

APPLIED GENETIC TECHNOLOGIES CORP
Form 10-Q
February 08, 2016

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, 2015

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

Alachua, Florida 32615

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

(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 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. (Check one):

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 1, 2016, a total of 18,037,994 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, 2015

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, 2015 and June 30, 2015</u>	3
<u>Condensed Statements of Operations (Unaudited) for the three and six months ended December 31, 2015 and 2014</u>	4
<u>Condensed Statements of Cash Flows (Unaudited) for the six months ended December 31, 2015 and 2014</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>	16
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. <u>RISK FACTORS</u>	25
ITEM 2.	25

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

ITEM 5.	<u>OTHER INFORMATION</u>	25
ITEM 6.	<u>EXHIBITS</u>	26
	<u>SIGNATURES</u>	27

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

APPLIED GENETIC TECHNOLOGIES CORPORATION

CONDENSED BALANCE SHEETS

(Unaudited)

	December 31, 2015	June 30, 2015
In thousands, except per share data		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 44,402	\$ 39,187
Investments	105,614	22,454
Grants receivable	896	883
Prepaid and other current assets	1,890	1,608
Total current assets	152,802	64,132
Investments	40,591	23,629
Property and equipment, net	513	478
Intangible assets, net	1,408	1,448
Grants receivable and other assets	763	487
Total assets	\$ 196,077	\$ 90,174
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 817	\$ 1,191
Accrued and other liabilities	6,122	3,451
Deferred revenue	46,898	—
Total current liabilities	53,837	4,642
Deferred revenue, net of current portion	40,215	—
Total liabilities	94,052	4,642
Stockholders' equity:		
Common stock, par value \$.001 per share, 150,000 shares authorized; 18,038 and 16,491 shares issued; 18,033 and 16,476 shares outstanding at December 31, 2015 and June 30, 2015, respectively		
	18	16
Additional paid-in capital	196,737	174,168
Accumulated deficit	(94,730)	(88,652)
Total stockholders' equity	102,025	85,532
Total liabilities and stockholders' equity	\$ 196,077	\$ 90,174

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,	
	2015	2014	2015	2014
Revenue:				
Collaboration revenue	\$11,843	\$—	\$22,835	\$—
Grant and other revenue	346	652	416	1,357
Total revenue	12,189	652	23,251	1,357
Operating expenses:				
Research and development	7,203	3,438	24,240	7,871
General and administrative	2,116	1,916	5,354	3,597
Total operating expenses	9,319	5,354	29,594	11,468
Income (loss) from operations	2,870	(4,702)	(6,343)	(10,111)
Other income:				
Investment income	175	52	265	80
Total other income	175	52	265	80
Net income (loss)	\$3,045	\$(4,650)	\$(6,078)	\$(10,031)
Net earnings (loss) per share, basic and diluted	\$0.17	\$(0.28)	\$(0.35)	\$(0.63)
Weighted average shares outstanding - basic	17,998	16,422	17,585	16,027
Weighted average shares outstanding - diluted	18,262	16,422	17,585	16,027

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,	
	2015	2014
Cash flows from operating activities		
Net loss	\$(6,078)	\$(10,031)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Share-based compensation expense	2,489	1,228
Share-based collaboration expense	636	—
Depreciation and amortization	196	184
Changes in operating assets and liabilities:		
Decrease (increase) in grants receivable	467	(484)
(Increase) decrease in prepaid and other assets	(876)	798
Decrease in accounts payable	(374)	(432)
Increase in deferred revenues	87,113	—
Increase in accrued and other liabilities	2,671	622
Net cash provided by (used in) operating activities	86,244	(8,115)
Cash flows from investing activities		
Purchase of property and equipment	(106)	(180)
Purchase of and capitalized costs related to intangible assets	(85)	(57)
Maturity of investments	20,344	88,450
Purchase of investments	(120,628)	(76,570)
Net cash (used in) provided by investing activities	(100,475)	11,643
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	19,211	32,009
Proceeds from exercise of common stock options	235	69
Net cash provided by financing activities	19,446	32,078
Net increase in cash and cash equivalents	5,215	35,606
Cash and cash equivalents, beginning of period	39,187	8,623
Cash and cash equivalents, end of period	\$44,402	\$44,229

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.

