February 9, 2018

AGTC Announces Financial Results and Business Update for the Quarter Ended December 31, 2017

GAINESVILLE, Fla. and CAMBRIDGE, Mass., Feb. 09, 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 quarter ended December 31, 2017.

"Our primary focus for 2018 is enrolling patients in the company's ongoing Phase 1/2 clinical trials for our XLRS, ACHM and XLRP product candidates," said Sue Washer, President and CEO of AGTC. "We have taken steps to add clinical staff, employ additional resources and increase awareness of our trials through patient advocacy. These efforts have already resulted in more patients entering and completing the screening process and we expect them to drive patient enrollment as we move forward."

Clinical Programs

The company has four ongoing clinical trials. The status of these programs is summarized below:

XLRS Phase 1/2 Clinical Trial

The company is currently enrolling patients in a Phase 1/2 clinical trial for its X-linked retinoschisis (XLRS) product candidate as part of AGTC's collaboration with Biogen.

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 children between the ages of 6 and 18 at the mid-dose level. As of February 9, 2018, a total of 22 patients have been enrolled in the trial across all groups. The primary endpoint of this clinical trial is safety, and available data thus far have shown that AGTC's XLRS product candidate has been generally safe and well tolerated.

The company expects to fully enroll the study by the end of March 2018 and present data after the last patient enrolled has been followed for six months.

ACHM Phase 1/2 Clinical Trials

The company is currently enrolling patients in parallel Phase 1/2 clinical trials of AGTC's product candidates for achromatopsia (ACHM) caused by mutations in the two most common ACHM genes, CNGB3 and CNGA3. In the ACHM CNGB3 trial, AGTC completed enrollment of four patients in one dose group before electing to adjust the dose downward and is currently scheduling patients for enrollment at this dose. In the ACHM CNGA3 trial the company has enrolled one patient at the new, lower dose.

XLRP Phase 1/2 Clinical Trial

The company is currently screening patients for a Phase 1/2 clinical trial of its product candidate for X-linked Retinitis Pigmentosa (XLRP) caused by mutations in the RPGR gene. For this trial, two out of five sites are now open for enrollment.

Preclinical Optogenetic Program

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 to develop a product to treat patients with advanced retinal disease. AGTC is working with Bionic Sight to file their IND for this product candidate, which the companies expect to occur in the second half of 2018.

Financial Results for the Three and Six Months Ended December 31, 2017

Revenues: Total revenue was $4.9 million for the three months ended December 31, 2017 and $15.2 million for the six months ended December 31, 2017, compared to $10.9 million and $22.7 million in the comparable periods in 2016. 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, and development services revenue, which primarily consists of reimbursement of development activities under the Biogen Collaboration. Amortization revenue decreased $9.0 million for the six months ended December 31, 2017 compared to the same period in 2016 primarily due to reaching the end of the XLRP service period in the first quarter of fiscal year 2018, and to a lesser extent, to changes in estimates associated with the period of performance under the XLRS and preclinical programs. Development services revenue increased $1.5 million for the six months ended December 31, 2017 compared to the same period in 2016 primarily due to activities associated with preparing to conduct a Phase 1/2 clinical trial for XLRP.

R&D Expenses: Research and development expenses were $7.7 million for the three months ended December 31, 2017 and $16.0 million for the six months ended December 31, 2017, compared to $6.0 million and $11.6 million in the comparable periods in 2016. The increase for the six-month period was primarily due to increased spending on general research and discovery programs, increased spending on the company's clinical programs, 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 three months ended December 31, 2017 and $7.1 million for the six months ended December 31, 2017, compared to $2.7 million and $5.6 million in the comparable periods in 2016. The increase for the six-month period was primarily due to increased employee-related and corporate expenses to support the company's continued expansion.

