

APPLIED GENETIC TECHNOLOGIES CORP
Form 10-Q
February 08, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended December 31, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-36370

APPLIED GENETIC TECHNOLOGIES CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware 59-3553710
(State or Other Jurisdiction of (I.R.S. Employer

Incorporation or Organization) Identification No.)

14193 NW 119th Terrace

Suite 10

Edgar Filing: APPLIED GENETIC TECHNOLOGIES CORP - Form 10-Q

Alachua, Florida 32615

(Address of Principal Executive Offices, Including Zip Code)

(386) 462-2204

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of February 3, 2017, a total of 18,083,563 shares of the registrant's outstanding common stock, \$0.001 par value per share, were outstanding.

APPLIED GENETIC TECHNOLOGIES CORPORATION

FORM 10-Q

FOR THE QUARTER ENDED DECEMBER 31, 2016

TABLE OF CONTENTS

	Pages
 <u>PART I. FINANCIAL INFORMATION</u>	
 ITEM 1. <u>FINANCIAL STATEMENTS</u>	
<u>Condensed Balance Sheets (Unaudited) as of December 31, 2016 and June 30, 2016</u>	3
<u>Condensed Statements of Operations (Unaudited) for the three and six months ended December 31, 2016 and 2015</u>	4
<u>Condensed Statements of Cash Flows (Unaudited) for the six months ended December 31, 2016 and 2015</u>	5
<u>Notes to Condensed Financial Statements (Unaudited)</u>	6
ITEM 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	18
ITEM 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	24
ITEM 4. <u>CONTROLS AND PROCEDURES</u>	24
 <u>PART II. OTHER INFORMATION</u>	
ITEM 1. <u>LEGAL PROCEEDINGS</u>	25
ITEM 1A.	25

RISK FACTORS

ITEM 6. <u>EXHIBITS</u>	25
-------------------------	----

<u>SIGNATURES</u>	26
-------------------	----

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

APPLIED GENETIC TECHNOLOGIES CORPORATION

CONDENSED BALANCE SHEETS

(Unaudited)

	December	
	31,	June 30,
	2016	2016
In thousands, except per share data		
ASSETS		
Current assets:		
Cash and cash equivalents	\$42,499	\$28,868
Investments	74,826	69,664
Grants receivable	78	954
Prepaid and other current assets	2,574	3,089
Total current assets	119,977	102,575
Investments	41,754	74,183
Property and equipment, net	2,881	2,627
Intangible assets, net	1,288	1,321
Other assets	52	91
Total assets	\$165,952	\$180,797
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$718	\$1,331
Accrued and other liabilities	6,167	6,514
Deferred revenue	36,033	46,898
Total current liabilities	42,918	54,743
Deferred revenue, net of current portion	5,103	16,766
Total liabilities	48,021	71,509
Stockholders' equity:		
Common stock—par value \$.001 per share; shares authorized: 150,000		
	at December 31, 2016 and June 30, 2016; shares issued and outstanding:	
	18,074 and 18,053 at December 31, 2016 and June 30, 2016, respectively.	
Additional paid-in capital	18	18
Accumulated deficit	202,240	199,303
Total stockholders' equity	(84,327)	(90,033)
Total liabilities and stockholders' equity	117,931	109,288
	\$165,952	\$180,797

The accompanying notes are an integral part of the financial statements.

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,	
	2016	2015	2016	2015
Revenue:				
Collaboration revenue	\$ 10,890	\$ 11,843	\$ 22,662	\$ 22,835
Grant and other revenue	43	346	77	416
Total revenue	10,933	12,189	22,739	23,251
Operating expenses:				
Research and development	6,041	7,203	11,612	24,240
General and administrative and other	2,740	2,116	5,586	5,354
Total operating expenses	8,781	9,319	17,198	29,594
Income (loss) from operations	2,152	2,870	5,541	(6,343)
Other income:				
Investment income, net	227	175	463	265
Total other income, net	227	175	463	265
Income (loss) before provision for income taxes	2,379	3,045	6,004	(6,078)
Less provision for income taxes	298	-	298	-
Net income (loss)	\$ 2,081	\$ 3,045	\$ 5,706	\$ (6,078)
Weighted Average Shares Outstanding				
Weighted average shares outstanding - basic	18,067	17,998	18,061	17,585
Weighted average shares outstanding - diluted	18,393	18,262	18,430	17,585
Net income (loss) per common share				
Net income (loss) per share, basic	\$ 0.12	\$ 0.17	\$ 0.32	\$ (0.35)
Net income (loss) per share, diluted	\$ 0.11	\$ 0.17	\$ 0.31	\$ (0.35)

The accompanying notes are an integral part of the financial statements.

APPLIED GENETIC TECHNOLOGIES CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

In thousands	For the Six Months Ended December 31,	
	2016	2015
Cash flows from operating activities		
Net income (loss)	\$5,706	\$(6,078)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Share-based compensation expense	2,912	2,489
Share-based collaboration expense	—	636
Depreciation and amortization	434	196
Changes in operating assets and liabilities:		
Grants receivable	876	467
Prepaid and other assets	772	(876)
Deferred revenues	(22,528)	87,113
Accounts payable	(614)	(374)
Accrued and other liabilities	(346)	2,671
Net cash provided by (used in) operating activities	(12,788)	86,244
Cash flows from investing activities		
Purchase of property and equipment	(563)	(106)
Purchase of and capitalized costs related to intangible assets	(92)	(85)
Maturity of investments	64,269	20,344
Purchase of investments	(37,219)	(120,628)
Net cash provided by (used in) investing activities	26,395	(100,475)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	—	19,211
Proceeds from exercise of common stock options	24	235
Net cash provided by financing activities	24	19,446
Net change in cash and cash equivalents	13,631	5,215
Cash and cash equivalents, beginning of period	28,868	39,187
Cash and cash equivalents, end of period	\$42,499	\$44,402

The accompanying notes are an integral part of the financial statements.

APPLIED GENETIC TECHNOLOGIES CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

1. Organization and Operations:

Applied Genetic Technologies Corporation (the “Company” or “AGTC”) was incorporated as a Florida corporation on January 19, 1999 and reincorporated as a Delaware corporation on October 24, 2003. The Company is a clinical-stage biotechnology company developing gene therapy products designed to transform the lives of patients with severe diseases, primarily in ophthalmology.

In April 2014, the Company completed its initial public offering (“IPO”) in which it sold 4,166,667 shares of common stock at a price of \$12.00 per share. The Company now trades on NASDAQ under the ticker symbol AGTC. In April 2014, the Company sold an additional 625,000 shares of common stock at the offering price of \$12.00 per share pursuant to the exercise of the underwriters’ over-allotment option. The aggregate net proceeds received by the Company from the IPO offering, including exercise of the over-allotment option, amounted to \$51.6 million, net of underwriting discounts and commissions and other issuance costs incurred by the Company.

In July 2014, the Company completed a follow on public offering in which it sold 2,000,000 shares of common stock at a public offering price of \$15.00 per share. In August 2014, the Company sold an additional 300,000 shares of common stock at a public offering price of \$15.00 per share pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the follow-on offering. The aggregate net proceeds received by the Company from the follow-on offering, including exercise of the overallotment option, amounted to \$32.0 million, net of underwriting discounts and commissions and other offering expenses.

