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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 10-Q**

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(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, 2020

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)

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**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**59-3553710**  
(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)

**Securities registered pursuant to Section 12(b) of the Act:**

Title of class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.001 par value	AGTC	Nasdaq Global Market

**Securities registered pursuant to Section 12(g) of the Act: None**

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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 every Interactive Data File required to be submitted 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 such files). Yes  No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 4, 2021 was 42,657,878.

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APPLIED GENETIC TECHNOLOGIES CORPORATION  
FORM 10-Q  
FOR THE QUARTER ENDED DECEMBER 31, 2020

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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, 2020	June 30, 2020
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 19,108	\$ 38,463
Investments	33,989	41,995
Prepaid and other current assets	2,080	2,506
Total current assets	55,177	82,964
Property and equipment, net	4,095	4,311
Intangible assets, net	1,194	1,098
Investment in Bionic Sight, LLC	8,046	8,096
Right-of-use assets – operating leases	3,249	3,422
Right-of-use asset – finance lease	57	80
Other assets	151	348
Total assets	<u>\$ 71,969</u>	<u>\$ 100,319</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,775	\$ 1,355
Accrued and other liabilities	11,352	10,502
Lease liabilities – operating	1,067	1,058
Lease liability – finance	50	48
Total current liabilities	14,244	12,963
Lease liabilities – operating, net of current portion	3,723	4,070
Lease liability – finance, net of current portion	13	38
Long-term debt, net of debt discounts and deferred financing fees	9,844	9,677
Other liabilities	2,623	2,555
Total liabilities	<u>30,447</u>	<u>29,303</u>
Stockholders' equity:		
Preferred stock, par value \$0.001 per share, 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value \$0.001 per share, 150,000 shares authorized; 25,946 and 25,813 shares issued; 25,905 and 25,793 shares outstanding at December 31, 2020 and June 30, 2020, respectively	25	25
Additional paid-in capital	253,990	252,519
Treasury stock at cost; 41 and 20 shares at December 31, 2020 and June 30, 2020, respectively	(211)	(88)
Accumulated deficit	(212,282)	(181,440)
Total stockholders' equity	41,522	71,016
Total liabilities and stockholders' equity	<u>\$ 71,969</u>	<u>\$ 100,319</u>

The accompanying notes are an integral part of these Unaudited Condensed Financial Statements.

**APPLIED GENETIC TECHNOLOGIES CORPORATION**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

<b>In thousands, except per share data</b>	<b>Three Months</b>		<b>Six Months</b>	
	<b>Ended December 31,</b>		<b>Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
<b>Revenue:</b>				
Collaboration and milestone revenue	\$ —	\$ 2,297	\$ —	\$ 2,297
Grant revenue	—	156	—	156
Total revenue	<u>—</u>	<u>2,453</u>	<u>—</u>	<u>2,453</u>
<b>Operating expenses:</b>				
Research and development	11,811	8,375	23,437	17,017
General and administrative and other	3,304	3,008	6,740	6,356
Total operating expenses	<u>15,115</u>	<u>11,383</u>	<u>30,177</u>	<u>23,373</u>
Loss from operations	<u>(15,115)</u>	<u>(8,930)</u>	<u>(30,177)</u>	<u>(20,920)</u>
<b>Other income (expense), net:</b>				
Investment income, net	29	336	93	782
Interest expense	(335)	(2)	(667)	(4)
Total other income (expense), net	<u>(306)</u>	<u>334</u>	<u>(574)</u>	<u>778</u>
Loss before provision for income taxes	<u>(15,421)</u>	<u>(8,596)</u>	<u>(30,751)</u>	<u>(20,142)</u>
Provision for income taxes	20	21	41	42
Loss before equity in net losses of an affiliate	<u>(15,441)</u>	<u>(8,617)</u>	<u>(30,792)</u>	<u>(20,184)</u>
Equity in net losses of an affiliate	(21)	(6)	(50)	(16)
Net loss	<u><u>\$ (15,462)</u></u>	<u><u>\$ (8,623)</u></u>	<u><u>\$ (30,842)</u></u>	<u><u>\$ (20,200)</u></u>
<b>Weighted average shares outstanding:</b>				
Basic	25,883	18,219	25,850	18,215
Diluted	25,883	18,219	25,850	18,215
<b>Net loss per common share:</b>				
Basic	\$ (0.60)	\$ (0.47)	\$ (1.19)	\$ (1.11)
Diluted	\$ (0.60)	\$ (0.47)	\$ (1.19)	\$ (1.11)

The accompanying notes are an integral part of these Unaudited Condensed Financial Statements.

**APPLIED GENETIC TECHNOLOGIES CORPORATION**  
**CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**THREE AND SIX MONTHS ENDED DECEMBER 31, 2020 AND 2019**  
**(Unaudited)**

<u>In thousands</u>	<u>Common Stock</u>		<u>Treasury Stock</u>		Additional Paid-in Capital	Accumulated Deficit	Totals
	Outstanding Shares	Amount	Shares	Amount			
Balances at June 30, 2020	25,793	\$ 25	20	\$ (88)	\$252,519	\$ (181,440)	\$ 71,016
Share-based compensation expense	—	—	—	—	646	—	646
Shares issued under employee plans and related share repurchases	67	—	21	(123)	43	—	(80)
Net loss	—	—	—	—	—	(15,380)	(15,380)
Balances at September 30, 2020	25,860	25	41	(211)	253,208	(196,820)	56,202
Share-based compensation expense	—	—	—	—	624	—	624
Shares issued under employee plans and related share repurchases	45	—	—	—	158	—	158
Net loss	—	—	—	—	—	(15,462)	(15,462)
Balances at December 31, 2020	<u>25,905</u>	<u>\$ 25</u>	<u>41</u>	<u>\$ (211)</u>	<u>\$253,990</u>	<u>\$ (212,282)</u>	<u>\$ 41,522</u>

<u>In thousands</u>	<u>Common Stock</u>		<u>Treasury Stock</u>		Additional Paid-in Capital	Accumulated Deficit	Totals
	Outstanding Shares	Amount	Shares	Amount			
Balances at June 30, 2019	18,207	\$ 18	19	\$ (85)	\$214,324	\$ (135,548)	\$ 78,709
Share-based compensation expense	—	—	—	—	810	—	810
Shares issued under employee plans and related share repurchases	11	—	1	(3)	34	—	31
Net loss	—	—	—	—	—	(11,577)	(11,577)
Balances at September 30, 2019	18,218	18	20	(88)	215,168	(147,125)	67,973
Share-based compensation expense	—	—	—	—	689	—	689
Shares issued under employee plans and related share repurchases	1	—	—	—	—	—	—
Net loss	—	—	—	—	—	(8,623)	(8,623)
Balances at December 31, 2019	<u>18,219</u>	<u>\$ 18</u>	<u>20</u>	<u>\$ (88)</u>	<u>\$215,857</u>	<u>\$ (155,748)</u>	<u>\$ 60,039</u>

The accompanying notes are an integral part of these Unaudited Condensed Financial Statements.

**APPLIED GENETIC TECHNOLOGIES CORPORATION**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
(Unaudited)

<b>In thousands</b>	<b>Six Months Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Operating activities:</b>		
Net loss	\$ (30,842)	\$ (20,200)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,270	1,499
Depreciation and amortization	771	649
Investment discount accretion, net	(2)	(278)
Amortization of debt discounts and deferred financing fees	167	—
Reduction in the carrying amount of operating lease right-of-use assets	173	145
Collaboration revenue from Bionic Sight, LLC	—	(2,197)
Equity in net losses of an affiliate	50	16
Changes in operating assets and liabilities:		
Grants receivable	—	(156)
Prepaid and other assets	623	289
Deferred revenue	—	149
Accounts payable	420	441
Operating lease liabilities	(338)	(301)
Accrued and other liabilities	1,400	908
Cash used in operating activities	(26,308)	(19,036)
<b>Investing activities:</b>		
Purchases of property and equipment	(768)	(434)
Purchases of and capitalized costs related to intangible assets	(213)	(257)
Maturities of investments	27,000	40,500
Purchases of investments	(18,992)	(29,409)
Cash provided by investing activities	7,027	10,400
<b>Financing activities:</b>		
Proceeds from exercises of common stock options	201	34
Payments for deferred financing fees	(129)	—
Taxes paid related to equity awards	(123)	(3)
Principal payments on finance lease	(23)	(22)
Cash provided by (used in) financing activities	(74)	9
Net decrease in cash and cash equivalents	(19,355)	(8,627)
Cash and cash equivalents, beginning of the period	38,463	26,703
Cash and cash equivalents, end of the period	\$ 19,108	\$ 18,076
<b>Supplemental information:</b>		
Payable related to investment in Bionic Sight, LLC (see Note 7)	\$ —	\$ 4,000
Costs for intangible assets included in accrued and other liabilities	33	—

The accompanying notes are an integral part of these Unaudited Condensed Financial Statements.

