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 September 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 November 8, 2021 was101,917,914 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; 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

	September 30, 2021 (Unaudited)	December 31, 2020

ASSETS		
Current assets:		
Cash and cash equivalents	$ 43,781,000	$ 12,596,000
Short-term investments	23,217,000	82,438,000
Prepaid expenses and other current assets	907,000	2,708,000
Total current assets	67,905,000	97,742,000
Property and equipment, net	9,869,000	11,322,000
Right-of-use lease assets	6,207,000	7,032,000
Licensed technology, net	1,413,000	1,500,000
Goodwill	32,466,000	32,466,000
Other assets and restricted cash	1,159,000	1,136,000
Total assets	$ 119,019,000	$ 151,198,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,861,000	$ 4,695,000
Accrued expenses	2,593,000	3,410,000
Current portion of lease liability	1,723,000	1,713,000
Current portion of PPP loan payable	-	330,000
Current portion of payable to licensor	20,000,000	31,515,000
Contract liability	296,000	296,000
Total current liabilities	26,473,000	41,959,000
PPP loan payable	-	1,428,000
Payable to licensor	8,360,000	-
Long-term lease liabilities	4,442,000	5,260,000
Total liabilities	39,275,000	48,647,000
Commitments and contingencies		
Stockholders' equity:		
Common stock - $0.01 par value; authorized 200,000,000 shares; issued and outstanding 101,867,539 at September 30, 2021; issued and outstanding 96,131,678 at December 31, 2020;	1,019,000	961,000
Additional paid-in capital	687,691,000	672,304,000
Accumulated deficit	(608,957,000)	(570,704,000)
Accumulated other comprehensive loss	(9,000)	(10,000)
Total stockholders' equity	79,744,000	102,551,000
Total liabilities and stockholders' equity	$ 119,019,000	$ 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 September 30,		For the nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenues	$ -	$ 7,000,000	$ -	$ 7,000,000
Expenses:				
Research and development	7,978,000	7,969,000	22,624,000	20,896,000
General and administrative	6,092,000	4,432,000	18,117,000	16,382,000
Depreciation and amortization	802,000	847,000	2,443,000	3,746,000
Licensed technology impairment charge	-	-	-	32,916,000
Total expenses	14,872,000	13,248,000	43,184,000	73,940,000
Loss from operations	(14,872,000)	(6,248,000)	(43,184,000)	(66,940,000)
Gain on settlement with licensor	6,743,000	-	6,743,000	-
PPP loan payable forgiveness income	1,758,000	-	1,758,000	-
Interest and miscellaneous income	10,000	338,000	33,000	1,261,000
Interest expense	(683,000)	(1,327,000)	(3,603,000)	(2,727,000)
Net loss	$ (7,044,000)	$ (7,237,000)	$ (38,253,000)	$ (68,406,000)
Basic and diluted loss per common share	$ (0.07)	$ (0.08)	$ (0.40)	$ (0.74)
Weighted average number of common shares outstanding – basic and diluted	97,990,338	92,714,983	96,258,681	92,594,339
Other comprehensive income/(loss):				

Change in unrealized gains/(losses) related to available-for-sale debt securities	1,000	(116,000)	10,000	17,000
Foreign currency translation adjustments	(9,000)	-	(9,000)	-
Comprehensive loss	$ (7,052,000)	$ (7,353,000)	$ (38,252,000)	$ (68,389,000)

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	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income/(Loss)	Equity
For the three months ended September 30, 2021						
Balance, June 30, 2021	101,251,023	$ 1,013,000	$ 684,987,000	$ (601,913,000)	$ (1,000)	$ 84,086,000
Stock option-based compensation expense	-	-	1,387,000	-	-	1,387,000
Restricted stock-based compensation expense	-	-	1,150,000	-	-	1,150,000
Common stock issued for cash exercise of options	121,950	1,000	139,000	-	-	140,000
Issuance of common stock in connection with restricted share awards	474,825	5,000	(5,000)	-	-	-
Common stock issued for cash under open market sale agreement	19,741	-	33,000	-	-	33,000
Net loss	-	-	-	(7,044,000)	-	(7,044,000)
Other comprehensive loss	-	-	-	-	(8,000)	(8,000)
Balance, September 30, 2021	101,867,539	$ 1,019,000	$ 687,691,000	$ (608,957,000)	$ (9,000)	$ 79,744,000
For the three months ended September 30, 2020						
Balance, June 30, 2020	84,781,241	$ 848,000	$ 667,712,000	$ (547,639,000)	$ 133,000	$ 121,054,000
Stock option-based compensation expense	-	-	1,249,000	-	-	1,249,000
Restricted stock-based compensation expense	-	-	161,000	-	-	161,000
Cancellation of restricted share awards	(265,080)	(3,000)	3,000	-	-	-
Net loss	-	-	-	(7,237,000)	-	(7,237,000)
Other comprehensive loss	-	-	-	-	(116,000)	(116,000)
Balance, September 30, 2020	84,516,161	$ 845,000	$ 669,125,000	$ (554,876,000)	$ 17,000	$ 115,111,000
For the nine months ended September 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	-	-	3,797,000	-	-	3,797,000
Restricted stock-based compensation expense	-	-	3,118,000	-	-	3,118,000
Common stock issued for cash exercise of options	630,675	6,000	825,000	-	-	831,000
Issuance of common stock in connection with restricted share awards	2,021,900	20,000	(20,000)	-	-	-
Common stock issued for cash under open market sale agreement	3,083,286	32,000	7,667,000	-	-	7,699,000
Net loss	-	-	-	(38,253,000)	-	(38,253,000)
Other comprehensive income	-	-	-	-	1,000	1,000
Balance, September 30, 2021	101,867,539	$ 1,019,000	$ 687,691,000	$ (608,957,000)	$ (9,000)	$ 79,744,000
For the nine months ended September 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	-	-	4,083,000	-	-	4,083,000
Restricted stock-based compensation expense	-	-	812,000	-	-	812,000
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	818,233	8,000	(8,000)	-	-	-
Net loss	-	-	-	(68,406,000)	-	(68,406,000)
Other comprehensive income	-	-	-	-	17,000	17,000
Balance, September 30, 2020	84,516,161	$ 845,000	$ 669,125,000	$ (554,876,000)	$ 17,000	$ 115,111,000

