

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

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(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

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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.