In July 2015, the Company entered into a collaboration agreement (the “Collaboration Agreement”) with Biogen MA, Inc., a wholly owned subsidiary of Biogen Inc. (“Biogen”), pursuant to which the Company and Biogen will collaborate to develop, seek regulatory approval for and commercialize gene therapy products to treat X-linked retinoschisis (“XLRs”), X-linked retinitis pigmentosa (“XLRP”), and discovery programs targeting three indications based on the Company’s adeno-associated virus vector technologies. The Collaboration Agreement became effective in August 2015. Under the Collaboration Agreement, the Company received a non-refundable upfront payment of \$94.0 million and a milestone payment of \$5.0 million during the fiscal year ended June 30, 2016. As a result of the upfront and milestone payments made by Biogen, the Company became liable to its various research partner institutions for sub-license and milestone payments, which led the Company to record an expense for collaboration-related license fees of \$12.0 million during the fiscal year ended June 30, 2016. These collaboration costs included \$0.6 million of expense that was settled during that period by the issuance of 40,000 shares of the Company’s common stock to a research partner institution, pursuant to the terms of the existing agreement with that institution. The remainder of these sub-license and milestone fees were fully paid in cash during the fiscal year ended June 30, 2016.

The Company is also eligible to receive payments of up to \$467.5 million under the Collaboration Agreement based on the successful achievement of future milestones under the two lead programs and up to \$592.5 million based on the exercise of the option for and the successful achievement of future milestones under the three discovery programs. Biogen will pay revenue-based royalties for each licensed product at tiered rates ranging from high single digit to mid-teen percentages of annual net sales of the XLRs or XLRP products and at rates ranging from mid-single digit to low-teen percentages of annual net sales for the discovery products. Due to the uncertainty surrounding the achievement of the future milestones, such payments were not considered fixed or determinable at the inception of the Collaboration Agreement and accordingly, will not be recognized as revenue unless and until they become earned. The Company achieved the first milestone under the XLRs program in August 2015, which triggered a milestone

payment from Biogen of \$5.0 million and the recording of milestone revenue. The Company is not able to reasonably predict if and when any of the remaining milestones will be achieved.

In addition to the Collaboration Agreement, in July 2015, the Company also entered into an equity agreement with Biogen. Under the terms of the equity agreement, Biogen purchased 1,453,957 shares of common stock, at a purchase price equal to \$20.63 per share, for an aggregate cash purchase price of \$30.0 million. The Company received these cash proceeds from Biogen in August 2015. The shares issued to Biogen constitute restricted securities that may not be resold by Biogen other than in a transaction registered under the Securities Act of 1933, as amended, or pursuant to an exemption from such registration requirement.

The Company also entered into a Manufacturing License and Technology Transfer Agreement, or manufacturing license, under which Biogen will receive an exclusive license to use AGTC's proprietary technology platform to make AAV vectors for up to six genes based on the selection process specified in the agreement. For each gene selected,

we are eligible to receive a selection fee, clinical and regulatory development milestones, and commercial sales milestones. Biogen will pay us incremental royalties for each licensed product that are a low single digit percentage of annual net sales of each product containing a gene of interest.

The Company has devoted substantially all of its efforts to research and development, including clinical trials. The Company has not completed the development of any products. The Company has generated revenue from collaboration agreements, sponsored research payments and grants, but has not generated product revenue to date and is subject to a number of risks similar to those of other early stage companies in the biotechnology industry, including dependence on key individuals, the difficulties inherent in the development of commercially viable products, the need to obtain additional capital necessary to fund the development of its products, development by the Company or its competitors of technological innovations, risks of failure of clinical studies, protection of proprietary technology, compliance with government regulations and ability to transition to large-scale production of products. As of December 31, 2016, the Company had an accumulated deficit of \$84.3 million and recorded net income of \$2.1 million and 5.7 million, respectively, during the three and six month periods ended December 31, 2016. While the Company expects to continue to generate some revenue from partnering, including under the collaboration with Biogen, the Company expects to incur losses for the foreseeable future. The Company has funded its operations to date primarily through public offerings of its common stock, private placements of its preferred stock, and collaborations. At December 31, 2016, the Company had cash and cash equivalents and investments of \$159.1 million.

2. Summary of Significant Accounting Policies:

- (a) Basis of presentation – The accompanying unaudited condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and, in the opinion of management, include all adjustments necessary for a fair presentation of the Company’s financial position, results of operations, and cash flows for each period presented.

The adjustments referred to above are of a normal and recurring nature. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to U.S. Securities and Exchange Commission (“SEC”) rules and regulations for interim reporting.

Certain amounts reported previously have been reclassified to conform to the current period presentation, with no effect on stockholders’ equity or net income (loss) as previously presented.

The Condensed Balance Sheet as of June 30, 2016 was derived from audited financial statements, but does not include all disclosures required by GAAP. These Unaudited Condensed Financial Statements should be read in conjunction with the audited financial statements included in the Company’s 2016 Annual Report on Form 10-K, as amended, (“June 30, 2016 Form 10-K”). Results of operations for the three and six months ended December 31, 2016 are not necessarily indicative of the results to be expected for the full year or any other interim period.

- (b) Use of estimates – The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Actual results could differ from those estimates.
- (c) Cash and cash equivalents— Cash consists of funds held in bank accounts. Cash equivalents consist of short-term, highly liquid investments with original maturities of 90 days or less at the time of purchase and generally include money market accounts.
- (d) Investments—The Company’s investments consist of certificates of deposit and debt securities classified as held-to-maturity. Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity

securities are stated at amortized cost, adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in investment income. Interest on securities classified as held-to-maturity is included in investment income.

The Company uses the specific identification method to determine the cost basis of securities sold.

Investments are considered to be impaired when a decline in fair value is judged to be other-than-temporary. The Company evaluates an investment for impairment by considering the length of time and extent to which market value has been less than cost or amortized cost, the financial condition and near-term prospects of the issuer as well as specific events or circumstances that may influence the operations of the issuer and the Company's intent to sell the security or the likelihood that it will be required to sell the security before recovery of the entire amortized cost. Once a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded to other income (expense) and a new cost basis in the investment is established.

(e) Fair value of financial instruments—The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The Financial Accounting Standards Board (“FASB”) Accounting Standard Codification (“ASC”) Topic 820, Fair Value Measurements and Disclosures, establishes a hierarchy of inputs used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of financial instruments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

(f) Intangible assets – Intangible assets primarily include licenses and patents. The Company obtains licenses from third parties and capitalizes the costs related to exclusive licenses that have alternative future use in multiple potential programs. The Company also capitalizes costs related to filing, issuance, and prosecution of patents. The Company reviews its capitalized costs periodically to determine that such costs relate to patent applications that have future value and an alternative future use, and writes off any costs associated with patents that are no longer being actively pursued or that have no future benefit. Amortization expense is computed using the straight-line method over the estimated useful lives of the assets, which are generally eight to twenty years. The Company amortizes in-licensed patents and patent applications from the date of the applicable license and internally developed patents and patent applications from the date of the initial application. Licenses and patents converted to research use only are expensed immediately.

(g) Revenue recognition – The Company has generated revenue through collaboration agreements, sponsored research arrangements with nonprofit organizations for the development and commercialization of product candidates and revenues from federal research and development grant programs. The Company recognizes revenue when amounts are realized or realizable and earned. Revenue is considered realizable and earned when the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been

rendered; (3) the price is fixed or determinable; and (4) collection of the amounts due is reasonably assured. Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's unaudited condensed balance sheets. Amounts expected to be recognized as revenue within the

12 months following the balance sheet date are classified as current liabilities. The Company recognizes revenue for reimbursements of research and development costs under collaboration agreements as the services are performed. The Company records these reimbursements as revenue and not as a reduction of research and development expenses, as the Company has the risks and rewards as the principal in the research and development activities.

