	2,728	2,807	(1,381)
Provision for income taxes	600	—	2,400	—
Net (loss) income	$ (3,197)	$ 2,728	$ 407	$ (1,381)
Net (loss) income per share, basic	$ (0.18)	$ 0.15	$ 0.02	$ (0.08)
Net (loss) income per share, diluted	$ (0.18)	$ 0.15	$ 0.02	$ (0.08)
Weighted average shares outstanding, basic	18,072	18,038	18,072	17,810
Weighted average shares outstanding, diluted	18,072	18,451	18,385	17,810

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