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 June 30, 2021

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 **001-15771**

ABEONA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**83-0221517**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer I.D. No.)

1330 Avenue of the Americas, 33rd Floor, New York, NY 10019
(Address of principal executive offices, zip code)

(646) 813-4701
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	ABEO	Nasdaq Capital Markets

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 ☐
Non-accelerated filer ☒

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 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 outstanding of the registrant's common stock as of July 21, 2021 was 101,227,014 shares.

ABEONA THERAPEUTICS INC.

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FORWARD-LOOKING STATEMENTS

This Form 10-Q contains statements that express management's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Words such as "expects," "anticipates," "intends," "plans," "believes," "could," "would," "seeks," "estimates," and variations of such words and similar expressions, and the negatives thereof, are intended to identify such forward-looking statements. Such "forward-looking statements" speak only as of the date made and are not guarantees of future performance and involve certain risks, uncertainties, estimates, and assumptions by management that are difficult to predict. Various factors, some of which are beyond the Company's control, could cause actual results to differ materially from those expressed in, or implied by, such forward-looking statements. In addition, we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of this report, except as may otherwise be required by the federal securities laws.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in forward-looking statements due to a number of factors. These statements include statements about: the potential impacts of the COVID-19 pandemic on our business, operations, and financial condition; the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals; our Phase 3 clinical trial (VIITAL™) for patients with recessive dystrophic epidermolysis bullosa ("RDEB") and our beliefs relating thereto; our ability to identify and enroll patients in the Phase 3 clinical trial; our pipeline of product candidates; our belief that we have sufficient resources on hand, access to additional financial resources and/or financial flexibility to fund operations for at least the next 12 months from the date of filing of this report; ongoing dispute with REGENXBIO; our belief that EB-101 could potentially benefit patients with RDEB; our belief that adeno-associated virus ("AAV") gene therapy could potentially benefit patients with Sanfilippo syndrome type A ("MPS IIIA") and Sanfilippo syndrome type B ("MPS IIIB"); our ability to develop our novel AAV-based gene therapy platform technology; our belief in the adequacy of the data from clinical trials, including VIITAL™ and our Phase 1/2 clinical trials in ABO-102 (AAV-SGSH) for MPS IIIA and ABO-101 (AAV-NAGLU) for MPS IIIB, together with the data generated in the program to date, to support regulatory approvals; the existence of intellectual property, a license to which might be required to market MPS IIIA and MPS IIIB; our dependence upon our third-party and related-party customers and vendors and their compliance with regulatory bodies; our intellectual property position and our ability to obtain, maintain and enforce intellectual property protection and exclusivity for our proprietary assets; our estimates regarding the size of the potential markets for our product candidates, the strength of our commercialization strategies and our ability to serve and supply those markets; and future economic conditions or performance.

Important factors that could affect performance and cause results to differ materially from management's expectations are described in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Form 10-K for the fiscal year ended December 31, 2020, as updated from time to time in the Company's Securities and Exchange Commission filings, including this Form 10-Q. These factors include: the impact of the COVID-19 pandemic on our business, operations (including our clinical trials), and financial condition, and on our ability to access the capital markets; our ability to access our existing at-the-market sale agreement and any dilution that may result from accessing such sales agreement; our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing; our ability to raise capital; our ability to fund our operating expenses and capital expenditure requirements for at least the next 12 months given our existing cash, cash equivalents and short-term investments, our ability to access additional financial resources and/or our financial flexibility to reduce operating expenses if required; our ability to obtain additional equity funding from current or new stockholders, out-licensing technology and/or other assets, deferring and/or eliminating planned expenditures, restructuring operations and/or reducing headcount, and sales of assets; the dilutive effect that raising additional funds by selling additional equity securities would have on the relative equity ownership of our existing investors, including under our existing at-the-market sale agreement; our ability to continue to develop our novel AAV-based gene therapy platform technology; the outcome of any interactions with the U.S. Food and Drug Administration ("FDA") or other regulatory agencies relating to any of our products or product candidates; our ability to execute a Phase 3 clinical trial for patients with RDEB; our ability to complete enrollment of patients into clinical trials to secure sufficient data to assess efficacy and safety; our ability to identify additional patients for our Phase 1/2 clinical trial for patients with MPS IIIA and MPS IIIB; our ability to continue to secure and maintain regulatory designations for our product candidates; our ability to develop manufacturing capabilities compliant with current good manufacturing practices for our product candidates; our ability to manufacture gene and cell therapy products and produce an adequate product supply to support clinical trials and potentially future commercialization; the rate and degree of market acceptance of our product candidates for any indication once approved; and our ability to meet our obligations contained in license agreements to which we are party.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,179,000	$ 12,596,000
Short-term investments	50,380,000	82,438,000
Prepaid expenses and other current assets	1,321,000	2,708,000
Total current assets	78,880,000	97,742,000
Property and equipment, net	10,240,000	11,322,000
Right-of-use lease assets	6,489,000	7,032,000
Licensed technology, net	1,442,000	1,500,000
Goodwill	32,466,000	32,466,000
Other assets and restricted cash	1,158,000	1,136,000
Total assets	$ 130,675,000	$ 151,198,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,469,000	$ 4,695,000
Accrued expenses	2,190,000	3,410,000
Current portion of lease liability	1,720,000	1,713,000
Current portion of loan payable	1,758,000	330,000
Payable to licensor	34,434,000	31,515,000
Contract liability	296,000	296,000
Total current liabilities	41,867,000	41,959,000
Loan payable	-	1,428,000
Long-term lease liabilities	4,722,000	5,260,000
Total liabilities	46,589,000	48,647,000
Commitments and contingencies		
Stockholders' equity:		
Common stock - $0.01 par value; authorized 200,000,000 shares; issued and outstanding 101,251,023 at June 30, 2021; issued and outstanding 96,131,678 at December 31, 2020;	1,013,000	961,000
Additional paid-in capital	684,987,000	672,304,000
Accumulated deficit	(601,913,000)	(570,704,000)
Accumulated other comprehensive loss	(1,000)	(10,000)
Total stockholders' equity	84,086,000	102,551,000
Total liabilities and stockholders' equity	$ 130,675,000	$ 151,198,000

The accompanying notes are an integral part of these condensed consolidated statements.

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	For the three months ended June 30,		For the six months ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenues	$ -	$ -	$ -	$ -
Expenses:				
Research and development	7,434,000	6,109,000	14,646,000	12,927,000
General and administrative	5,457,000	5,538,000	12,025,000	11,950,000
Depreciation and amortization	824,000	834,000	1,641,000	2,899,000
Licensed technology impairment charge	-	-	-	32,916,000
Total expenses	13,715,000	12,481,000	28,312,000	60,692,000
Loss from operations	(13,715,000)	(12,481,000)	(28,312,000)	(60,692,000)
Interest and miscellaneous income	8,000	271,000	23,000	923,000
Interest expense	(1,500,000)	(800,000)	(2,920,000)	(1,400,000)
Net loss	$ (15,207,000)	$ (13,010,000)	$ (31,209,000)	$ (61,169,000)
Basic and diluted loss per common share	$ (0.16)	$ (0.14)	$ (0.33)	$ (0.66)
Weighted average number of common shares outstanding – basic and diluted	96,509,783	92,704,203	95,378,503	92,533,354
Other comprehensive (loss)/income:				
Change in unrealized (losses)/gains related to available-for-sale debt securities	(4,000)	(253,000)	9,000	133,000
Comprehensive loss	$ (15,211,000)	$ (13,263,000)	$ (31,200,000)	$ (61,036,000)

The accompanying notes are an integral part of these condensed consolidated statements.