On April 1, 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 shares began trading on the Nasdaq Global Select Market on March 27, 2014 under the ticker symbol AGTC. On April 3, 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.

On July 30, 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. On August 1, 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.

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, 2015, the Company had an accumulated deficit of \$94.7 million and expects to continue 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, 2015, the Company had cash and cash equivalents and investments of \$190.6 million and believes that these capital resources will be sufficient to allow it to fund its operations for at least the next two years.

(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.

The Condensed Balance Sheet as of June 30, 2015 was derived from audited financial statements, but does not include all disclosures required by GAAP. These Condensed Financial Statements should be read in conjunction with the audited financial statements included in the Company's 2015 Annual Report on Form 10-K. Results of operations for the three and six months ended December 31, 2015 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. 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 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 a collaboration and license agreement (the "Collaboration Agreement") with a wholly owned subsidiary of Biogen Inc. 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.

During the six months ended December 31, 2015, we recorded and received \$5.0 million of milestone revenue after having achieved a patient enrollment-based milestone under our collaboration arrangement with Biogen.

(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 \$1.3 million and \$958 thousand at December 31, 2015 and June 30, 2015, respectively, and are included within the Prepaid and other current assets line item on the balance sheets.

- (i) 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, or IRS, notified us of an income tax audit for the tax period ending June 30, 2014. As of December 31, 2015, the Company had no liability recorded as an uncertain tax benefit. Currently, the Company cannot reasonably estimate the ultimate outcome of the IRS audit, however, it believes that it has followed applicable U.S. tax laws and will defend its income tax positions.
- (j) 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.
- (k) Comprehensive loss – Comprehensive loss consists of net loss and changes in equity during a period from transactions and other equity and circumstances generated from non-owner sources. The Company’s net loss equals comprehensive loss for all periods presented.
- (l) New Accounting Pronouncements – In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes, requiring all deferred tax assets and liabilities, and any related valuation allowance, to be classified as noncurrent on the balance sheet. The classification change for all deferred taxes as noncurrent simplifies entities’ processes as it eliminates the need to separately identify the net current and net noncurrent deferred tax asset or liability in each jurisdiction and allocate valuation allowances. The Company has elected to prospectively adopt the accounting standard with effect from the beginning of its third fiscal quarter ending March 31, 2016 and anticipates that the adoption of this standard will not have a material impact on its financial statements.
- In August 2014, the FASB issued Accounting Standard Update No. 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. The amendments require management to perform interim and annual assessments of an entity’s ability to continue as a going concern and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. The standard applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The Company has elected to prospectively adopt the accounting standard with effect from the beginning of its third fiscal quarter ending March 31, 2016 and anticipates that the adoption of this standard will not have a material impact 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 impacts 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, 2015 and 2014 is as follows:

	For the Six Months Ended December			
	31, 2015		2014	
		Weighted		Weighted
		Average		Average
		Exercise		Exercise
(In thousands, except per share amounts)	Shares	Price	Shares	Price
Outstanding at June 30,	1,484	\$ 11.83	1,024	\$ 6.21
Granted	514	17.76	252	16.81
Exercised	(44)	5.27	—	—
Forfeited	(29)	10.31	(19)	12.00
Expired	(5)	15.19	—	—
Outstanding at December 31,	1,920	\$ 13.60	1,257	\$ 8.25
Exercisable at December 31,	550		318	
Weighted average fair value of options granted				
during the period		\$ 11.90		\$ 12.38

For the three and six months ended December 31, 2015, share-based expense related to stock options awarded to employees, non-employee directors and consultants amounted to approximately \$1.3 million and \$2.3 million, respectively, compared to \$626 thousand and \$931 thousand, respectively, for the three and six months ended December 31, 2014.

