APPLIED GENETIC TECHNOLOGIES CORP
Form 10-Q
February 09, 2018
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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, 2017

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 Incorporation or Organization)	(I.R.S. Employer Identification No.)

14193 NW 119th Terrace

Suite 10

Alachua, Florida 32615

(Address of Principal Executive Offices, Including Zip Code)

(386) 462-2204

(Registrant s Telephone Number, Including Area Code)

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

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

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

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

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

The number of shares of the registrant s common stock outstanding as of February 3, 2018 was 18,104,901.

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APPLIED GENETIC TECHNOLOGIES CORPORATION

FORM 10-Q

FOR THE QUARTER ENDED DECEMBER 31, 2017

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

APPLIED GENETIC TECHNOLOGIES CORPORATION

CONDENSED BALANCE SHEETS

(Unaudited)

In thousands, except per share data	December 31, 2017	June 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,345	$ 30,706
Investments	49,312	95,994
Grants receivable	203	174
Prepaid and other current assets	4,012	3,361
Total current assets	123,872	130,235
Investments, net of current portion		11,749
Property and equipment, net	3,235	2,661
Investment in Bionic Sight	2,000	2,000
Other assets	2,226	1,278
Total assets	$ 131,333	$ 147,923
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,036	$ 998
Accrued and other liabilities	6,116	6,162
Deferred revenue	11,945	20,996
Total current liabilities	19,097	28,156
Deferred revenue, net of current portion		4,438
Other liabilities	653	
Total liabilities	19,750	32,594
Stockholders equity:		
Common stock par value $.001 per share; shares authorized: 150,000 at December 31, 2017 and June 30, 2017; shares issued and outstanding: 18,105 and 18,088 at December 31, 2017 and June 30, 2017, respectively.	18	18

Additional paid-in capital		207,778	204,937
Accumulated deficit		(96,213)	(89,626)
Total stockholders equity		111,583	115,329
Total liabilities and stockholders equity	$	131,333	$ 147,923

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

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APPLIED GENETIC TECHNOLOGIES CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

In thousands, except per share amounts	For the Three Months Ended December 31, 2017	For the Three Months Ended December 31, 2016 (as adjusted)	For the Six Months Ended December 31, 2017	For the Six Months Ended December 31, 2016 (as adjusted)
Revenue:				
Collaboration revenue	$ 4,831	$ 10,890	$ 15,139	$ 22,662
Grant and other revenue	21	43	28	77
Total revenue	4,852	10,933	15,167	22,739
Operating expenses:				
Research and development	7,726	6,041	16,002	11,612
General and administrative and other	3,368	2,740	7,074	5,586
Total operating expenses	11,094	8,781	23,076	17,198
Income (loss) from operations	(6,242)	2,152	(7,909)	5,541
Other income:				
Investment income, net	271	227	541	463
Other expense	(10)		(10)	
Total other income, net	261	227	531	463
Income (loss) before provision for income taxes	(5,981)	2,379	(7,378)	6,004
Provision (benefit) for income taxes	(791)	600	(791)	1,200
Net income (loss)	$ (5,190)	$ 1,779	$ (6,587)	$ 4,804
Weighted Average Shares Outstanding				
Weighted average shares outstanding basic	18,094	18,067	18,091	18,061
Weighted average shares outstanding diluted	18,094	18,393	18,091	18,430
Net income (loss) per common share				
Net income (loss) per share, basic	$ (0.29)	$ 0.10	$ (0.36)	$ 0.27
Net income (loss) per share, diluted	$ (0.29)	$ 0.10	$ (0.36)	$ 0.26

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

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APPLIED GENETIC TECHNOLOGIES CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