The Company evaluates the terms of sponsored research agreement grants and federal grants to assess the Company's obligations and if the Company's obligations are satisfied by the passage of time, revenue is recognized on a straight-line basis. In situations where the performance of the Company's obligations has been satisfied when the grant is received, revenue is recognized upon receipt of the grant. Certain grants contain refund provisions. The Company reviews those refund provisions to determine the likelihood of repayment. If the likelihood of repayment of the grant is determined to be remote, the grant is recognized as revenue. If the probability of repayment is determined to be more than remote, the Company records the grant as a deferred revenue liability, until such time that the grant requirements have been satisfied.

Collaboration revenue

On July 1, 2015, the Company entered into the Collaboration Agreement. This collaboration is discussed further in Note 6 to these financial statements. The terms of this agreement and other potential collaboration or commercialization agreements the Company may enter into generally contain multiple elements, or deliverables, which may include, among others, (i) licenses, or options to obtain licenses, to its technology, and (ii) research and development activities to be performed on behalf of the collaborative partner. Payments made under such arrangements typically include one or more of the following: non-refundable, up-front license fees; option exercise fees; funding of research and/or development efforts; milestone payments; and royalties on future product sales.

Multiple element arrangements are analyzed to determine whether the deliverables within the agreement can be separated or whether they must be accounted for as a single unit of accounting. Deliverables under an agreement are required to be accounted for as separate units of accounting provided that (i) a delivered item has value to the customer on a stand-alone basis; and (ii) if the agreement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units.

The Company determines the estimated selling price for deliverables within each agreement using vendor-specific objective evidence ("VSOE") of selling price, if available, third-party evidence ("TPE") of selling price if VSOE is not available, or best estimate of selling price ("BESP") if neither VSOE nor TPE are available. Determining the best estimate of selling price for a deliverable requires significant judgment. The Company uses BESP to estimate the selling price related to licenses to its proprietary technology, since it often does not have VSOE or TPE of selling price for these deliverables. In those circumstances where it utilizes BESP to determine the estimated selling price of a license to its proprietary technology, the Company considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements as well as internally developed models that include assumptions related to the market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating its best estimate of selling price, the Company evaluates whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

If the delivered element does not have stand-alone value, the arrangement is then accounted for as a single unit of accounting and the Company recognizes the consideration received under the arrangement as revenue on a straight-line basis over its estimated period of performance. The Company's anticipated periods of performance, typically the terms of its research and development obligations, are subject to estimates by management and may

change over the course of the collaboration agreement. Such changes could have a material impact on the amount of revenue recorded in future periods.

Milestone revenue

The Company applies the milestone method of accounting to recognize revenue from milestone payments when earned, as evidenced by written acknowledgement from the collaborator or other persuasive evidence that the milestone has been achieved and the payment is non-refundable, provided that the milestone event is substantive. A milestone event is defined as an event (i) that can only be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance; (ii) for which there is substantive uncertainty at the inception of the arrangement that the event will be achieved; and (iii) that would result in additional payments being due to the Company. Events for which the occurrence is either contingent solely upon the passage of time or the result of a counterparty's performance are not considered to be milestone events. A milestone event is substantive if all of the following conditions are met: (i) the consideration is commensurate with either the Company's performance to achieve the milestone, or the enhancement of the value to the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone; (ii) the consideration relates solely to past performance; and (iii) the consideration is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

The Company assesses whether a milestone is substantive at the inception of the arrangement. If a milestone is deemed substantive and the milestone payment is nonrefundable, the Company recognizes revenue upon the successful accomplishment of that milestone. Where a milestone is deemed non-substantive, we account for that milestone payment in accordance with the multiple element arrangements guidance and recognize revenue consistent with the related units of accounting for the arrangement over the related performance period.

No milestone revenues were recognized during the three and six month periods ended December 31, 2016. During the three and six month periods ended December 31, 2015, the Company recognized \$0 million and \$5.0 million, respectively, in milestone revenues that is reflected in collaboration revenue on our unaudited statements of operations.

Deferred revenue

Amounts received by the Company prior to satisfying the above revenue recognition criteria are recorded as deferred revenue on the balance sheet. Amounts not expected to be recognized within 12 months of the balance sheet date are classified as non-current deferred revenue.

- (h) Research and development – Research and development costs include costs incurred in identifying, developing and testing product candidates and generally comprise compensation and related benefits and non-cash share-based compensation to research related employees; laboratory costs; animal and laboratory maintenance and supplies; rent; utilities; clinical and pre-clinical expenses; and payments for sponsored research, scientific and regulatory consulting fees and testing.

Research and development costs also include license and sub-license fees and other direct and incremental costs incurred pursuant to the negotiation of and entry into collaborative and other partnership arrangements. Such costs associated with collaborative and other arrangements are expensed as incurred.

As part of the process of preparing its financial statements, the Company is required to estimate its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for services for which the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice the Company monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial

statements based on facts and circumstances known to it at that time. The significant estimates in the Company's accrued research and development expenses are related to expenses incurred with respect to academic research centers, contract research organizations, and other vendors in connection with research and development activities for which it has not yet been invoiced.

There may be instances in which the Company's service providers require advance payments at the inception of a contract or in which payments made to these vendors will exceed the level of services provided, resulting

in a prepayment of the research and development expense. Such prepayments are charged to research and development expense as and when the service is provided or when a specific milestone outlined in the contract is reached.

Prepayments related to research and development activities were \$1.8 million and \$2.0 million at December 31, 2016 and June 30, 2016, respectively, and are included within the prepaid and other current assets line item on the unaudited condensed balance sheets.

(i) Share-based compensation – The Company accounts for share-based awards issued to employees in accordance with ASC Topic 718, Compensation—Stock Compensation and generally recognizes share-based compensation expense on a straight-line basis over the periods during which the employees are required to provide service in exchange for the award. In addition, the Company issues stock options and restricted shares of common stock to non-employees in exchange for consulting services and accounts for these in accordance with the provisions of ASC Subtopic 505-50, Equity-Based Payments to Non-employees (“ASC 505-50”). Under ASC 505-50, share-based awards to non-employees are subject to periodic fair value re-measurement over their vesting terms. For purposes of calculating stock-based compensation, the Company estimates the fair value of stock options using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the Company’s stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. If factors change and the Company employs different assumptions, stock-based compensation expense may differ significantly from what has been recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, the Company may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact the Company’s results of operations in the period such changes are made.

(j) Income taxes – The Company uses the asset and liability method for accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The Company is subject to examination of its income tax returns in the federal and state income tax jurisdictions in which it operates. On December 28, 2015, the United States Internal Revenue Service (“IRS”), notified the Company of an income tax audit for the tax period ending June 30, 2014. On November 7, 2016 the IRS notified the Company that the audit was closed and no changes to the tax return will be issued.

