UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-36370

APPLIED GENETIC TECHNOLOGIES CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**59-3553710**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

14193 NW 119th Terrace, Suite 10, Alachua, Florida 32615
(Address of Principal Executive Offices) (Zip Code)

(386) 462-2204
(Registrant's Telephone Number, Including Area Code)

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

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**

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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The number of shares of the registrant’s common stock outstanding as of May 12, 2022 was 50,731,903.

APPLIED GENETIC TECHNOLOGIES CORPORATION
FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2022

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

APPLIED GENETIC TECHNOLOGIES CORPORATION
CONDENSED BALANCE SHEETS
(Unaudited)

In thousands, except per share data	March 31, 2022	June 30, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 67,849	$ 105,052
Investments	—	2,000
Prepaid and other current assets	2,678	2,655
Total current assets	70,527	109,707
Property and equipment, net	4,244	4,658
Intangible assets, net	1,381	1,287
Investment in Bionic Sight, LLC	7,884	8,000
Right-of-use assets - operating leases	3,029	3,167
Right-of-use asset - financing lease	—	34
Other assets	126	113
Total assets	$ 87,191	$ 126,966
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,561	$ 1,879
Accrued and other liabilities	11,946	14,500
Lease liabilities - operating	1,232	1,116
Lease liability - finance	—	38
Current portion of long-term debt	9,070	2,181
Total current liabilities	25,809	19,714
Lease liabilities - operating, net of current portion	2,900	3,418
Long-term debt, net of debt discounts and deferred financing fees	11,358	17,727
Other liabilities	97	299
Total liabilities	40,164	41,158
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; 50,786 and 42,835 shares issued; 50,732 and 42,794 shares outstanding at March 31, 2022 and June 30, 2021, respectively	51	43
Additional paid-in capital	337,058	325,245
Treasury stock at cost; 54 and 41 shares at March 31, 2022 and June 30, 2021, respectively	(256)	(211)
Accumulated deficit	(289,826)	(239,269)
Total stockholders' equity	47,027	85,808
Total liabilities and stockholders' equity	$ 87,191	$ 126,966

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

APPLIED GENETIC TECHNOLOGIES CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

In thousands, except per share data	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	Nine Months Ended March 31, 2022	Nine Months Ended March 31, 2021
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	9,162	10,960	35,941	34,397
General and administrative and other	4,421	3,528	12,510	10,268
Total operating expenses	13,583	14,488	48,451	44,665
Loss from operations	(13,583)	(14,488)	(48,451)	(44,665)
Other income (expense), net:				
Investment income, net	9	13	21	106
Interest expense	(667)	(330)	(2,011)	(997)
Total other income (expense), net	(658)	(317)	(1,990)	(891)
Loss before provision for income taxes	(14,241)	(14,805)	(50,441)	(45,556)
Provision for income taxes	—	21	—	62
Loss before equity in net losses of an affiliate	(14,241)	(14,826)	(50,441)	(45,618)
Equity in net losses of an affiliate	(53)	(25)	(116)	(75)
Net loss	$(14,294)	$(14,851)	$(50,557)	$(45,693)
Weighted average shares outstanding:				
Basic	43,639	36,751	43,112	29,431
Diluted	43,639	36,751	43,112	29,431
Net loss per common share:				
Basic	$ (0.33)	$ (0.40)	$ (1.17)	$ (1.55)
Diluted	$ (0.33)	$ (0.40)	$ (1.17)	$ (1.55)

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

APPLIED GENETIC TECHNOLOGIES CORPORATION
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
THREE AND NINE MONTHS ENDED MARCH 31, 2022 AND 2021
(Unaudited)

	Common Stock		Treasury Stock				
In thousands	Outstanding Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Totals
Balances at June 30, 2021	42,794	$ 43	41	$ (211)	$325,245	$ (239,269)	$ 85,808
Share-based compensation expense	—	—	—	—	810	—	810
Shares issued under employee plans and related share repurchases	65	—	13	(45)	71	—	26
Net loss	—	—	—	—	—	(17,119)	(17,119)
Balances at September 30, 2021	42,859	43	54	(256)	326,126	(256,388)	69,525
Issuance of common stock, net of issuance costs	56	—	—	—	143	—	143
Share-based compensation expense	—	—	—	—	946	—	946
Shares issued under employee plans and related share repurchases	6	—	—	—	20	—	20
Net loss	—	—	—	—	—	(19,144)	(19,144)
Balances at December 31, 2021	42,921	43	54	(256)	327,235	(275,532)	51,490
Issuance of common stock, net of issuance costs	7,690	8	—	—	8,938	—	8,946
Share-based compensation expense	—	—	—	—	843	—	843
Shares issued under employee plans and related share repurchases	121	—	—	—	42	—	42
Net loss	—	—	—	—	—	(14,294)	(14,294)
Balances at March 31, 2022	50,732	$ 51	54	$ (256)	$337,058	$ (289,826)	$ 47,027

	Common Stock		Treasury Stock				
In thousands	Outstanding Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Totals
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	25,905	25	41	(211)	253,990	(212,282)	41,522
Issuance of common stock and accompanying warrants, net of issuance costs	16,742	17	—	—	69,244	—	69,261
Share-based compensation expense	—	—	—	—	595	—	595
Shares issued under employee plans and related share repurchases	108	—	—	—	473	—	473
Net loss	—	—	—	—	—	(14,851)	(14,851)
Balances at March 31, 2021	42,755	$ 42	41	$ (211)	$324,302	$ (227,133)	$ 97,000

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

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

In thousands	Nine Months Ended March 31, 2022	2021
Operating activities:		
Net loss	$ (50,557)	$ (45,693)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	2,599	1,865
Expense for shares of common stock issued to a vendor	27	—
Depreciation and amortization	1,130	1,123
Investment discount accretion, net	—	(10)
Amortization of debt discounts and deferred financing fees	520	252
Reduction in the carrying amount of operating lease right-of-use assets	381	264
Equity in net losses of an affiliate	116	75
Changes in operating assets and liabilities:		
Prepaid and other assets	(36)	975
Accounts payable	1,569	571
Operating lease liabilities	(645)	(516)
Accrued and other liabilities	(2,594)	3,356
Cash used in operating activities	(47,490)	(37,738)
Investing activities:		
Purchases of property and equipment	(900)	(987)
Purchases of and capitalized costs related to intangible assets	(254)	(363)
Maturities of investments	2,000	41,500
Purchases of investments	—	(20,992)
Cash provided by investing activities	846	19,158
Financing activities:		
Proceeds from the issuance of common stock and accompanying warrants, net of issuance costs	9,391	69,261
Proceeds from exercises of common stock options	133	674
Payments for deferred financing fees	—	(129)
Taxes paid related to equity awards	(45)	(123)
Principal payments on a finance lease	(38)	(35)
Cash provided by financing activities	9,441	69,648
Net increase (decrease) in cash and cash equivalents	(37,203)	51,068
Cash and cash equivalents, beginning of the period	105,052	38,463
Cash and cash equivalents, end of the period	$ 67,849	$ 89,531
Supplemental non-cash information:		
Costs for purchases of property and equipment included in accounts payable	$ 82	$ —
Costs for intangible assets included in accrued and other liabilities	14	27
Right-of-use assets obtained in exchange for new operating lease liabilities	243	—

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

General

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 people suffering from rare and debilitating ophthalmic, otologic and central nervous system diseases.

The Company has devoted substantially all of its efforts to research and development activities, including conducting clinical trials for its product candidates, and has not completed the development of any products. The Company has generated revenue from collaboration agreements, licensing of its intellectual property, sponsored research agreements 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 need to obtain additional capital necessary to fund the development of its product candidates, the risk of failure of ongoing or future clinical studies, the difficulties inherent in the development of commercially viable products, the development by the Company or its competitors of technological innovations, the protection of proprietary technology, compliance with government regulations and the ability to transition to large-scale production of products.