In thousands	For the Six Months Ended December 31, 2017	2016 (as adjusted)
Cash flows from operating activities		
Net income (loss)	$ (6,587)	$ 4,804
Adjustments to reconcile net income (loss) to net cash (used in) operating activities:		
Share-based compensation expense	2,800	2,912
Depreciation and amortization	544	434
Investment premium accretion	143	216
Changes in operating assets and liabilities:		
Grants receivable	(29)	876
Prepaid and other assets	(1,747)	556
Deferred revenues	(13,489)	(22,528)
Accounts payable	38	(614)
Accrued and other liabilities	(173)	556
Net cash (used in) operating activities	(18,500)	(12,788)
Cash flows from investing activities		
Purchase of property and equipment	(134)	(563)
Purchase of and capitalized costs related to intangible assets		(92)
Maturity of investments	58,288	64,269
Purchase of investments		(37,219)
Net cash provided by investing activities	58,154	26,395
Cash flows from financing activities		
Proceeds from exercise of common stock options	3	24
Payments made toward capital lease obligations	(18)	
Net cash (used in) provided by financing activities	(15)	24
Net change in cash and cash equivalents	39,639	13,631
Cash and cash equivalents, beginning of period	30,706	28,868
Cash and cash equivalents, end of period	$ 70,345	$ 42,499
Supplemental disclosure of non cash financing activities		

Capital lease obligation related to the purchase of equipment	209
Lease incentive obligation related to the purchase of leasehold improvements	627
Issuance of restricted stock for no consideration	38

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

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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 that uses a proprietary gene therapy platform to develop transformational genetic therapies for patients suffering from rare and debilitating diseases.

In July 2015, the Company entered into a collaboration agreement (the Collaboration Agreement) with Biogen MA, Inc., a wholly owned subsidiary of Biogen Inc. (Biogen), pursuant to which the Company and Biogen will collaborate to develop, seek regulatory approval for and commercialize gene therapy products to treat X-linked retinoschisis (XLRS), X-linked retinitis pigmentosa (XLRP), and discovery programs targeting three indications based on the Company s adeno-associated virus vector technologies. The Collaboration Agreement became effective in August 2015. The Collaboration Agreement and other transactions with Biogen are discussed further in Note 6 to these financial statements.

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, 2017, the Company had an accumulated deficit of $97.0 million. While the Company expects to continue to generate some revenue from partnering, including under the collaboration with Biogen, the Company expects to incur losses for the foreseeable future. The Company has funded its operations to date primarily through public offerings of its common stock, private placements of its preferred stock, and collaborations. At December 31, 2017, the Company had cash and cash equivalents and investments of $119.7 million.

2. Summary of Significant Accounting Policies:

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 periods presented.

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

Certain amounts reported previously have been reclassified to conform to the current period presentation, with no effect on stockholders equity or net income (loss) as previously presented. See Note 7 for a discussion on a revision of prior financial results presented related to the recording of our income tax provision for fiscal year 2017.

The Condensed Balance Sheet as of June 30, 2017 was derived from audited financial statements, but does not include all disclosures required by GAAP. These Unaudited Condensed Financial Statements should be read in conjunction with the audited financial statements included in the Company s 2017 Annual Report on Form 10-K, as amended, (June 30, 2017 Form 10-K). Results of operations for the three and six months ended December 31, 2017 are not necessarily indicative of the results to be expected for the full year or any other interim period.

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Segment reporting

Operating segments are identified as components of an enterprise about which separate discrete financia information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, we have viewed our operations and managed our business as one segment.

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.

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.

Investments

The Company s investments consist of certificates of deposit and debt securities classified as held-to maturity. Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost, adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in investment income. Interest on securities classified as held-to-maturity is included in investment income.

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

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

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.

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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.

Revenue recognition

The Company has primarily 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: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the price is fixed or determinable; and (iv) collection of the amounts due are 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 Agreement with Biogen. This collaboration is discussed further in Note 6 of notes to the financial statements. The terms of the Collaboration 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 allocation of consideration amongst the deliverables under the agreement is derived using a best estimate of selling price if vendor specific objective evidence and third-party evidence of fair value is not available. 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 the Company recognizes the consideration received under the arrangement as revenue on a straight-line basis over the estimated period of performance.

The Company determines 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. 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 our 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 non-substantive, the Company accounts for that milestone payment in accordance with the multiple element arrangements guidance and recognizes revenue consistent with the related units of accounting for the arrangement over the related performance period.

No milestone revenues were recognized during the three and six month periods ended December 31, 2017 and December 31, 2016.

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.

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The Tax Cuts and Jobs Act of 2017 was signed into law on December 22, 2017. The law includes significant changes to the U.S. corporate income tax system, including a Federal