AGTC Announces Financial Results and Business Update for the Quarter Ended December 31, 2020

February 11, 2021

- Company on track to provide multiple data readouts for XLRP and ACHM clinical programs in 2021 and 2022 -

- Net proceeds of approximately $69.2 million from a recent public offering provide cash runway into calendar year 2023 -

- Company to host conference call and webcast today at 8:00 a.m. ET -

GAINESVILLE, Fla. and CAMBRIDGE, Mass., Feb. 11, 2021 (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, 2020.

"We believe that the data generated to date in our XLRP trials continue to give us a leading position in this indication and we are eager to move our Phase 1/2 expansion (Skyline) and Phase 2/3 (Vista) trials forward," said Sue Washer, President and CEO of AGTC. "The latest data from our ongoing Phase 1/2 trials in patients with achromatopsia provide the first reported quantitative evidence of improvements in visual sensitivity and provide a path forward to collect additional data and to fully realize the potential of this treatment. Continued progress in our clinical and earlier-stage development efforts is expected to create multiple data milestones, including four important data releases for XLRP and two for achromatopsia over the next two years, while bringing us closer to our goal of developing best-in-class therapies that provide meaningful benefit to patients."

X-linked Retinitis Pigmentosa (XLRP)
In November 2020, the Company reported additional positive data from its Phase 1/2 clinical trial in patients with XLRP that indicated durable improvements observed in visual sensitivity and supportive trends in visual acuity over a wide dose range with a favorable safety profile out to month 12 in two of the dose groups. The Company believes it has a best-in-class product candidate that may provide significant benefit to patients with XLRP. The Company expects to:

- Provide 12-month data for Phase 1/2 dose groups 5 and 6 in 2Q 2021;
- Provide Skyline trial results from the 3-month masked interim analysis in 4Q 2021;
- Provide Skyline trial results from the 12-month data in 3Q 2022; and
- Provide Vista trial results from the 6-month masked interim analysis in 3Q 2022.

Achromatopsia (ACHM)
In January 2021, the Company announced the first reported quantitative evidence of improvement in visual sensitivity, as measured by full field static perimetry, supported in some patients by other endpoints. Seven of the 16 patients in the three highest dose groups in the ACHMB3 trial showed these improvements in visual sensitivity in the treated area. No consistent results were seen in the other dose groups. In a subset of these patients with evaluable multi-focal electroretinograms (mfERG), improvements in electrical signaling were measurable in the same treated area.

For ACHMA3, of the 16 patients in the four highest dose groups, three patients showed improvements in visual sensitivity in the treated area, as measured by static perimetry. No consistent results were seen in other dose groups. None of these three patients with improvements in visual sensitivity had evaluable mfERGs.

AGTC currently plans to focus on completing enrollment of pediatric patients in the two highest dose groups in its ACHMB3 and ACHMA3 trials and to follow all patients through 12 months. The Company expects to:

- Provide 12-month data from the adult patients in both trials in 2Q 2021; and
- Provide preliminary 3-month data from the pediatric patients in both trials in 4Q 2021, AGTC currently plans to focus on completing enrollment depending on any effects of the COVID pandemic.

Financial Results for the Three and Six Months Ended December 31, 2020

Revenue: There was no revenue for the three and six months ended December 31, 2020, as compared to $2.5 million in each of the comparable 2019 periods. Revenue during the three and six months ended December 31, 2019 was primarily due to $2.2 million of non-cash collaboration revenue in connection with in-kind contributions made to Bionic Sight, LLC pursuant to a collaborative agreement.

R&D Expenses: Research and development expenses for the three and six months ended December 31, 2020 were $11.8 million and $23.4 million, respectively, compared to $8.4 million and $17.0 million, respectively, during the comparable 2019 periods. The increase of $6.4 million during the 2020 six-month period was primarily due to increased external XLRP spending for planned manufacturing, clinical site preparation and other activities related to the Skyline and Vista trials, partially offset by decreased external ACHM spending.

G&A Expenses: General and administrative expenses for the three and six months ended December 31, 2020 were $3.3 million and $6.7 million, respectively, compared to $3.0 million and $6.4 million, respectively, during the comparable 2019 periods. The increase of $0.3 million during the 2020 six-month period was primarily due to higher fees from outside legal counsel, partially offset by lower employee-related expenses and share-based compensation expense.

Investment Income, net: Investment income, net for the three and six months ended December 31, 2020 declined by $0.3 million and $0.7 million, respectively, when compared to the comparable 2019 periods, which was primarily due to lower interest rates in the marketplace.

Interest Expense: Interest expense for the three and six months ended December 31, 2020 increased by $0.3 million and $0.7 million, respectively, when compared to the comparable 2019 periods due to the loan agreement that the Company entered into on June 30, 2020.

Net Loss: The Company's net loss for the three and six months ended December 31, 2020 was $15.5 million and $30.8 million, respectively, compared to $8.6 million and $20.2 million, respectively, during the comparable 2019 periods.

Financial Guidance: As of December 31, 2020, the Company's cash, cash equivalents and investments totaled $53.1 million. The Company believes that these funds, along with net proceeds of approximately $69.2 million from an underwritten public offering that closed in February 2021, will be sufficient to allow the Company to generate data from its ongoing and planned clinical programs and fund currently planned research and discovery programs into calendar year 2023.