For the three and six months ended December 31, 2015, share-based expense associated with restricted share awards granted to employees and non-employee consultants amounted to \$68 thousand and \$166 thousand, respectively, compared to \$195 thousand and \$297 thousand, respectively, for the three and six months ended December 31, 2014.

As of December 31, 2015, there was \$12.2 million of unrecognized compensation expense related to non-vested stock options and \$77 thousand of unrecognized compensation expense associated with non-vested restricted share awards.

(4) Investments:

The following is a summary of the Company's investments by category for each of the periods presented:

In thousands	December	
	31, 2015	June 30, 2015
Investments - Current:		
Certificates of deposit	\$21,764	\$10,776
Debt securities - held-to-maturity	83,850	11,678
	\$105,614	\$22,454
Investments - Noncurrent:		
Certificates of deposit	\$3,590	\$5,310
Debt securities - held-to-maturity	37,001	18,319
	\$40,591	\$23,629

As of December 31, 2015, a summary of the debt securities classified as held-to-maturity is as follows:

In thousands	Amortized Cost	Gross		Fair Value
		Unrealized Gains	Unrealized Losses	
Investments - Current:				
U.S. government and agency obligations	\$ 77,329	\$ —	\$ (44)	77,285
Corporate obligations	6,521	—	(10)	6,511
	\$ 83,850	\$ —	\$ (54)	\$83,796
Investments - Noncurrent:				
U.S. government and agency obligations	\$ 34,999	\$ —	\$ (174)	\$34,825
Corporate obligations	2,002	—	(4)	1,998
	\$ 37,001	\$ —	\$ (178)	\$36,823

The amortized cost and fair value of held-to-maturity debt securities as of December 31, 2015, by contractual maturity, were as follows:

In thousands	Amortized Cost	Fair Value
Due in one year or less	\$83,850	\$83,796

Due after one year through two years	37,001	36,823
	\$ 120,851	\$ 120,619

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, 2015, 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 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, commercial paper, 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, commercial paper 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, commercial paper 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, 2015					
Cash and cash equivalents	\$44,402	\$ —	\$ —	\$44,402	\$44,402
Certificates of deposit	—	25,354	—	25,354	25,354
Held-to-maturity investments:					
Corporate obligations	—	8,509	—	8,509	8,523
U.S. government and agency obligations	54,413	57,697	—	112,110	112,328
Total assets	\$98,815	\$ 91,560	\$ —	\$ 190,375	\$ 190,607
June 30, 2015					
Cash and cash equivalents	\$39,187	\$ —	\$ —	\$39,187	\$39,187
Certificates of deposit	—	16,086	—	16,086	16,086
Held-to-maturity investments:					

Corporate obligations	—	7,935	—	7,935	7,937
U.S. government and agency obligations	3,824	18,232	—	22,056	22,060
Total assets	\$43,011	\$ 42,253	\$ —	\$85,264	\$85,270

(6) Collaboration Agreement with Biogen

On July 1, 2015, the Company entered into a Collaboration Agreement (the “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. 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 will grant to Biogen upon exercise of the option with respect to 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 purpose of researching, developing, manufacturing and commercializing licensed products developed under the Collaboration Agreement. The Company has granted Biogen a non-exclusive, worldwide, royalty-free, fully paid license, with the right to grant sublicenses, of its interest in other intellectual property developed pursuant to the Collaboration Agreement.

Biogen will also receive an exclusive license to use the Company's proprietary manufacturing technology platform to make 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 ("ASC 605-25") (as amended by ASU 2009-13, Revenue Recognition) 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% of our 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 3 years.