Tax Provision: Income tax benefit was $0.8 million for the three and six months ended December 31, 2017 compared to an income tax expense of $0.6 million and $1.2 million in the comparable periods in 2016. The income tax expense for the three and six months ended December 31, 2016 results from the recognition of revenue related to the Biogen agreement for tax purposes, which is accelerated compared to the company's recognition of revenue for financial accounting purposes in accordance with generally accepted accounting principles (GAAP), resulting in significantly more taxable income than GAAP net income. While the company's taxable income is largely offset by the use of net operating losses (NOLs), AGTC's income tax expense is primarily due to federal alternative minimum tax expense, the apportionment of income to certain state jurisdictions where we do not have NOLs and the recognition of a reserve for uncertain tax positions. 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 Income or Loss: Net loss was $5.2 million for the three months ended December 31, 2017 and $6.6 million for the six months ended December 31, 2017 compared to net income of $1.8 million and $4.8 million in the comparable periods in 2016.

Financial Guidance: As of December 31, 2017, the company's cash, cash equivalents, and investments amounted to $119.7 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, 2018 to be between $90 and $100 million. Any milestone payments received by the company from Biogen before June 30, 2018 would increase these projected cash balances. Notably, upon dosing of the first and fourth patient in the XLRP Phase 1/2 clinical trial, the company would be entitled to receive milestone payments of $2.5 million and $10.0 million, respectively, less sublicensing fees of approximately 23%.

Conference Call and Webcast

AGTC will host a conference call and webcast to discuss financial results for the second fiscal quarter ended December 31, 2017 today at 8:00 a.m. ET. To access the call, 877-407-6184 (US) or 201-389-0877 (outside of the US). The passcode is 13676228. 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 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), achromatopsia (ACHM CNGB3 & ACHM CNGA3) and X-linked retinitis pigmentosa (XLRP). 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. 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 reduced 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 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, 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	December 31, 2017	June 30, 2017
ASSETS		
Current assets:		

Cash and cash equivalents	$ 70,345	$ 30,706
Investments	49,312	95,994
Grants receivable	203	174
Prepaid and other current assets	4,012	3,361
Total current assets	123,872	130,325
Investments	—	11,749
Property and equipment, net	3,235	2,661
Intangible assets, net	2,000	2,000
Other assets	2,226	1,278
Total assets	$ 131,333	$ 147,923
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,036	$ 998
Accrued and other liabilities	6,116	6,162
Deferred revenue	11,945	20,996
Total current liabilities	19,097	28,156
Deferred revenue, net of current portion	—	4,438
Other liabilities	653	—
Total liabilities	19,750	32,594
Stockholders' equity:		
Common stock—par value $.001 per share; shares authorized: 150,000 at December 31, 2017 and June 30, 2017; shares issued and outstanding: 18,105 and 18,088 at December 31, 2017 and June 30, 2017, respectively.	18	18
Additional paid-in capital	207,778	204,937
Accumulated deficit	(96,213)	(89,626)
Total stockholders' equity	111,583	115,329
Total liabilities and stockholders' equity	$ 131,333	$ 147,923

APPLIED GENETIC TECHNOLOGIES CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

In thousands, except per share amounts	For the Three Months Ended December 31,		For the Six Months Ended December 31,	
	2017	**2016** (as adjusted)	**2017**	**2016** (as adjusted)
Revenue:				
Collaboration revenue	$ 4,831	$ 10,890	$ 15,139	$ 22,662
Grant and other revenue	21	43	28	77
Total revenue	4,852	10,933	15,167	22,739
Operating expenses:				
Research and development	7,726	6,041	16,002	11,612
General and administrative and other	3,368	2,740	7,074	5,586
Total operating expenses	11,094	8,781	23,076	17,198
Income (loss) from operations	(6,242)	2,152	(7,909)	(5,541)
Other income:				
Investment income, net	271	227	541	463
Other expense	(10)	—	(10)	—
Total other income, net	261	227	531	463
Income (loss) before provision for income taxes	(5,981)	2,379	(7,378)	(6,004)
Provision (benefit) for income taxes	(791)	600	(791)	1,200
Net income (loss)	$ (5,190)	$ 1,779	$ (6,587)	$ (4,804)

Weighted Average Shares Outstanding				
Weighted average shares outstanding - basic	18,094	18,067	18,091	18,061
Weighted average shares outstanding - diluted	18,094	18,393	18,091	18,430
Net income (loss) per common share				
Net income (loss) per share, basic	$ (0.29)	$ 0.10	$ (0.36)	$ 0.27
Net income (loss) per share, diluted	$ (0.29)	$ 0.10	$ (0.36)	$ 0.26

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