Conference Call and Webcast
AGTC will host a conference call and webcast to discuss financial results for the fiscal quarter ended December 31, 2020 today at 8:00 a.m. 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 developing genetic therapies for people with rare and debilitating ophthalmic, otologic and central nervous system (CNS) diseases. AGTC is a leader in designing and constructing all critical gene therapy elements and bringing them together to develop customized therapies that address real patient needs. AGTC's most advanced clinical programs leverage its best-in-class technology platform to potentially improve vision for patients with an inherited retinal disease. AGTC has active clinical trials in X-linked retinitis pigmentosa (XLRP) and achromatopsia (ACHM CNGB3 and ACHM CNGA3). Its preclinical programs build on the Company's industry-leading AAV manufacturing technology and scientific expertise. AGTC is advancing multiple important pipeline candidates to address substantial unmet clinical need in optogenetics, otology and CNS disorders.

About 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 or 5th decade of life. AGTC was granted U.S. Food and Drug Administration (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 ACHM
ACHM 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 ACHM, even under subdued light conditions, is usually about 20/200, a level at which people are considered legally blind.

Forward-Looking Statements
This press release contains forward-looking statements that reflect AGTC's plans, estimates, assumptions and beliefs, including statements regarding the projected timing for its planned Vista (Phase 2/3 XLRP) and Skyline (Expanded Phase 1/2 XLRP) clinical trials, the timing for reporting data in both its Skyline and Vista trials and the potential of its ACHM clinical programs. 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, the effects of competition and the impact of the COVID-19 pandemic, including the impact on AGTC's ability to enroll patients. 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; the direct and indirect impacts of the ongoing COVID-19 pandemic on the Company's business, results of operations, and financial condition; 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 AGTC's most recent annual and subsequently filed quarterly reports 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.

APPLIED GENETIC TECHNOLOGIES CORPORATION
CONDENSED BALANCE SHEETS
(Unaudited)

In thousands, except per share data	December 31, 2020	June 30, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,108	$ 38,463

Investments	33,989	41,995
Prepaid and other current assets	2,080	2,506
Total current assets	55,177	82,964
Property and equipment, net	4,095	4,311
Intangible assets, net	1,194	1,098
Investment in Bionic Sight, LLC	8,046	8,096
Right-of-use assets – operating leases	3,249	3,422
Right-of-use asset – finance lease	57	80
Other assets	151	348
Total assets	$ 71,969	$ 100,319
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,775	$ 1,355
Accrued and other liabilities	11,352	10,502
Lease liabilities – operating	1,067	1,058
Lease liability – finance	50	48
Total current liabilities	14,244	12,963
Lease liabilities – operating, net of current portion	3,723	4,070
Lease liability – finance, net of current portion	13	38
Long-term debt, net of debt discounts and deferred financing fees	9,844	9,677
Other liabilities	2,623	2,555
Total liabilities	30,447	29,303
Stockholders' equity:		
Preferred stock	—	—
Common stock	25	25
Additional paid-in capital	253,990	252,519
Treasury stock at cost	(211)	(88)
Accumulated deficit	(212,282)	(181,440)
Total stockholders' equity	41,522	71,016
Total liabilities and stockholders' equity	$ 71,969	$ 100,319

APPLIED GENETIC TECHNOLOGIES CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31,		Six Months Ended December 31,	
In thousands, except per share data	**2020**	**2019**	**2020**	**2019**
Revenue:				
Collaboration and milestone revenue	$ —	$ 2,297	$ —	$ 2,297
Grant revenue	—	156	—	156
Total revenue	—	2,453	—	2,453
Operating expenses:				
Research and development	11,811	8,375	23,437	17,017
General and administrative and other	3,304	3,008	6,740	6,356
Total operating expenses	15,115	11,383	30,177	23,373
Loss from operations	(15,115)	(8,930)	(30,177)	(20,920)
Other income (expense), net:				
Investment income, net	29	336	93	782
Interest expense	(335)	(2)	(667)	(4)
Total other income (expense), net	(306)	334	(574)	778
Loss before provision for income taxes	(15,421)	(8,596)	(30,751)	(20,142)
Provision for income taxes	20	21	41	42
Loss before equity in net losses of an affiliate	(15,441)	(8,617)	(30,792)	(20,184)
Equity in net losses of an affiliate	(21)	(6)	(50)	(16)
Net loss	$ (15,462)	$ (8,623)	$ (30,842)	$ (20,200)
Weighted average shares outstanding:				

Basic	25,883	18,219	25,850	18,215
Diluted	25,883	18,219	25,850	18,215
Net loss per common share:				
Basic	$ (0.60)	$ (0.47)	$ (1.19)	$ (1.11)
Diluted	$ (0.60)	$ (0.47)	$ (1.19)	$ (1.11)

IR/PR CONTACTS:
David Carey (IR) or Glenn Silver (PR)
Lazar FINN Partners
T: (212) 867-1768 or (646) 871-8485
david.carey@finnpartners.com or glenn.silver@finnpartners.com

Corporate Contacts:
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

Source: Applied Genetic Technologies Corporation