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

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

	For the Three Months Ended December 31, 2015		For the Six Months Ended December 31, 2014	
	(dollars in thousands)		(dollars in thousands)	
Amortization of non-refundable upfront fees	\$ 11,725	\$ —	\$ 17,717	\$ —
Milestone revenue	—	—	5,000	—
Other	118	—	118	—
Total collaboration revenue	\$ 11,843	\$ —	\$ 22,835	\$ —

During the six months ended December 31, 2015, the Company recorded and received \$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% to 10% 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 \$636 thousand of expense that was settled during this 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. Other amounts payable in cash to the research partner institutions were due at varying dates ranging from 15 days following receipt of the upfront payment from Biogen to 75 days following the end of the fiscal quarter in which such proceeds were received.

The Company is also eligible to receive payments from Biogen of up to \$467.5 million upon the successful achievement of future milestones under the two lead programs and up to \$592.5 million upon the exercise by Biogen 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 are 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, 2015, and results of operations for the three and six months ended December 31, 2015 and 2014. This discussion should be read in conjunction with the accompanying Condensed Financial Statements and accompanying notes, as well as our Annual Report on Form 10-K for the year ended June 30, 2015. 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," "projects," "should," "will," "would" or similar expressions and their 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 that uses our proprietary gene therapy platform to develop products designed to transform the lives of patients with severe diseases in ophthalmology. Our lead product candidates are treatments for X-linked retinoschisis, or XLRs, and achromatopsia, or ACHM, each of which are currently in phase 1/2 human clinical trials, and X-linked retinitis pigmentosa, or XLRP, which is in the preclinical stage. These rare diseases of the eye are caused by mutations in single genes, significantly affect visual function and currently lack effective medical treatments. Updates to our development pipeline goals include the following:

- During the six months ended December 31, 2015, we partnered the XLRs program with Biogen, continued the conduct of our phase 1/2 human clinical trial for XLRs and received a milestone from Biogen related to successful clinical trial enrollment. We continue to expect to report initial clinical data for this program at an appropriate scientific meeting in 2016.
- For our ACHM product candidate, we filed an investigational new drug application in October 2015 in order to begin a phase 1/2 clinical trial. We also partnered with Biogen our product candidate for XLRP, a disease characterized by progressive degeneration of the retina, leading to total blindness in adult men, and are conducting IND-enabling studies.
- As part of our partnership with Biogen, we are also developing new treatments for three new indications, of which two are in ophthalmic diseases and one in a non-ophthalmic condition. Biogen has designated adrenoleukodystrophy (ALD) as the non-ophthalmic discovery program under this partnership. ALD is an X-linked genetic disorder that causes damage to the nervous system and adrenal glands, primarily in young boys.
- In addition to the indications being developed under our partnership with Biogen, we have other new treatments under development that are solely owned by us.
- We have begun to develop new product candidates for the treatment of age-related macular degeneration, or 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.

In the longer term, we will seek opportunities to take advantage of the adaptability of our gene therapy platform to address a range of genetic diseases, both within and beyond our initial focus area of orphan ophthalmology. Since our inception in 1999, we have devoted substantially all of our resources to development efforts relating to our proof-of-concept programs for our multiple product candidates in ophthalmology and alpha-1 antitrypsin deficiency, or AAT deficiency, an inherited orphan lung disease, including activities to manufacture product in compliance with good manufacturing practices, 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 funded our operations primarily through the private placement of preferred stock, common stock, convertible notes and warrants to purchase preferred stock and through our public offerings consummated in 2014 as well as revenue from partnering. We have also been the recipient, either independently or with our collaborators, of grant funding administered through federal, state, and local governments and agencies, including the National Institutes of Health, or NIH, the United States Food

and Drug Administration, or FDA, and by patient advocacy groups such as the Foundation Fighting Blindness, or FFB, and the Alpha-1 Foundation.

While we expect to continue to generate some revenue from partnering, 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 numerous 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.