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Stockholders' Equity
	Shares	Amount				
For the three months ended June 30, 2021						
Balance, March 31, 2021	99,038,933	$ 990,000	$ 680,103,000	$ (586,706,000)	$ 3,000	$ 94,390,000
Stock option-based compensation expense	-	-	1,327,000	-	-	1,327,000
Restricted stock-based compensation expense	-	-	1,101,000	-	-	1,101,000
Common stock issued for cash exercise of options	20,521	-	24,000	-	-	24,000
Issuance of common stock in connection with restricted share awards	706,348	7,000	(7,000)	-	-	-
Common stock issued for cash under open market sale agreement	1,485,221	16,000	2,439,000	-	-	2,455,000
Net loss	-	-	-	(15,207,000)	-	(15,207,000)
Other comprehensive loss	-	-	-	-	(4,000)	(4,000)
Balance, June 30, 2021	101,251,023	$ 1,013,000	$ 684,987,000	$ (601,913,000)	$ (1,000)	$ 84,086,000
For the three months ended June 30, 2020						
Balance, March 31, 2020	83,622,135	$ 836,000	$ 665,784,000	$ (534,629,000)	$ 386,000	$ 132,377,000
Stock option-based compensation expense	-	-	1,578,000	-	-	1,578,000
Restricted stock-based compensation expense	-	-	187,000	-	-	187,000
Common stock issued for cash exercise of options	75,793	1,000	174,000	-	-	175,000
Issuance of common stock in connection with restricted share awards	1,083,313	11,000	(11,000)	-	-	-
Net loss	-	-	-	(13,010,000)	-	(13,010,000)
Other comprehensive loss	-	-	-	-	(253,000)	(253,000)
Balance, June 30, 2020	84,781,241	$ 848,000	$ 667,712,000	$ (547,639,000)	$ 133,000	$ 121,054,000
For the six months ended June 30, 2021						
Balance, December 31, 2020	96,131,678	$ 961,000	$ 672,304,000	$ (570,704,000)	$ (10,000)	$ 102,551,000
Stock option-based compensation expense	-	-	2,410,000	-	-	2,410,000
Restricted stock-based compensation expense	-	-	1,968,000	-	-	1,968,000
Common stock issued for cash exercise of options	508,725	5,000	686,000	-	-	691,000
Issuance of common stock in connection with restricted share awards	1,547,075	15,000	(15,000)	-	-	-
Common stock issued for cash under open market sale agreement	3,063,545	32,000	7,634,000	-	-	7,666,000
Net loss	-	-	-	(31,209,000)	-	(31,209,000)
Other comprehensive income	-	-	-	-	9,000	9,000
Balance, June 30, 2021	101,251,023	$ 1,013,000	$ 684,987,000	$ (601,913,000)	$ (1,000)	$ 84,086,000
For the six months ended June 30, 2020						
Balance, December 31, 2019	83,622,135	$ 836,000	$ 664,064,000	$ (486,470,000)	$ -	$ 178,430,000
Stock option-based compensation expense	-	-	2,834,000	-	-	2,834,000
Restricted stock-based compensation expense	-	-	651,000	-	-	651,000
Common stock issued for cash exercise of options	75,793	1,000	174,000	-	-	175,000
Issuance of common stock in connection with restricted share awards	1,083,313	11,000	(11,000)	-	-	-
Net loss	-	-	-	(61,169,000)	-	(61,169,000)
Other comprehensive income	-	-	-	-	133,000	133,000
Balance, June 30, 2020	84,781,241	$ 848,000	$ 667,712,000	$ (547,639,000)	$ 133,000	$ 121,054,000

The accompanying notes are an integral part of these condensed consolidated statements.

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For the six months ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (31,209,000)	$ (61,169,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Non-cash licensed technology impairment charge	-	32,916,000
Depreciation and amortization	1,641,000	2,899,000
Stock option-based compensation expense	2,410,000	2,834,000
Restricted stock-based compensation expense	1,968,000	651,000
Non-cash interest expense	-	600,000
Accretion and interest on short-term investments	266,000	(156,000)
Amortization of right-of-use lease assets	543,000	496,000
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	1,387,000	2,208,000
Other assets	(22,000)	-
Accounts payable, accrued expenses and lease liabilities	(4,977,000)	(4,786,000)
Change in payable to licensor	2,919,000	800,000
Net cash used in operating activities	(25,074,000)	(22,707,000)
Cash flows from investing activities:		
Capital expenditures	(501,000)	(1,032,000)
Purchases of short-term investments	(15,164,000)	(123,062,000)
Proceeds from maturities of short-term investments	46,965,000	30,014,000
Net cash provided by (used in)/investing activities	31,300,000	(94,080,000)
Cash flows from financing activities:		
Proceeds from loan payable	-	1,758,000
Proceeds from open market sales of common stock	7,666,000	-
Proceeds from exercise of stock options	691,000	175,000
Net cash provided by financing activities	8,357,000	1,933,000
Net increase/(decrease) in cash, cash equivalents and restricted cash	14,583,000	(114,854,000)
Cash, cash equivalents and restricted cash at beginning of period	13,571,000	130,368,000
Cash, cash equivalents and restricted cash at end of period	$ 28,154,000	$ 15,514,000
Supplemental cash flow information:		
Cash and cash equivalents	$ 27,179,000	$ 14,542,000
Restricted cash	975,000	972,000
Total cash, cash equivalents and restricted cash	$ 28,154,000	$ 15,514,000
Cash paid for interest	$ -	$ -
Cash paid for taxes	$ -	$ -

The accompanying notes are an integral part of these condensed consolidated statements.

NOTE 1 – NATURE OF OPERATIONS AND SIGNIFICANT ACCOUNTING POLICIES

Background

Abeona Therapeutics Inc. (together with our subsidiaries, "we," "our," "Abeona" or the "Company"), a Delaware corporation, is a clinical-stage biopharmaceutical company developing gene and cell therapies for life-threatening rare genetic diseases. Our lead clinical programs consist of: (i) EB-101, an autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa ("RDEB"), (ii) ABO-102, an adeno-associated virus ("AAV")-based gene therapy for Sanfilippo syndrome type A ("MPS IIIA"), and (iii) ABO-101, an AAV-based gene therapy for Sanfilippo syndrome type B ("MPS IIIB"). We continue to develop additional AAV-based gene therapies designed to treat ophthalmic and other diseases, next-generation AAV-based gene therapies using the novel AIM™ capsid platform that we have exclusively licensed from the University of North Carolina at Chapel Hill, and internal AAV vector research programs.