Liquidity and Financial Condition

As of March 31, 2022, the Company had (i) an accumulated deficit of $289.8 million and (ii) cash and cash equivalents of $67.8 million. Management believes that there is presently insufficient funding available to allow the Company to generate data from its ongoing and planned clinical programs and fund currently planned research and discovery programs for a period exceeding one year from the date of this filing with the Securities and Exchange Commission. While the Company expects to generate some revenue from collaborations, sponsored research agreements, grants and licensing of its intellectual property, management believes that the Company will incur losses and generate negative operating cash flows for the foreseeable future. As such, these circumstances collectively raise substantial doubt about the Company's ability to continue as a going concern. The accompanying Unaudited Condensed Financial Statements do not include any adjustments that might result from the outcome of this uncertainty. 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.

The ability of an entity to continue as a going concern depends on, among other things, positive cash flows and the availability of suitable financing. The Company's future liquidity needs will be primarily based on: (i) the success and progression of its product candidates; (ii) its repayment obligations under the long-term debt agreement that is described in Note 5 to these Notes to Unaudited Condensed Financial Statements; and (iii) its costs to operate the leased build-to-suit manufacturing and quality control facility that is described in Note 8 to these Notes to Unaudited Condensed Financial Statements. To provide the maximum degree of financial flexibility and mitigate the abovementioned going concern risk, management's near-term plans consider various potential opportunities to fund the Company's future operations and/or modulate its liquidity needs, such as: (i) raising new capital through equity or debt financings or other sources, including the "at-the-market offering" program that is described in Note 7 to these Notes to Unaudited Condensed Financial Statements; (ii) amending the Company's long-term debt agreement; (iii) out-licensing the rights to certain product candidates; (iv) entering into one or more collaborations to offset the costs of the leased manufacturing and quality control facility through third-party cash milestone and other payments; and (v) reducing spending on research and development activities and/or restructuring the Company's operations. However, management may be unable to successfully execute any of the plans described above, or raise additional funds or enter into such other arrangements when needed on favorable terms, or at all.

2. Summary of Significant Accounting Policies

Basis of presentation

The accompanying Unaudited Condensed Financial Statements have been prepared assuming that the Company will continue as a going concern and 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 presentation of the Company's financial position, results of operations and cash flows as of and for the periods presented. The accompanying Condensed Balance Sheet as of June 30, 2021 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, 2021 (the "2021 Form 10-K"). The Company's significant accounting policies are described in Note 2 to the Notes to Financial Statements in the 2021 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 nine months ended March 31, 2022 are not necessarily indicative of the Company's operating results for the full year ending June 30, 2022 or any subsequent interim period within that year.

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

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.

Income Taxes

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.

The Company's provision for income taxes was $21,000 and $62,000 for the three and nine months ended March 31, 2021, respectively, which was entirely attributable to estimated interest and penalties on uncertain tax positions. There was no provision for income taxes during the three and nine months ended March 31, 2022 because, among other things, the Company had no uncertain tax positions in those reporting periods.

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, warrants to purchase the Company's common stock, stock options, restricted stock awards, restricted stock units and performance service awards are considered to be common stock equivalents if they are dilutive. The dilutive impact of common stock equivalents for each of the (i) three and nine months ended March 31, 2022 was approximately 0.1 million shares and (ii) three and nine months ended March 31, 2021 was approximately 0.4 million shares. However, those common stock equivalents were excluded from the calculations of diluted net loss per share for all periods presented herein because their effects were anti-dilutive.

Common stock equivalents for the three and nine months ended March 31, 2022 and 2021 excluded certain warrants to purchase the Company's common stock, which are described in Note 7 to these Notes to Unaudited Condensed Financial Statements, because the exercise price of such warrants was greater than the average market price of the Company's common stock during the related periods.

New Accounting Pronouncements

Adopted during the nine months ended March 31, 2022

Financial Instruments—Credit Losses

In June 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("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. The Company early adopted the new standard on July 1, 2021; however, it did not have a significant impact on the Company's financial statements.

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. The Company adopted the new standard on July 1, 2021; however, it did not 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 Accounting Standards Codification ("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*. The Company adopted the new standard on July 1, 2021; however, it did not 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, nonemployee 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.

Stock Options

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

	Nine Months Ended March 31,			
	2022		2021	
(In thousands, except per share amounts)	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at the beginning of the period	4,186	$ 7.69	3,846	$ 7.82
Granted	2,444	3.07	1,280	5.26
Exercised	(150)	0.89	(165)	4.10
Forfeited	(339)	4.13	(539)	4.38
Expired	(602)	10.82	(87)	10.29
Outstanding at the end of the period	5,539	$ 5.71	4,335	$ 7.58
Exercisable at the end of the period	2,680		2,757	
Weighted average fair value of options granted during the period	$ 2.17		$ 3.79	

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.

	Nine Months Ended March 31,	
Assumption	2022	2021
Dividend yield	0.00%	0.00%
Expected term	6.00 to 6.25 years	6.00 to 6.25 years
Risk-free interest rate	0.80% to 1.80%	0.30% to 1.08%
Expected volatility	82.51%	82.60%

In addition to the stock option activity described above, the Company also granted 100,000 performance-based stock options to an 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, the related tranche will be forfeited. As of March 31, 2022, only one of the six performance criteria had been met. In May 2022, the officer's employment with the Company ended and, as a result, all unvested performance-based stock options will be forfeited. 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 required management to estimate the likelihood of the achievement of the performance targets.

Restricted Stock Units

During August 2019, 175,500 restricted stock units with 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. Those awards had a weighted average grant date fair value of $2.56. Because the award's market and service conditions were met, on August 15, 2021 and 2020, 54,500 and 76,500 restricted stock units, respectively, vested and the underlying shares were issued to the grantees. A total of 44,500 restricted stock units were forfeited through August 15, 2021 and, subsequent to that date, no restricted stock units with market-based vesting conditions remain outstanding. 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.

From May 2021 to July 2021, the Company granted 579,500 restricted stock units to certain employees under the 2013 Equity and Incentive Plan with a weighted average grant date fair value of $4.16. Those awards generally vest in equal amounts on each of the first and second anniversaries of the date of grant, assuming continuing service by the grantee. As of March 31, 2022, 137,250 restricted stock units have been forfeited. The fair value of each restricted stock unit awarded was determined based on the market value of the Company's common stock on the date of grant and the related expense is being recognized using a graded vesting schedule that is aligned with the grantees' vesting dates. No additional restricted stock unit awards are expected to be granted under this program.

General

Share-based compensation expense for the three and nine months ended March 31, 2022 was $0.8 million and $2.6 million, respectively, compared to $0.6 million and $1.9 million for the three and nine months ended March 31, 2021, respectively. The portion of such expense pertaining to stock options awarded to employees, nonemployee directors and consultants was $1.7 million and $1.8 million for the nine months ended March 31, 2022 and 2021, respectively. Share-based compensation expense pertaining to restricted stock awards and restricted stock units awarded to employees and consultants totaled $0.9 million and $0.1 million for the nine months ended March 31, 2022 and 2021, respectively.

4. Investments and Fair Values of Financial Instruments

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 June 30, 2021, the Company's investments consisted of a held-to-maturity debt security that matured in July 2021 (the $2.0 million amortized cost of that investment approximated its fair value on such date). The Company held no investments at March 31, 2022.

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.

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 the 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 have historically consisted of U.S. Treasury securities that were valued using quoted market prices. Valuation adjustments were 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.