**APPLIED GENETIC TECHNOLOGIES CORPORATION**  
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**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.

On February 11, 2020, the Company closed an underwritten public offering of 6.5 million shares of its common stock at \$5.00 per share, generating gross proceeds of \$32.5 million, before deducting underwriting discounts, commissions and other offering expenses payable by the Company. Additionally, the underwriters exercised their option to purchase an additional 975,000 shares of common stock to cover over-allotments. Such transaction closed on February 13, 2020 and generated additional gross proceeds of \$4.9 million. As discussed at Note 10 in these Notes to Unaudited Condensed Financial Statements, subsequent to December 31, 2020, the Company also completed an underwritten public offering of its common stock and certain warrants to purchase its common stock.

On June 30, 2020, the Company entered into a loan agreement for a term loan in the aggregate principal amount of up to \$25.0 million. On that date, the Company received net loan proceeds of \$9.9 million, before consideration of any related debt financing fees. The loan agreement is further discussed at Note 6 in these Notes to Unaudited Condensed 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 the ability to transition to large-scale production of products.

As of December 31, 2020, the Company had (i) an accumulated deficit of \$212.3 million and (ii) cash and cash equivalents and liquid investments of \$53.1 million. Management believes that, after considering the underwritten public offering that is discussed at Note 10 in these Notes to Unaudited Condensed Financial Statements, there is sufficient funding available to allow the Company to generate data from its ongoing and planned clinical programs and fund currently planned research and discovery programs. While the Company expects to continue to generate some revenue from partnering, management believes that the Company will incur losses for the foreseeable future. The Company has funded its operations to date primarily through public offerings of its common stock and warrants to purchase its common stock, private placements of its preferred stock, collateralized borrowing and collaborations.

**2. Summary of Significant Accounting Policies**

***Basis of presentation***

The accompanying Unaudited Condensed Financial Statements have been prepared in accordance with (i) U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information and (ii) the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, such financial statements do not include all the information and footnotes required by U.S. GAAP for a complete set of financial statements. In the opinion of management, the Unaudited Condensed Financial Statements include all adjustments, consisting of normal recurring accruals and other adjustments, considered necessary for a fair statement of the Company’s financial position, results of operations, stockholders’ equity and cash flows as of and for the periods presented. The accompanying Condensed Balance Sheet as of June 30, 2020 was derived from the Company’s audited financial statements at that date but does not include all of the footnote disclosures required by U.S. GAAP.

The Unaudited Condensed Financial Statements should be read in conjunction with the Company’s audited financial statements and related notes included in its Annual Report on Form 10-K for the year ended June 30, 2020 (the “2020 Form 10-K”). The Company’s significant accounting policies are described in Note 2 to the Notes to Financial Statements in the 2020 Form 10-K and are updated, as necessary, in subsequent Form 10-Q filings.

The Company’s fiscal year is the twelve-month period from July 1 to June 30. The results of operations for the three and six months ended December 31, 2020 are not necessarily indicative of the Company’s operating results for the full year ending June 30, 2021 or any other subsequent interim period within that year.

Management views the Company’s operations and manages its business as one segment.



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### *Use of estimates*

The preparation of financial statements in conformity with U.S. GAAP and guidelines from the Securities and Exchange Commission 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 amounts of revenue and expenses during reporting periods. Actual results could differ from those estimates.

### *Net income or loss per share*

Basic net income or loss per share is calculated by dividing net income or loss by the weighted average shares outstanding during the period, without consideration of common stock equivalents. Diluted net income or loss per share is calculated by adjusting the weighted average shares outstanding for the dilutive effects of common stock equivalents outstanding during the period, determined using the treasury stock method. For purposes of diluted net income or loss per share calculations, stock options, restricted stock awards and performance service awards are considered to be common stock equivalents if they are dilutive. The dilutive impact of common stock equivalents for (i) the three and six months ended December 31, 2020 was approximately 0.3 million shares and 0.4 million shares, respectively, and (ii) both the three and six months ended December 31, 2019 was approximately 0.3 million shares. However, the dilutive impact of common stock equivalents was excluded from the calculations of diluted net loss per share for the three and six month periods ended December 31, 2020 and 2019 because their effects were anti-dilutive.

### *New Accounting Pronouncements*

*Adopted during the six months ended December 31, 2020*

#### Fair Value Measurement

In August 2018, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. The new standard eliminates, adds and modifies certain disclosure requirements for fair value measurement as part of the FASB’s disclosure framework project. Under the new standard, the amount and reason for a transfer between Level 1 and Level 2 of the fair value hierarchy (as described at Note 5 in these Notes to Unaudited Condensed Financial Statements) are no longer required to be disclosed, but public companies are required to disclose a range and weighted average of significant unobservable inputs for Level 3 fair value measurements. The Company adopted the new standard on July 1, 2020; however, it did not have a significant impact on the Company’s financial statements.

#### Collaborative Arrangements

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. The new standard clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“Topic 606”), when the counterparty is a customer. The new standard also precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The guidance amends ASC Topic 808, *Collaborative Arrangements* (“Topic 808”), to refer to the unit-of-account guidance in Topic 606 and requires it to be used only when assessing whether a transaction is in the scope of Topic 606. The Company adopted the new standard on July 1, 2020; however, it did not have a significant impact on the Company’s financial statements.

*To be adopted in future periods*

#### Financial Instruments—Credit Losses

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The new standard requires that financial assets measured at amortized cost be presented at the net amount expected to be collected and separately measure an allowance for credit losses that is deducted from the amortized cost basis of those financial assets. This standard will be effective for the Company on July 1, 2023. Early adoption is permitted. Management continues to evaluate the provisions of this new standard and its potential impact; however, the adoption thereof is not expected to have a significant impact on the Company’s financial statements.

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### Income Taxes

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The new standard includes several provisions that simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and increasing consistency and clarity for the users of financial statements. This standard will be effective for the Company on July 1, 2021. Early adoption is permitted. The adoption of this guidance is not expected to have a significant impact on the Company's financial statements.

### Investments – Equity Securities, Investments – Equity Method and Joint Ventures, and Derivatives and Hedging

In January 2020, the FASB issued ASU No. 2020-01, *Investments – Equity Securities (Topic 321), Investments – Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)—Clarifying the Interactions between Topic 321, Topic 323, and Topic 815*. The new standard addresses interactions between the guidance to account for certain equity securities under ASC Topic 321, the guidance to account for investments under the equity method of accounting in ASC Topic 323 and the guidance in ASC Topic 815, which could change how an entity accounts for an equity security under the measurement alternative or a forward contract or purchased option to purchase securities that, upon settlement of the forward contract or exercise of the purchased option, would be accounted for under the equity method of accounting or the fair value option in accordance with ASC Topic 825, *Financial Instruments*. These amendments improve current U.S. GAAP by reducing diversity in practice and increasing comparability of the accounting for any such interactions. This standard will be effective for the Company on July 1, 2021. Early adoption is permitted. The adoption of this guidance is not expected to have a significant impact on the Company's financial statements.

### **3. Share-based Compensation Plans**

The Company uses stock options, performance service awards, restricted stock awards and restricted stock units to provide long-term incentives to 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, as such, all of the 128,571 shares previously authorized under that plan remain available for issuance.

Information about the Company's stock options that do not have performance conditions is provided below.

