AGTC Announces Financial Results and Business Update for the Fourth Quarter and Fiscal Year Ended June 30, 2018

September 10, 2018

GAINESVILLE, Fla. and CAMBRIDGE, Mass., Sept. 10, 2018 (GLOBE NEWSWIRE) -- 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 fourth quarter and fiscal year ended June 30, 2018.

"We have achieved significant progress across our broad and diverse portfolio of five ophthalmology development programs," said Sue Washer, President and CEO of AGTC. "We expanded our clinical and medical leadership teams, maintained a robust balance sheet and ended our fiscal year with strong momentum having our highest annual enrollment in clinical trials to date."

Recent Highlights

- AGTC received milestone payments of $12.5 million from Biogen following the successful enrollment of the first patient of the first dose group and the first patient of the second dose group in the company's Phase 1/2 clinical trial evaluating the safety and efficacy of an investigational AAV-based gene therapy for the treatment of X-linked retinitis pigmentosa (XLRP).

- AGTC strengthened its senior management team by hiring, Lanita C. Scott, M.D., as Vice President of Clinical Research and Medical Affairs; and Karen M. Carroll, RN, as Vice President of Clinical Development Operations. Dr. Scott and Ms. Carroll will leverage their extensive clinical experience to advance the company's portfolio.

AGTC Clinical Program Update

AGTC continues to enhance its clinical infrastructure resulting in the acceleration of clinical enrollment in all of the company's ongoing clinical trials. These resources have allowed AGTC to expand patient recruitment efforts, introduce new clinical trial sites, conduct surgical training and enhance clinical site support.

XLRP Phase 1/2 Clinical Trial
In the Phase 1/2 clinical trial of its product candidate for XLRP AGTC enrolled patients in each of the first two dosing groups and earned milestone payments of $2.5 million and $10.0 million, respectively, from Biogen as part of its ongoing collaboration. The company has three sites open for enrollment with additional sites expected to launch over the next several months. AGTC has enrolled 5 patients and expects to complete the dose escalation portion of the XLRP trial in the first quarter of 2019.

ACHM Phase 1/2 Clinical Trials
The company is presently enrolling patients in two parallel Phase 1/2 clinical trials of its product candidates for achromatopsia (ACHM) caused by mutations in the two most common ACHM genes, CNGB3 and CNGA3. In the ACHM CNGB3 trial, AGTC has enrolled a total of 8 patients across three dosing groups. The company expects to complete the dose escalation portion of the CNGB3 trial in the first quarter of 2019. In the ACHM CNGA3 trial, the company has enrolled two patients in the low dose group and its first international site in Israel has begun genotyping and screening their patient pool in order to begin enrollment.

XLRS Phase 1/2 Clinical Trial
In April, AGTC completed its target enrollment of 27 patients in the Phase 1/2 clinical trial for its x-linked retinoschisis (XLRS) product candidate as part of the company's collaboration with Biogen. The primary endpoint of this clinical trial is safety, and available data to date have shown that the XLRS product candidate is generally safe and well tolerated. In addition to safety, this trial will measure biologic activity by analyzing changes in a wide number of visual function, retinal structure, and quality of life assessments. The company expects to provide topline interim six-month data across both safety and biologic activity endpoints by the end of 2018 with the primary analysis of the full twelve-month active trial data to follow six months later. The company is also expanding the XLRS trial to include five pediatric patients at the high dose based on acceptable interim safety data for pediatric patients in the middle dose group.

AGTC-Bionic Sight Collaboration
Through the AGTC-Bionic Sight collaboration, the companies are pursuing the development of a novel optogenetic therapy to treat patients with advanced retinal disease that utilizes AGTC's broad experience in gene therapy and ophthalmology and Bionic Sight's revolutionary neuro-prosthetic device and novel algorithm for retinal coding. Bionic Sight expects to file the IND for this product candidate in the first half of 2019.

Financial Results for the Fourth Quarter and Fiscal Year Ended June 30, 2018

Revenues: Revenue was $5.4 million for the fourth quarter of 2018 and $24.2 million for the year ended June 30, 2018, compared to $8.3 million and $39.5 million in the comparable periods in fiscal year 2017. Revenue primarily consists of non-refundable upfront fees received under the company's collaboration with Biogen, which are amortized to collaboration revenue on a straight-line basis over the estimated service period, milestone revenue and development services revenue, which primarily consists of reimbursement of development activities under the Biogen collaboration. Amortization revenue decreased $19.7 million for the year ended June 30, 2018 compared to the same period in 2017 primarily due to reaching the end of the XLRP service period in the first quarter of fiscal year 2018, and to a lesser extent, due to changes in estimates associated with the period of performance under the XLRS and preclinical programs. Milestone revenue increased $2.5 million for the year ended June 30, 2018 compared to the

comparable period in 2017 due to AGTC earning a milestone payment associated with the first patient dosed in the XLRP Phase 1/ 2 clinical trial. Development services revenue increased $2.0 million for the year ended June 30, 2018 compared to the same period in 2017 primarily due to activities associated with the initiation of the XLRP Phase 1/2 clinical trial.

R&D Expenses: Research and development expenses were $8.8 million for the fourth quarter of 2018 and $32.2 million for the year ended June 30, 2018, compared to $8.3 million and $26.2 million in the comparable periods in fiscal year 2017. The increase in research and development expenses for the full year was primarily due to increased spending on general research and discovery programs, increased spending on the company's clinical programs, increased sublicense expense associated with the company's collaboration arrangement with Biogen on the XLRP program and increased employee-related expenses associated with the hiring of additional employees to support clinical trial execution and research and development activities.