In thousands	Level 1	Level 2	Level 3	Total Fair Value
March 31, 2022				
Cash and cash equivalents	$ 67,849	$ —	$ —	$ 67,849
June 30, 2021				
Cash and cash equivalents	$105,052	$ —	$ —	$105,052
Held-to-maturity investment (U.S. Treasury security)	2,000	—	—	2,000
Total assets	$107,052	$ —	$ —	$107,052

The Company's financial instruments also include its variable-rate borrowing under a debt agreement that is described in Note 5 to these Notes to Unaudited Condensed Financial Statements. Management believes that the carrying amount of such debt (i.e., $20.4 million and $19.9 million at March 31, 2022 and June 30, 2021, respectively) reasonably approximates its fair value on those dates 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.

5. 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 2021 Form 10-K.

On June 30, 2020, the Company entered into a Loan and Security Agreement (as amended effective May 13, 2021, the "Amended Loan Agreement") with several banks and other financial institutions or entities from time to time parties to the Amended 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 Amended 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 "Term Loan"). In connection with the Amended Loan Agreement, the Company received term loan advances of $10.0 million on each of June 30, 2020 and May 13, 2021. Prior to April 1, 2022, the Company had the right to request additional term loan advances in an aggregate principal amount of up to $5.0 million; however, no such request was made by the Company.

As of March 31, 2022 and June 30, 2021, the per annum variable contractual interest rate on the Term Loan was 10.00% and 9.75%, respectively, and the effective interest rate on the Term Loan was approximately 13.5% and 13.3%, respectively. Prior to completing the loan amendment in May 2021, the effective interest rate on the Term Loan was approximately 13.5%. Effective May 5, 2022, the per annum variable contractual interest rate on the Term Loan increased to 10.50%.

As of March 31, 2022, the Company was in full compliance with all covenants of the Amended Loan Agreement.

6. Collaboration Agreements and Contract Liabilities

Bionic Sight, LLC

On February 2, 2017, the Company entered into a strategic research and development collaboration agreement with Bionic Sight, LLC ("Bionic Sight") to develop product candidates 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 for an equity interest of approximately 5% in Bionic Sight. During March 2020, the Company's equity interest in Bionic Sight increased to approximately 15.5% in connection with (i) AGTC's purchase of additional equity for $4.0 million and (ii) the conversion of certain AGTC-provided research and development support costs and in-kind contributions, which aggregated approximately $2.2 million, to an equity interest in Bionic Sight, in each case, consistent with the provisions of the collaboration agreement. AGTC is not obligated to purchase additional equity in Bionic Sight or make any additional in-kind contributions under the agreement. The Company recorded its initial investment in Bionic Sight using the equity method of accounting for investments. Upon receipt of additional equity in March 2020, management concluded that equity method accounting remained appropriate.

Otonomy, Inc.

During October 2019, the Company entered into a strategic collaboration agreement with Otonomy, Inc. ("Otonomy") to co-develop and co-commercialize an adeno-associated virus-based gene therapy product candidate designed 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. People 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 any proceeds from potential licensing transactions in January 2020 and can include additional genetic hearing loss targets in the future. Effective January 1, 2022, the Otonomy collaboration agreement was amended to increase Otonomy's responsibility for the overall development and commercialization of the program, which resulted in (i) a reduction in the Company's share of future product development costs and (ii) the Company's potential receipt of future payments, and royalties on any product sales in lieu of equal sharing of any potential profits or proceeds related to the program.

The Company concluded that the Otonomy collaboration agreement is within the scope of ASC Topic 808, *Collaborative Arrangements* ("Topic 808"), which defines collaborative arrangements and addresses the presentation of transactions between the parties in an entity's statement of operations and the 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 each of the nine months ended March 31, 2022 and 2021, 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 March 31, 2022 and June 30, 2021, accrued and other liabilities on the Company's balance sheets included $449,000 and $374,000, respectively, of deferred revenue. In the account balance at June 30, 2021 was $225,000 that was billed to a customer and collected by the Company in July 2021. Management expects that $300,000 of the deferred revenue at March 31, 2022 will be recognized as revenue during the three months ending June 30, 2022; however, management is unable to estimate when the Company will satisfy the performance obligations pertaining to its residual deferred revenue at March 31, 2022.

7. Stockholders' Equity

Public Offerings of AGTC Equity Securities

Nine months ended March 31, 2022

On March 24, 2022, the Company closed an underwritten public offering of 7.5 million shares of its common stock, with Cantor Fitzgerald & Co. ("Cantor") acting as the sole underwriter for the offering. The indicative public offering price of each share of common stock was $1.30, generating gross proceeds of $9.8 million, before deducting underwriting discounts, commissions and other offering expenses payable by the Company, which totaled $1.2 million. Issuance costs totaling $329,000 were unpaid on March 31, 2022 and have been included in accounts payable/accrued and other liabilities on the Company's Unaudited Condensed Balance Sheet as of such date. Separately, the period for Cantor to exercise its option to purchase an additional 1.125 million shares of common stock to cover over-allotments has expired.

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

Nine months ended March 31, 2021

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 totaled $5.2 million.

The warrants have an initial exercise price of $6.00 per share (subject to certain adjustments), are immediately exercisable and expire on February 1, 2026. The warrants are legally detachable from the common stock that was issued on February 1, 2021 and are separately exercisable by the warrant holders. While the warrants are outstanding (but unexercised), the warrant holders will participate in any dividend or other distribution of the Company's assets to its common stockholders by way of return of capital or otherwise. As of March 31, 2022, none of the warrants have been exercised.

At-The-Market Offering Program

On April 2, 2021, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor as sales agent to sell shares of the Company's common stock, from time to time, through an "at-the-market offering" program with an aggregate offering amount of up to $50.0 million. Cantor is entitled to aggregate compensation equal to 3.0% of the gross sales price of the shares sold through it pursuant to the Sales Agreement. During the nine months ended March 31, 2022, the Company received net proceeds of $519,000 from selling 230,478 shares of its common stock under the Sales Agreement. Neither Cantor nor the Company is obligated to sell additional shares under this program in the future.

Shares Issued to a Vendor

During the nine months ended March 31, 2022, the Company issued 15,000 shares of its unregistered common stock to a vendor for services rendered.

8. Commitments and Contingencies

Lease Commitment

On May 13, 2021, the Company entered into a non-cancelable long-term lease (the "Lease") for a to-be-constructed build-to-suit single story facility of approximately 21,250 square feet in Alachua, Florida (the "Premises") for office, research and development, laboratory, light pharmaceutical and medical systems manufacturing and fabrication and distribution use. The new facility will be adjacent to the Company's corporate headquarters. The landlord is responsible for all permitting, site and infrastructure preparation work, and construction of the shell and core of the building and the quality control laboratory portion of the building. The Company is responsible for completion of the remaining tenant fit out work. On May 3, 2022, the Company entered into a First Amendment to Lease (the "Amendment"). Pursuant to the Amendment, the Company and the landlord finalized the architectural plans and specifications for the development and construction of the Premises and agreed that the budget for the tenant fit out work is approximately $10.9 million. The Company and the landlord also agreed in the Amendment that the landlord's contribution to the tenant fit out work is $8.0 million, and the Company's contribution to the fit out work is approximately $2.9 million, which is to be paid by the Company into an escrow account. Because this real property lease agreement that has not yet commenced, it is not recorded on the Company's balance sheets.

The lease will commence upon substantial completion of the Premises, including the tenant fit out work, estimated to be completed in the fourth quarter of 2022 (the "Commencement Date"), and the rent commencement date will occur simultaneous with the Commencement Date. The initial lease term has been extended by the Amendment from 20 years to 20 years and one month from the Commencement Date (the "Term"). As provided by the Amendment, the Company will pay annual base rent aggregating $30.4 million (assuming that the Company does not elect its early termination option) during the Term (beginning on the Commencement Date) as set forth below.

Lease Months	Annual Base Rent
1	$ —
2-7	743,750
8-19	$ 1,336,625
Base rent shall increase 1.5% each lease year (12-month period) thereafter commencing in month 20 for the remainder of the Term.	