	Six Months Ended December 31,			
	2020		2019	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
<b>(In thousands, except per share amounts)</b>				
Outstanding at the beginning of the period	3,846	\$ 7.82	3,585	\$ 9.19
Granted	1,237	5.28	984	3.09
Exercised	(57)	3.55	(10)	3.22
Forfeited	(407)	4.43	(244)	4.05
Expired	(62)	10.23	(299)	11.50
Outstanding at the end of the period	<u>4,557</u>	\$ 7.45	<u>4,016</u>	\$ 7.84
Exercisable at the end of the period	<u>2,690</u>		<u>2,267</u>	
Weighted average fair value of options granted during the period	<u>\$ 3.81</u>		<u>\$ 2.00</u>	

The fair value of each stock option granted is estimated on the date of grant using a Black-Scholes stock option pricing model. Below are the assumptions that were used when estimating fair value for the periods indicated.

Assumption	Six Months Ended December 31,	
	2020	2019
Dividend yield	0.00%	0.00%
Expected term	6.00 to 6.25 years	6.00 to 6.25 years
Risk-free interest rate	0.30% to 0.54%	1.45% to 1.90%
Expected volatility	82.60%	71.20%

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In addition to the stock option activity described above, the Company also granted 100,000 performance-based stock options to a senior officer during July 2019 with an exercise price of \$3.91. That award: (i) was issued under the 2013 Equity and Incentive Plan; (ii) has a term of ten years; and (iii) includes six separate tranches with performance criteria that will each vest 25% upon their achievement, with the remaining 75% of the tranche vesting on a monthly basis over a period of three years subsequent to achieving the underlying performance objective (assuming continued service by the awardee). Each tranche represents one-sixth of the total award. If any of the performance criteria are not satisfied, that corresponding tranche will be forfeited. As of December 31, 2020, one of the six performance criteria has been met. The Company used a Black-Scholes stock option pricing model to estimate the grant date fair value of each option to be \$2.58; however, determining the appropriate periodic share-based compensation expense for this award requires management to estimate the likelihood of the achievement of the performance targets.

During August 2019, 175,500 restricted stock units, which included a market-based vesting condition related to the trading price of the Company's common stock, were granted to certain employees under the 2013 Equity and Incentive Plan with a weighted average grant date fair value of \$2.56. Prior to June 30, 2020, the market condition embedded in the award was met. On August 15, 2020, 76,500 restricted stock units vested and, through December 31, 2020, a total of 25,000 awards have been forfeited. Assuming continuing service by the grantees, the remaining restricted stock units that are outstanding will vest on August 15, 2021. The fair value of each restricted stock unit awarded was estimated on the grant date using a Monte Carlo simulation pricing model, which incorporated the probability of satisfying the related market-based vesting condition.

Share-based compensation expense for the three and six months ended December 31, 2020 was \$0.6 million and \$1.3 million, respectively, compared to \$0.7 million and \$1.5 million, respectively, for the three and six months ended December 31, 2019.

#### 4. Investments

Cash in excess of immediate requirements is invested in accordance with the Company's investment policy, which primarily seeks to maintain adequate liquidity and preserve capital. At both December 31, 2020 and June 30, 2020, the Company's investments consisted entirely of held-to-maturity debt securities that were due in one year or less from the respective balance sheet dates.

The Company's debt securities that are classified as held-to-maturity are summarized below.

<u>In thousands</u>	<u>December 31, 2020</u>	<u>June 30, 2020</u>
U.S. Treasury securities:		
Amortized cost	\$ 33,989	\$ 41,995
Gross unrealized gains	4	54
Gross unrealized losses	(1)	(3)
Fair value of investments	<u>\$ 33,992</u>	<u>\$ 42,046</u>

The Company expects to collect the principal and interest due on its debt securities that have an amortized cost in excess of fair value. At the end of each reporting period, the Company evaluates its securities for impairment, if and when, the fair value of an investment is less than its amortized cost. In the event that the fair value of an investment is less than its amortized cost, the Company will evaluate the underlying credit quality and credit ratings of the issuer. Specifically, the Company believes that the unrealized losses disclosed in the above table were primarily driven by interest rate changes rather than by unfavorable changes in the credit ratings associated with those securities. The Company does not intend to sell any of its investments before recovering its amortized cost, which may be at maturity.

#### 5. Fair Value of Financial Instruments and Investments

The Company is required to disclose information regarding all assets and liabilities reported at fair value that enables an assessment of the inputs used when determining the reported fair values. 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 when pricing an 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 when pricing an 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 when determining the reported fair value of financial instruments and is not a measure of an investment's 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 a 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 when determining fair value is greatest for financial 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.

Certain assets and liabilities are measured at fair value in the Company’s financial statements or have fair values disclosed in these Notes to Unaudited Condensed Financial Statements. Such assets and liabilities are classified into one of three levels of the fair value hierarchy. 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 methods and assumptions described below were used to estimate fair values and determine the fair value hierarchy classification of each class of financial instrument held by the Company.

**Cash and Cash Equivalents.** The carrying value of cash and cash equivalents approximates fair value because the maturities thereof are less than three months.

**Debt securities—held-to-maturity.** The Company’s investments in debt securities classified as held-to-maturity consist of U.S. Treasury securities that are valued using quoted market prices. Valuation adjustments are not applied.

The fair value hierarchy table below provides information about each major category of the Company’s financial assets and liabilities measured at fair value on a recurring basis or disclosed at fair value in these Notes to Unaudited Condensed Financial Statements.

<u>In thousands</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total Fair Value</u>
<b>December 31, 2020</b>				
Cash and cash equivalents	\$19,108	\$ —	\$ —	\$ 19,108
Held-to-maturity investments (U.S. Treasury securities)	33,992	—	—	33,992
Total assets	<u>\$53,100</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 53,100</u>
<b>June 30, 2020</b>				
Cash and cash equivalents	\$38,463	\$ —	\$ —	\$ 38,463
Held-to-maturity investments (U.S. Treasury securities)	42,046	—	—	42,046
Total assets	<u>\$80,509</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 80,509</u>

The Company’s financial instruments also include its variable-rate borrowing under a debt agreement that is described at Note 6 in these Notes to Unaudited Condensed Financial Statements. The Company believes that the carrying amount of such debt (i.e., \$9.8 million and \$9.7 million at December 31, 2020 and June 30, 2020, respectively) reasonably approximates its fair value because the rate of interest on such borrowing reflects current market rates of interest for similar instruments with comparable maturities and risk profiles. This assessment primarily uses Level 2 inputs under the fair value hierarchy.

## **6. Debt**

The following discussion of the Company’s debt should be read in conjunction with Note 8 to the Notes to Financial Statements in the 2020 Form 10-K.

On June 30, 2020, the Company entered into a Loan and Security Agreement (the “Loan Agreement”) with several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively, referred to as the “Lenders”) and Hercules Capital, Inc. in its capacity as administrative agent and collateral agent for itself and the Lenders.

The Loan Agreement provides for a term loan in an aggregate principal amount of up to \$25.0 million to be delivered in multiple tranches. The tranches consist of (i) a term loan advance of \$10.0 million on June 30, 2020 (the “Closing Date”) and (ii) subject to the Lenders’ investment committee’s sole discretion, the Company has the right to request that the Lenders make additional term loan advances in an aggregate principal amount of up to \$15.0 million prior to January 1, 2022 or, if certain conditions are satisfied, then July 1, 2022. There can be no assurances that any term loan advances will be funded by the Lenders in the future. As of December 31, 2020, the Company has not borrowed any amount under the Loan Agreement other than the initial term loan advance on the Closing Date.

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As of both December 31, 2020 and June 30, 2020, the variable contractual interest rate on the Term Loan was 9.75% per annum and the effective rate on the Term Loan was 13.53%.

As of December 31, 2020, the Company was in full compliance with all covenants of the Loan Agreement.

### **7. Collaboration Agreements and Contract Liabilities**

#### **Bionic Sight**

On February 2, 2017, the Company entered into a strategic research and development collaboration agreement with Bionic Sight, LLC (“Bionic Sight”) to develop therapies for patients with visual deficits and blindness due to retinal disease. Through the AGTC-Bionic Sight collaboration, the companies seek to develop a new optogenetic therapy that leverages AGTC’s deep experience in gene therapy and ophthalmology and Bionic Sight’s innovative neuro-prosthetic device and algorithm for retinal coding. The collaboration agreement grants to AGTC, subject to achievement by Bionic Sight of certain development milestones, an option to exclusively negotiate for a limited period of time to acquire: (i) a majority equity interest in Bionic Sight; (ii) the Bionic Sight assets to which the collaboration agreement relates; or (iii) an exclusive license with respect to the product to which the collaboration agreement relates.