Basis of Presentation

The condensed consolidated balance sheet as of June 30, 2021, the condensed consolidated statements of operations and comprehensive loss and stockholders' equity for the three and six months ended June 30, 2021 and 2020, and the condensed consolidated statement of cash flows for the six months ended June 30, 2021 were prepared by management without audit. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted. These interim financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in our Form 10-K for the year ended December 31, 2020. The results of operations for the period ended June 30, 2021 are not necessarily indicative of the operating results that may be expected for a full year. The condensed consolidated balance sheet as of December 31, 2020 contains financial information taken from the audited Abeona consolidated financial statements as of that date.

Uses and Sources of Liquidity

The financial statements have been prepared on the going concern basis, which assumes the Company will have sufficient cash to pay its operating expenses, as and when they become payable, for a period of at least 12 months from the date the financial report was issued.

As of June 30, 2021, we had cash, cash equivalents and short-term investments of $77.6 million and net assets of $84.1 million. For the six months ended June 30, 2021, we had cash outflows from operations of $25.1 million. We have not generated significant product revenues and have not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and nonclinical testing, and commercialization of our products will require significant additional financing.

We are subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of product candidates, obtaining the necessary regulatory approval to market our product candidates, raising additional capital to continue to fund our operations, development of competing drugs and therapies, protection of proprietary technology and market acceptance of our products. As a result of these and other risks and the related uncertainties, there can be no assurance of our future success.

Based on our existing cash, cash equivalents and short-term investments, our ability to access additional financial resources and/or our financial flexibility to reduce operating expenses if required, we believe that we have sufficient resources to fund operations through at least the next 12 months. We will need to secure additional funding in the future to carry out all of our planned research and development activities. If we are unable to obtain additional financing or generate license or product revenue, the lack of liquidity and sufficient capital resources could have a material adverse effect on our future prospects.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reported period. Actual results could differ from these estimates and assumptions.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. We maintain deposits primarily in financial institutions, which may at times exceed amounts covered by insurance provided by the U.S. Federal Deposit Insurance Corporation ("FDIC"). We have not experienced any losses related to amounts in excess of FDIC limits.

Short-term Investments

Short-term investments consist of investments in U.S. government, U.S. agency and U.S. treasury securities. We determine the appropriate classification of the securities at the time they are acquired and evaluate the appropriateness of such classifications at each balance sheet date. We classify our short-term investments as available-for-sale pursuant to Accounting Standards Codification ("ASC") 320, *Investments – Debt and Equity Securities*. Investments classified as current have maturities of less than one year. We review our short-term investments for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a short-term investment's carrying amount is not recoverable within a reasonable period of time.

Leases

We account for leases in accordance with ASC 842, *Leases*. Right-of-use lease assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The right-of-use asset is based on the measurement of the lease liability and includes any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. Rent expense for our operating leases is recognized on a straight-line basis over the lease term. We do not have any leases classified as finance leases.

Our leases do not have significant rent escalation, holidays, concessions, material residual value guarantees, material restrictive covenants or contingent rent provisions. Our leases include both lease (e.g., fixed payments including rent, taxes, and insurance costs) and non-lease components (e.g., common-area or other maintenance costs), which are accounted for as a single lease component as we have elected the practical expedient to group lease and non-lease components for all leases.

Most leases include one or more options to renew. The exercise of lease renewal options is typically at our sole discretion; therefore, the majority of renewals to extend the lease terms are not included in our right-of-use assets and lease liabilities as they are not reasonably certain of exercise. We regularly evaluate the renewal options and when they are reasonably certain of exercise, we include the renewal period in our lease term.

Additional information and disclosures required under ASC 842 are included in Note 7.

Restricted Cash

Restricted cash, which is recorded within other assets and restricted cash in the accompanying consolidated balance sheets and is included as a component of cash, cash equivalents and restricted cash on our consolidated statements of cash flows, consists of cash and cash equivalents held as collateral for a corporate credit card and office space in New York. As such, the cash and cash equivalents are restricted in use.

Loss Per Common Share

We have presented basic and diluted loss per common share on the statement of operations and comprehensive loss. Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock and shares underlying "pre-funded" warrants outstanding during the period. The "pre-funded" warrants were included in the computation of basic net loss per share as the exercise price was negligible and the warrants were fully vested and exercisable. In October 2020, all of the 9,017,055 "pre-funded" warrants were exercised and converted into shares of common stock.

We do not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive. Potential dilutive securities result from outstanding stock options, restricted stock and "non-pre-funded" warrants. We did not include the following potentially dilutive securities in the computation of diluted net loss per common share during the periods presented:

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Stock options	7,726,468	7,790,596	7,726,468	7,790,596
Restricted stock	3,328,125	1,083,313	3,328,125	1,083,313
Warrants	-	20,000	-	20,000
Total	11,054,593	8,893,909	11,054,593	8,893,909

NOTE 2 – SHORT-TERM INVESTMENTS

The following table summarizes the available-for-sale investments held:

Description	June 30, 2021	December 31, 2020
U.S. government and agency securities and treasuries	$ 50,380,000	$ 82,438,000

The amortized cost of the available-for-sale debt securities, which is adjusted for amortization of premiums and accretion of discounts to maturity, was $50,381,000 and $82,448,000 as of June 30, 2021 and December 31, 2020, respectively. There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale debt securities during the six months ended June 30, 2021 or 2020.

NOTE 3 – LICENSED TECHNOLOGY

On November 4, 2018, we entered into a license agreement with REGENXBIO Inc. ("REGENXBIO") to obtain rights to an exclusive worldwide license (subject to certain non-exclusive rights previously granted for MPS IIIA), with rights to sublicense, to REGENXBIO's NAV AAV9 vector for gene therapies for treating MPS IIIA, MPS IIIB, CLN1 Disease and CLN3 Disease. Consideration for the rights granted under the original agreement included fees totaling $180 million and a running royalty on net sales, including: (i) an initial fee of $20 million, $10 million of which was due to REGENXBIO shortly after the effective date of the agreement, and $10 million of which was to be due on the first anniversary of the effective date of the agreement in November 2019, (ii) annual fees totaling up to $100 million, payable in $20 million annual installments beginning on the second anniversary of the effective date (the first of which was to remain payable if the agreement were terminated before the second anniversary in November 2020), (iii) sales milestone payments totaling $60 million, and (iv) royalties payable in the low double digits to low teens on net sales of products covered under the agreement. The license was being amortized over the life of the patent of eight years. On November 1, 2019, we entered into an amendment of the original license agreement. The amended agreement replaced the $10 million payment due on November 4, 2019 with a $3 million payment due on November 4, 2019 and an additional $8 million payment (which included $1 million of interest) that would have been due no later than April 1, 2020. That $8 million payment that had been scheduled to be paid by April 1, 2020 and the $20 million that had been due to be paid on November 4, 2020 are both recorded as payable to licensor on the consolidated balance sheet. The Company disputed that it was responsible for the $8 million and $20 million payments, and those payments were the subject of an arbitration between the Company and REGENXBIO as noted below.