For each of the three and six month periods ended December 31, 2016, the Company recorded an income tax provision of \$0.3 million based on the Company’s alternative minimum taxable income (“AMTI”). The Company calculates its AMTI using the alternative minimum tax (AMT) system. The Company’s federal income tax liability is the greater of the tax computed using the regular tax system or the tax under the AMT system. Corporations are exempt from AMT for all prior years in which their annual gross receipts for the 3-year period ending before the current tax year did not exceed \$7.5 million. For the fiscal year ending June 30, 2017, the Company no longer qualifies for the small company exclusion. The AMT system limits the use of net operating losses used by taxpayers to offset taxable income. In 2017, the Company anticipates being subject to alternative income tax and therefore estimated tax payments of approximately \$0.3 million have been made as of December 31, 2016. A credit may be earned for the tax paid on an alternative minimum tax basis and this credit can be carried forward indefinitely and used to reduce regular tax, but not below the alternative minimum tax for that future year. There were no income tax provisions during the three and six month periods ended December 31, 2015, due to the cumulative operating losses for the six months ended December 31, 2015.

As of December 31, 2016 and June 30, 2016, the Company did not have any significant uncertain tax positions.

(k) Net income (loss) per share - Basic net income (loss) per share is based on the weighted-average number of common shares outstanding during the three and six month periods ended December 31, 2016 and 2015.

Diluted net income (loss) per share is based on the weighted-average number of common shares outstanding during the three and six month periods ended December 31, 2016 and 2015, adjusted for the dilutive effect of employee share-based compensation and other share-based compensation awards.

The dilutive impact of options and other share-based compensation awards during the three and six months ended December 31, 2016, were 0.3 million shares and 0.4 million shares, respectively, and 0.3 million shares during the three months ended December 31, 2015. Due to the net loss in the six months ended December 31, 2015, common stock equivalents of 0.4 million shares were excluded from the computation of diluted loss per share due to their anti-dilutive effect.

- (l) Comprehensive income or loss – Comprehensive income or loss consists of net income or loss and changes in equity during a period from transactions and other equity and circumstances generated from non-owner sources. The Company’s net income or loss equals comprehensive income or loss for both periods presented.

(m) New accounting pronouncements – In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet for those leases previously classified as operating leases under GAAP. The standard requires, in most instances, a lessee to recognize on its balance sheet a liability to make lease payments (the lease liability) and also a right-of-use asset representing its right to use the underlying asset for the lease term. The amendments are effective for fiscal years beginning after December 15, 2018, including interim periods within those periods, using a modified retrospective approach and early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of this standard on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, which amends Accounting Standards Codification (“ASC”) Topic 718, Compensation – Stock Compensation. The amendments simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, forfeitures, and classification on the statement of cash flows. The amendments are effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of this standard on its financial statements.

In May 2014, the FASB issued guidance that requires companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which the company expects to be entitled in exchange for those goods or services. It also requires enhanced disclosures about revenue, provides guidance for transactions that were not previously addressed comprehensively, and improves guidance for multiple-element arrangements. The guidance applies to any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. In July 2015, the FASB delayed the effective date of this guidance by one year. The guidance is now effective for public companies for annual periods beginning after December 15, 2017 as well as interim periods within those annual periods using either the full retrospective approach or modified retrospective approach. The Company is currently evaluating the impact of the new guidance on its financial statements.

3. Share-based Compensation Plans:

The Company uses stock options and awards of restricted stock to provide long-term incentives for its employees, non-employee directors and certain consultants. The Company has two equity compensation plans under which awards are currently authorized for issuance, the 2013 Employee Stock Purchase Plan and the 2013 Equity and Incentive Plan. No awards have been issued to date under the 2013 Employee Stock Purchase Plan and all of the 128,571 shares previously authorized under this plan remain available for issuance. A summary of the stock option activity for the six months ended December 31, 2016 and 2015 is as follows:

	For the Six Months Ended December 31,			
	2016		2015	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
(In thousands, except per share amounts)				
Outstanding at June 30,	2,037	\$ 13.71	1,484	\$ 11.83
Granted	658	11.85	514	17.76
Exercised	(21)	1.16	(44)	5.27
Forfeited	(31)	17.80	(29)	10.31
Expired	(3)	22.64	(5)	15.19
Outstanding at December 31,	2,640	\$ 13.28	1,920	\$ 13.60
Exercisable at December 31,	1,267		550	
Weighted average fair value of options granted during the period		\$ 8.12		\$ 11.90

For the three and six months ended December 31, 2016, share-based compensation expense related to stock options awarded to employees, non-employee directors and consultants amounted to approximately \$1.5 million and \$2.9 million, respectively, compared to \$1.3 million and \$2.3 million, respectively, for the three and six months ended December 31, 2015.

For the three and six months ended December 31, 2016 share-based compensation expense associated with restricted share awards granted to employees and non-employee consultants was not material. For the three and six months ended December 31, 2015, share-based compensation expense associated with restricted share awards granted to employees and non-employee consultants amounted to \$68 thousand and \$166 thousand, respectively.

As of December 31, 2016, there was \$13.5 million of unrecognized compensation expense related to non-vested stock options.

4. Investments:

Cash in excess of immediate requirements is invested in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

The following table summarizes the Company's investments by category as of December 31, 2016 and June 30, 2016:

In thousands	December 31, 2016	June 30, 2016
Investments - Current:		
Certificates of deposit	\$ 7,110	\$ 18,093
Debt securities - held-to-maturity	67,716	51,571
Total investments - current	\$ 74,826	\$ 69,664
Investments - Noncurrent:		
Certificates of deposit	\$ 2,603	\$ 2,544
Debt securities - held-to-maturity	39,151	71,639
Total investments - non-current	\$ 41,754	\$ 74,183

A summary of the Company's debt securities classified as held-to-maturity is as follows:

In thousands	At December 31, 2016			
	Gross		Gross	
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Investments - Current:				
U.S. government and agency obligations	\$61,558	\$ —	\$ (42)) 61,516
Corporate obligations	6,158	—	(1)) 6,157
Total investments - current	\$67,716	\$ —	\$ (43)) \$67,673
Investments - Noncurrent:				
U.S. government and agency obligations	\$37,024	\$ —	\$ (148)) \$36,876
Corporate obligations	2,127	—	(11)) 2,116
Total investments - non-current	\$39,151	\$ —	\$ (159)) \$38,992

In thousands	At June 30, 2016			
	Gross		Gross	
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Investments - Current:				
U.S. government and agency obligations	\$40,609	\$ 12	\$ (2)) 40,619
Corporate obligations	10,962	3	(1)) 10,964
	\$51,571	\$ 15	\$ (3)) \$51,583
Investments - Noncurrent:				
U.S. government and agency obligations	\$71,639	\$ 53	\$ (11)) \$71,681
	\$71,639	\$ 53	\$ (11)) \$71,681

The amortized cost and fair value of held-to-maturity debt securities as of December 31, 2016, by contractual maturity, were as follows:

In thousands	Amortized Cost	Fair Value
Due in one year or less	\$67,716	\$67,673

Due after one year through two years	39,151	38,992
	\$ 106,867	\$ 106,665

The Company believes that the unrealized losses disclosed above were primarily driven by interest rate changes rather than by unfavorable changes in the credit ratings associated with these securities and as a result, the Company continues to expect to collect the principal and interest due on its debt securities that have an amortized cost in excess of fair value. At each reporting period, the Company evaluates securities for impairment when the fair value of the investment is less than its amortized cost. The Company evaluated the underlying credit quality and credit ratings of the issuers, noting neither a significant deterioration since purchase nor other factors leading to an other-than-temporary impairment. Therefore, the Company believes these losses to be temporary. As of December 31, 2016, the Company did not have the intent to sell any of the securities that were in an unrealized loss position at that date.