Under the agreement, AGTC made an initial \$2.0 million payment to Bionic Sight for an equity interest in that company. This initial investment represented an equity interest of approximately 5% in Bionic Sight. In addition to the initial investment, AGTC contributed ongoing research and development support costs through additional payments and other in-kind contributions (the “AGTC Ongoing R&D Support”). The AGTC Ongoing R&D Support payments and in-kind contributions were made over time and continued until December 2019, the month that Bionic Sight received both Investigational New Drug (“IND”) clearance from the United States Food and Drug Administration (the “FDA”) and receipt of written approval from an internal review board to conduct clinical trials at one clinical site for that product candidate (the “IND Trigger”). Prior to the achievement of the IND Trigger, the Company had incurred approximately \$2.2 million of research and development support costs and in-kind contributions, which were reported as research and development expenses in the Company’s financial statements.

Upon achievement of the IND Trigger, AGTC was (i) entitled to receive additional equity in Bionic Sight, based on a valuation that was in place at the beginning of the agreement, for the AGTC Ongoing R&D Support payments and in-kind contributions, and (ii) obligated to purchase additional equity in Bionic Sight for \$4.0 million based on certain pre-determined valuation criteria. The Company recorded a liability of \$4.0 million to Bionic Sight in December 2019, satisfied that obligation with a payment in January 2020 and received the incremental shares during March 2020 upon the execution of a subscription agreement between the parties. The Company’s equity interest in Bionic Sight increased to approximately 15.5% upon the issuance of the additional shares. AGTC is not obligated to purchase additional equity in Bionic Sight or make any additional in-kind contributions under the agreement.

The Company concluded that the AGTC Ongoing R&D Support was within the scope of Topic 606 because the services rendered represented a distinct service delivered to a counterparty that meets the definition of a customer. The Company further concluded that those services represented one combined performance obligation. Because the consideration that the Company was entitled to was contingent upon achievement of the IND Trigger, that consideration was determined to be variable and the amount was fully constrained until achievement of the IND Trigger. As a result of achieving the IND Trigger in December 2019, the Company recognized \$2.2 million of collaboration revenue during the three months ended December 31, 2019. With regard to the obligation to purchase additional equity in Bionic Sight, the Company concluded at contract inception that such option represented a forward contract to be accounted for within the scope of ASC 321, *Investments—Equity Securities*. The Company assessed the fair value of this forward contract at the inception of the Bionic Sight agreement and determined the value to be de minimis. As the forward contract did not have a readily determinable fair value, the Company elected to use a measurement alternative for all subsequent measurements of the financial instrument. Under such measurement alternative, the forward contract was remeasured at fair value when observable transactions involving the underlying equity securities or impairment of those securities occurred. As noted above, the Company made a supplemental investment of \$4.0 million in Bionic Sight and the underlying equity interests were delivered in March 2020, resulting in the settlement of the forward contract at that time. From the inception of the Bionic Sight arrangement and through the settlement date in March 2020, no observable transactions or impairment involving the underlying equity securities had occurred.

The Company recorded its initial investment in Bionic Sight using the equity method of accounting for investments. Upon receipt of additional shares in March 2020, the Company concluded that equity method accounting was still appropriate. Given that the conversion price used to calculate the number of additional shares that the Company was to receive was based on contractually fixed valuation amounts, the Company assessed whether there was a difference between the cost of the investment and the underlying equity in the net assets of Bionic Sight. The Company concluded that any such difference was not material to the Company’s financial statements and, therefore, recorded its additional investment in Bionic Sight at \$6.2 million during March 2020.

### **Otonomy, Inc.**

During October 2019, the Company entered into a strategic collaboration agreement with Otonomy, Inc. (“Otonomy”) to co-develop and co-commercialize an AAV-based gene therapy to restore hearing in patients with sensorineural hearing loss caused by a mutation in the gap junction protein beta 2 gene (GJB2) – the most common cause of congenital hearing loss. Mutations in GJB2 account for approximately 30% of all genetic hearing loss cases. Patients with this mutation can have severe-to-profound deafness in both ears that is identified in screening tests routinely performed on newborns. Under the collaboration agreement, the parties began equally sharing the program costs and proceeds in January 2020 and can include additional genetic hearing loss targets in the future.

The Company concluded that the Otonomy collaboration agreement is within the scope of Topic 808, which defines collaborative arrangements and addresses the presentation of transactions between the two parties in the income statement and related disclosures. However, Topic 808 does not provide guidance on the recognition of consideration exchanged or accounting for the obligations that may arise between the parties. The Company concluded that ASC Topic 730, *Research and Development*, should be applied by analogy to payments between the parties during the development activities. As such, payments made to or received from Otonomy for development activities are recorded as research and development expenses. For the six months ended December 31, 2020, settlement activity between the parties under the Otonomy agreement had an immaterial effect on the Company’s research and development expenses.

### **Contract Liabilities**

As of both December 31, 2020 and June 30, 2020, accrued and other liabilities on the Condensed Balance Sheets included \$149,000 of deferred revenue. Management is unable to estimate when the Company will satisfy the performance obligations pertaining to such deferred revenue, which does not pertain to either the Bionic Sight or Otonomy collaboration agreements.

## **8. Income Taxes**

As required by U.S. GAAP, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. Interest and penalties related to uncertain tax positions are reflected in the provision for income taxes.

Income tax expense for the three and six months ended December 31, 2020 was \$20,000 and \$41,000, respectively, compared to \$21,000 and \$42,000 for the three and six months ended December 31, 2019, respectively. During those periods, income tax expense was primarily attributable to estimated interest and penalties on uncertain tax positions. The Company’s aggregate reserve for uncertain tax positions was \$2.1 million at both December 31, 2020 and June 30, 2020, including aggregate interest and penalties of \$0.5 million on each such date. For the six months ended December 31, 2020, the Company’s gross unrecognized tax benefits, excluding interest and penalties, was unchanged at \$1.6 million. If recognized, the entire amount of the uncertain tax position liability at December 31, 2020 would reduce the Company’s annual effective tax rate. It is reasonably possible that the Company’s gross unrecognized tax benefits as of December 31, 2020, which relate to certain state tax matters, will decline by approximately \$1.6 million during the next twelve months due to the expiration of certain statutes of limitations. Any such decline would also affect the then-outstanding balance of accrued interest and penalties. The Company’s liability for uncertain tax positions is included in other long-term liabilities on its Condensed Balance Sheets.

## **9. Contingencies**

### **COVID-19 Pandemic**

On January 30, 2020, the World Health Organization (“WHO”) announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (“COVID-19”) and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic based on the rapid increase in exposure globally. National, state and local governments in affected regions have implemented, and are likely to continue to implement, safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter in place orders and shutdowns, business closures, cancellations of public gatherings and other measures. Organizations and individuals are taking additional steps to avoid or reduce infection, including limiting travel and staying home from work.



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The worldwide spread of COVID-19 led to a global slowdown of economic activity and decreased demand for a broad variety of goods and services, while also disrupting sales channels and marketing activities and precipitating many corporate bankruptcy filings. As a result of the COVID-19 outbreak, the Company has experienced delays in enrollment of pediatric patients in the dose escalation portions of certain of its clinical trials for achromatopsia. The Company could also experience delays resulting from critical follow-up visits required under clinical trial protocols, which could increase the cost of those trials and also impact their expected timelines. Management's ability to fully interpret the trial outcomes and the ability of certain lab-based employees to perform their jobs due to stay-at-home orders or other restrictions related to COVID-19 could also result in delays and increase the Company's operating expenses. Furthermore, third-party vendors, such as raw material suppliers and contracted manufacturing, testing or research organizations, could also be impacted by COVID-19, which could result in unavoidable delays and/or increases in the Company's operating costs.

Notwithstanding the recent development and initial rollout of certain vaccines, it is unknown how long the COVID-19 outbreak will continue before the virus, including newly identified strains and variants, is adequately contained, the severity of the virus and the effectiveness of actions to contain and treat those who have contracted the virus. The extent to which the COVID-19 outbreak may impact the Company's financial condition, results of operations or cash flows is uncertain; however, as of the date of these financial statements, management is not aware of any specific event or circumstance that would require the Company to update its estimates, judgments or revise the carrying values of its assets or liabilities. Because future events are subject to change, management's best estimates and judgments may require future modification. Therefore, actual results could differ materially from current estimates. Management is closely monitoring the evolving impact of the pandemic on all aspects of the Company's business and periodically evaluates its estimates, which are adjusted prospectively based on such evaluations.