Prior to the April 1, 2020 deadline, we engaged REGENXBIO in discussions in an attempt to renegotiate the financial terms of the agreement, but we were unable to reach a mutual understanding that we believed would have been favorable for the Company or our programs, and we did not make the $8 million payment due by April 1, 2020. On April 17, 2020, REGENXBIO sent us a written demand for the $8 million fee, payable within a 15-day cure period after receipt of the demand letter. The license terminated on May 2, 2020, when the 15-day period expired. We considered the status of our discussions with REGENXBIO in March 2020 as a potential indicator of impairment in accordance with ASC 360-10-35-21. Our impairment test indicated that the carrying value of the license agreement exceeded its fair value and we recorded a $32.9 million non-cash impairment charge during the three months ended March 31, 2020.

On May 25, 2020, we filed an arbitration claim with the American Arbitration Association ("AAA") alleging that REGENXBIO materially breached the license agreement prior to termination and seeking, among other things, a declaration that as a result of REGENXBIO's material breach, we were not responsible for payments totaling $28 million (which would otherwise have been due in 2020) plus accrued interest ($6.4 million as of June 30, 2021 based on invoices received from REGENXBIO). REGENXBIO disputed our arbitration claim and filed a counterclaim seeking payment of the $28 million plus interest, which REGENXBIO argued remained due. An arbitration hearing before a tribunal of three AAA arbitrators was held on March 8 and March 9, 2021. On July 13, 2021, the tribunal found in favor of REGENXBIO Inc. in connection with the parties' arbitration claims and counterclaims. Although the tribunal awarded REGENXBIO $28.0 million plus interest, we believe that prior to the arbitration decision, the two companies had entered into a binding settlement agreement, including $18.0 million payable to REGENXBIO over a two-year period. We intend to seek enforcement of the settlement agreement.

On May 15, 2015, we acquired Abeona Therapeutics LLC, which had an exclusive license through Nationwide Children's Hospital to the AB-101 and AB-102 patent portfolios for developing treatments for patients with Sanfilippo Syndrome Type A and Type B. The license is amortized over the life of the license of 20 years.

Licensed technology consists of the following:

	June 30, 2021	December 31, 2020
Licensed technology	$ 2,156,000	$ 2,156,000
Less accumulated amortization	714,000	656,000
Licensed technology, net	$ 1,442,000	$ 1,500,000

The aggregate estimated amortization expense for intangible assets remaining as of June 30, 2021 is as follows:

2021, remainder	$ 58,000
2022	117,000
2023	117,000
2024	117,000
2025	117,000
Thereafter	916,000
Total	$ 1,442,000

Amortization on licensed technology was $29,000 and $58,000 for the three and six months ended June 30, 2021 and $44,000 and $1.3 million for the three and six months ended June 30, 2020, respectively.

NOTE 4 - LOAN PAYABLE

On May 2, 2020, we received loan proceeds in the amount of approximately $1.8 million (the "PPP Loan") under the Paycheck Protection Program ("PPP"). The PPP was established under the Coronavirus Aid, Relief and Economic Security Act, as amended ("CARES Act") and is administered by the U.S. Small Business Administration ("SBA"). Under the terms of the CARES Act, PPP loan recipients can apply for loan forgiveness. The potential loan forgiveness for all or a portion of PPP loans is determined, subject to limitations, based on the use of loan proceeds over the 24 weeks after the loan proceeds are disbursed. The amount of loan forgiveness will be reduced if PPP loan recipients terminate employees or reduce salaries during the covered period. The unforgiven portion of our PPP Loan, if any, is payable over two years at an interest rate of 1%, with a deferral of principal and interest payments to either (i) the date that the SBA remits the borrower's loan forgiveness amount to the lender or (ii) if the borrower does not apply for forgiveness, 10 months after the end of the borrower's loan forgiveness covered period. Principal and interest payments on our PPP Loan are deferred until August 15, 2021 and the unforgiven portion of our PPP Loan, if any, matures on October 15, 2023.

In July 2021, we received notice from the SBA that our PPP loan has been forgiven. We will record the extinguishment of the PPP loan payable and other income in the third quarter of 2021.

NOTE 5 – FAIR VALUE MEASUREMENTS

We calculate the fair value of our assets and liabilities that qualify as financial instruments and include additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of prepaid expenses and other current assets, other assets, accounts payable, accrued expenses, loan payable, payable to licensor and contract liability approximate their carrying amounts due to the relatively short maturity of these instruments.

U.S. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. This guidance establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The lowest level fair value inputs are used to assign a fair value level. The three levels of inputs used to measure fair value are as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

We have segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below.

Financial assets and liabilities measured at fair value on a recurring and non-recurring basis as of June 30, 2021 and December 31, 2020 are summarized below:

Description	June 30, 2021	Level 1	Level 2	Level 3	Total Gains/(Losses)
Recurring					
Assets:					
Short-term investments	$ 50,380,000	$ -	$ 50,380,000	$ -	$ -
Non-recurring					
Assets:					
Licensed technology, net	$ 1,442,000	$ -	$ -	$ 1,442,000	$ -
Goodwill	32,466,000	-	-	32,466,000	-

Description	December 31, 2020	Level 1	Level 2	Level 3	Total Gains/(Losses)
Recurring					
Assets:					
Short-term investments	$ 82,438,000	$ -	$ 82,438,000	$ -	$ -
Non-recurring					
Assets:					
Licensed technology, net	$ 1,500,000	$ -	$ -	$ 1,500,000	$ (32,916,000)
Goodwill	32,466,000	-	-	32,466,000	-

NOTE 6 – STOCK-BASED COMPENSATION

Stock Options: The following table summarizes stock option-based compensation for the three and six months ended June 30, 2021 and 2020:

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Research and development	$ 608,000	$ 871,000	$ 1,217,000	$ 1,615,000
General and administrative	719,000	707,000	1,193,000	1,219,000
Stock option-based compensation expense included in operating expense	$ 1,327,000	$ 1,578,000	$ 2,410,000	$ 2,834,000

We estimate the fair value of each option award on the date of grant using the Black-Scholes option valuation model. We then recognize the grant date fair value of each option as compensation expense ratably using the straight-line attribution method over the service period (generally the vesting period). The Black-Scholes model incorporates the following assumptions:

- Expected volatility - we estimate the volatility of our share price at the date of grant using a “look-back” period which coincides with the expected term, defined below. We believe using a “look-back” period which coincides with the expected term is the most appropriate measure for determining expected volatility.
- Expected term - we estimate the expected term using the “simplified” method, as outlined in Staff Accounting Bulletin No. 107, “Share-Based Payment.”
- Risk-free interest rate - we estimate the risk-free interest rate using the U.S. Treasury yield curve for periods equal to the expected term of the options in effect at the time of grant.
- Dividends - we use an expected dividend yield of zero because we have not declared or paid a cash dividend, nor do we have any plans to declare a dividend.