Recent Developments

Collaboration with Biogen

On July 1, 2015, we entered into a collaboration and license agreement, which we refer to as the collaboration agreement, with a wholly owned subsidiary of Biogen Inc., pursuant to which we 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 our adeno-associated virus vector technologies. The collaboration agreement became effective on August 14, 2015, following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

Under the collaboration agreement, we 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 we 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. Under the terms of the collaboration agreement, we, in part through our participation in joint committees with Biogen, will participate in overseeing the development and commercialization of these specific programs.

We have granted Biogen for the XLRS and XLRP programs, and will grant upon the 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 us for the purpose of researching, developing, manufacturing and commercializing licensed products developed under the collaboration agreement. We have granted Biogen a non-exclusive, worldwide, royalty-free, fully paid license, with the right to grant sublicenses, of our interest in other intellectual property developed pursuant to the Collaboration Agreement.

Under the collaboration agreement, we received a non-refundable upfront payment of \$94.0 million and a milestone payment of \$5.0 million during the six months ended December 31, 2015. As a result of the upfront payment made by Biogen and our achievement of this milestone, we became liable to various research partner institutions for sub-license, milestone and other payments and accordingly, incurred costs of collaboration revenue totaling approximately \$12.0 million which were recorded during the six months ended December 31, 2015. In addition, we recorded other revenue of \$118 thousand under the collaboration agreement during the three months ended December 31, 2015 which was primarily comprised of reimbursable costs for post-funding development activities that we conducted.

We are also eligible to receive payments from Biogen of up to \$467.5 million upon the successful achievement of future milestones under the two lead programs and up to \$592.5 million upon the exercise by Biogen 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 low-double digit to mid-teen percentages of annual net sales of the XLRS product, high-single digit to low-teen percentages of annual net sales of the XLRP product and mid-single digit to low-teen percentages of annual net sales of the three 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 are earned. We achieved the first milestone under the XLRS program in late August 2015, which triggered a milestone payment from Biogen of \$5.0 million. We are not able to reasonably predict if or when the remaining milestones will be achieved.

Biogen will also receive an exclusive license to use our proprietary manufacturing technology platform to make AAV vectors for up to six genes, three of which are at our discretion, in exchange for payment of milestones and royalties.

In addition to the collaboration agreement, on July 1, 2015, we also entered into an equity agreement with Biogen. Under the terms of the equity agreement, Biogen purchased 1,453,957 shares of our common stock, at a purchase price equal to \$20.63 per share, for an aggregate cash purchase price of \$30.0 million which we received from Biogen in August 2015. We 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, we

allocated this total premium of \$10.8 million, together with the upfront payment of \$94.0 million, to the separate units of accounting identified under our collaboration Biogen using the relative selling price method, and will record revenue based on the revenue recognition criteria applicable to each of the separate units.

The shares issued to Biogen represented approximately 8.1% of our outstanding common stock on a post-issuance basis, calculated based on the number of shares that were outstanding at June 30, 2015.

Collaboration with Synpromics Limited

In December 2015, we entered into an agreement with Synpromics Limited (“Synpromics”) to utilize Synpromics' proprietary technology to develop and optimize synthetic promoters. In the event that results from the research are promising, we have options to license promoters that result from the collaboration efforts.

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, 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 those 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 Annual Report on Form 10-K for the year ended June 30, 2015. Following our collaboration with Biogen as described above, our critical accounting policies and estimates have been impacted as follows:

Collaboration revenue

During the three and six months ended December 31, 2015, we recognized revenue of approximately \$11.8 million and \$22.8 million, respectively, from our collaboration with Biogen. Below is a summary of the components of the collaboration revenue:

	For the Three Months Ended December 31, 2015		For the Six Months Ended December 31, 2014	
	(dollars in thousands)	2014	(dollars in thousands)	2014
Amortization of non-refundable upfront fees	\$11,725	\$	—\$17,717	\$
Milestone revenue	—	—	5,000	—
Other	118	—	118	—

Total collaboration revenue \$11,843 \$ —\$22,835 \$ —

The terms of the collaboration agreement and other potential collaboration or commercialization agreements we may enter into generally contain multiple elements, or deliverables, which may include, among others, (i) licenses, or options to obtain licenses, to our 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.

