AGTC Announces Financial Results and Business Update for the Quarter Ended December 31, 2018

February 7, 2019

GAINESVILLE, Fla., and CAMBRIDGE, Mass., Feb. 07, 2019 (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 quarter ended December 31, 2018.

"AGTC is positioned for significant progress in 2019, including data readouts from our achromatopsia B3, achromatopsia A3 and X-linked retinitis pigmentosa clinical trials," said Sue Washer, President and CEO of AGTC. "We also expect that our optogenetics partner, Bionic Sight, will file an Investigational New Drug application with the U.S. Food and Drug Administration in the first half of 2019. This diverse pipeline, combined with our strong financial position, affords us multiple opportunities to advance new approaches for patients experiencing vision loss that today have few or no treatment options."

AGTC Clinical Program Update

AGTC continues to enhance its clinical infrastructure resulting in the acceleration of clinical enrollment in all 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.

X-linked Retinitis Pigmentosa (XLRP) Phase 1/2 Clinical Trial
AGTC completed enrollment of the nine patients in the dose escalation portion of the Phase 1/2 clinical trial of its product candidate for XLRP in December and has also treated three patients in the expansion group of the Phase 1/2 clinical trial. The Company expects to:

- Complete enrollment in the expansion group of the trial in the first quarter of 2019;
- Provide interim six-month data on the dose escalation portion of the trial in the third quarter of 2019; and
- Provide interim six-month data on the expansion group portion of the trial in the fourth quarter of 2019.

Achromatopsia (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 ACHM caused by mutations in the two most common ACHM genes, CNGB3 and CNGA3. AGTC has enrolled ten patients in the ACHM CNGB3 trial and five patients in the ACHM CNGA3 trial. The Company expects to:

- Complete enrollment of the dose escalation portion of the CNGB3 trial in the first quarter of 2019 and the CNGA3 trial in the second quarter of 2019 and provide topline interim six-month data for the CNGB3 and CNGA3 trials in the second half 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 that utilizes AGTC's broad experience in gene therapy and ophthalmology, and Bionic Sight's 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 Three and Six Months Ended December 31, 2018

Revenue: Total revenue was $5.9 million for the three months ended December 31, 2018 and $20.0 million for the six months ended December 31, 2018, compared to $4.9 million and $15.2 million in the comparable periods in 2017. The increase of $4.8 million for the six-month period was primarily due to recognizing revenue of $8.3 million associated with the receipt of a $10.0 million milestone payment from Biogen, partially offset by decreased license and related service revenue due to the Company's revised pattern of revenue recognition under ASC Topic 606, Revenue from Contracts with Customers.

R&D Expenses: Research and development expenses were $7.6 million for the three months ended December 31, 2018 and $17.6 million for the six months ended December 31, 2018, compared to $7.7 million and $16.0 million in the comparable periods in 2017. The increase of $1.6 million for the six-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 were $3.0 million for the three months ended December 31, 2018 and $6.2 million for the six months ended December 31, 2018, compared to $3.4 million and $7.1 million for comparable periods in 2017. The decrease was primarily driven by decreased employee-related and shared based compensation expenses.

Tax Provision: Income tax expense was $19 thousand for the three months ended December 31, 2018 and $38 thousand for the six months ended December 31, 2018, compared to $0.8 million income tax benefit for both comparable periods in 2017. The income tax benefit for the three and six months ended December 31, 2017 was primarily due to certain tax credit carryforwards becoming refundable under The Tax Cuts and Jobs Act of 2017.

Net Loss: Net loss was $4.2 million for the three months ended December 31, 2018 and $3.0 million for the six months ended December 31, 2018 compared to a net loss of $5.2 million and $6.6 million in the comparable periods in 2017.

Financial Guidance: As of December 31, 2018, the Company's cash, cash equivalents, and investments amounted to $96.1 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 $70 and $75 million.

Conference Call and Webcast
AGTC will host a conference call and webcast to discuss financial results for the second fiscal quarter ended December 31, 2018 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), 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 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.

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, 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	December 31, 2018	June 30, 2018
ASSETS		
Current assets:		

Cash and cash equivalents	$ 23,978	$ 31,065
Investments	72,097	73,840
Grants receivable	116	210
Prepaid and other current assets	2,959	4,009
Total current assets	99,150	109,124
Property and equipment, net	4,778	5,254
Intangible assets, net	954	968
Investment in Bionic Sight	1,961	1,980
Other assets	1,260	1,206
Total assets	$ 108,103	$ 118,532
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,664	$ 945
Accrued and other liabilities	5,823	7,155
Deferred revenue	12,701	6,295
Total current liabilities	20,188	14,395
Deferred revenue, net of current portion	7,731	610
Other liabilities	4,209	4,345
Total liabilities	32,128	19,350
Stockholders' equity:		
Common stock, par value $.001 per share, 150,000 shares authorized; 18,179 and 18,137 shares issued; 18,164 and 18,126 shares outstanding at December 31, 2018 and June 30, 2018, respectively	18	18
Additional paid-in capital	212,550	210,139
Shares held in treasury of 15 and 11 at December 31, 2018 and June 30, 2018, respectively	(70)	(49)
Accumulated deficit	(136,523)	(110,926)
Total stockholders' equity	75,975	99,182
Total liabilities and stockholders' equity	$ 108,103	$ 118,532

APPLIED GENETIC TECHNOLOGIES CORPORATION
STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended December 31,		For the Six Months Ended December 31,	
In thousands, except per share amounts	**2018**	**2017**	**2018**	**2017**
Revenue:				
Collaboration revenue	$ 5,895	$ 4,831	$ 19,920	$ 15,139
Grant and other revenue	39	21	48	28
Total revenue	5,934	4,852	19,968	15,167
Operating expenses:				
Research and development	7,583	7,726	17,648	16,002
General and administrative and other	3,022	3,368	6,235	7,074
Total operating expenses	10,605	11,094	23,883	23,076
Income (loss) from operations	(4,671)	(6,242)	(3,915)	(7,909)
Other income:				
Investment income, net	520	271	991	541
Other expense	–	(10)	–	(10)
Total other income, net	520	261	991	531
Income (loss) before provision for income taxes	(4,151)	(5,981)	(2,924)	(7,378)
Provision (benefit) for income taxes	19	(791)	38	(791)
Income (loss) before equity in net losses of affiliate	(4,170)	(5,190)	(2,962)	(6,587)
Equity in net losses of affiliate	(11)	-	(19)	-
Net income (loss)	$ (4,181)	$ (5,190)	$ (2,981)	$ (6,587)
Weighted Average Shares Outstanding				
Weighted average shares outstanding - basic	18,151	18,094	18,140	18,091
Weighted average shares outstanding - diluted	18,151	18,094	18,140	18,091
Net income (loss) per common share				
Net income (loss) per share, basic	$ (0.23)	$ (0.29)	$ (0.16)	$ (0.36)
Net income (loss) per share, diluted	$ (0.23)	$ (0.29)	$ (0.16)	$ (0.36)

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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