We used the following weighted-average assumptions to estimate the fair value of the options granted for the periods indicated:

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Expected volatility	97%	111%	98%	111%
Expected term	5.67 years	6.25 years	5.93 years	6.25 years
Risk-free interest rate	0.96%	0.23%	0.99%	0.30%
Expected dividend yield	0%	0%	0%	0%

The following table summarizes the options granted for the periods indicated:

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Options granted	1,205,808	1,897,119	3,355,308	3,073,046
Weighted-average:				
Exercise price	$ 1.60	$ 2.83	$ 2.05	$ 2.30
Grant date fair value	$ 1.22	$ 2.36	$ 1.59	$ 1.92

Restricted Common Stock: The following table summarizes restricted common stock compensation expense for the three and six months ended June 30, 2021 and 2020:

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Research and development	$ 484,000	$ 147,000	$ 1,030,000	$ 472,000
General and administrative	617,000	40,000	938,000	179,000
Restricted stock-based compensation expense included in operating expense	$ 1,101,000	$ 187,000	$ 1,968,000	$ 651,000

The following table summarizes the restricted common stock granted for the periods indicated:

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Restricted common stock granted	926,484	1,083,313	1,975,734	1,083,313
Restricted common stock forfeited	(220,136)	-	(428,659)	-
Weighted-average:				
Grant date fair value-granted awards	$ 1.60	$ 3.19	$ 1.97	$ 3.19
Grant date fair value-forfeited awards	$ 2.05	$ -	$ 1.89	$ -

NOTE 7 – COMMITMENTS AND CONTINGENCIES

Arbitration Proceeding

We were engaged in an arbitration proceeding with REGENXBIO regarding the former license agreement between the parties relating to use of the AAV9 capsid in our MPS IIIA, MPS IIIB, CLN1 (which has now been sold to Taysha Gene Therapies), and CLN3 programs. The license terminated on May 2, 2020, and on May 25, 2020, we filed an arbitration claim with the American Arbitration Association ("AAA") alleging that REGENXBIO materially breached the license agreement prior to termination and seeking, among other things, a declaration that as a result of REGENXBIO's material breach, we were not responsible for payments totaling $28 million (which would otherwise have been due in 2020) plus accrued interest ($6.4 million as of June 30, 2021 based on invoices received from REGENXBIO). REGENXBIO disputed our arbitration claim and filed a counterclaim seeking payment of these amounts. An arbitration hearing before a tribunal of three AAA arbitrators was held on March 8 and March 9, 2021. On July 13, 2021, the tribunal found in favor of REGENXBIO Inc. in connection with the parties' arbitration claims and counterclaims. Although the tribunal awarded REGENXBIO $28.0 million plus interest, we believe that prior to the arbitration decision, the two companies had entered into a binding settlement agreement, including $18.0 million payable to REGENXBIO over a two-year period. We intend to seek enforcement of the settlement agreement.

Operating Leases

We lease space under operating leases for manufacturing and laboratory facilities and administrative offices in Cleveland, Ohio, as well as administrative offices in New York, New York. We also lease office space in Madrid, Spain as well as certain office equipment under operating leases, which have a non-cancelable lease term of less than one year and, therefore, we have elected the practical expedient to exclude these short-term leases from our right-of-use assets and lease liabilities.

Components of lease cost are as follows:

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Operating lease cost	$ 434,000	$ 434,000	$ 868,000	$ 868,000
Variable lease cost	$ 104,000	$ 92,000	$ 239,000	$ 175,000
Short-term lease cost	$ 5,000	$ 6,000	$ 10,000	$ 24,000

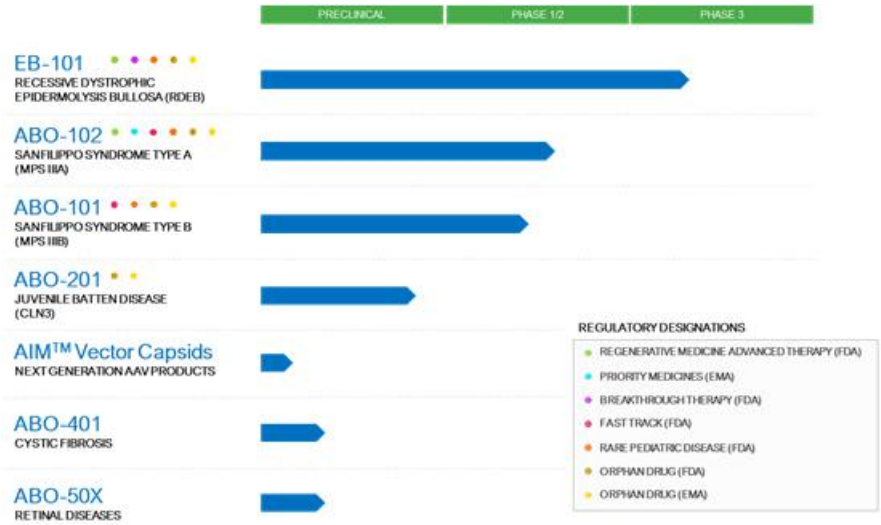
The following table presents information about the amount and timing of cash flows arising from operating leases as of June 30, 2021:

Maturity of lease liabilities:		
2021, remainder	$	858,000
2022		1,727,000
2023		1,741,000
2024		1,781,000
2025		1,799,000
Thereafter		87,000
Total undiscounted operating lease payments		7,993,000
Less: imputed interest		1,551,000
Present value of operating lease liabilities	$	6,442,000
Balance sheet classification:		
Current portion of lease liability	$	1,720,000
Long-term lease liability		4,722,000
Total operating lease liabilities	$	6,442,000
Other information:		
Weighted-average remaining lease term for operating leases		55 months
Weighted-average discount rate for operating leases		9.6%

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

OVERVIEW

Abeona Therapeutics Inc., a Delaware corporation (together with our subsidiaries, "we," "our," "Abeona" or the "Company"), is a clinical-stage biopharmaceutical company developing gene and cell therapies for life-threatening rare genetic diseases. Our lead clinical programs consist of: (i) EB-101, an autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa ("RDEB"), (ii) ABO-102, an adeno-associated virus ("AAV")-based gene therapy for Sanfilippo syndrome type A ("MPS IIIA"), and (iii) ABO-101, an AAV-based gene therapy for Sanfilippo syndrome type B ("MPS IIIB"). We continue to develop additional AAV-based gene therapies designed to treat ophthalmic and other diseases, next-generation AAV-based gene therapies using the novel AIM™ capsid platform that we have exclusively licensed from the University of North Carolina at Chapel Hill, and internal AAV vector research programs. A number of our product candidates are eligible for orphan drug designation, breakthrough therapy designation, or other expedited review processes in the U.S., Europe, Japan, or other world markets. Our pipeline includes three programs in clinical development—EB-101, ABO-101 and ABO-102— for which we hold several U.S. and European Union ("EU") regulatory designations, and a pipeline of additional earlier stage programs:



Our robust pipeline features early- and late-stage candidates with the potential to transform the treatment of devastating genetic diseases, and we are conducting clinical trials in the U.S. and abroad.

Our Mission and Strategy

Abeona is at the forefront of gene and cell therapy research and development. We are a fully-integrated company featuring therapies in clinical development, in-house manufacturing facilities, a robust pipeline, and scientific and clinical leadership. We see our mission as working to create, develop, manufacture, and deliver gene and cell therapies for people impacted by serious diseases. We partner with leading academic researchers, patient advocacy organizations and caregivers to develop therapies that address the underlying cause of a broad spectrum of rare genetic diseases for which no effective treatment options exist today.