The other substantive terms and conditions of the Lease, which is discussed in Note 3 to the Notes to Financial Statements in the 2021 Form 10-K under the heading "Build-To-Suit Manufacturing and Quality Control Facility in Alachua, Florida," were generally unchanged by the Amendment. In connection with the new leased facility, the Company had financial commitments for equipment and shared building fit out costs aggregating approximately $4.2 million as of March 31, 2022.

COVID-19 Pandemic

On January 30, 2020, the World Health Organization (the "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 spread 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.

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 its clinical trials and may continue to see delays as the rise in COVID-19 and/or related variants causes capacity constraints at various clinical trial sites. 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 contract manufacturing, testing or research organizations, have also been impacted by COVID-19 and could continue to be impacted, which could result in unavoidable delays and/or increases in the Company's operating costs.

Notwithstanding the development and rollout of certain vaccines, it is unknown: (i) how long the COVID-19 outbreak will continue before the virus, including newly identified strains and variants, is adequately contained; (ii) the severity of the virus; and (iii) the effectiveness of actions to prevent transmission and treat those who have contracted COVID-19. 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 or judgments, or adjust 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.

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 March 31, 2022 and our results of operations for the three and nine months ended March 31, 2022 and 2021. 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, 2021 (the "2021 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 2021 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 our proprietary gene therapy platform technology to develop transformational genetic therapies for people suffering from rare and debilitating diseases. Our initial focus is in the field of ophthalmology, where we have wholly owned clinical-stage programs in X-linked retinitis pigmentosa ("XLRP") and achromatopsia ("ACHM"), and an optogenetics program through our collaboration with Bionic Sight, LLC ("Bionic Sight"). Our preclinical pipeline includes a program in dry age-related macular degeneration ("dAMD"), two programs targeting central nervous system ("CNS") disorders, including frontotemporal dementia ("FTD") and amyotrophic lateral sclerosis ("ALS"), and a program in otology through our collaboration with Otonomy, Inc. ("Otonomy"). With the interim, masked, clinical data we recently released from the Skyline trial in our XLRP program and additional 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 through collaborations with others.

Since our inception, we have devoted substantially all of our resources to the development of our clinical and preclinical programs in ophthalmology, otology and CNS, including manufacturing product candidates in compliance with good manufacturing practices, preparing to conduct and conducting clinical trials of our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily through public offerings of our common stock and warrants to purchase our common stock, private placements of our 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 and by patient advocacy groups such as The Foundation Fighting Blindness.

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 nine months ended March 31, 2022 and 2021, we reported net losses of $50.6 million and $45.7 million, respectively. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and general and administrative and other 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 clinical trials for our XLRP and ACHM product candidates;
- manufacture clinical trial materials and develop larger-scale manufacturing capabilities, including the lease of our new build-to-suit manufacturing and quality control facility;
- continue to develop our gene therapy platform and expand our pipeline by investing in our preclinical product candidates, including those for:
    - additional orphan and non-orphan ophthalmology indications, such as dAMD and other retinal diseases; and

- other inherited diseases in CNS and otology;
- seek regulatory approval for our product candidates;
- add personnel to support our scientific, collaboration, product development and commercialization efforts; and
- continue to operate as a public company.

As of March 31, 2022, we had cash and cash equivalents totaling $67.8 million. We do not expect to generate revenue from product sales unless and until we successfully complete development of 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 available cash and cash equivalents 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. We will require substantial additional funding to complete our XLRP Phase 2/3 ("Vista") trial, move our ACHMB3 product candidate forward, obtain regulatory approval for our lead product candidates, build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved, and execute our plan to open and operate a leased current Good Manufacturing Practices ("cGMP") manufacturing and quality control facility. However, 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. 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.

Program Updates and Recent Developments

AGTC-501 for the Treatment of XLRP

AGTC-501, our lead gene therapy development program for the treatment of XLRP, is designed to use an engineered adeno-associated virus ("AAV") vector to insert a stabilized and functional copy of the Retinitis Pigmentosa GTSase Regulator ("RPGR") gene into a patient's photoreceptor cells. AGTC-501 is comprised of a stabilized RPGR gene and a promoter that was specifically selected to drive efficient gene expression in primate rods and cones, maintain photoreceptor function and delay disease progression in preclinical models of disease. In addition, published non-human primate studies showed that AGTC's proprietary AAV capsid had as much as twice the transfection efficiency in photoreceptors when compared to capsids used in competing programs.

We are currently conducting multiple clinical trials of AGTC-501 that are intended to support the potential submission of a Biologics License Application ("BLA") including a Phase 1/2 trial, which incorporates an expansion portion that we refer to as the Skyline trial. The Skyline trial is a 14 patient multi-site, Phase 2 trial in which patients are randomized to either a high dose of AGTC-501 (the dose received by patients in Group 5 of the Phase 1/2 trial), or a low dose of AGTC-501 (the dose received by patients in Group 2 of the Phase 1/2 trial). The primary endpoint in the Skyline trial is the proportion of treated eyes with an improvement of 7 decibels ("dB") or greater in visual sensitivity from baseline in at least 5 loci at twelve months. Secondary endpoints include the proportion of treated eyes with improvements in best corrected visual acuity at twelve months, a patient's ability to navigate a mobility navigation maze more successfully under varying light and challenge conditions at twelve months, and improvements in retinal structure at twelve months. The Skyline trial is masked in that we, the patients and the sites do not know which patient is in which dose group or which dose group received the high or low dose. Accordingly, we refer to the two groups as Dose Group A and Dose Group B. The primary endpoint in the Skyline trial is the proportion of treated eyes with improvement from baseline in visual sensitivity. Secondary endpoints include improvements in visual acuity, a patient's ability to navigate a mobility maze more successfully under varying light and challenge conditions, and improvements in retinal structure. We completed enrollment in the Skyline trial in the first quarter of calendar year 2022 and recently reported 3-month interim results for 13 of the 14 enrolled patients. Safety, visual sensitivity, visual acuity and the mobility maze were the only endpoints evaluated at 3 months. Retinal structure improvements, another important endpoint, was not evaluated as changes in retinal structure are not expected until between 9 and 12 months.

Similar to safety results reported for the first portion of the Phase 1/2 trial, safety results to date for the Skyline trial support that AGTC-501 is generally well tolerated and there are no clinically significant safety concerns. There were non-serious ocular adverse events (grade 2) related to the study agent that were similar between the two dose groups and two ocular serious adverse events an increase in intraocular pressure determined to be related to corticosteroids which has resolved, and one of visual impairment deemed related to the surgical procedure which is resolving.

Demographic and baseline characteristics were well balanced between the two dose groups in the Skyline trial. Notably, compared to the Phase 1/2 trial, patients in the Skyline trial were younger, with better baseline visual sensitivity and visual acuity.

Improvements in visual sensitivity, the primary efficacy endpoint in the Skyline trial, were observed in both dose groups at three months. We define responders as patients who have at least 5 loci increase by at least 7 dB. The response rate in Dose Group A was 25% (1 of 4 patients, as one patient in this group was unevaluable) and in Dose Group B was 62.5% (5 of 8 patients), representing a clear difference between the two groups. Notably, while we did not observe an increase in visual sensitivity of at least 7 dB in 5 pre-specified loci, we did observe an increase in visual sensitivity of at least 7 dB in 9 to 17 loci in the treated area. These responders also had improvements in visual sensitivity across the treated region above the repeatability coefficient for the test that resulted in improved functional vision in a larger area of the retina.

The 13 patients in the Skyline trial had better baseline best corrected visual acuity, a mean of 66.9 ETDRS letters on an eye chart, which correlates to a Snellen visual acuity equivalent of approximately 20/40. Because these patients started with better visual acuity, we believe there was less ability for them to improve relative to patients in the Phase 1/2 trial.