We determine the estimated selling price for deliverables within each agreement using vendor-specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, of selling price if VSOE is not available, or best estimate of selling price, or BESP, if neither VSOE nor TPE are available. Determining the best estimate of selling price for a deliverable requires significant judgment. We use BESP to estimate the selling price related to licenses to our proprietary technology, since we often do

not have VSOE or TPE of selling price for these deliverables. In those circumstances where we utilize BESP to determine the estimated selling price of a license to our proprietary technology, we consider 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 our best estimate of selling price, we evaluate 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 or if the fair value of any of the undelivered elements cannot be determined, the arrangement is then accounted for as a single unit of accounting, and we recognize the consideration received under the arrangement as revenue on a straight-line basis over our estimated period of performance. Our anticipated periods of performance, typically the terms of our 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 we record in future periods.

Milestone revenue

We apply 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 our performance or on the occurrence of a specific outcome resulting from our 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 us. 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 our 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 our 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.

We assess whether a milestone is substantive at the inception of the arrangement. If a milestone is deemed substantive and the milestone payment is nonrefundable, we recognize 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.

During the six months ended December 31, 2015, we recorded \$5.0 million of milestone revenue after having achieved a patient enrollment-based milestone under our collaboration arrangement with Biogen.

Deferred Revenue

Amounts received by us 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.

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 three months ended December 31, 2015 to three months ended December 31, 2014

Revenue

	For the Three Months Ended		Increase	% Increase
	December 31, 2015	2014	(Decrease)	(Decrease)
	(dollars in thousands)			
Collaboration revenue	\$11,843	\$—	\$ 11,843	n/m
Grant revenue	346	652	(306)	(47)%
Total revenue	\$12,189	\$652	\$ 11,537	n/m

Total revenue for the three months ended December 31, 2015 was \$12.2 million compared to \$652 thousand generated during the same period in 2014. Revenue recorded during the three months ended December 31, 2015 resulted primarily from the amortization of upfront fees received under our collaboration with Biogen. Grant revenue generated in the three months ended December 31, 2015 decreased year over year due largely to reduced research and development activities on grant-funded projects.

Research and development expense

	For the Three Months Ended		Increase	% Increase
	December 31, 2015	2014	(Decrease)	(Decrease)
	(dollars in thousands)			
Outside program costs	\$2,749	\$2,032	\$ 717	35 %
Licenses and related fees	1,506	—	1,506	n/m
Employee-related costs	1,358	677	681	101 %
Share-based compensation	873	285	588	206 %
Other	717	444	273	61 %
Total research and development expense	\$7,203	\$3,438	\$ 3,765	110 %

Research and development expense for the three months ended December 31, 2015 increased by \$3.8 million to \$7.2 million compared to the same period in 2014. The increase was largely a result of higher outside program costs and license and related fees due to the increased activity during the period relating to the development of our product candidates. Employee-related and share-based compensation costs also increased year-over-year due primarily to the hiring of additional employees to support the company's increased level of research and development activity.

General and administrative expense

	For the Three Months Ended				
	December 31, 2015	2014	Increase (Decrease)	% Increase (Decrease)	
	(dollars in thousands)				
Employee-related costs	\$ 739	\$ 478	\$ 261	55	%
Share-based compensation	493	536	(43)	(8)	%
Legal and professional fees	240	245	(5)	(2)	%
Other	644	657	(13)	(2)	%
Total general and administrative expense	\$2,116	\$1,916	\$ 200	10	%

General and administrative expense for the three months ended December 31, 2015 increased by \$200 thousand to \$2.1 million compared to the same period in 2014. The increase was driven by higher employee-related costs resulting from the hiring of additional employees to support our continued expansion.