Since our last fiscal year, we have continued to make progress toward fulfilling our goal of harnessing the promise of genetic medicine to transform the lives of people impacted by serious diseases and redefining the standard of care through gene and cell therapies. Our strategy to achieve this goal consists of:

Advancing Our Clinical Gene and Cell Therapy Programs and Research and Development with a Focus on Rare and Orphan Diseases.

We have three programs in clinical development—EB-101, ABO-101 and ABO-102—and a pipeline of additional earlier stage programs. Through our gene and cell therapy research and development expertise, we believe we are positioned to introduce efficacious and safe therapeutics to transform the standard of care in devastating diseases and establish our leadership position in the field.

Applying Novel Next Generation AAV Capsid Technology to Develop New In-Vivo Gene Therapies.

We are researching and developing next-generation AAV-based gene therapy using our novel capsids developed from the AIM™ Capsid Technology Platform and additional Company-invented AAV capsids. We plan to continue to develop chimeric AAV capsids capable of improved tissue targeting for various indications and potentially evading immunity to wildtype AAV vectors.

Establishing Leadership Position in Commercial-Scale Gene and Cell-Therapy Manufacturing.

We established current Good Manufacturing Practice ("cGMP"), clinical-scale manufacturing capabilities for gene-corrected cell therapy and AAV-based gene therapies in our state-of-the-art Cleveland facility. We believe that our platform provides us with distinct advantages, including flexibility, scale, reliability, and the potential for reduced development risk, reduced cost, and faster times to market. We have focused on establishing internal Chemistry, Manufacturing and Controls ("CMC") capabilities that drive value for our organization through process development, assay development and manufacturing. We have also deployed robust quality systems governing all aspects of product lifecycle from preclinical through commercial stage.

Establishing Additional Gene and Cell Therapy Franchises and Adjacencies through In-Licensing and Strategic Partnerships.

We seek to be the partner of choice in gene therapy treatment and have closely collaborated with leading academic institutions, key opinion leaders, patient foundations, and industry partners to generate novel intellectual property, accelerate research and development, and understand the needs of patients and their families.

Maintaining and Growing IP Portfolio.

We strive to have a leading intellectual property portfolio. To that end, we seek patent rights for various aspects of our programs, including vector engineering and construct design, our production process, and all features of our clinical products including composition of matter and method of administration and delivery. We expect to continue to expand our intellectual property portfolio by aggressively seeking patent rights for promising aspects of our product engine and product candidates.

IMPACT OF COVID-19 PANDEMIC ON OUR BUSINESS

We continue to assess the evolving impact of the COVID-19 pandemic on our business and take appropriate actions to manage our spending activities and preserve our cash resources. While we are unable to determine or predict the extent, duration or scope of the overall impact the COVID-19 pandemic will have on our business, operations, financial condition or liquidity, we believe it is important to keep our stakeholders informed about how our response to COVID-19 is progressing and how our operations and financial condition may change.

The extent of the impact of the COVID-19 pandemic on our business, operations, and clinical trials continues to evolve and will depend on certain developments, including: (i) the duration of the declared health emergencies; (ii) future actions taken by governmental authorities and regulators with respect to the pandemic, including reinstituting state and local lockdowns; (iii) the impact on our partners, collaborators, and suppliers; and (iv) actions being taken by us in response to this crisis. We remain dedicated to communicating regularly and openly with our stakeholders as more information becomes available, including updates on material changes to prior guidance as we continue to follow applicable government, regulatory and institutional guidelines.

RESULTS OF OPERATIONS

Comparison of Three Months Ended June 30, 2021 and June 30, 2020

Total research and development spending was $7.4 million for the second quarter of 2021, as compared to $6.1 million for the same period of 2020, an increase of $1.3 million. The increase in expenses was primarily due to:

- increased clinical and development work for our gene and cell therapy product candidates ($1.0 million); and
- increased salary and related costs ($0.3 million).

Total general and administrative spending was $5.5 million in both the second quarter of 2021 and the second quarter of 2020.

Depreciation and amortization was $0.8 million in both the second quarter of 2021 and the second quarter of 2020.

Interest and miscellaneous income was approximately nil for the second quarter of 2021, as compared to $0.3 million for the same period in 2020. The decrease resulted from lower earnings on short-term investments driven by lower interest rates and a lower average balance of short-term investments.

Interest expense was $1.5 million for the second quarter of 2021, as compared to $0.8 million for the same period of 2020. The increase results primarily from invoices received from REGENXBIO for accrued interest on the disputed amounts that we may owe to REGENXBIO under the prior license agreement, which is discussed in Note 3 of our Notes to Condensed Consolidated Financial Statements.

Net loss was $15.2 million for the second quarter of 2021, or a $0.16 basic and diluted loss per common share as compared to a net loss of $13.0 million, or a $0.14 basic and diluted loss per common share, for the same period in 2020. The increase in the net loss results primarily from increased research and development spending and increased interest expense.

Comparison of Six Months Ended June 30, 2021 and June 30, 2020

Total research and development spending was $14.6 million for the first six months of 2021, as compared to $12.9 million for the same period of 2020, an increase of $1.7 million. The increase in expenses was primarily due to:

- increased clinical and development work for our gene and cell therapy product candidates ($1.2 million); and
- increased salary and related costs ($0.5 million).

Total general and administrative spending was $12.0 million in both the first six months of 2021 and the same period of 2020.

Depreciation and amortization was $1.6 million for the first six months of 2021, as compared to $2.9 million for the same period in 2020, a decrease of $1.3 million. The decrease was driven by decreased amortization expense of $1.3 million on licensed technology in the first six months of 2021, as compared to the same period in 2020, due to the write-off of the REGENXBIO licensed technology in the first quarter of 2020.

Our license agreement with REGENXBIO terminated on May 2, 2020. Since our impairment testing indicated that the carrying value of the license agreement with REGENXBIO exceeded its fair value, we recorded a $32.9 million non-cash impairment charge in the first six months of 2020.

Interest and miscellaneous income was approximately nil for the first six months of 2021, as compared to $0.9 million for the same period in 2020. The decrease resulted from lower earnings on short-term investments driven by lower interest rates and a lower average balance of short-term investments.

Interest expense was $2.9 million for the first six months of 2021, as compared to $1.4 million for the same period of 2020. The increase results primarily from invoices received from REGENXBIO for accrued interest on the disputed amounts that we may owe to REGENXBIO under the prior license agreement, which is discussed in Note 3 of our Notes to Condensed Consolidated Financial Statements.

Net loss was $31.2 million for the first six months of 2021, or a $0.33 basic and diluted loss per common share as compared to a net loss of $61.2 million, or a $0.66 basic and diluted loss per common share, for the same period in 2020. The decrease in the net loss results primarily from a licensed technology impairment charge of $32.9 million in the first six months of 2020.

LIQUIDITY AND CAPITAL RESOURCES

We have historically funded our operations primarily through sale of common stock. The COVID-19 pandemic has negatively affected the global economy and created significant volatility and disruption of financial markets. An extended period of economic disruption could negatively affect our business, financial condition, and access to sources of liquidity.