### **General**

From time to time, the Company may be involved in claims and legal actions that arise in the normal course of business. Management has no reason to believe that the outcome of any such legal actions would have a significant adverse effect on the Company's financial position, results of operations or cash flows.

### **10. Subsequent Event**

On February 1, 2021, the Company closed an underwritten public offering of 16,741,573 shares of its common stock, together with accompanying warrants to purchase 8,370,786 shares of its common stock. The combined offering price of each share of common stock and accompanying warrant was \$4.45, generating gross proceeds of \$74.5 million, before deducting underwriting discounts, commissions and other offering expenses payable by the Company, which total approximately \$5.3 million. The warrants may only be exercised in integral multiples of two, have an exercise price of \$6.00 per share (subject to certain adjustments), are immediately exercisable and expire on February 1, 2026.

The Company intends to use the net proceeds from the offering, together with other available funds, to fund ongoing clinical trials in its X-linked retinitis pigmentosa program and ongoing Phase 1/2 clinical trials in its achromatopsia program, and for working capital and other general corporate purposes.

## 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, 2020 and our results of operations for the three and six months ended December 31, 2020 and 2019. This discussion should be read in conjunction with the Unaudited Condensed Financial Statements and related notes included in this Quarterly Report on Form 10-Q, as well as our Annual Report on Form 10-K for the year ended June 30, 2020 (the "2020 Form 10-K"). In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates 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 under the heading "Risk Factors" in Part II, Item 1A, and elsewhere in this report, as well as those set forth in Part I, Item 1A, "Risk Factors," of the 2020 Form 10-K. Forward-looking statements include information concerning our possible or assumed future results of operations, including results and timing of our clinical trials and planned clinical trials, business strategies and operations, financing plans, potential growth opportunities, potential market opportunities and the effects of competition, as well as assumptions relating to the foregoing. 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," "hopes," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or similar expressions and the negatives of those terms. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's plans, estimates, assumptions and beliefs only as of the date of this report. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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

### Overview

We are 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. Our initial focus is in the field of ophthalmology, where we have active clinical programs in X-linked retinitis pigmentosa ("XLRP"), achromatopsia ("ACHM"), and optogenetics as well as preclinical programs in Stargardt disease and age-related macular degeneration ("AMD"). In addition to ophthalmology, we have initiated one preclinical program in otology and three preclinical programs targeting central nervous system disorders ("CNS"), including adrenoleukodystrophy ("ALD"), frontotemporal dementia ("FTD") and amyotrophic lateral sclerosis ("ALS"). Our optogenetics program is being developed in collaboration with Bionic Sight, LLC ("Bionic Sight") and our otology program is being developed in collaboration with Otonomy, Inc. ("Otonomy"). With a number of important clinical milestones on the horizon, we believe that we are well positioned to advance multiple programs toward pivotal studies. In addition to our product pipeline, we have also developed broad technological and manufacturing capabilities utilizing both our internal scientific resources and collaborations with others, such as our efforts with Synpromics Limited, which was acquired by AskBio and provides expertise in synthetic promoter development and optimization, and the University of Florida, which provides us with expertise in vector design and access to novel capsids.

Since our inception, we have devoted substantially all of our resources to development efforts relating to our proof-of-concept programs in ophthalmology, otology, CNS, and alpha-1 antitrypsin deficiency, an inherited orphan lung disease, including manufacturing 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. We have funded our operations to date primarily through public offering of our common stock, private placement of preferred stock, collateralized borrowing and collaborations. 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 United States Food and Drug Administration, or the FDA, and by patient advocacy groups such as The Foundation Fighting Blindness and the Alpha-1 Foundation.

We have incurred losses from operations in each year since inception, except for fiscal year 2017, wherein we reported net income of \$0.4 million due, in part, to profits from a collaboration agreement that was ultimately terminated in March 2019. For the six months ended December 31, 2020 and 2019, we reported net losses of \$30.8 million and \$20.2 million, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and general and administrative expenses associated with our operations. We expect to continue to incur significant operating expenses for at least the next several years and anticipate that such expenses will increase substantially in connection with our ongoing activities as we:

- continue to conduct preclinical studies and clinical trials for our XLRP and ACHM product candidates and preclinical studies for our other ophthalmology, otology and CNS product candidates;



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- continue our research and development efforts, including exploration through early preclinical studies of potential applications of our gene therapy platform in:
  - orphan ophthalmology indications;
  - non-orphan ophthalmology indications, including AMD and other retinal diseases; and
  - other inherited diseases, such as otology and CNS indications;
- manufacture clinical trial materials and develop larger-scale manufacturing capabilities;
- seek regulatory approval for our product candidates;
- further develop our gene therapy platform;
- add personnel to support our scientific, collaboration, product development and commercialization efforts; and
- continue to operate as a public company.

As of December 31, 2020, we had cash and cash equivalents and liquid investments totaling \$53.1 million. We do not expect to 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. We believe that our cash and cash equivalents and investments on December 31, 2020, along with net proceeds of approximately \$69.2 million that we received in February 2021 from the underwritten public offering that is described below under “Recent Developments,” will be sufficient to allow us to generate data from our ongoing and planned clinical programs and fund currently planned research and discovery programs into calendar year 2023. In order to complete the XLRP Phase 2/3 trial, obtain regulatory approval for our lead product candidates and 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. Also, our current operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, acquisitions or other business development activities, or a combination of these approaches. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates and continue our research and development efforts.

## **Recent Developments**

### **XLRP**

In July 2020, we announced our updated development plans for the XLRP clinical program, including the dosing of additional patients in our current Phase 1/2 trial to collect more functional data, which expansion trial we refer to as Skyline, and a Phase 2/3 trial, which we refer to as our XLRP Vista trial.

In November 2020, we announced a modification to the primary endpoint for our XLRP Vista trial based on comments received from the FDA. The design of our XLRP Vista trial is expected to include approximately 60 patients randomized across three arms: a low-dose group (the 1.2E+11 vg/mL Group 2 dose from the ongoing Phase 1/2 trial), a high-dose group (the 1.1E+12 vg/mL Group 5 dose from the ongoing Phase 1/2 trial) and an untreated control group. The primary endpoint will be visual sensitivity defined as having at least a 7 decibel improvement in visual sensitivity in at least 5 pre-specified loci at Month 12. Together with a third-party vendor, we have developed a machine learning algorithm that, on a patient-by-patient basis, predicts the loci most likely to improve through evaluation of baseline visual sensitivity. The algorithm was developed using the microperimetry data available to date from the Phase 1/2 dose escalation study. Secondary endpoints include mean change in visual sensitivity, improvements in visual acuity and improvements in performance on a visual navigation course. We also plan to include a masked interim analysis at Month 6, with that data expected to be released in the third quarter of calendar year 2022, which may provide us with the opportunity to adjust the trial, if necessary, to optimize outcomes.

In November 2020, we also provided additional data from our XLRP Phase 1/2 trial that indicated 2 of 8 evaluable centrally dosed patients in Groups 2 and 4 were responders at Month 12. A third patient, who was a responder at Month 6, fell just below the responder criterion. All eight evaluable patients also showed stable or improving visual acuity. In addition, we provided six-month data for the 11 centrally dosed patients in Groups 5 and 6 and reported that 5 of 11 patients were responders at Month 6. Nine of these patients also had stable or improving visual acuity. If we apply the planned XLRP Vista trial inclusion criteria, 3 of the 11 patients in Groups 5 and 6 would be removed from the analysis, and 5 of 8 patients, or 62%, would be considered responders. We do not currently have a complete set of Month 12 data available nor do we have a control arm in the Phase 1/2 trial, both of which will be part of our planned XLRP Vista trial and necessary to evaluate efficacy. We expect to report 12-month data for Groups 5 and 6 in the second quarter of calendar year 2021.