In addition, there was a correlation between visual sensitivity improvements and trends for patients able to complete the maze more rapidly and with fewer errors. We are working with the maze vendor on potential adjustments to account for the fact that only one eye was treated in this analysis, whereas previous use of the maze has been for patients treated in both eyes. It is possible that the better visual acuity of the patients in the Skyline trial at baseline affected the interpretation of the maze results.

The Skyline trial has a similar design and endpoints to the Vista clinical trial. We believe that if the Vista trial has similar outcomes as both the Phase 1/2 trial and the Skyline trial, the body of data will support a BLA submission for AGTC-501.

The Vista trial is a multi-site, Phase 2/3 clinical trial expected to include approximately 60 patients randomized across three arms: a low-dose group (the 1.2E+11 vg/mL dose from the ongoing Phase 1/2 and Skyline trials), a high-dose group (the 1.1E+12 vg/mL dose from the ongoing Phase 1/2 and Skyline trials) and an untreated control group. The primary endpoint will be improvement in visual sensitivity, defined as having at least a 7 dB increase 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 based on the available microperimetry data from our Phase 1/2 dose escalation trial that, on a patient-by-patient basis, predicts the loci most likely to improve through evaluation of baseline visual sensitivity. Based on the results of the Skyline trial we will be working with the vendor to fortify the algorithm with the data from those 14 patients. Secondary efficacy endpoints in the Vista trial include mean change in visual sensitivity, improvements in visual acuity and performance on the mobility maze as well as structural improvements in retinal health as measured by changes in the ellipsoid zone (the “EZ”), a defined region within the photoreceptor layer of the retina that degenerates over time and is eventually lost in patients with XLRP. We plan to complete a masked interim analysis, with the interim data expected to be released in the first half of calendar year 2023. We believe the interim analysis, together with data from the Phase 1/2 trial, including the Skyline expansion portion, may provide us with the opportunity to discuss with the United States Food and Drug Administration (the “FDA”) potential amendments to the Vista trial, if necessary, that may support an earlier BLA submission than we would otherwise anticipate, or optimize the design of the trial.

To date, we have released a significant amount of preclinical and clinical data including improvements in visual sensitivity and visual acuity, as well as improvements in retinal health that we believe support both the potential safety and biological activity of AGTC-501. These data include the recent release of the interim data from the ongoing Skyline trial and a presentation of data from the ongoing Phase 1/2 trial at the Association for Research in Vision and Ophthalmology (ARVO) 2022 Annual Meeting, by Dr. Paul Yang, Assistant Professor of Ophthalmology at the Casey Eye Institute, Oregon Health & Science University and one of our study investigators. The Phase 1/2 trial data that Dr. Yang presented showed that certain baseline characteristics of the EZ were highly associated with improved outcomes starting as early as nine months after treatment with AGTC-501 and lasting up to 18 months after treatment. Specifically, the data showed a statistically significant association between improvements in visual sensitivity as measured by Macular Integrity Assessment (“MAIA”) and improvements in retinal health as measured by improvement in the EZ in dose Groups 4 to 6. We are continuing to follow these patients and incorporated these findings into the inclusion/exclusion criteria for the Skyline and Vista clinical trials.

Given the efficacy and safety data generated to date, we believe that AGTC-501 is a potential best-in-class product candidate that may provide significant benefits to patients with XLRP, if approved. We expect to achieve the following milestones in the XLRP development program, subject to any continuing impact of the COVID-19 pandemic:

- provide 24-month data from patients in the ongoing Phase 1/2 clinical trial in the third quarter of calendar year 2022;
- provide 12-month data from the Skyline expansion portion of the Phase 1/2 clinical trial in the first quarter of calendar year 2023; and
- provide interim Vista trial data in the first half of calendar year 2023.

AGTC-401 and AGTC-402 for the Treatment of ACHM

We have been developing two gene therapy product candidates for the treatment of ACHM. The product candidates are designed to use the same engineered AAV vector to insert a stabilized and functional copy of the Cyclic Nucleotide Gated Channel Subunit Beta 3 (CNGB3) gene in the case of AGTC-401 and a stabilized and functional copy of the Cyclic Nucleotide Gated Channel Subunit Alpha 3 (CNGA3) gene in the case of AGTC-402. The product candidates are designed to use the same proprietary cone-specific promoter that was designed to maximize gene expression into a patient's photoreceptor cells. We chose the promoter based on data from preclinical studies that showed the promoter drove efficient gene expression in all three types of primate cone photoreceptors and restored cone photoreceptor function in dog, mouse and sheep models of ACHM.

We are currently conducting a Phase 1/2 clinical trial of AGTC-401 in ACHM patients with mutations of the CNGB3 gene (ACHMB3) and a separate Phase 1/2 clinical trial of AGTC-402 in ACHM patients with mutations of the CNGA3 gene (ACHMA3). Each Phase 1/2 clinical trial is being conducted at multiple clinical sites that specialize in inherited retinal diseases. The primary objective of these trials is to identify a well-tolerated dose that provides clinical benefit to patients. To date, we have enrolled a total of 31 adult and pediatric patients into the ACHMB3 trial of AGTC-401 and 24 adult and pediatric patients in the ACHMA3 trial of AGTC-402 and do not currently plan to enroll any additional patients in either trial. We have data from a portion of the patients in these trials up to 24 months after treatment, including our most recent release in February 2022 of 3-month data for the two highest dose groups of ACHMB3 and ACHMA3 pediatric patients that also included updated adult safety data. These data are consistent with the data previously released in adult and pediatric ACHMB3 and ACHMA3 patients.

In the Phase 1/2 dose escalation study of AGTC-401 in ACHMB3 patients, a total of 21 adults were treated over an approximately 80-fold dose range in five groups and a total of 10 pediatric patients were treated at the three highest dose groups. Secondary outcome measures evaluating efficacy were assessed by standard visual function tests, such as perimetry. We defined two pediatric patients (17 and 7 years old) in the 1.1E+12 vg/mL dose group as responders based on improvements in visual sensitivity as measured by the Octopus static perimeter. Therefore, of the three adults and four children (total n=7) in the 1.1E+12 vg/mL dose group, four (>50%) were responders based on improvements in visual sensitivity. These patients also reported improvements in quality of life as measured by a patient reported outcome survey developed specifically for patients with ACHM.

The two other pediatric patients in the 1.1E+12 vg/mL dose group and three pediatric patients ages 7 years and younger in the 3.2E+12 vg/mL dose group (total n=5) could not sufficiently concentrate and consistently complete the visual sensitivity testing. Similar to other trials where endpoints are adapted for young children, we plan to work closely with clinicians and regulators to develop potential adaptations for younger patients for visual sensitivity testing. Despite their inability to complete the tests, we received anecdotal feedback from certain patients that indicate improvements in visual sensitivity. Based on the totality of data generated to date, we believe that the 1.1E+12 vg/mL dose has been well tolerated and has potential in both adult and pediatric patients.

We also reported updated interim 3-month pediatric data and adult and pediatric safety data for the 24 patients enrolled in the Phase 1/2 study of AGTC-402 targeting CNGA3 mutations in patients with ACHMA3. Data from the five pediatric patients in the two highest dose groups were consistent with previously reported results, indicating no evidence of clinical improvements, and do not support further clinical development. Most patients with CNGA3 mutations express a mutant protein that is not typically found in patients with CNGB3 mutations, which we believe may have impacted the results seen in patients that received AGTC-402. We will continue to follow the ACHMA3 patients for long-term safety observations.