Our principal source of liquidity is cash, cash equivalents and short-term investments. As of June 30, 2021 and December 31, 2020, our cash, cash equivalents, receivables and short-term investments were $77.6 million and $95.0 million, respectively. Based on our existing cash, cash equivalents and short-term investments, our ability to access additional financial resources and/or our financial flexibility to reduce operating expenses if required, we believe that we have sufficient resources to fund operations through at least the next 12 months. We will need to secure additional funding in the future to carry out all of our planned research and development activities. If we are unable to obtain additional financing or generate license or product revenue, the lack of liquidity and sufficient capital resources could have a material adverse effect on our future prospects.

As of June 30, 2021 and December 31, 2020, our working capital was $38.0 million and $55.8 million, respectively. The decrease in working capital as of June 30, 2021 resulted primarily from $25.1 million of cash used for operating activities, partially offset by $8.4 million of cash provided by financing activities.

On August 17, 2018, we entered into an open market sale agreement with Jefferies LLC (the “2018 ATM Agreement”). Pursuant to the terms of the 2018 ATM Agreement, we are able to sell from time to time, through Jefferies LLC, shares of our common stock for an aggregate sales price of up to $150 million. Any sales of shares pursuant to the 2018 ATM Agreement are made under an effective “shelf” registration statement on Form S-3 that is on file with and has been declared effective by the SEC. We sold 3,063,545 shares of our common stock under the 2018 ATM Agreement and received $7.7 million of net proceeds during the six months ended June 30, 2021. Cumulatively, as of June 30, 2021, we have sold an aggregate of 6,150,495 shares of our common stock under the 2018 ATM Agreement and received $24.6 million of net proceeds.

License Agreement

On November 4, 2018, we entered into a license agreement with REGENXBIO to obtain rights to an exclusive worldwide license (subject to certain non-exclusive rights previously granted for MPS IIIA), with rights to sublicense, to REGENXBIO’s NAV AAV9 vector for gene therapies for treating MPS IIIA, MPS IIIB, CLN1 Disease and CLN3 Disease. Consideration for the rights granted under the original agreement included fees totaling $180 million and a running royalty on net sales, including: (i) an initial fee of $20 million, $10 million of which was due to REGENXBIO shortly after the effective date of the agreement, and $10 million of which was to be due on the first anniversary of the effective date of the agreement in November 2019, (ii) annual fees totaling up to $100 million, payable in $20 million annual installments beginning on the second anniversary of the effective date (the first of which was to remain payable if the agreement were terminated before the second anniversary in November 2020), (iii) sales milestone payments totaling $60 million, and (iv) royalties payable in the low double digits to low teens on net sales of products covered under the agreement. The license was being amortized over the life of the patent of eight years. On November 1, 2019, we entered into an amendment of the original license agreement. The amended agreement replaced the $10 million payment due on November 4, 2019 with a $3 million payment due on November 4, 2019 and an additional $8 million payment (which included $1 million of interest) that would have been due no later than April 1, 2020. That $8 million payment that had been scheduled to be paid by April 1, 2020 and the $20 million that had been due to be paid on November 4, 2020 are both recorded as payable to licensor on the consolidated balance sheet. The Company disputed that it was responsible for the $8 million and $20 million payments, and those payments were the subject of an arbitration between the Company and REGENXBIO as noted below.

Prior to the April 1, 2020 deadline, we engaged REGENXBIO in discussions in an attempt to renegotiate the financial terms of the agreement, but we were unable to reach a mutual understanding that we believed would have been favorable for the Company or our programs, and we did not make the $8 million payment due by April 1, 2020. On April 17, 2020, REGENXBIO sent us a written demand for the $8 million fee, payable within a 15-day cure period after receipt of the demand letter. The license terminated on May 2, 2020, when the 15-day period expired. There were no penalties for early termination of the license.

On May 25, 2020, we filed an arbitration claim with the American Arbitration Association ("AAA") alleging that REGENXBIO materially breached the license agreement prior to termination and seeking, among other things, a declaration that as a result of REGENXBIO's material breach, we were not responsible for payments totaling $28 million (which would otherwise have been due in 2020) plus accrued interest ($6.4 million as of June 30, 2021 based on invoices received from REGENXBIO). REGENXBIO disputed our arbitration claim and filed a counterclaim seeking payment of the $28 million plus interest, which REGENXBIO argued remained due. An arbitration hearing before a tribunal of three AAA arbitrators was held on March 8 and March 9, 2021. On July 13, 2021, the tribunal found in favor of REGENXBIO Inc. in connection with the parties' arbitration claims and counterclaims. Although the tribunal awarded REGENXBIO $28.0 million plus interest, we believe that prior to the arbitration decision, the two companies had entered into a binding settlement agreement, including $18.0 million payable to REGENXBIO over a two-year period. We intend to seek enforcement of the settlement agreement.

Since our inception, we have incurred negative cash flows from operations and have expended, and expect to continue to expend, substantial funds to complete our planned product development efforts. We have not been profitable since inception and to date have received limited revenues from the sale of products. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials, and regulatory compliance and cannot provide assurance that we will ever be able to generate sufficient product sales or royalty revenue to achieve profitability on a sustained basis, or at all.

If we raise additional funds by selling additional equity securities, the relative equity ownership of our existing investors will be diluted, and the new investors could obtain terms more favorable than previous investors. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

We are carefully and continually reassessing key business activities and all associated spending decisions. Nonetheless, we are spending necessary funds on manufacturing activities and preclinical studies and clinical trials of potential products, including research and development with respect to our acquired and developed technology. Our future capital requirements and adequacy of available funds depend on many factors, including:

- the evolving impact to our business, operations, and clinical programs from the COVID-19 pandemic and related effects on the U.S. and global economy;
- the successful development and commercialization of our gene and cell therapy and other product candidates;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development, and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting, and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- the successful outcome of our regulatory filings.

Due to uncertainties and certain of the risks described above, including those relating to the COVID-19 pandemic, our ability to successfully commercialize our product candidates, our ability to obtain applicable regulatory approval to market our product candidates, our ability to obtain necessary additional capital to fund operations in the future, our ability to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes, government regulation to which we are subject, the uncertainty associated with preclinical and clinical testing, intense competition that we face, market acceptance of our products, the potential necessity of licensing technology from third parties and protection of our intellectual property, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed in the risks above.

We plan to continue our policy of investing any available funds in suitable certificates of deposit, money market funds, government securities and investment-grade, interest-bearing securities. We do not invest in derivative financial instruments.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management and consultants, including the Chief Executive Officer (our principal executive officer) and Chief Accounting Officer (our principal financial officer), we have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures ("Disclosure Controls and Procedures"), as of June 30, 2021, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Conclusion of Evaluation — Based on this Disclosure Controls and Procedures evaluation, the Chief Executive Officer and Chief Accounting Officer concluded that our Disclosure Controls and Procedures as of June 30, 2021 were effective.