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As part of the Skyline trial, we intend to dose a total of 12 additional patients across two dose groups. The Skyline trial is intended to evaluate the correlation of a new mobility navigation course developed for use with retinitis pigmentosa patients, with the primary endpoint of visual sensitivity at pre-specified loci, providing such data within the earliest timeframe. This trial will have the same overall design as the XLRP Vista trial and we expect to review 3-month data from the Skyline trial in the fourth quarter of calendar year 2021, subject to delays related to the COVID-19 pandemic. We anticipate reporting our formal Month 12 analysis of these data in the third quarter of calendar year 2022.

### **ACHM**

In January 2020, we provided 3-month ACHM data indicating evidence of biologic activity in the dose escalation portions in both our ACHMB3 and ACHMA3 trials, based on improvements in light discomfort. In November 2020, we provided 12-month data for the original three dose groups (low, medium and high), as well as 6- to 9-month data at two higher dose groups (higher and highest dose groups). The ACHMB3 trial included an additional group of four patients at an intermediate dose with 12-month data. In addition, we provided data for six pediatric subjects (three in each study; 11-17 years old) at the first of three planned dose levels. Across all patients evaluated, the safety profile remained favorable. While some patients showed improvements in at least one measure of visual function, no consistent sustained improvements were observed based on current assessments within the dose groups tested on a groupwise basis. Anecdotal statements, however, and assessments from patient-reported outcome surveys continued to provide us with confidence that patients were subjectively experiencing improved vision.

In January 2021, we reported results based on a patient-by-patient analysis of data from both ACHMB3 and ACHMA3 trials. For ACHMB3, this consisted of 12-month data from 15 patients, 9-month data from five patients, 6-month data from three patients and 3-month data from three patients for a total of 26 patients across all dose groups. These results reflect a further analysis of certain data discussed in November 2020 together with new data that became available in January 2021. Seven of the 16 patients in the three highest dose groups in the ACHMB3 trial showed improvements in visual sensitivity in the treated area, as measured by static perimetry. No consistent results were seen in the other dose groups. In a subset of these patients with evaluable multi-focal electroretinograms (“ERG”), improvements in electrical signaling were measurable in the same treated area.

For ACHMA3, the new data analysis consisted of 12-month data from 10 patients, 9-month data from four patients, 6-month data from one patient and 2 or 3-month data from three patients for a total of 18 patients across five dose groups. One additional patient did not have evaluable data. In the 16 patients in the four highest dose groups, three patients showed improvements in visual sensitivity in the treated area, as measured by static perimetry. No consistent results were seen in other dose groups. None of these three patients with improvements in visual sensitivity had evaluable ERGs.

We currently plan to focus on completion of enrollment of pediatric patients in the two highest dose groups in our ACHMB3 and ACHMA3 trials. Our progress was previously hampered by the COVID-19 pandemic, but patients are now being identified and scheduled for screening at multiple sites. In addition, we have amended the study protocol for these trials to allow enrollment of patients as young as 4 years of age and to include both functional magnetic resonance imaging (“fMRI”) and improved color brightness tests. We are hopeful that these changes, combined with longer follow-up times, will add to the developing body of evidence and support the anecdotal patient-reported outcomes. We expect to report 12-month data from the adult patients in both trials in second quarter of calendar year 2021, and preliminary 3-month data from the pediatric patients in both trials are anticipated in the fourth quarter of calendar year 2021.

### **Underwritten Public Offering**

On February 1, 2021, we closed an underwritten public offering of 16,741,573 shares of our common stock, together with accompanying warrants to purchase 8,370,786 shares of our common stock. The combined offering price of each share of common stock and accompanying warrant was \$4.45, generating gross proceeds of \$74.5 million, before deducting underwriting discounts, commissions and other offering expenses payable by us, which total approximately \$5.3 million. The warrants may only be exercised in integral multiples of two, have an exercise price of \$6.00 per share (subject to certain adjustments), are immediately exercisable and expire on February 1, 2026.

We intend to use the net proceeds from the offering, together with other available funds, to fund our ongoing Skyline trial and XLRP Vista trial and our ongoing Phase 1/2 clinical trials in our ACHMB3 and ACHMA3 programs, and for working capital and other general corporate purposes.

## **Strategic Collaborations**

### ***Bionic Sight***

During February 2017, we entered into a strategic research and development collaboration agreement with Bionic Sight to develop therapies for patients with visual deficits and blindness due to retinal disease. Through the AGTC-Bionic Sight collaboration, the companies seek to develop a new optogenetic therapy that leverages AGTC's deep experience in gene therapy and ophthalmology and Bionic Sight's innovative neuro-prosthetic device and algorithm for retinal coding. The collaboration agreement grants to us, subject to achievement by Bionic Sight of certain development milestones, an option to exclusively negotiate for a limited period of time to acquire (i) a majority equity interest in Bionic Sight, (ii) the Bionic Sight assets to which the collaboration agreement relates or (iii) an exclusive license with respect to the product to which the collaboration agreement relates.

### ***Otonomy***

In October 2019, we entered into a strategic collaboration agreement with Otonomy to co-develop and co-commercialize an AAV-based gene therapy to restore hearing in patients with sensorineural hearing loss caused by a mutation in the gap junction protein beta 2 gene (GJB2) – the most common cause of congenital hearing loss. Mutations in GJB2 account for approximately 30% of all genetic hearing loss cases. Patients with this mutation can have severe-to-profound deafness in both ears that is identified in screening tests routinely performed in newborns. Under the collaboration agreement, the parties began equally sharing the program costs and proceeds in January 2020 and can include additional genetic hearing loss targets in the future.

Additional information regarding the Bionic Sight and Otonomy collaborative agreements can be found in Note 7 to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q.

## **Critical Accounting Policies and Estimates**

Management's Discussion and Analysis of Financial Condition and Results of Operations included in this Quarterly Report on Form 10-Q is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and the instructions to Form 10-Q and Article 8 of Regulation S-X. The preparation of those financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates, judgments and methodologies, including those related to accrued expenses and share-based compensation. We base our estimates on historical experience, current conditions, 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 our estimates under different assumptions or conditions. Moreover, we may need to change the assumptions underlying our estimates due to risks and uncertainties related to the COVID-19 pandemic or otherwise and those changes could have a material adverse effect on our statements of operations, financial condition and cash flows.

During the six months ended December 31, 2020, there were no significant changes to our critical accounting policies and estimates. For a description of our accounting policies that, in our opinion, involve the most significant application of judgment or involve complex estimation and which could, if different judgments or estimates were made, materially affect our reported results of operations, financial position and cash flows, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates" in the 2020 Form 10-K.

## **New Accounting Pronouncements**

Refer to Note 2 to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q for further information about recently issued accounting standards.

## **Financial Operations Review**

### ***Revenue***

We primarily generate revenue through: (i) collaboration agreements; (ii) sponsored research arrangements with nonprofit organizations for the development and commercialization of product candidates; and (iii) federal research and development grant programs. However, we did not recognize any revenue during the three and six months ended December 31, 2020. In the future, we may generate revenue from product sales (if any products are approved), license fees, milestone payments, development services, research and development grants, or from collaboration and royalty payments for the sales of products developed under licenses of our intellectual property.

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We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development programs, manufacturing efforts and reimbursements, collaboration milestone payments, and the sale of our products, to the extent that any are approved and successfully commercialized. We do not expect to generate revenue from product sales for the foreseeable future, if at all. If we or our collaborators fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, our results of operations, financial position and cash flows would be materially adversely affected.

### *Research and development expenses*

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with academic research centers, contract research organizations, or CROs, and investigative sites that conduct our clinical trials;
- license and sublicense fees and collaboration expenses;
- the cost of acquiring, developing and manufacturing clinical trial materials; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress toward completion of specific tasks, using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expense of our ongoing clinical trials, as well as any additional clinical trials that we are required to, or decide to, initiate and other research and development activities;
- the timing and level of activity as determined by us or jointly with our partners;
- the level of funding, if any, received from our partners;
- whether or not we elect to cost share with our collaborators;
- the countries in which trials are conducted;
- future clinical trial results;
- uncertainties in clinical trial enrollment rates or drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies or elected as best practice by us;
- increased cost and delay associated with manufacturing or testing issues, including ongoing quality assurance, qualifying new vendors and developing in-house capabilities;
- significant and changing government regulation; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in or execution of any of our clinical trials, which could be adversely impacted by the COVID-19 pandemic, we could be required to expend significant additional financial resources and time on the completion of clinical development.