5. Fair Value of Financial Instruments and Investments:

Certain assets and liabilities are measured at fair value in the Company's financial statements or have fair values disclosed in the notes to the financial statements. These assets and liabilities are classified into one of three levels of a hierarchy defined by GAAP. The Company's assessment of the significance of a particular item to the fair value measurement in its entirety requires judgment, including the consideration of inputs specific to the asset or liability.

The following methods and assumptions were used to estimate the fair value and determine the fair value hierarchy classification of each class of financial instrument included in the table below.

Cash and Cash Equivalents. The carrying value of cash and cash equivalents approximates fair value as maturities are less than three months.

Certificates of Deposit. The Company's certificates of deposit are placed through an account registry service. The fair value measurement of the Company's certificates of deposit is considered Level 2 of the fair value hierarchy as the inputs are based on quoted prices for identical assets in markets that are not active. The carrying amounts of the Company's certificates of deposit reported in the unaudited condensed balance sheets approximate fair value.

Debt securities – held-to-maturity. The Company's investments in debt securities classified as held-to-maturity generally include U.S. Treasury Securities, government agency obligations, and corporate obligations. U.S. Treasury Securities are valued using quoted market prices. Valuation adjustments are not applied. Accordingly, U.S. Treasury Securities are considered Level 1 of the fair value hierarchy. The fair values of U.S. government agency obligations and corporate obligations are generally determined using recently executed transactions, broker quotes, market price quotations where these are available or other observable market inputs for the same or similar securities. As such, the Company classifies its investments in U.S. government agency obligations and corporate obligations within Level 2 of the hierarchy.

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis:

	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total Fair Value	Total Carrying Value
In thousands					
December 31, 2016					
Cash and cash equivalents	\$42,499	\$ —	\$ —	\$42,499	\$42,499
Certificates of deposit	—	9,694	—	9,694	9,713
Held-to-maturity investments:					
Corporate obligations	—	8,273	—	8,273	8,285
U.S. government and agency obligations	75,519	22,873	—	98,392	98,582
Total assets	\$118,018	\$40,840	\$ —	\$158,858	\$159,079
June 30, 2016					
Cash and cash equivalents	\$28,868	\$ —	\$ —	\$28,868	\$28,868
Certificates of deposit	—	20,626	—	20,626	20,637
Held-to-maturity investments:					
Corporate obligations	—	10,964	—	10,964	10,962
U.S. government and agency obligations	73,809	38,491	—	112,300	112,248
Total assets	\$102,677	\$70,081	\$ —	\$172,758	\$172,715

6. Collaboration Agreement with Biogen

On July 1, 2015, the Company entered into a Collaboration Agreement with Biogen, pursuant to which the Company and Biogen will collaborate to develop, seek regulatory approval for and commercialize gene therapy products to treat XLRS, XLRP, and discovery programs targeting three indications based on the Company's adeno-associated virus vector technologies. The Collaboration Agreement became effective on August 14, 2015.

Under the Collaboration Agreement, the Company will conduct all development activities through regulatory approval in the United States for the XLRS program, and all development activities through the completion of the first in human clinical trial for the XLRP program. In addition, the Collaboration Agreement provides for discovery programs targeting three indications whereby the Company will conduct discovery, research and development activities for those additional drug candidates through the stage of clinical candidate designation, after which, Biogen may exercise an option to continue to develop, seek regulatory approval for and commercialize the designated clinical candidate. In February 2016, the Company announced Biogen's selection of adrenoleukodystrophy as the non-ophthalmic indication of the three discovery programs. Under the terms of the Collaboration Agreement, the Company, in part through its participation in joint committees with Biogen, will participate in overseeing the development and commercialization of these specific programs.

The Company has granted to Biogen with respect to the XLRS and XLRP programs, and upon exercise of the option for the applicable discovery program, an exclusive, royalty-bearing license, with the right to grant sublicenses, to use adeno-associated virus vector technology and other technology controlled by the Company for the licensed products or discovery programs developed under the Collaboration Agreement. Biogen and the Company have also granted each other worldwide licenses, with the right to grant sublicenses, of their respective interests in other intellectual property developed under the collaboration outside of the licensed products or discovery programs.

Biogen will also receive an exclusive license to use the Company's proprietary manufacturing technology platform to make Adeno-Associated Virus ("AAV") vectors for up to six genes, three of which are at the Company's discretion, in exchange for payment of milestones and royalties.

Activities under the Collaboration Agreement were evaluated under ASC 605-25, Revenue Recognition—Multiple Element Arrangements, as amended by ASU 2009-13, Revenue Recognition ("ASC 605-25"), to determine if they represented a multiple element revenue arrangement. The Collaboration Agreement includes the following significant deliverables: (1) for each of the XLRS and XLRP programs, exclusive, royalty-bearing licenses, with the right to grant sublicenses, to use adeno-associated virus vector technology and other technology controlled by the Company for the purpose of researching, developing, manufacturing and commercializing licensed products developed under the arrangement (the "License Deliverables"); (2) for each of the three discovery programs, exercisable options to obtain exclusive licenses to develop, seek regulatory approval for and commercialize any of the designated clinical candidates under such discovery programs (the "Option Deliverables"); and (3) the performance obligations to conduct research and development activities through (a) regulatory approval in the United States, in the case of the XLRS program; (b) completion of the first in human clinical trial, in the case of the XLRP program; and (c) the stage of clinical candidate designation, in the case of each of the three discovery programs (the "R&D Activity Deliverables").

The Company determined that all of the License Deliverables and Option Deliverables did not have stand-alone value and did not meet the criteria to be accounted for as separate units of accounting under ASC 605-25. The factors considered by the Company in making this determination included, among other things, the unique and specialized nature of its proprietary technology and intellectual property, and the development stages of each of the XLRS, XLRP and the discovery programs targeting three indications. Accordingly, the License Deliverables under each of the XLRS and XLRP programs and the Option Deliverables under each of the discovery programs have been combined with the R&D Activity Deliverables associated with each related program and as a result, the Company's separate units of accounting under its collaboration with Biogen, comprise the XLRS program, the XLRP program, and each of the three discovery programs.

Under the Collaboration Agreement, the Company received a non-refundable upfront payment of \$94.0 million in August 2015 which it recorded as deferred revenue. This upfront payment of \$94.0 million was allocated among the separate units of accounting discussed above using the relative selling price method. In addition to the Collaboration Agreement, on July 1, 2015, the Company also entered into an equity agreement with Biogen. Under the terms of this equity agreement, Biogen purchased 1,453,957 shares of the Company's common stock, at a purchase price equal to \$20.63 per share, for an aggregate cash purchase price of \$30.0 million which the Company also received in August 2015. The shares issued to Biogen represented approximately 8.1 percent of the Company's outstanding common stock on a post-issuance basis, calculated on the number of shares that were outstanding at June 30, 2015, and constitute restricted securities that may not be resold by Biogen other than in a transaction registered under, or pursuant to an exemption from the registration requirements of, the Securities Act of 1933, as amended. Accounting standards for multiple element arrangements contain a presumption that separate contracts negotiated or entered into at or near to the same time with the same entity were likely negotiated as a package and should be evaluated as a single agreement. The Company determined that the price of \$20.63 paid by Biogen included a premium of \$7.45 per share over the fair value of the Company's stock price, calculated based upon the stock price on the date of close of the agreement and adjusted for lack of marketability due to restrictions. Accordingly, the total premium of \$10.8 million

was also recorded as deferred revenue and, together with the \$94.0 million, allocated to the separate units of accounting identified above using the relative selling price method as discussed in Note 2 to these financial statements. The Company will record revenue based on the revenue recognition criteria applicable to each separate unit of accounting. For amounts received up-front and initially deferred, the Company will recognize the deferred revenue on a straight-line basis over the estimated service periods in which it is required to perform the research and development activities associated with each unit of accounting, anticipated to be between 2 and 4 years.