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

Comparison of six months ended December 31, 2015 to six months ended December 31, 2014

Revenue

	For the Six Months Ended December 31, 2015		2014	Increase (Decrease)	% Increase (Decrease)	
	(dollars in thousands)					
Collaboration revenue	\$22,835	\$—	\$ 22,835	100	%	
Grant revenue	416	1,257	(841)	(67)%	
Other	—	100	(100)	(100)%	
Total revenue	\$23,251	\$ 1,357	\$ 21,894	n/m		

Total revenue for the six months ended December 31, 2015 was \$23.3 million compared to \$1.4 million generated during the same period in 2014. The increase was largely driven by revenue generated from our collaboration with Biogen, primarily comprised of the amortization of upfront fees and milestone revenue of \$5.0 million that was recorded in the prior quarter following achievement of a patient enrollment-based milestone under the terms of that collaboration agreement. The year over year decrease in grant revenue was largely attributable to reduced research and development activities on grant-funded projects. Other revenue generated in 2014 was from a right of reference agreement that was entered into with a strategic partner in that period.

Research and development expense

	For the Six Months Ended December 31, 2015		2014	Increase (Decrease)	% Increase (Decrease)	
	(dollars in thousands)					
Collaboration costs	\$12,034	\$—	\$ 12,034	100	%	
Outside program costs	5,806	5,319	487	9	%	
Employee-related costs	2,596	1,270	1,326	104	%	
Licenses and related fees	1,506	—	1,506	n/m		
Share-based compensation	1,172	454	718	158	%	
Other	1,126	828	298	36	%	
Total research and development expense	\$24,240	\$ 7,871	\$ 16,369	208	%	

Research and development expense for the six months ended December 31, 2015 increased by \$16.4 million to \$24.2 million compared to the same period in 2014, driven largely by the incremental costs associated with our collaboration arrangement with Biogen as discussed above. Higher license and related fees due to the increased activity relating to the development of our product candidates and increased employee-related and share-based compensation expenses resulting from the hiring of additional employees and the impact of new incentive awards also contributed to the year-over-year increase in research and development expense.

General and administrative expense

	For the Six Months Ended				
	December 31, 2015	2014	Increase (Decrease)	% Increase (Decrease)	
	(dollars in thousands)				
Employee-related costs	\$1,353	\$953	\$ 400	42	%
Share-based compensation	1,317	774	543	70	%
Legal and professional fees	713	607	106	17	%
Other	1,971	1,263	708	56	%
Total general and administrative expense	\$5,354	\$3,597	\$ 1,757	49	%

General and administrative expense for the six months ended December 31, 2015 increased by \$1.8 million to \$5.4 million compared to the same period in 2014. The increase was primarily driven by the hiring of additional employees which resulted in higher share-based compensation and other employee-related costs. Other administrative expenses were also higher on a year-over-year basis due primarily to our ongoing expansion and the increasing costs of operating as a publicly-traded company.

Liquidity and capital resources

As of December 31, 2015, we had an accumulated deficit of \$94.7 million. It will be several years, if ever, before we have a product candidate ready for commercialization, and we anticipate that we will continue to incur losses for at least the next several years. 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.

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, 2015, we had cash, cash equivalents, and investments totaling \$190.6 million. As of December 31, 2015, 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,	
	2015	2014
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$86,244	\$(8,115)
Investing activities	(100,475)	11,643
Financing activities	19,446	32,078
Net increase (decrease) in cash and cash equivalents	\$5,215	\$35,606

Operating activities. 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 received in connection with our collaboration with Biogen, which included an allocation of \$10.8 million from the equity agreement, and a milestone payment of \$5.0 million. These proceeds were partially offset by the impact of our net loss, including payments to certain research partner institutions for sub-license, milestone and other payments associated with the aforementioned collaboration, and changes during the period in our working capital accounts. For the six months ended December 31, 2014, the net cash used in operating activities was primarily the result of our net loss during that period and changes in working capital accounts.