As previously reported, in both the ACHMB3 and ACHMA3 trials, treatment with the highest dose (3.2 E+12vg/ml) of AGTC-401 and AGTC-402, respectively, led to three cases of severe ocular inflammation in pediatric patients, which were reported as Suspected Unexpected Serious Adverse Reactions, or SUSARs. No new additional SUSARs in any adult or pediatric patients have been reported and the inflammation in all previously reported SUSARs improved with an adjusted steroid regimen. Two SUSARs (one in ACHMA3 and one in ACHMB3) have since fully resolved and one (ACHMA3) continues to improve, with all three patients' best corrected visual acuity returning to baseline after initial declines in visual acuity were observed following the SUSARs. Importantly, we have not yet observed any comparable inflammation in any of our XLRP clinical trials.

We recently had a collaborative and productive End of Phase 2 ("EOP2") meeting with the FDA to discuss the potential future development of AGTC-401 and received constructive feedback from the FDA on our proposed primary and secondary endpoints for a Phase 2/3 clinical trial. With respect to the primary endpoint of improvement in visual sensitivity relative to baseline, the FDA reiterated that a 7 dB change in at least 5 pre-specified loci is required. However, they indicated a willingness to review an alternative approach to perimetry from a model used in other trials, which would need to be adapted specifically for ACHMB3. They also indicated that improvements in light discomfort may be an acceptable secondary endpoint in a Phase 2/3 clinical trial of AGTC-401 and we intend to provide additional data to support our position that a 1 loglux improvement from baseline is clinically meaningful. We are currently working through the details of the future development plan for AGTC-401 including the proposed protocol for a potential Phase 2/3 clinical trial for submission to the FDA. Our anticipated future development plan will be based on the feedback we received from the FDA during the EOP2 meeting and subsequent comments to the full protocol.

Build-To-Suit Manufacturing and Quality Control Facility in Alachua, Florida

In May 2021, we signed a 20-year lease for a build-to-suit 21,250 square foot potential cGMP manufacturing and quality control facility adjacent to our existing Florida facility to prepare for late-stage development and potential commercialization of our XLRP and ACHMB3 programs. The facility is also intended to provide supply chain redundancy, reduce manufacturing risk and enhance quality controls. We anticipate that the build-out of the new manufacturing and quality control facility will be completed during the fourth quarter of calendar year 2022.

Additional information regarding our new cGMP manufacturing and quality control facility can be found in Note 8 to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q under the heading “Lease Commitment.”

Strategic Collaborations and Preclinical Pipeline

Bionic Sight

During February 2017, we entered into a strategic research and development collaboration agreement with Bionic Sight to develop product candidates 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.

In March 2021, Bionic Sight, which has responsibility for conducting the clinical trial, reported promising results in its first two cohorts of patients in the Phase 1/2 retinitis pigmentosa optogenetics study. Bionic Sight reported that these patients, all of whom have complete or near-complete blindness, can now see light and motion, and, in two cases, can detect the direction of motion. Bionic Sight also announced that the product candidate was well-tolerated and that it is continuing to enroll patients at higher doses.

Otonomy

During October 2019, we entered into a strategic collaboration agreement with Otonomy to co-develop and co-commercialize an AAV-based gene therapy product candidate designed 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 any proceeds from potential licensing transactions in January 2020 and can include additional genetic hearing loss targets in the future. Effective January 1, 2022, we amended the Otonomy collaboration agreement to increase Otonomy’s responsibility for the overall development and commercialization of the program, which resulted in (i) a reduction in our share of future product development costs and (ii) our potential receipt of future payments, and royalties on any product sales in lieu of equal sharing of any potential profits or proceeds related to the program.

We and Otonomy announced promising preclinical data at the American Society of Gene and Cell Therapy meeting in May 2021, which showed that the product candidate was associated with rescue of hearing loss and cochlear morphology in two independent mouse models. Collectively, we are conducting investigational new drug (“IND”)-enabling activities based on pre-IND meeting feedback from the FDA, with an IND submission anticipated in the first half of calendar year 2023.

Additional information regarding the Bionic Sight and Otonomy collaborative agreements can be found in Note 6 to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q.

Preclinical Pipeline

We also have three wholly-owned product candidates in preclinical testing, including AGTC-701 for the treatment of dAMD, AGTC-601 for the treatment of FTD and AGTC-801 for the treatment of ALS.

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 assuming that the Company will continue as a going concern and in accordance with (i) U.S. generally accepted accounting principles for interim financial information and (ii) 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. 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 nine months ended March 31, 2022, 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 estimations 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 2021 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 generate revenue primarily through: (i) collaboration agreements; (ii) sponsored research arrangements with nonprofit organizations for the development and commercialization of product candidates; (iii) federal research and development grant programs; and (iv) licensing arrangements. However, we did not recognize any revenue during the three and nine months ended March 31, 2022 or the same periods in the prior year. 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.

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 and 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 and include:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with academic research centers, contract research organizations and investigative sites that conduct our clinical trials;
- license and sublicense fees and collaboration expenses;
- costs 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;
- future clinical trial results;
- uncertainties in clinical trial enrollment rates or drop-out or discontinuation rates of patients;
- increased cost and delay associated with manufacturing or testing issues, including ongoing quality assurance, qualifying new vendors and developing in-house capabilities through, among other things, our lease of a new cGMP build-to-suit manufacturing and quality control facility;
- the countries in which trials are conducted;
- potential additional safety monitoring or other studies requested by regulatory agencies or elected as best practice by us;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals; and
- broader market forces, such as inflation and wage/salary growth.

Changes in any of these variables over time 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 trial activities and development of our product candidates.

From our inception and through March 31, 2022, we have incurred approximately $318.6 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, explore potential applications of our gene therapy platform in other indications and execute our plan to open and operate a leased cGMP manufacturing and quality control facility.

General and administrative and other expenses

General and administrative and other 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, patent-related expenses, and accounting, investor relations, corporate communications and information technology services. We anticipate that our general and administrative and other expenses will continue to increase in the future as we hire additional employees to support our research and development efforts, collaboration arrangements, and the potential commercialization of our product candidates, if approved. Inflation and wage/salary growth could also contribute to higher future costs. 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 any such product candidate. Our general and administrative expenses are also expected to increase as we execute our plan to open and operate a leased cGMP manufacturing and quality control facility.

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 nine months ended March 31, 2022, investment income, net declined by $4,000 and $85,000, respectively, when compared to the same periods in the prior year, primarily due to a smaller investment portfolio in the current periods.

Interest expense

Interest expense during the three and nine months ended March 31, 2022 increased by $0.3 million and $1.0 million, respectively, when compared to the same periods in the prior year. These increases were primarily due to higher average outstanding balances under our collateralized term loan agreement during each of the three and nine months ended March 31, 2022. Additional information regarding our long-term loan agreement can be found in Note 5 to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q.

On May 4, 2022, the Federal Reserve Board announced an increase of 0.50% in the federal funds rate and indicated that further rate increases will be announced in the short-term to combat rising inflation in the United States. When the prime rate reported in *The Wall Street Journal* increases, as was the case with the most recent federal funds rate increase and is expected to continue in response to projected hikes in the federal funds rate by the Federal Reserve Board, the Company's cost of borrowing and related interest expense on its variable-rate debt also increases.

Provision for income taxes

The provision for income taxes was $21,000 and $62,000 during the three and nine months ended March 31, 2021, which was entirely attributable to estimated interest and penalties on uncertain tax positions. There was no provision for income taxes during the three and nine months ended March 31, 2022 because, among other things, the Company had no uncertain tax positions during those reporting periods.

Results of Operations

Comparison of the three months ended March 31, 2022 and 2021

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 March 31, 2022	2021	Increase (Decrease)	% Increase (Decrease)
External research and development expenses:				
XLRP	$ 984	$ 3,201	$ (2,217)	(69)%
ACHM	748	1,147	(399)	(35)%
Research and discovery programs and X-linked retinoschisis	189	1,358	(1,169)	(86)%
Total external research and development expenses	1,921	5,706	(3,785)	(66)%
Internal research and development expenses:				
Employee-related costs	4,377	3,051	1,326	43%
Share-based compensation	412	280	132	47%
Other	2,452	1,923	529	28%
Total internal research and development expenses	7,241	5,254	1,987	38%
Total research and development expenses	$9,162	$10,960	$ (1,798)	(16)%

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 employee-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.