The Company recognized collaboration revenue of \$10.9 million and \$11.8 million during the three months ended December 31, 2016 and 2015, respectively, and \$22.7 million and \$22.8 million during the six months ended December 31, 2016 and 2015, respectively, from its collaboration with Biogen. Below is a summary of the components of the collaboration revenue:

	For the Three Months Ended December 31, 2016		For the Six Months Ended December 31, 2015	
	2016	2015	2016	2015
	(dollars in thousands)			
Amortization of non-refundable upfront fees	\$10,803	\$11,725	\$22,528	\$17,717
Milestone revenue	—	—	—	5,000
Other	87	118	134	118
Total collaboration revenue	\$10,890	\$11,843	\$22,662	\$22,835

During the six months ended December 31, 2015, the Company recorded \$5.0 million of milestone revenue after having achieved a patient enrollment-based milestone under the Collaboration Agreement. Other revenue is primarily comprised of reimbursable costs for post-funding development activities conducted by the Company.

As a result of the upfront payment of \$94.0 million made by Biogen and achievement of the \$5.0 million milestone as discussed above, the Company became liable to various research partner institutions for sub-license and other payments under existing agreements with such institutions. These agreements obligate the Company to pay to each research partner institution, amounts that range from 5 percent to 10 percent of certain proceeds received from collaboration and other arrangements, including any milestone payments received under such arrangements. As a result, the Company recorded total collaboration costs of approximately \$12.0 million associated with such obligations during the six months ended December 31, 2015. These collaboration costs included \$0.6 million of expense that was settled during that period by the issuance of 40,000 shares of the Company's common stock to a research partner institution, pursuant to the terms of the existing agreement with that institution. The remainder of these sub-license and milestone fees were fully paid in cash during the fiscal year ended June 30, 2016.

The Company is also eligible to receive payments of up to \$467.5 million based on the successful achievement of future milestones under the two lead programs and up to \$592.5 million based on the exercise of the option for and the successful achievement of future milestones under the three discovery programs. Biogen will pay revenue-based royalties for each licensed product at tiered rates ranging from high single digit to mid-teen percentages of annual net sales of the XLRS or XLRP products and at rates ranging from mid-single digit to low-teen percentages of annual net sales for the discovery products. Due to the uncertainty surrounding the achievement of the future milestones, such payments were not considered fixed or determinable at the inception of the Collaboration Agreement and accordingly, will not be recognized as revenue unless and until they become earned. The Company is not able to reasonably predict if or when the remaining milestones will be achieved.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides an overview of our financial condition as of December 31, 2016, and results of operations for the three and six months ended December 31, 2016 and 2015. This discussion should be read in conjunction with the accompanying Unaudited Condensed Financial Statements and accompanying notes, as well as our Annual Report on Form 10-K for the year ended June 30, 2016, as amended, ("June 2016 Form 10-K"). In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, assumptions and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this report under "Part II, Other Information—Item 1A, Risk Factors." Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies and operations, financing plans, 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," "should," "will," "would" or similar expressions and the negatives of those terms. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's plans, estimates, assumptions and beliefs only as of the date of this report. 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.

As used herein, except as otherwise indicated by context, references to "we," "us," "our," or the "Company" refer to Applied Genetic Technologies Corporation.

Overview

We are a clinical-stage biotechnology company using gene therapy based on the adeno-associated virus ("AAV"), to develop genetic therapies to treat patients with inherited diseases. Each treatment is precisely designed to address a specific genetic disorder. Our most advanced gene therapy programs are designed to produce treatments that will restore visual function in patients with rare blinding diseases. Gene therapies are complex with interdependent components that must work in harmony. Fifteen years of gene therapy experience allows us to design and construct all critical gene therapy components and bring them together to develop potentially effective treatments for patients. We are committed to attracting and maintaining a team with a substantial breadth of clinical and scientific expertise who can foster an atmosphere of scientific growth and discovery.

Our most advanced products consist of four ophthalmology product candidates: X linked retinoschisis ("XLRS"), X-linked retinitis pigmentosa ("XLRP"), caused by mutations in the RPGR gene, and achromatopsia ("ACHM"), caused by mutations in either the CNGB3 gene or the CNGA3 gene. These inherited orphan diseases of the eye are caused by mutations in single genes that significantly affect visual function and currently lack effective medical treatments. Our XLRS and XLRP product candidates are subject to our collaboration agreement with Biogen. Our XLRS and CNGB3-related ACHM product candidates are currently in Phase 1/2 human clinical trials, we recently filed an Investigational New Drug ("IND") application for our CNGA3-related ACHM product candidate, and we expect to file the IND for our XLRP product candidate in 2017. Updates to our development pipeline goals include the following:

For our XLRS program, we currently have enrolled a total of eleven patients – six of whom are in the low dose group, three are in the middle dose group which completes those two groups, and two in the high dose group. The Company is scheduling the final patient to complete this three-patient dose group. Safety data to date have shown that our XLRS product candidate has been generally well tolerated, though we have observed mild to moderate ocular

inflammation in the majority of patients, which resolved either without treatment or after treatment with topical or oral corticosteroids and which led us to amend the protocol to include consistent use of corticosteroids as stated in our June 2016 10-K.

For our CNGB3-related ACHM product candidate, we currently have three patients enrolled in the low dose group, which completes that group. The Data and Safety Monitoring Committee (“DSMC”) has requested follow-up testing on patients in this group which the Company expects to complete this quarter. The Company has identified patients to enroll in the next dose group upon review of the follow-up testing with the DSMC.

For our CNGA3-related ACHM product candidate, we filed an IND with the United States Food and Drug Administration (“FDA”), in October 2016 and are now working with domestic and international investigative sites to complete site initiation activities prior to enrolling patients in the Phase 1/2 clinical trial for that program.

For our XLRP product candidate, IND-enabling toxicology studies, conducted in compliance with good laboratory practices (“GLP”), are underway in two relevant disease models — a naturally occurring dog model and a RPGR knockout mouse model. After completion of these studies, we expect to submit an IND for that product candidate to the FDA in 2017.

As part of our collaboration with Biogen, we are also developing new treatments for three additional indications, two of which are for ophthalmic diseases and one for a non-ophthalmic condition. Biogen has designated adrenoleukodystrophy (“ALD”), as the non-ophthalmic discovery program under this collaboration agreement. ALD is an X-linked genetic disorder that causes damage to the nervous system and adrenal glands, primarily in young boys.

We have other new product candidates in the early stages of development that are solely owned by us, including several indications in our new otology initiative.

We are also conducting preclinical research to develop new product candidates for the treatment of age-related macular degeneration (“AMD”), by leveraging our experience developing products in orphan ophthalmology and our work with a previous partner on a first-generation product for wet AMD.