Investing activities. Net cash used in investing activities for the six months ended December 31, 2015 consisted primarily of cash outflows of \$120.6 million related to the purchase of investments, partially offset by \$20.3 million of proceeds from the maturity of investments. For the six months ended December 31, 2014, net cash provided by investing activities consisted primarily of \$88.5 million of proceeds from the maturity of investments, partially offset by cash outflows of \$76.6 million related to the purchase of investments.

Financing activities. Net cash provided by financing activities of \$19.4 million during the six months ended December 31, 2015 was primarily related to our sale of shares of common stock to Biogen pursuant to the equity

agreement executed on July 1, 2015. For the six months ended December 31, 2014, net cash provided by financing activities was \$32.1 million, of which \$32.0 million was related to our follow-on public offering that was completed during the period.

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 expect to continue to generate revenue from partners. 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.

We believe that our existing cash and cash equivalents and investments at December 31, 2015 will be sufficient to enable us to advance planned preclinical studies and clinical trials for our lead product candidates for at least the next two years. 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, 2015, 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, 2015, 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, 2015 for a discussion of the actions that we have undertaken and are currently undertaking to remediate this material weakness. Although we had not fully remediated this material weakness as of December 31, 2015, we believe we have made substantial progress and will continue to actively engage in the implementation of other remediation efforts to address this material weakness. During the current reporting period, we made use of equity compensation management software to enhance the accounting processes associated with our share-based compensation and implemented procedures to improve review and approval of all transactions in the appropriate accounting period.

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, 2015 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, 2015.

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 have taken and are taking 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, 2015 for a listing of our risk factors. There has been no material change in such risk factors since June 30, 2015.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(b) Use of Proceeds

On April 1, 2014, we consummated the closing of the initial public offering, or IPO, of our common stock pursuant to our Registration Statement on Form S-1 (File No. 333-193309), which was declared effective by the Securities and Exchange Commission on March 26, 2014. The underwriters for the offering were BMO Capital Markets Corp., Wedbush Securities Inc., Cantor Fitzgerald & Co. and Roth Capital Partners, LLC. We used approximately \$14.7 million of the net proceeds from this offering to finance our operating activities in the three months ended December 31, 2015.

ITEM 5. OTHER INFORMATION

(b) We are providing the following information under this Item 5 in lieu of reporting the information under Item 8.01, "Other Events," of a Current Report on Form 8-K with a due date on or after the date hereof:

On February 4, 2016, our board of directors established February 28, 2017 as the date for our 2017 annual meeting of stockholders. Stockholders who wish to present proposals pursuant to Rule 14a-8 promulgated under the Exchange Act for consideration at our 2017 annual meeting of stockholders must submit the proposals in proper form to us at the address set forth on the cover page of this quarterly report on Form 10-Q no later than September 15, 2016 in order for the proposals to be considered for inclusion in our proxy statement and form of proxy relating to the 2017 annual meeting.

Stockholder proposals intended to be presented at our 2017 annual meeting submitted outside the processes of Rule 14a-8 must be received in writing by us no later than the close of business on November 20, 2016, nor earlier than October 31, 2016, together with all supporting documentation and information required by our by-laws. Proxies solicited by us will confer discretionary voting authority with respect to these proposals, subject to SEC rules governing the exercise of this authority.

In order to have a director candidate considered by the nominating and corporate governance committee, the recommendation must be submitted to our Secretary at the address set forth on the cover page of this quarterly report on Form 10-Q no later than the close of business on November 20, 2016, nor earlier than October 31, 2016, and must include all supporting documentation and information required by our by-laws.

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)
- 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)

*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

Date: February 8, 2016