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From our inception and through December 31, 2020, we have incurred approximately \$261.6 million in research and development expenses. We expect our research and development expenses to increase for the foreseeable future as we continue the development of our product candidates and explore potential applications of our gene therapy platform in other indications.

### *General and administrative expenses*

General and administrative expenses primarily consist of salaries and related costs for personnel, including share-based compensation and travel expenses for our employees in executive, operational, legal, business development, finance and human resource functions. Other general and administrative expenses include costs to support employee training and development, board of directors' costs, depreciation, insurance, facility-related costs not otherwise included in research and development expenses, professional fees for legal services, including patent-related expenses, and accounting, investor relations, corporate communications and information technology services. We anticipate that our general and administrative expenses will continue to increase in the future as we hire additional employees to support our continued research and development efforts, collaboration arrangements, and the potential commercialization of our product candidates. Additionally, if and when we believe that regulatory approval of our first product candidate appears likely, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

### *Investment income, net*

Investment income, net consists of interest earned on cash and cash equivalents and held-to-maturity investments in debt securities. During the three and six months ended December 31, 2020, investment income, net declined by \$0.3 million and \$0.7 million, respectively, when compared to the comparable periods in the prior year. The reduction in investment income, net during 2020 was primarily due to lower interest rates in the marketplace and a smaller average year-over-year balance of investments in debt securities.

### *Interest expense*

Interest expense during the three and six months ended December 31, 2020 was primarily attributable to the loan agreement that we entered into on June 30, 2020.

### *Provision for income taxes*

Income tax expense for the three and six months ended December 31, 2020 was \$20,000 and \$41,000, respectively, compared to \$21,000 and \$42,000 for the three and six months ended December 31, 2019, respectively. During those periods, income tax expense was primarily due to estimated interest and penalties on our uncertain tax positions.

## **Results of Operations**

### **Comparison of the three months ended December 31, 2020 and 2019**

#### *Revenue*

During the three months ended December 31, 2019, we recognized total revenue of \$2.5 million. We did not recognize any revenue during the three months ended December 31, 2020.

In December 2019, Bionic Sight met a milestone related to clearance of filing of an Investigational New Drug application under its collaboration agreement with us and, as a result, we recognized \$2.2 million of non-cash collaboration revenue during the three months ended December 31, 2019 in connection with in-kind contributions made since inception of the Bionic Sight collaboration agreement. Additional information regarding the Bionic Sight collaborative agreement can be found in Note 7 to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q. During the three months ended December 31, 2019, we also recorded \$0.2 million and \$0.1 million of grant revenue and other milestone revenue, respectively.

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### Research and development expenses

The table below summarizes our research and development expenses by product candidate or program for the periods indicated.

In thousands	Three Months Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2020	2019		
External research and development expenses:				
XLRP	\$ 4,869	\$ 799	\$ 4,070	>100%
ACHM	1,212	2,142	(930)	(43)%
XLRS	59	221	(162)	(73)%
Research and discovery programs	516	483	33	7%
Total external research and development expenses	6,656	3,645	3,011	83%
Internal research and development expenses:				
Employee-related costs	3,193	2,830	363	13%
Share-based compensation	269	312	(43)	(14)%
Other	1,693	1,588	105	7%
Total internal research and development expenses	5,155	4,730	425	9%
Total research and development expenses	\$11,811	\$ 8,375	\$ 3,436	41%

External research and development expenses consist of collaboration, licensing, manufacturing, testing and other miscellaneous costs that are directly attributable to our most advanced product candidates and discovery programs. We do not allocate personnel-related costs, including share-based compensation, costs associated with broad technology platform improvements or other indirect costs, to specific programs, as they are deployed across multiple projects under development and, as such, are separately classified as internal research and development expenses in the table above.

Research and development expenses for the three months ended December 31, 2020 and 2019 were \$11.8 million and \$8.4 million, respectively, an increase of \$3.4 million, or 41%. Such increase was primarily attributable to:

- \$4.1 million of increased external spending for our XLRP trials due to our planned manufacturing, clinical site preparation and other activities related to our Skyline trial and XLRP Vista trial; and
- \$0.4 million of increased internal spending for employee-related costs due to a slightly higher 2020 research and development headcount when compared to the prior year, annual salary increases and certain employee incentive costs.

Such increases were partially offset by a \$0.9 million decrease in external spending for our ACHM trials and a \$0.2 million decrease in expenses in connection with the wind-down of our X-linked retinosis, or XLRS, program. The decrease in ACHM expenses was primarily due to reduced patient enrollment, patient visits and new site activations during the 2020 period when compared to the prior year, all of which reduce our overall clinical programs costs, partially offset by incremental expenses for our mobile vision center.

### General and administrative expenses

The table below summarizes our general and administrative and other expenses for the periods indicated.

In thousands	Three Months Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2020	2019		
Employee-related costs	\$ 1,195	\$ 1,342	\$ (147)	(11)%
Share-based compensation	355	376	(21)	(6)%
Legal and professional fees	365	73	292	>100%
Other	1,389	1,217	172	14%
Total general and administrative and other expenses	\$ 3,304	\$ 3,008	\$ 296	10%

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General and administrative and other expenses for the three months ended December 31, 2020 and 2019 were \$3.3 million and \$3.0 million, respectively, an increase of \$0.3 million, or 10%. Such increase was primarily due to higher legal fees during the 2020 period resulting from expanded use of outside legal counsel following certain personnel changes, partially offset by a reduction in employee-related costs of \$0.1 million that resulted from a slightly lower 2020 headcount when compared to the prior year.

### **Comparison of the six months ended December 31, 2020 and 2019**

#### *Revenue*

See above under “Results of Operations – Comparison of the three months ended December 31, 2020 and 2019 - Revenue,” for a discussion of our revenue during the six-month periods, which was the same as the corresponding three-month periods.

#### *Research and development expenses*

The table below summarizes our research and development expenses by product candidate or program for the periods indicated.

<b>In thousands</b>	<b>Six Months Ended December 31,</b>		<b>Increase (Decrease)</b>	<b>% Increase (Decrease)</b>
	<b>2020</b>	<b>2019</b>		
<b>External research and development expenses:</b>				
XLRP	\$ 8,729	\$ 1,571	\$ 7,158	>100%
ACHM	2,850	3,406	(556)	(16)%
XLRS	152	440	(288)	(65)%
Research and discovery programs	1,017	1,114	(97)	(9)%
<b>Total external research and development expenses</b>	<b>12,748</b>	<b>6,531</b>	<b>6,217</b>	<b>95%</b>
<b>Internal research and development expenses:</b>				
Employee-related costs	6,415	6,294	121	2%
Share-based compensation	586	675	(89)	(13)%
Other	3,688	3,517	171	5%
<b>Total internal research and development expenses</b>	<b>10,689</b>	<b>10,486</b>	<b>203</b>	<b>2%</b>
<b>Total research and development expenses</b>	<b>\$23,437</b>	<b>\$17,017</b>	<b>\$ 6,420</b>	<b>38%</b>

Research and development expenses for the six months ended December 31, 2020 and 2019 were \$23.4 million and \$17.0 million, respectively, an increase of \$6.4 million, or 38%. Such increase was primarily attributable to \$7.2 million of increased external spending for our XLRP trials due to our planned manufacturing, clinical site preparation and other activities related to our Skyline trial and XLRP Vista trial. Such increase was partially offset by a \$0.6 million decrease in external spending for our ACHM trials and a \$0.3 million decrease in expenses in connection with the wind-down of our XLRS program. The decrease in ACHM expenses was primarily due to reduced patient enrollment, patient visits and new site activations during the 2020 period when compared to the prior year, all of which reduce our overall clinical programs costs, partially offset by incremental expenses for our mobile vision center.

#### *General and administrative expenses*

The table below summarizes our general and administrative and other expenses for the periods indicated.