As part of the process of preparing our financial statements, estimates of accrued expenses are necessary. The estimation process involves reviewing quotations and contracts, identifying services that have been performed on our behalf, and determining the level of services performed and associated costs incurred for services for which we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice monthly in arrears for services performed or when contractual milestones are

met. We estimate our accrued expenses at the end of each reporting period based on the facts and circumstances known at that time. As a result, estimates recorded in our financial statements and disclosed in the accompanying notes may change in the future and such changes in estimates, if any, will be recorded in our operating results in the period they are identified by us. The significant estimates in our accrued research and development expenses primarily relate to expenses incurred with respect to academic research centers, contract research organizations and other vendors in connection with research and development activities for which we have not yet been invoiced.

Research and development expenses for the three months ended March 31, 2022 and 2021 were $9.2 million and $11.0 million, respectively, a decrease of $1.8 million, or 16%. The year-over-year decline was due to various factors, including: (i) planned temporary reductions in manufacturing activities relating to our XLRP and preclinical product candidates; (ii) lower external spending related to our Skyline trial for which we are not activating new sites and/or enrolling new patients; (iii) a decrease in ACHM expenses due to reduced site activity as our two clinical studies have progressed to a point where they are no longer activating new sites or enrolling new patients; and (iv) lower costs in connection with the wind-down of our X-linked retinoschisis, or XLRS, program. Additionally, research and development expenses for the three months ended March 31, 2022 were favorably impacted by changes in estimates that reduced certain vendor accruals during such reporting period. These reductions in research and development expenses were partially offset by: (i) higher employee-related costs that were primarily attributable to new employees who were hired in connection with our strategic operating plans; (ii) an increase in internal research and development costs for certain assay development that we are now conducting in-house; and (iii) higher share-based compensation costs that were primarily due to restricted stock units granted to certain employees from May 2021 to July 2021 (the “2021 RSUs”).

General and administrative and other expenses

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

In thousands	Three Months Ended March 31, 2022	2021	Increase (Decrease)	% Increase (Decrease)
Employee-related costs	$1,961	$1,241	$ 720	58%
Share-based compensation	431	315	116	37%
Legal and professional fees	102	329	(227)	(69)%
Other	1,927	1,643	284	17%
Total general and administrative and other expenses	$4,421	$3,528	$ 893	25%

General and administrative and other expenses for the three months ended March 31, 2022 and 2021 were $4.4 million and $3.5 million, respectively, an increase of $0.9 million, or 25%. Such increase was primarily due to: (i) compensation for new employees; (ii) recruiting costs for new employees; (iii) incremental share-based compensation costs for the 2021 RSUs; and (iv) higher operating and business development costs pertaining to our recurring operations as we execute our strategic plans. Lower legal fees during the three months ended March 31, 2022 were due to reduced use of external legal counsel.

Comparison of the nine months ended March 31, 2022 and 2021

Research and development expenses

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

In thousands	Nine Months Ended March 31, 2022	2021	Increase (Decrease)	% Increase (Decrease)
External research and development expenses:				
XLRP	$10,085	$11,930	$ (1,845)	(15)%
ACHM	2,639	3,997	(1,358)	(34)%
Research and discovery programs and X-linked retinoschisis	3,402	2,527	875	35%
Total external research and development expenses	16,126	18,454	(2,328)	(13)%
Internal research and development expenses:				
Employee-related costs	12,307	9,466	2,841	30%
Share-based compensation	1,302	866	436	50%
Other	6,206	5,611	595	11%
Total internal research and development expenses	19,815	15,943	3,872	24%
Total research and development expenses	$35,941	$34,397	$ 1,544	4%

Research and development expenses for the nine months ended March 31, 2022 and 2021 were $35.9 million and $34.4 million, respectively, an increase of $1.5 million, or 4%. The year-over-year increase was due to various factors, including: (i) higher employee-related costs that were primarily attributable to new employees who were hired in connection with our strategic operating plans; (ii) increased external spending for our research and discovery programs, which was primarily for planned material production costs in connection with our preclinical programs; (iii) higher share-based compensation costs that were primarily due to the 2021 RSUs; and (iv) an increase in internal research and development costs for certain assay development that we are now conducting in-house. These increases in research and development expenses were partially offset by: (i) a year-over-year reduction in manufacturing activities for Vista clinical trial materials; (ii) a decrease in ACHM expenses due to reduced site activity as our two clinical studies have progressed to a point where they are no activating new sites or enrolling new patients; and (iii) lower costs in connection with the wind-down of our XLRS program. Additionally, research and development expenses for the nine months ended March 31, 2022 were favorably impacted by changes in estimates that reduced certain vendor accruals during such reporting period.

General and administrative and other expenses

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

In thousands	Nine Months Ended March 31, 2022	2021	Increase (Decrease)	% Increase (Decrease)
Employee-related costs	$ 4,549	$ 3,675	$ 874	24%
Share-based compensation	1,297	999	298	30%
Legal and professional fees	688	1,238	(550)	(44)%
Other	5,976	4,356	1,620	37%
Total general and administrative and other expenses	$12,510	$10,268	$ 2,242	22%

General and administrative and other expenses for the nine months ended March 31, 2022 and 2021 were $12.5 million and $10.3 million, respectively, an increase of $2.2 million, or 22%. Such increase was primarily due to: (i) compensation for new employees; (ii) recruiting costs for new employees; (iii) incremental share-based compensation costs for the 2021 RSUs; and (iv) higher operating and business development costs pertaining to our recurring operations as we execute our strategic plans. Lower legal fees during the nine months ended March 31, 2022 were due to reduced use of external legal counsel.

Liquidity and Capital Resources

We have incurred cumulative losses and negative cash flows from operations since our inception and, as of March 31, 2022, we had an accumulated deficit of $289.8 million. It will be several years, if ever, before we have a product candidate ready for commercialization. We expect that our research and development expenses and general and administrative and other 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, we received (i) net proceeds of $9.4 million and $69.3 million during the nine months ended March 31, 2022 and 2021, respectively, from underwritten public offerings and selling our common stock through an “at-the-market offering” program, which are described in Note 7 to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q and (ii) $9.9 million of loan proceeds, net of debt discounts, in May 2021. Moreover, through a tenant improvement allowance and tiered rental rates, we have structured the third-party leasing costs for our build-to-suit manufacturing and quality control facility in Alachua, Florida in a way that will not significantly impact our cash runway until the fiscal year ending June 30, 2024. Notwithstanding the foregoing, we plan to use our available cash and cash equivalents to fund approximately $2.9 million of tenant fit out work at such facility, which represents our required contribution pursuant to a recent lease amendment whereby the funding must be completed within 30 days of May 3, 2022. Additional information regarding our long-term loan agreement and new manufacturing and quality control facility can be found in Notes 5 and 8, respectively, to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q.

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 March 31, 2022, our cash and cash equivalents were held in bank accounts and money market funds.