G&A Expenses: General and administrative expenses were $3.4 million for the fourth quarter of 2018 and $14.4 million for the fiscal year ended June 30, 2018, compared to $2.8 million and $11.4 million in the comparable periods in fiscal year 2017. The increase in general and administrative expenses for the full year was primarily due to increased employee-related and corporate expenses to support the company's continued expansion.

Tax Provision: Income tax expense was $138,000 for the fourth quarter of 2018 and $72,000 for the year ended June 30, 2018 compared to $0.6 million for the fourth quarter of 2017 and $2.4 million in fiscal year 2017. The fiscal year 2018 tax expense was primarily driven by the apportionment of income to certain state jurisdictions where the company had not generated net operating losses (NOL's) offset by certain tax credit carryforwards becoming refundable under The Tax Cuts and Jobs Act of 2017. 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.

Net Income or Loss: Net loss was $6.6 million for the fourth quarter of 2018 and $21.3 million for the year ended June 30, 2018, compared to net loss of $3.2 million and net income of $0.4 million in the comparable periods in 2017.

Financial Guidance: As of June 30, 2018, the company's cash, cash equivalents, and investments amounted to $104.9 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. The company expects total cash, cash equivalents and investments as of June 30, 2019 to be between $65 and $75 million. These projected cash balances include the $10.0 million milestone payment, less sublicensing fees of approximately 23%, associated with dosing of the fourth patient in the XLRP trial which was triggered in July 2019.

Conference Call and Webcast

AGTC will host a conference call and webcast to discuss financial results for the fourth quarter and fiscal year 2018 today at 4:30pm ET. To access the call, dial 877-407-6184 (US) or 201-389-0877 (outside of the US). The passcode is 13682770. 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 retinoschisis (XLRS), X-linked retinitis pigmentosa (XLRP), and achromatopsia (ACHM CNGB3 & ACHM CNGA3). 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 otology. The clinical-stage XLRS and XLRP programs, the discovery program in ALD and two additional ophthalmology programs are being developed in collaboration with Biogen, and 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 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 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 U.S. Food and Drug (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.

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: 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 amended and 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
BALANCE SHEETS
(Unaudited)

In thousands, except per share data	June 30, 2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,065	$ 30,706
Investments	73,840	95,994
Grants receivable	210	174
Prepaid and other current assets	4,009	3,361
Total current assets	109,124	130,235
Investments, net of current portion	-	11,749
Property and equipment, net	5,254	2,661
Intangible assets, net	968	1,219
Investment in Bionic Sight	1,980	2,000
Other assets	1,206	59
Total assets	$ 118,532	$ 147,923
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 945	$ 998
Accrued and other liabilities	7,155	6,162
Deferred revenue	6,295	20,996
Total current liabilities	14,395	28,156
Deferred revenue, net of current portion	610	4,438
Other long term liabilities	4,345	-
Total liabilities	19,350	32,594
Stockholders' equity:		
Common stock, par value $.001 per share, 150,000 shares authorized; 18,137 and 18,088 shares issued; 18,126 and 18,088 shares outstanding at June 30, 2018 and June 30, 2017, respectively	18	18
Additional paid-in capital	210,139	204,937
Shares held in treasury of: 11 and 0 at June 30, 2018 and June 30, 2017 respectively	(49)	-
Accumulated deficit	(110,926)	(89,626)
Total stockholders' equity	99,182	115,329
Total liabilities and stockholders' equity	$ 118,532	$ 147,923

APPLIED GENETIC TECHNOLOGIES CORPORATION
STATEMENTS OF OPERATIONS
(Unaudited)

	For the three months ended June 30,		For the year ended June 30,	
In thousands, except per share amounts	2018	2017	2018	2017
Revenue:				
Collaboration revenue	$ 5,331	$ 8,323	$ 24,057	$ 39,282
Grant revenue	85	22	129	191
Total revenue	5,416	8,345	24,186	39,473
Operating expenses:				
Research and development	8,827	8,301	32,181	26,217

General and administrative	3,368	2,847	14,389	11,354
Total operating expenses	12,195	11,148	46,570	37,571
Income (loss) from operations	(6,779)	(2,803)	(22,384)	1,902
Other income (expense):				
Investment income, net	435	253	1,301	952
Other expense	(114)	(47)	(125)	(47)
Total other income, net	321	206	1,176	905
Income (loss) before provision for income taxes	(6,458)	(2,597)	(21,208)	2,807
Provision for income taxes	138	600	72	2,400
Income (loss) before equity in net losses of affiliate	(6,596)	(3,197)	(21,280)	407
Equity in net losses of affiliate	(15)	-	(20)	-
Net income (loss)	$ (6,611)	$ (3,197)	$ (21,300)	$ 407
Net income (loss) per share, basic	$ (0.37)	$ (0.18)	$ (1.18)	$ 0.02
Net income (loss) per share, diluted	$ (0.37)	$ (0.18)	$ (1.18)	$ 0.02
Weighted average shares outstanding, basic	18,112	18,081	18,105	18,072
Weighted average shares outstanding, diluted	18,112	18,081	18,105	18,385

IR/PR CONTACTS:
David Carey (IR) or Tom Vickery (PR)
Lazar Partners Ltd.
T: (212) 867-1768 or (646) 871-8482
dcarey@lazarpartners.com or tvickery@lazarpartners.com

Corporate Contact:
Bill Sullivan
Chief Financial Officer
Applied Genetic Technologies Corporation
T: (617) 843-5728
bsullivan@agtc.com

Stephen Potter
Chief Business Officer
Applied Genetic Technologies Corporation
T: (617) 413-2754
spotter@agtc.com

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