<b>In thousands</b>	<b>Six Months Ended December 31,</b>		<b>Increase (Decrease)</b>	<b>% Increase (Decrease)</b>
	<b>2020</b>	<b>2019</b>		
Employee-related costs	\$ 2,434	\$ 2,737	\$ (303)	(11)%
Share-based compensation	684	824	(140)	(17)%
Legal and professional fees	909	233	676	>100%
Other	2,713	2,562	151	6%
<b>Total general and administrative and other expenses</b>	<b>\$ 6,740</b>	<b>\$ 6,356</b>	<b>\$ 384</b>	<b>6%</b>

General and administrative and other expenses for the six months ended December 31, 2020 and 2019 were \$6.7 million and \$6.4 million, respectively, an increase of \$0.4 million, or 6%. Such increase was primarily due to higher legal fees during the 2020 period resulting from expanded use of outside legal counsel following certain personnel changes, partially offset by a reduction in employee-related costs of \$0.3 million that resulted from a slightly lower 2020 headcount when compared to the prior year.



## Liquidity and Capital Resources

We have incurred cumulative losses and negative cash flows from operations since our inception and, as of December 31, 2020, we had an accumulated deficit of \$212.3 million. It will be several years, if ever, before we have a product candidate ready for commercialization. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we anticipate that we will require additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Most recently, the Company received: (i) \$34.8 million of proceeds from the issuance of its common stock, net of issuance costs, in February 2020; (ii) \$9.9 million of loan proceeds, net of debt discounts, in June 2020; and (iii) net proceeds of approximately \$69.2 million in February 2021 from the underwritten public offering that is described above under “Recent Developments.”

We are closely monitoring ongoing developments in connection with the COVID-19 pandemic, which may negatively impact our projected cash position and access to capital. We will continue to assess our cash position and, if circumstances warrant, make appropriate adjustments to our operating plan.

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 twelve months. As of December 31, 2020, our cash and cash equivalents were held in bank accounts and money market funds, while our investments consisted of U.S. Treasury securities, none of which mature more than twelve months after the balance sheet date, consistent with our investment policy that seeks to maintain adequate liquidity and preserve capital.

## Cash flows

The table below sets forth the primary sources and uses of cash for the periods indicated.

In thousands	Six Months Ended December 31,		Increase (Decrease)	% Increase (Decrease)
	2020	2019		
Net cash provided by (used in):				
Operating activities	\$(26,308)	\$(19,036)	\$ (7,272)	(38)%
Investing activities	7,027	10,400	(3,373)	(32)%
Financing activities	(74)	9	(83)	>(100)%
Net decrease in cash and cash equivalents	<u>\$(19,355)</u>	<u>\$ (8,627)</u>	<u>\$(10,728)</u>	<u>&gt;(100)%</u>

**Operating activities.** For both the six months ended December 31, 2020 and 2019, cash used in operating activities was primarily the result of research and development and general and administrative expenses incurred in conducting normal business operations. Specifically, the cash used in operating activities of \$26.3 million during the six months ended December 31, 2020 was due to a net loss of \$30.8 million, partially offset by non-cash items in our statement of operations of \$2.4 million and favorable changes in our operating assets and liabilities of \$2.1 million. The cash used in operating activities of \$19.0 million during the six months ended December 31, 2019 was due to a net loss of \$20.2 million and non-cash items in our statement of operations of \$0.2 million, partially offset by favorable changes in our operating assets and liabilities of \$1.3 million.

**Investing activities.** Cash provided by investing activities of \$7.0 million during the six months ended December 31, 2020 consisted primarily of cash proceeds of \$27.0 million from maturities of investments, net of investment purchases of \$19.0 million, partially offset by purchases of property and equipment of \$0.8 million and intellectual property costs of \$0.2 million. Cash provided by investing activities of \$10.4 million during the six months ended December 31, 2019 consisted primarily of cash proceeds of \$40.5 million from maturities of investments, net of investment purchases of \$29.4 million, partially offset by purchases of property and equipment of \$0.4 million and intellectual property costs of \$0.3 million.

**Financing activities.** Cash used in financing activities of \$0.1 million during the six months ended December 31, 2020 consisted of (i) payments for deferred financing fees and taxes related to equity awards and (ii) principal payments on a finance lease, partially offset by proceeds from exercises of common stock options. The nominal cash provided by financing activities during the six months ended December 31, 2019 primarily consisted of proceeds from exercises of common stock options, partially offset by principal payments on a finance lease.



### ***Operating capital requirements***

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

We believe that our cash and cash equivalents and investments on December 31, 2020, which totaled \$53.1 million, along with the net proceeds that we received in February 2021 from an underwritten public offering, will be sufficient to allow us to generate data from our ongoing and planned clinical programs and fund currently planned research and discovery programs into calendar year 2023. However, we will require substantial additional funding to finish our XLRP Vista trial, complete the process necessary to seek regulatory approval for our lead product candidates and build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide this information.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **a) Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15e and 15d-15e under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this quarterly report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that these disclosure controls and procedures were effective as of December 31, 2020.

#### **b) Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Securities Exchange Act of 1934, as amended) during the quarter ended December 31, 2020 that have materially affected, or are 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, due to the nature of our business, we may be subject to lawsuits or other claims arising at any particular time in the ordinary course of our business, and we expect that this situation will continue to be the case in the future.

### **ITEM 1A. RISK FACTORS**

Refer to Part I, Item 1A, “Risk Factors,” of our Annual Report on Form 10-K for the year ended June 30, 2020 for information regarding our risk factors. Except as noted below, there have been no material changes in our risk factors since June 30, 2020.

***Third parties may initiate legal proceedings alleging claims of intellectual property infringement, including claims related to our XLRP product candidate, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* reexamination proceedings before the United States Patent and Trademark Office and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

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Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies or product candidates infringes upon these patents.

For example, we are aware of a third-party U.S. patent that may be construed to cover our gene therapy compositions for treating XLRP. We are also aware of corresponding international applications owned by such third party, which are counterparts to such U.S. patent. If such third party asserts this U.S. patent or any other patents that may issue from such corresponding international patent applications against us and our XLRP product candidate, we believe that we would have defenses against any such assertion, however, there can be no assurance that any such defenses will be successful. If such patents, or any other third-party patents, were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, and are not held to be invalid or unenforceable, the holders of any such patents may be able to block our ability to commercialize such product candidate, including our XLRP product candidate, unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, methods for manufacture or methods of use, including combination therapy, and are not held to be invalid or unenforceable, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, including our XLRP product candidate. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement. If a license is available from the applicable third party, we may have to pay royalties, upfront fees and other amounts, and/or grant cross-licenses under our intellectual property rights. Further, we may be required to redesign our infringing products so they do not infringe the applicable third-party patents or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

## **ITEM 6. EXHIBITS**

<u>Exhibit Number</u>	<u>Description</u>
3.1	<a href="#">Fifth Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on April 1, 2014 (File No. 001-36370))</a>
3.2	<a href="#">Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on April 1, 2014 (File No. 001-36370))</a>
4.1	<a href="#">Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, event date January 28, 2021, filed with the SEC on January 29, 2021 (File No. 001-36370))</a>
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
31.2*	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1**	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
101.1*	The following interactive Data Files pursuant to Rule 405 of Regulation S-T, formatted in XBRL (eXtensible Business Reporting Language): (a) Condensed Balance Sheets as of December 31, 2020 and June 30, 2020; (b) Condensed Statements of Operations for the three and six months ended December 31, 2020 and 2019; (c) Condensed Statements of Stockholders' Equity for the three and six months ended December 31, 2020 and 2019; (d) Condensed Statements of Cash Flows for the six months ended December 31, 2020 and 2019; and (e) Notes to such Unaudited Condensed Financial Statements.

\* 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/ William A. Sullivan  
William A. Sullivan, Chief Financial Officer

Date: February 11, 2021

## CERTIFICATION

I, Susan B. Washer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Applied Genetic Technologies Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 11, 2021

By: /s/ Susan B. Washer  
Susan B. Washer  
President and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATION

I, William A. Sullivan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Applied Genetic Technologies Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 11, 2021

By: /s/ William A. Sullivan  
William A. Sullivan  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Applied Genetic Technologies Corporation (the "Company") for the period ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to her or his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 11, 2021

By: /s/ Susan B. Washer  
Susan B. Washer  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: February 11, 2021

By: /s/ William A. Sullivan  
William A. Sullivan  
Chief Financial Officer  
(Principal Financial Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Applied Genetic Technologies Corporation and will be retained by Applied Genetic Technologies Corporation and furnished to the Securities and Exchange Commission or its staff upon request.