Cash flows

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

In thousands	Nine Months Ended March 31, 2022	2021	Increase (Decrease)	% Increase (Decrease)
Cash provided by (used in):				
Operating activities	$(47,490)	$(37,738)	$ (9,752)	(26)%
Investing activities	846	19,158	(18,312)	(96)%
Financing activities	9,441	69,648	(60,207)	(86)%
Net increase (decrease) in cash and cash equivalents	$(37,203)	$ 51,068	$(88,271)	>(100)%

Operating activities. For both the nine months ended March 31, 2022 and 2021, cash used in operating activities was primarily the result of research and development expenses and general and administrative and other expenses incurred in conducting normal business operations. Specifically, the cash used in operating activities of $47.5 million during the nine months ended March 31, 2022 was due to a net loss of $50.6 million and unfavorable changes in our operating assets and liabilities of $1.7 million, partially offset by non-cash items in our statement of operations of $4.8 million. The cash used in operating activities of $37.7 million during the nine months ended March 31, 2021 was due to a net loss of $45.7 million, partially offset by non-cash items in our statement of operations of $3.6 million and favorable changes in our operating assets and liabilities of $4.4 million.

Investing activities. Cash provided by investing activities of $0.8 million during the nine months ended March 31, 2022 consisted of cash proceeds of $2.0 million from maturities of investments, partially offset by purchases of property and equipment of $0.9 million and intellectual property costs of $0.3 million. Cash provided by investing activities of $19.2 million during the nine months ended March 31, 2021 consisted of cash proceeds of $41.5 million from maturities of investments, net of investment purchases of $21.0 million, partially offset by purchases of property and equipment of $1.0 million and intellectual property costs of $0.4 million.

Financing activities. Cash provided by financing activities of $9.4 million during the nine months ended March 31, 2022 consisted of proceeds of $9.4 million from issuances of our common stock, net of issuance costs, and proceeds from exercises of common stock options of $0.1 million, partially offset by (i) payments for taxes related to equity awards and (ii) principal payments on a finance lease. Cash provided by financing activities of $69.6 million during the nine months ended March 31, 2021 included (i) proceeds of $69.3 million from the issuance of common stock and accompanying warrants, net of issuance costs, and (ii) proceeds from exercises of common stock options of $0.7 million. These items were partially offset by (i) payments for deferred financing fees and taxes related to equity awards and (ii) principal payments on a finance lease.

Operating capital requirements

We have not generated any revenue from product sales and we do not know when, or if, we will generate such revenue. We do not expect to have 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 available cash and cash equivalents, which totaled $67.8 million on March 31, 2022, 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: (i) finish our Vista trial; (ii) move our ACHMB3 product candidate forward; (iii) complete the process necessary to seek regulatory approval for our lead product candidates; (iv) build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved; and (v) execute our plan to open and operate a leased cGMP manufacturing and quality control facility.

To provide the maximum degree of financial flexibility, we may consider various potential opportunities to fund future operations and/or modulate liquidity needs including: (i) raising new capital through equity or debt financings or other sources, including our “at-the-market offering” program; (ii) amending our long-term debt agreement; (iii) out-licensing the rights to certain of our product candidates; (iv) entering into one or more collaborations to offset the costs of our leased manufacturing and quality control facility; and (v) reducing our expenditures on research and development activities and/or restructuring our operations. However, we may be unable to successfully execute any of the plans described above, or raise additional funds or enter into such other arrangements when

needed on favorable terms, or at all. Additional information regarding our liquidity and related matters can be found in Note 1 to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q under the heading ”Liquidity and Financial Condition.”

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 principal executive officer and principal 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 principal executive officer and principal financial officer concluded that these disclosure controls and procedures were effective as of March 31, 2022.

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 March 31, 2022 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 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, 2021 (the “2021 Form 10-K”) for information regarding our risk factors. Except as noted below, there have been no material changes in the risk factors included in the 2021 Form 10-K.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

We may be forced to amend, delay, limit, reduce or terminate the scope of our clinical and preclinical programs and/or limit or cease our operations if we are unable to obtain additional funding. As of March 31, 2022, we had cash and cash equivalents totaling $67.8 million. We believe that there is presently insufficient funding available to allow us to generate data from our ongoing and planned clinical programs and fund currently planned research and discovery programs for a period exceeding 12 months from the date of filing this Quarterly Report on Form 10-Q. During such 12-month period, our future liquidity needs will be primarily based on the: (i) success and progression of our product candidates; (ii) repayment obligations under our long-term debt agreement; and (iii) costs to operate our leased build-to-suit manufacturing and quality control facility. We will also require substantial additional funding to: (i) finish our Vista trial; (ii) move our ACHMB3 product candidate forward; (iii) complete the process necessary to seek regulatory approval for our lead product candidates; and (iv) build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved. To provide the maximum degree of financial flexibility, we may consider various potential opportunities to fund future operations and/or modulate liquidity needs, including: (i) raising new capital through equity or debt financings or other sources, including our “at-the-market offering” program; (ii) amending our long-term debt agreement; (iii) out-licensing the rights to certain of our product candidates; (iv) entering into one or more collaborations to offset the costs of our leased manufacturing and quality control facility; and (v) reducing our expenditures on research and development activities and/or restructuring our operations. However, we may be unable to successfully execute any of the plans described above, or raise additional funds or enter into such other arrangements when needed on favorable terms, or at all. On May 4, 2022, the Federal Reserve Board announced an increase of 0.50% in the federal funds rate and indicated that further rate increases will be announced in the short-term to combat rising inflation in the United States. Such rate increases may have an adverse impact on our ability to raise funds through the offering of our securities or through the issuance of debt due to higher debt capital costs, diminished credit

availability and less favorable equity markets. The failure to obtain sufficient funds on commercially acceptable terms when needed would have a material adverse effect on our business, results of operations and financial condition and would jeopardize our ability to continue our operations. These factors raise substantial doubt about our ability to continue as a going concern.

Additional information regarding our ability to continue as a going concern can be found in Note 1 to the Unaudited Condensed Financial Statements included in this Quarterly Report on Form 10-Q under the heading ”Liquidity and Financial Condition.”

Our stock price is currently trading below $1.00 per share and, if it continues to trade below $1.00 per share, our common stock may be subject to delisting from the Nasdaq Global Market.

If the bid price of our common stock were to close below the required minimum $1.00 per share for 30 consecutive business days, we may receive a deficiency notice from Nasdaq regarding our failure to comply with Nasdaq Marketplace Rule 5450(a)(1). If we receive such a notice, pursuant to Marketplace Rule 5810(c)(3)(A), we will be afforded a compliance period of 180 calendar days to regain compliance with Rule 5450(a)(1). If at any time during the 180-day compliance period the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, we will regain compliance with Rule 5450(a)(1). In the event that we do not regain compliance with Rule 5450(a)(1) prior to the expiration of the initial 180-day compliance period, we may be eligible for a second 180-day compliance period. To qualify for this additional compliance period, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq’s Global Market, other than the minimum bid price requirement. In addition, we would also be required to notify Nasdaq of our intent to cure the minimum bid price deficiency. However, if it appears to Nasdaq staff that we will not be able to cure the deficiency, we do not meet the other listing standards or we fail to regain compliance with the Nasdaq continued listing standards following the second 180-day compliance period, Nasdaq could provide notice that our common stock will be subject to delisting. We would be entitled to appeal such a delisting determination to a Nasdaq hearing panel and the delisting may be stayed pending the panel’s determination. To the extent that we are unable to resolve a listing deficiency, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact the liquidity of our common stock and potentially result in even lower bid prices for our common stock.

ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	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)
3.2	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)
31.1*	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
31.2*	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
32.1**	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
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	The cover page for the Company’s Quarterly Report on Form 10-Q has been formatted in Inline XBRL and contained in Exhibit 101

* 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/ Jonathan I. Lieber
Jonathan I. Lieber, Chief Financial Officer

Date: May 16, 2022

Exhibit 31.1

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: May 16, 2022

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

Exhibit 31.2

CERTIFICATION

I, Jonathan I. Lieber, 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: May 16, 2022

By: /s/ Jonathan I. Lieber
Jonathan I. Lieber
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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 March 31, 2022, 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: May 16, 2022

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

Date: May 16, 2022

By: /s/ Jonathan I. Lieber
Jonathan I. Lieber
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.