APPLIED GENETIC TECHNOLOGIES CORP
Form 10-Q
May 11, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 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 Incorporation or Organization) | (I.R.S. Employer Identification No.) |

11801 Research Drive

Suite D

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 x 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 x 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 x (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 x

As of April 30, 2015, a total of 16,475,654 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 MARCH 31, 2015

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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 | March 31, 2015 | June 30, 2014 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $44,483 | $8,623 |
| Investments | 17,796 | 64,450 |
| Grants receivable | 1,255 | 487 |
| Prepaid and other current assets | 1,575 | 1,876 |
| Total current assets | 65,109 | 75,436 |
| Investments | 29,489 | — |
| Property and equipment, net | 533 | 402 |
| Intangible assets, net | 1,447 | 1,565 |
| Other assets | 7 | 4 |
| Total assets | $96,585 | $77,407 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $764 | $949 |
| Accrued and other liabilities | 3,028 | 1,585 |
| Total current liabilities | 3,792 | 2,534 |
| Total liabilities | 3,792 | 2,534 |
| Stockholders' equity: | | |
| Common stock, par value $.001 per share, 150,000 shares authorized; 16,486 and 14,082 shares issued; 16,476 and 14,082 shares outstanding at March 31, 2015 and June 30, 2014, respectively | 16 | 14 |
| Additional paid-in capital | 173,468 | 139,193 |
| Accumulated deficit | (80,691 ) | (64,334 ) |
| Total stockholders' equity | 92,793 | 74,873 |
| Total liabilities and stockholders' equity | $96,585 | $77,407 |

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 March 31, 2015 | 2014 | For the Nine Months Ended March 31, 2015 | 2014 |
|---|---|---|---|---|
| Revenue: | | | | |
| Grant revenue | $284 | $182 | $1,541 | $648 |
| Sponsored research and other revenue | — | 50 | 100 | 357 |
| Total revenue | 284 | 232 | 1,641 | 1,005 |
| Operating expenses: | | | | |
| Research and development | 4,104 | 2,128 | 11,975 | 5,801 |
| General and administrative | 2,571 | 1,364 | 6,168 | 3,335 |
| Total operating expenses | 6,675 | 3,492 | 18,143 | 9,136 |
| Loss from operations | (6,391) | (3,260) | (16,502) | (8,131) |
| Other income (expense): | | | | |
| Investment income | 67 | 8 | 147 | 23 |
| Fair value adjustments to warrant liabilities | — | (336) | — | (441) |
| Fair value adjustments to Series B purchase rights | — | — | — | (2,838) |
| Other expense | (2) | — | (2) | — |
| Total other income (expense), net | 65 | (328) | 145 | (3,256) |
| Net loss | $(6,326) | $(3,588) | $(16,357) | $(11,387) |
| Net loss per share, basic and diluted | $(0.38) | $(25.45) | $(1.01) | $(95.69) |
| Weighted average shares outstanding, basic and diluted | 16,463 | 141 | 16,172 | 119 |

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 Nine Months Ended March 31, 2015 | 2014 |
|---|---|---|
| Cash flows from operating activities | | |
| Net loss | $(16,357) | $(11,387) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation expense | 2,120 | 200 |
| Depreciation and amortization | 279 | 242 |
| Fair value adjustments to warrant liabilities | — | 441 |
| Fair value adjustments to Series B purchase rights | — | 2,838 |
| Changes in operating assets and liabilities: | | |
| Increase in grants receivable | (768) | (220) |
| Decrease (increase) in prepaid and other assets | 392 | (1,963) |
| (Decrease) increase in accounts payable | (185) | 461 |
| Decrease in deferred revenues | — | (212) |
| Increase in accrued and other liabilities | 1,443 | 562 |
| Net cash used in operating activities | (13,076) | (9,038) |
| Cash flows from investing activities | | |
| Purchase of property and equipment | (225) | (89) |
| Purchase of and capitalized costs related to intangible assets | (68) | (113) |
| Maturity of investments | 108,130 | 22,000 |
| Purchase of investments | (91,058) | (24,500) |
| Net cash provided by (used in) investing activities | 16,779 | (2,702) |
| Cash flows from financing activities | | |
| Proceeds from issuance of common stock, net of issuance costs | 32,009 | — |
| Proceeds from exercise of common stock options | 148 | 194 |
| Proceeds from issuance of preferred stock and Series B purchase rights, net of issuance costs | — | 10,683 |
| Net cash provided by financing activities | 32,157 | 10,877 |
| Net increase (decrease) in cash and cash equivalents | 35,860 | (863) |
| Cash and cash equivalents, beginning of period | 8,623 | 8,893 |
| Cash and cash equivalents, end of period | $44,483 | $8,030 |

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 March 31, 2015, the Company had an accumulated deficit of $80.7 million and expects to continue to incur losses for the foreseeable future. The Company has funded its operations primarily through the private placement of preferred stock, common stock, convertible notes and warrants to purchase preferred stock and through public offerings consummated in 2014. At March 31, 2015, the Company's capital resources, consisting of cash, cash equivalents, and investments, amounted to $91.8 million.