On January 24, 2017, we entered into a strategic research and development collaboration with Bionic Sight. We will combine our expertise in gene therapy and ophthalmology with Bionic Sight’s innovative neuro-prosthetic device and algorithm for retinal coding to develop an optogenetic therapy for patients with visual deficits or blindness due to retinal disease. Financial terms of the relationship have not been disclosed, but under the agreement we have made a minority investment in Bionic Sight.

- An important initiative for 2017 is the ongoing work in capsid and promoter selection, assay development and process development to keep AGTC at the forefront of AAV technology. Examples of these efforts include our collaborations with 4D Molecular Therapeutics, LLC, the University of Florida and Synpromics Ltd, as well as our on-going internal research efforts.

Since our inception in 1999, we have devoted substantially all of our resources to development efforts relating to our proof-of-concept programs in ophthalmology and other orphan indications, including activities to manufacture products in compliance with good manufacturing practices (“GMP”), preparing to conduct and conducting clinical trials of our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily through the sale of equity securities, proceeds from our collaboration with Biogen and, to a lesser extent through research grants from third parties.

While we expect to continue to generate some revenue from partnering, including our collaboration with Biogen, we do not anticipate that we will generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and which we believe is subject to significant uncertainty. As a result, we expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Because of the risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

Critical Accounting Policies

Our management’s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and share-based compensation. We base our estimates on historical experience, known trends and events,

and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For a description of our accounting policies that, in our opinion, involve the most significant application of judgment or involve complex estimation and which could, if different judgments or estimates were made, materially affect our reported

results of operations, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates” in our June 2016 Form 10-K, for the year ended June 30, 2016.

New Accounting Pronouncements

Refer to Note 2 to the condensed financial statements included in this quarterly report for further information on recently issued accounting standards.

Results of Operations

Comparison of the three months ended December 31, 2016 to the three months ended December 31, 2015

Revenue

	For the Three Months Ended			
	December 31, 2016	2015	Increase (Decrease)	% Increase (Decrease)
	(dollars in thousands)			
Collaboration revenue	\$10,890	\$11,843	\$ (953)	(8)%
Grant revenue	43	346	(303)	(88)%
Total revenue	\$10,933	\$12,189	\$ (1,256)	(10)%

Total revenue for the three months ended December 31, 2016 was \$10.9 million compared to \$12.2 million generated during the same period in 2015. Collaboration revenue recorded during the three months ended December 31, 2016 and 2015 resulted primarily from the amortization of upfront fees received under our collaboration with Biogen which began in August 2015. Grant revenue decreased \$0.3 million during the three months ended December 31, 2016 compared to the same period in 2015, largely attributable to reduced research and development activities on grant-funded projects.

Research and development expense

	For the Three Months Ended			
	December 31, 2016	2015	Increase (Decrease)	% Increase (Decrease)
	(dollars in thousands)			

Edgar Filing: APPLIED GENETIC TECHNOLOGIES CORP - Form 10-Q

Outside program costs	\$2,232	\$2,749	\$ (517)	(19)%
Employee-related costs	1,916	1,358	558	41 %
Share-based compensation	646	873	(227)	(26)%
Laboratory supplies	492	271	221	82 %
Licenses and related fees	3	1,506	(1,503)	(100)%
Other	752	446	306	69 %
Total research and development expense	\$6,041	\$7,203	\$ (1,162)	(16)%

Research and development expense for the three months ended December 31, 2016 decreased by \$1.2 million to \$6.0 million compared to the same period in 2015. The period-over-period decrease was largely driven by the reduction of licenses and related fees which were lower during the three months ended December 31, 2016 compared to the three months ended December 31, 2015 due to technology access fees that were incurred in 2015 and did not recur in 2016. In addition, outside program costs decreased during the three months ended December 31, 2016 compared to the three months ended December 31, 2015, due largely to temporary delays encountered during the conduct of Phase 1/2 human clinical trials for our XLRS and CNGB3-related ACHM product candidates. The impact of these decreases was partially offset by higher employee-related costs that were driven primarily by hiring additional employees, as well as higher laboratory supply costs.

General and administrative expense

	For the Three Months Ended				
	December 31, 2016	2015	Increase (Decrease)	% Increase (Decrease)	
	(dollars in thousands)				
Employee-related costs	\$954	\$739	\$ 215	29	%
Share-based compensation	846	493	353	72	%
Legal and professional fees	201	240	(39)	(16)	%
Other	739	644	95	15	%
Total general and administrative expense	\$2,740	\$2,116	\$ 624	29	%

General and administrative expense for the three months ended December 31, 2016 increased by \$0.6 million to \$2.7 million compared to the same period in 2015. The increase was primarily driven by higher share-based compensation and employee-related costs which resulted from hiring additional employees to support our continued expansion. The increases were partially offset by lower legal and professional fees during the three months ended December 31, 2016 compared to the three months ended December 31, 2015.

Comparison of six months ended December 31, 2016 to the six months ended December 31, 2015

Revenue

	For the Six Months Ended				
	December 31, 2016	2015	Increase (Decrease)	% Increase (Decrease)	
	(dollars in thousands)				
Collaboration revenue	\$22,662	\$22,835	\$ (173)	(1)	%
Grant revenue	77	416	(339)	(81)	%
Total revenue	\$22,739	\$23,251	\$ (512)	(2)	%

Total revenue for the six months ended December 31, 2016 was \$22.7 million compared to \$23.3 million generated during the same period in 2015. Collaboration revenue recorded during the six months ended December 31, 2016 and 2015 resulted primarily from the amortization of upfront fees received under our collaboration agreement with Biogen which began in August 2015. Grant revenue decreased \$0.3 million during the six months ended December 31, 2016 compared to same period in 2015, largely attributable to reduced research and development activities on grant-funded projects.

Research and development expense

	For the Six Months Ended	Increase	% Increase
--	-----------------------------	----------	------------

Edgar Filing: APPLIED GENETIC TECHNOLOGIES CORP - Form 10-Q

	December 31,		(Decrease)	(Decrease)	
	2016	2015			
	(dollars in thousands)				
Collaboration costs	\$-	\$12,034	\$(12,034)	(100)	%
Outside program costs	4,511	5,806	(1,295)	(22)	%
Employee-related costs	3,520	2,596	924	36	%
Share-based compensation	1,281	1,172	109	9	%
Licenses and related fees	6	1,506	(1,500)	(100)	%
Laboratory supplies	854	462	392	85	%
Other	1,440	664	776	117	%
Total research and development expense	\$11,612	\$24,240	\$(12,628)	(52)	%

Research and development expense for the six months ended December 31, 2016 decreased by \$12.6 million to \$11.6 million compared to the same period in 2015. The decrease was largely driven by the impact of collaboration-related costs and license fees that were incurred in 2015 as a result of our entry into and receipt of fees and payments under the collaboration agreement with Biogen and which did not recur in 2016. Also, licenses and related fees decreased during the six months ended December 31, 2016 compared to the six months ended December 31, 2015 due to technology access fees that were incurred in 2015 and did not recur in 2016. In addition, outside program costs decreased in 2016 compared to 2015 due largely to temporary delays encountered during the conduct of Phase 1/2 human clinical trials for our XLRS and CNGB3-related ACHM product candidates. The impact of these decreases was partially offset by higher employee-related and share-based compensation expenses that were driven primarily by hiring additional employees and the incremental impact of new share-based incentives awarded in 2016, as well as higher laboratory supplies and other costs during 2016, when compared to 2015.

