AGTC Announces Financial Results and Business Update for the Quarter Ended September 30, 2018

November 8, 2018

GAINESVILLE, Fla. and CAMBRIDGE, Mass., Nov. 08, 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 September 30, 2018.

“Advancing our diversified pipeline of differentiated product candidates continues to be a key priority, and I am pleased with the progress we are making toward that goal,” said Sue Washer, President and CEO of AGTC. “Our four clinical-stage programs, all of which are designed to provide significant clinical benefits to patients with rare ophthalmic diseases offer multiple opportunities for AGTC to establish itself as a leader in delivering real clinical solutions. Additionally, we continue to make progress in our pre-clinical programs in optogenetics and otology.”

Recent Highlights

- AGTC received a milestone payment of $10.0 million from Biogen following the successful enrollment of 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 enhanced its Board with the appointment of William Aliski. Mr. Aliski has extensive leadership and management experience in the life sciences industry and has contributed to the commercialization of several rare disease products and will add insight in advancing commercialization strategies for the Company’s four clinical-stage programs.

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
AGTC has enrolled eight patients in the Phase 1/2 clinical trial of its product candidate for XLRP 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 ten patients. 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 four patients.

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 December 2018 with the primary analysis of the full twelve-month active trial data to follow six months later.

AGTC-Bionic Sight Collaboration
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 Quarter Ended September 30, 2018

Revenue: Total revenue for the three months ended September 30, 2018 was $14.0 million, compared to $10.3 million for the three months ended September 30, 2017. The increase was primarily due to increased milestone revenue of $8.3 million and increased development services revenue of $0.5 million, partially offset by decreased license and related services revenue of $5.1 million. The increase in milestone revenue was primarily due to recognizing revenue of $8.3 million associated with the receipt of a $10 million milestone payment from Biogen. Effective July 1, 2018, the Company adopted the provisions of ASC Topic 606, Revenue from Contracts with Customers (“Topic 606”). Based on the Company’s Topic 606 revenue recognition methodology, milestone payments are recognized based on the proportional performance of the underlying performance obligation for which the milestone payment relates. The increase in development services revenue was primarily due to additional Phase 1/2 study activities related to the Company’s XLRP program. The decrease in license and related service revenue was due to decreased Pre-Funded XLRP activities and due to the Company’s revised pattern of revenue recognition under Topic 606. For the three months ended September 30, 2018, license and related services, which includes the Pre-Funded Activities associated with each program under the Biogen Collaboration, are recognized on a proportional performance basis under Topic 606. For the three months ended September 30, 2017, license and related services revenue was recognized based on a straight-line basis over the estimated service period under the Company’s prior revenue recognition methodology.

R&D Expenses: Research and development expenses for the three months ended September 30, 2018 were $10.1 million, compared to $8.3 million for the three months ended September 30, 2017, an increase of $1.8 million. The increase 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 for the three months ended September 30, 2018 were $3.2 million, compared to $3.7 million for the three months ended September 30, 2017, a decrease of $0.5 million. The decrease was primarily driven by decreased employee-related and shared based compensation expenses.

Net Income or Loss: Net income was $1.2 million for the three months ended September 30, 2018 compared to a net loss of $1.4 million for the three months ended September 30, 2017.

Financial Guidance: As of September 30, 2018, the company's cash, cash equivalents, and investments amounted to $105.4 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. The company expects total cash, cash equivalents and investments as of June 30, 2019 to be between $65 and $75 million.

Conference Call and Webcast

AGTC will host a conference call and webcast to discuss financial results for the first fiscal quarter ended September 30, 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), 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 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.

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, 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	**Sept 30, 2018**	**June 30, 2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,472	$ 31,065
Investments	78,968	73,840
Grants receivable	219	210
Prepaid and other current assets	2,527	4,009
Total current assets	108,186	109,124
Investments, net of current portion	-	-
Property and equipment, net	5,016	5,254
Intangible assets, net	949	968
Investment in Bionic Sight	1,972	1,980
Other assets	1,205	1,206
Total assets	$ 117,328	$ 118,532
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,029	$ 945
Accrued and other liabilities	5,677	7,155
Deferred revenue	16,319	6,295
Total current liabilities	25,025	14,395
Deferred revenue, net of current portion	9,106	610
Other liabilities	4,258	4,345
Total liabilities	38,389	19,350
Stockholders' equity:		
Common stock, par value $.001 per share, 150,000 shares authorized; 18,143 and 18,137 shares issued; 18,130 and 18,126 shares outstanding at September 30, 2018 and June 30, 2018, respectively	18	18
Additional paid-in capital	211,320	210,139
Shares held in treasury of: 13 and 11 at September 30, 2018 and June 30, 2018, respectively	(57)	(49)
Accumulated deficit	(132,342)	(110,926)
Total stockholders' equity	78,939	99,182
Total liabilities and stockholders' equity	$ 117,328	$ 118,532

APPLIED GENETIC TECHNOLOGIES CORPORATION
STATEMENTS OF OPERATIONS
(Unaudited)

	For the three months ended Sept 30,	
In thousands, except per share amounts	**2018**	**2017**
Revenue:		
Collaboration revenue	$ 14,025	$ 10,308
Grant and other revenue	9	7
Total revenue	14,034	10,315
Operating expenses:		
Research and development	10,065	8,276
General and administrative and other	3,213	3,706
Total operating expenses	13,278	11,982
Income (loss) from operations	756	(1,667)
Other income:		
Investment income, net	471	270
Total other income, net	471	270
Income (loss) before provision for income taxes	1,227	(1,397)
Provision for income taxes	19	-

Income (loss) before equity in net losses of affiliate	1,208	(1,397)
Equity in net losses of affiliate	(8)	-
Net income (loss)	$ 1,200	$ (1,397)
Net income (loss) per share, basic	$ 0.07	$ (0.08)
Net income (loss) per share, diluted	$ 0.07	$ (0.08)
Weighted average shares outstanding, basic	18,128	18,088
Weighted average shares outstanding, diluted	18,158	18,088

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