Changes in Internal Control Over Financial Reporting – There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2021 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 were engaged in an arbitration proceeding with REGENXBIO regarding the former license agreement between the parties relating to use of the AAV9 capsid in our MPS IIIA, MPS IIIB, CLN1 (which has now been sold to Taysha Gene Therapies), and CLN3 programs. The license terminated on May 2, 2020, and on May 25, 2020, we filed an arbitration claim with the American Arbitration Association ("AAA") alleging that REGENXBIO materially breached the license agreement prior to termination and seeking, among other things, a declaration that as a result of REGENXBIO's material breach, we were not responsible for payments totaling $28 million (which would otherwise have been due in 2020) plus accrued interest ($6.4 million as of June 30, 2021 based on invoices received from REGENXBIO). REGENXBIO disputed our arbitration claim and filed a counterclaim seeking payment of the $28 million plus interest, which REGENXBIO argued remained due. An arbitration hearing before a tribunal of three AAA arbitrators was held on March 8 and March 9, 2021. On July 13, 2021, the tribunal found in favor of REGENXBIO Inc. in connection with the parties' arbitration claims and counterclaims. Although the tribunal awarded REGENXBIO $28.0 million plus interest, we believe that prior to the arbitration decision, the two companies had entered into a binding settlement agreement, including $18.0 million payable to REGENXBIO over a two-year period. We intend to seek enforcement of the settlement agreement.

ITEM 1A. RISK FACTORS

Our business and financial results are subject to numerous risks and uncertainties. As a result, the risks and uncertainties discussed in Part I, Item 1A. Risk Factors in our Form 10-K for the year ended December 31, 2020 should be carefully considered. The following updated risk factor should be considered in addition to the risks and uncertainties discussed in Part I, Item 1A. Risk Factors in our Form 10-K for the year ended December 31, 2020:

Our rights to develop and commercialize our product candidates are subject to, in part, the terms and conditions of licenses granted to us by others.

We rely upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our technology and products, including technology related to our manufacturing process and our product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. These licenses may also require us to grant back certain rights to licensors and to pay certain amounts relating to sublicensing patent and other rights under the agreement.

If our licensors fail to maintain such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. In certain circumstances, we have or may license technology from third parties on a non-exclusive basis. In such instances, other licensees may have the right to enforce our licensed patents in their respective fields, without our oversight or control. Those other licensees may choose to enforce our licensed patents in a way that harms our interest, for example, by advocating for claim interpretations or agreeing on invalidity positions that conflict with our positions or our interest. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future.

Further, in connection with our license agreements we may be responsible for bringing any actions against third parties for infringing claims of the patents we have licensed. Certain of our license agreements also require us to meet development milestones to maintain the license, including establishing a set timeline for developing and commercializing products and minimum yearly diligence obligations in developing and commercializing the product. Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe intellectual property rights of the licensor that are not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If we fail to comply with our obligations under these license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we may not be able to manufacture, or market products covered by the license or may face other penalties. If any dispute over in-licensed intellectual property prevents or impairs our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully commercialize the affected product candidates. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. It is possible that such termination may occur even if we believe that we have complied with our obligations under a license agreement, if a dispute arises between us and a licensor. Our license agreement with REGENXBIO had granted us an exclusive worldwide license (subject to certain non-exclusive rights previously granted for MPS IIIA), with rights to sublicense, to use REGENXBIO's NAV AAV9 capsid in gene therapies for treating MPS IIIA, MPS IIIB, CLN1 Disease, and CLN3 Disease. (Our CLN1 program was sold to Taysha Gene Therapies in August 2020.) On May 2, 2020, REGENXBIO terminated the license agreement. On May 25, 2020, we filed an arbitration claim with the American Arbitration Association ("AAA") alleging that REGENXBIO materially breached the license agreement prior to termination and seeking, among other things, a declaration that as a result of REGENXBIO's material breach, we were not responsible for payments totaling $28 million (which would otherwise have been due in 2020) plus accrued interest ($6.4 million as of June 30, 2021 based on invoices received from REGENXBIO). REGENXBIO disputed our arbitration claim and filed a counterclaim seeking payment of the $28 million plus interest, which REGENXBIO argued remained due. An arbitration hearing before a tribunal of three AAA arbitrators was held on March 8 and March 9, 2021. On July 13, 2021, the tribunal found in favor of REGENXBIO Inc. in connection with the parties' arbitration claims and counterclaims. Although the tribunal awarded REGENXBIO $28.0 million plus interest, we believe that prior to the arbitration decision, the two companies had entered into a binding settlement agreement, including $18.0 million payable to REGENXBIO over a two-year period. We intend to seek enforcement of the settlement agreement. It is possible that REGENXBIO may in the future assert that our proposed products infringe one or more of REGENXBIO's AAV9 patent claims, and we still may ultimately need a license to use the AAV9 capsid in our proposed MPS IIIA, MPS IIIB, or CLN3 products, if such a product is commercialized before the expiration of one or more REGENXBIO patent claims that cover our commercial product. Absent such a license, if we are found to infringe a valid and enforceable REGENXBIO AAV9 patent claim before the expiration of a relevant REGENXBIO patent, it is possible that a court may order us to pay a reasonable royalty to REGENXBIO until relevant patents expire. Although courts generally impose a reasonable royalty and it is very unlikely based on the current state of the relevant law that a court would grant a permanent injunction to prevent the launch of one of our products, it is possible that a court could enjoin us from commercializing our MPS IIIA, MPS IIIB, or CLN3 products until relevant AAV9 patents expire if the court finds that any harm to REGENXBIO would not be compensable by money damages.

Furthermore, to the extent that the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive, royalty-free license authorizing the U.S. government, or a third party on its behalf, to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government, or a third party on its behalf, of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

ITEM 6. EXHIBITS

See Exhibit Index below, which is incorporated by reference herein.

Exhibit Index

Exhibits:

31.1	Principal Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Principal Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at June 30, 2021 and December 31, 2020, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2021 and 2020, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2021 and 2020, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2021 and 2020, and (v) Notes to Condensed Consolidated Financial Statements.

* Pursuant to Item 601(b)(32)(ii) of Regulation S-K, this exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ABEONA THERAPEUTICS INC.

Date: July 28, 2021

By: */s/ Michael Amoroso*
Michael Amoroso
President and Chief Executive Officer
(Principal Executive Officer)

Date: July 28, 2021

By: */s/ Edward Carr*
Edward Carr
Chief Accounting Officer
(Principal Financial Officer)

EXHIBIT 31.1

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION PURSUANT TO 18 U.S.C.
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Amoroso, certify that:

1. I have reviewed this report on Form 10-Q of Abeona Therapeutics Inc.;

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 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: July 28, 2021

By: */s/ Michael Amoroso*
Michael Amoroso
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

PRINCIPAL FINANCIAL OFFICER CERTIFICATION PURSUANT TO 18 U.S.C.
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Edward Carr, certify that:

1. I have reviewed this report on Form 10-Q of Abeona Therapeutics Inc.;

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 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: July 28, 2021

By: */s/ Edward Carr*
Edward Carr
Chief Accounting Officer
(Principal Financial Officer)

EXHIBIT 32

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 of Abeona Therapeutics Inc. (the "Company") on Form 10-Q for the three months ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Michael Amoroso, President and Chief Executive Officer of the Company, and Edward Carr, Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(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: July 28, 2021

By: */s/ Michael Amoroso*
Michael Amoroso
President and Chief Executive Officer
(Principal Executive Officer)

Date: July 28, 2021

By: */s/ Edward Carr*
Edward Carr
Chief Accounting Officer
(Principal Financial Officer)