General and administrative expense

	For the Six Months Ended				
	December 31, 2016	2015	Increase (Decrease)	% Increase (Decrease)	
	(dollars in thousands)				
Employee-related costs	\$1,976	\$1,353	\$ 623	46	%
Share-based compensation	1,631	1,317	314	24	%
Legal and professional fees	485	713	(228)	(32)	%
Other	1,494	1,971	(477)	(24)	%
Total general and administrative expense	\$5,586	\$5,354	\$ 232	4	%

General and administrative expense for the six months ended December 31, 2016 increased by \$0.2 million to \$5.6 million compared to the same period in 2015. The increase was primarily driven by higher employee-related and share-based compensation costs which resulted from hiring additional employees to support our continued expansion, partially offset by lower legal and professional fees and other expenses. The higher legal and professional fees incurred in 2015 were largely attributable to professional consultations associated with the negotiation and entry into our collaboration with Biogen.

Liquidity and capital resources

We have incurred cumulative losses and negative cash flows from operations since our inception in 1999, and as of December 31, 2016, we had an accumulated deficit of \$84.3 million. It will be several years, if ever, before we have a product candidate ready for commercialization. We expect that our research and development and general and administrative expenses will continue to increase and as a result, we anticipate that we will require additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

As of December 31, 2016, we had cash, cash equivalents, and investments totaling \$159.1 million. We believe that our existing cash, cash equivalents, and investments at December 31, 2016 will be sufficient to enable us to advance planned preclinical studies and clinical trials for our lead product candidates and currently planned discovery programs for at least the next two years.

Cash in excess of immediate requirements is invested in accordance with our investment policy which primarily seeks to maintain adequate liquidity and preserve capital by generally limiting investments to certificates of deposit and investment-grade debt securities that mature within 24 months. As of December 31, 2016, our cash and cash equivalents were held in bank accounts and money market funds, while our short and long-term investments consisted of certificates of deposit and corporate and government bonds, none of which mature more than 24 months after the balance sheet date, consistent with our investment policy that seeks to maintain adequate liquidity and preserve capital.

Cash flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	For the Six Months Ended December 31,	
	2016	2015
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$(12,788)	\$86,244
Investing activities	26,395	(100,475)
Financing activities	24	19,446
Net increase in cash and cash equivalents:	\$13,631	\$5,215

Operating activities. For the six months ended December 31, 2016, net cash used in operating activities was primarily the result of cash payments made for normal business operations and the impact of changes in our working capital accounts. For the six months ended December 31, 2015, net cash provided by operating activities was primarily associated with the upfront cash proceeds of \$104.8 million, which included an allocation of \$10.8 million from the equity agreement, and milestone payment of \$5.0 million received during that period following our collaboration with

Biogen. Those cash proceeds were partially offset by the impact of the net loss incurred during the six months ended December 31, 2015 and changes in our working capital accounts.

Investing activities. Net cash provided by investing activities for the six months ended December 31, 2016 consisted primarily of cash proceeds of \$64.3 million from the maturity of investments, partially offset by cash outflows of \$37.2 million related to the purchase of investments securities. For the six months ended December 31, 2015, net cash used in investing activities consisted primarily of cash outflows of \$120.6 million related to the purchase of investment securities, partially offset by \$20.3 million of proceeds from the maturity of investments.

Financing activities. Net cash provided by financing activities during the six months ended December 31, 2016 was associated with the exercise of common stock options. For the six months ended December 31, 2015, net cash provided by financing activities of \$19.4 million was primarily related to the shares of common stock purchased by Biogen pursuant to the equity agreement that was negotiated and entered into contemporaneously with the Biogen collaboration agreement in July 2015.

Operating capital requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks incident in the development of new gene therapy products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

In order to complete the process of obtaining regulatory approval for our lead product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved, we will require substantial additional funding.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Refer to Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended June 30, 2016, which is incorporated by reference herein, for a description of our market risks.

ITEM 4. CONTROLS AND PROCEDURES

Material Weakness in Internal Control over Financial Reporting

As discussed in our Annual Report on Form 10-K for the year ended June 30, 2016, our management has determined that we have a material weakness in our internal control over financial reporting which relates to the design and operation of our closing and financial reporting processes. Refer to Part II, Item 9A, “Controls and Procedures,” in our Annual Report on Form 10-K for the year ended June 30, 2016 for a discussion of the actions that we have previously undertaken to remediate this material weakness. During the period covered by this Quarterly Report on Form 10-Q, we continued to: (a) provide functional and system training to employees and to prepare detailed documentation to clearly define key tasks and actions; (b) document and formalize our accounting policies and internal control processes and to help strengthen supervisory reviews by our management; (c) hire additional employees to provide further support to our finance and accounting team; and (d) design and implement monthly manual controls to manage our financial reporting close processes and to help ensure an adequate level of segregation of duties within our finance and accounting function. Although we had not fully remediated this material weakness as of December 31, 2016, we continue to actively engage in the implementation of these and other remediation efforts to address this material weakness.

Notwithstanding the material weakness described above, our management has concluded that the financial statements covered by this report present fairly, in all material respects, our financial position, results of operation and cash flows in conformity with U.S. generally accepted accounting principles.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized and reported within the time periods specified in the rules and forms, and that such information is accumulated and communicated to us, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and we necessarily were required to apply our judgment in evaluating whether the benefits of the controls and procedures that we adopt outweigh their costs.

As required by Rule 13a-15(b) under the Exchange Act, an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of June 30, 2016 was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. As a result of the material weakness in internal control over financial reporting relating to the design and operation of our closing and financial reporting processes disclosed below, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2016.

Changes in Internal Control over Financial Reporting

As described under “Material Weakness in Internal Control over Financial reporting,” above, during the period covered by this Quarterly Report on Form 10-Q we took and are continuing to take remedial actions intended to correct material weaknesses in our system of internal controls over financial reporting, which remedial actions have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting. Except for those remedial actions, there was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any pending legal proceedings. However, because of the nature of our business, we may be subject at any particular time to lawsuits or other claims arising in the ordinary course of our business, and we expect that this will continue to be the case in the future.

ITEM 1A. RISK FACTORS

Refer to Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the year ended June 30, 2016 for a listing of our risk factors. There has been no material change in such risk factors since June 30, 2016.

ITEM 6. EXHIBITS

Exhibit

Number Description

- 3.1 Fifth Amended and Restated Certificate of Incorporation of Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, event date March 26, 2014, filed on April 1, 2014)
- 3.2 Amended and Restated Bylaws of Applied Genetic Technologies Corporation (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, event date March 26, 2014, filed on April 1, 2014)
- 10.1* Employment Letter Agreement dated as of October 29, 2016 between Applied Genetic Technologies Corporation and Michael Goldstein
- 31.1** Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer of Applied Genetic Technologies Corporation
- 31.2** Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer of Applied Genetic Technologies Corporation
- 32.1*** Section 1350 Certification of Principal Executive Officer and Principal Financial Officer of Applied Genetic Technologies Corporation
- 101** Interactive Data Files pursuant to Rule 405 of Regulation S-T (XBRL)

*Management Compensation Agreement

** Filed herewith.

*** Furnished herewith.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

APPLIED GENETIC TECHNOLOGIES
CORPORATION

(Registrant)

By: /s/ Lawrence E. Bullock
Lawrence E. Bullock, Chief Financial Officer

Date: February 8, 2017