(2) Summary of Significant Accounting Policies:

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

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

The Condensed Balance Sheet as of June 30, 2014 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 2014 Annual Report on Form 10-K. Results of operations for the three and nine months ended March 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— The Company considers all highly liquid investments with a maturity of 90 days or less at the time of purchase to be cash equivalents. Cash and cash equivalents include cash held in banks, investments in money market accounts, certificates of deposit, and debt securities. The fair values of cash equivalents approximate their carrying amounts.

(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.

New information and the passage of time can change these judgments. The Company manages its investment portfolio to limit its exposure to any one issuer or market sector, and largely limits its investments to U.S. government and agency securities, commercial paper, and corporate debt obligations, all of which are investment grade quality. Securities downgraded below policy minimums after purchase will be disposed of in accordance with the investment policy.

(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 ("ASC 820"), 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 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 costs recorded include costs for patent applications that have future value. The Company evaluates costs related to patents that it is not actively pursuing and writes off any of these costs. 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.

(h) Research and development – Research and development costs include costs incurred in identifying, developing and testing product candidates. Costs consist primarily of payroll expenses for research related employees, laboratory costs, animal and laboratory maintenance and supplies, rent, utilities, and clinical and pre-clinical expenses, as well as payments for sponsored research, scientific and regulatory consulting fees and testing. Costs are charged to expense as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided by the Company's vendors and clinical sites. When outside contracts for research products or testing require advance payments, these payments are recorded on the balance sheet as a prepaid expense and subsequently recognized as an operating expense when the service is provided or when a specific milestone outlined in the contract is reached. Advance payments related to research and development were \$1.3 million and \$1.4 million at March 31, 2015 and June 30, 2014, respectively, and are included in other current assets on the balance sheets.

(i) Share-based compensation – The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost is recognized on a straight-line basis over the period during which the employee is required to provide service in exchange for the award. The fair value of stock options on the date of grant is calculated using the Black-Scholes option pricing model based on key assumptions such as expected volatility, risk-free interest rate and expected term. For stock options awarded to employees, an assumption is also made for the estimated forfeiture rate based on the historical behavior of employees. The forfeiture rate reduces the total fair value of the awards to be recognized as compensation expense. The fair value of restricted stock awards is based on the Company's closing share price on the date of grant.

The Company accounts for stock options and awards of restricted stock issued to non-employees in accordance with the provisions of FASB ASC Subtopic 505-50, Equity-Based Payments to Non-employees, which states that equity instruments issued in exchange for the receipt of goods or services should be measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

(j) 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.

(k) New Accounting Pronouncements – 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 is currently evaluating the impact that this new guidance will have 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. The guidance is effective for public companies for annual periods beginning after December 15, 2016 as well as interim periods within those annual periods using either the full retrospective approach or modified retrospective approach. Early adoption is not permitted. The Company is currently evaluating the impact of the new guidance on its financial statements.

In July 2013, the FASB issued amended guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss, or tax credit carryforward exists. The guidance requires an unrecognized tax benefit, or a portion of an unrecognized tax benefit, to be presented as a reduction of a deferred tax asset when a net operating loss carryforward, similar tax loss, or tax credit carryforward exists, with certain exceptions. This accounting guidance was effective for annual and interim periods beginning after December 15, 2013. The Company adopted this new guidance beginning with its interim financial statements for the three months ended March 31, 2014. The adoption of this standard did not have a material impact on the Company's 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.   A summary of the stock option activity for the nine months ended March 31, 2015 and 2014 is as follows:

| | For the Nine Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2015 | | 2014 | |
| (In thousands, except per share amounts) | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding, June 30 | 1,024 | $ 6.21 | 380 | $ 1.45 |
| Granted | 409 | 19.64 | 559 | 6.88 |
| Exercised | (46 ) | 3.24 | (57 ) | 3.39 |
| Terminated | (109 ) | 6.43 | (10 ) | 3.50 |
| Outstanding, March 31 | 1,278 | $ 10.59 | 872 | $ 4.78 |
| Exercisable, end of period | 408 | | 166 | |
| Weighted average fair value of options granted during the period | $14.43 | | $4.48 | |

For the three and nine months ended March 31, 2015, share-based expense related to stock options awarded to employees, non-employee directors and consultants amounted to $746 thousand and $1.7 million, respectively.

In addition, during the three and nine months ended March 31, 2015, the Company granted restricted share awards of 10 thousand and 43 thousand shares to employees and non-employee consultants and recorded share-based expense of $147 thousand and $444 thousand, respectively, associated with these awards.  For the three and nine months ended March 31, 2014, share-based expense related to stock options awarded to employees, non-employee directors and consultants amounted to $89 thousand and $200 thousand, respectively.

As of March 31, 2015, there was $7.4 million of unrecognized compensation expense related to non-vested stock options and $232 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 | March 31, 2015 | June 30, 2014 |
|---|---|---|
| Investments - Current: | | |
| Certificates of deposit | $ 10,350 | $64,450 |
| Debt securities - held-to-maturity | 7,446 | — |
| | $ 17,796 | $64,450 |
| Investments - Noncurrent: | | |
| Certificates of deposit | $ 3,133 | $— |
| Debt securities - held-to-maturity | 26,356 | — |
| | $ 29,489 | $— |

As of March 31, 2015, a summary of the debt securities that were held-to-maturity is as follows:

| In thousands | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Investments - Current: | | | | |
| Commercial paper | $ 1,999 | | | |