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 nine months ended September 30,	
	2021	2020
Cash flows from operating activities:		

Net loss	$ (38,253,000)	$ (68,406,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Non-cash licensed technology impairment charge	-	32,916,000
Non-cash gain on settlement with licensor	(6,743,000)	-
Non-cash PPP loan payable forgiveness income	(1,758,000)	-
Non-cash interest expense	-	600,000
Depreciation and amortization	2,443,000	3,746,000
Stock option-based compensation expense	3,797,000	4,083,000
Restricted stock-based compensation expense	3,118,000	812,000
Accretion and interest on short-term investments	256,000	(237,000)
Amortization of right-of-use lease assets	825,000	752,000
Change in operating assets and liabilities:		
Receivables	-	(7,000,000)
Prepaid expenses and other current assets	1,801,000	2,443,000
Other assets	(23,000)	(62,000)
Accounts payable, accrued expenses and lease liabilities	(4,459,000)	(5,183,000)
Change in payable to licensor	3,588,000	2,127,000
Net cash used in operating activities	(35,408,000)	(33,409,000)
Cash flows from investing activities:		
Capital expenditures	(903,000)	(1,303,000)
Purchases of short-term investments	(15,164,000)	(139,230,000)
Proceeds from maturities of short-term investments	74,130,000	51,037,000
Net cash provided by (used in)/investing activities	58,063,000	(89,496,000)
Cash flows from financing activities:		
Proceeds from loan payable	-	1,758,000
Proceeds from open market sales of common stock	7,699,000	-
Proceeds from exercise of stock options	831,000	175,000
Net cash provided by financing activities	8,530,000	1,933,000
Net increase/(decrease) in cash, cash equivalents and restricted cash	31,185,000	(120,972,000)
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	$ 44,756,000	$ 9,396,000
Supplemental cash flow information:		
Cash and cash equivalents	$ 43,781,000	$ 8,424,000
Restricted cash	975,000	972,000
Total cash, cash equivalents and restricted cash	$ 44,756,000	$ 9,396,000
Cash paid for interest	$ -	$ -
Cash paid for taxes	$ -	$ -

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

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements
(Unaudited)

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 September 30, 2021, the condensed consolidated statements of operations and comprehensive loss and stockholders' equity for the three and nine months ended September 30, 2021 and 2020, and the condensed consolidated statement of cash flows for the nine months ended September 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 September 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 September 30, 2021, we had cash, cash equivalents and short-term investments of $67.0 million and net assets of $79.7 million. For the nine months ended September 30, 2021, we had cash outflows from operations of $35.4 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 September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Stock options	7,755,196	6,431,183	7,755,196	6,431,183

Restricted stock	2,989,224	818,233	2,989,224	818,233
Total	10,744,420	7,249,416	10,744,420	7,249,416

NOTE 2 – SHORT-TERM INVESTMENTS

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

Description	September 30, 2021	December 31, 2020
U.S. government and agency securities and treasuries	$ 23,217,000	$ 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 $23,217,000 and $82,448,000 as of September 30, 2021 and December 31, 2020, respectively. There wereno significant realized gains or losses recognized on the sale or maturity of available-for-sale debt securities during the nine months ended September 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 an agreement, 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. 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 in connection with the parties' arbitration claims and counterclaims. The tribunal awarded REGENXBIO $28.0 million plus interest.

On August 9, 2021, we filed a second arbitration claim with the AAA asserting that a settlement had been reached before the tribunal's award in the first arbitration was issued. On September 14, 2021, REGENXBIO filed its answer, a counterclaim seeking attorney fees and costs, and a request for permission to file a case dispositive motion. A preliminary hearing was held on November 1, 2021, during which the AAA Tribunal set timetables for discovery and for REGENXBIO's filing of its case dispositive motion. Those timetables were formalized in a procedural order issued by the Tribunal on November 8, 2021. Under the schedule set by the Tribunal, REGENXBIO's opening brief in support of its case dispositive motion was filed on November 8, 2021, briefing was scheduled to be completed on December 29, 2021, and oral argument was scheduled for January 14, 2022. REGENXBIO had also filed suit in the New York State Supreme Court Commercial Division seeking enforcement of the original arbitration award, and we had requested that the Court stay that proceeding until the second arbitration is complete. Oral argument on our request for a stay was set for March 10, 2022.

On November 12, 2021, we entered into a settlement agreement ("Settlement Agreement") with REGENXBIO to resolve all current disputes between the parties including the aforementioned AAA arbitration and New York State Court action. In accordance with the Settlement Agreement, we agreed to pay REGENXBIO a total of $ 30 million, payable as follows: (1) $20 million payable within one business day of the execution of the Settlement Agreement, (2) $5 million on the first anniversary of the effective date of the Settlement Agreement, and (3) $5 million upon the earlier of: (i) the third anniversary of the effective date of the Settlement Agreement or (ii) the closing of a Strategic Transaction, as defined in the Settlement Agreement. Under the Settlement Agreement's terms, the prior license agreement between the parties was not reinstituted, and any future license agreement would need to be negotiated separately and require consideration in addition to the consideration set forth in the Settlement Agreement. As of September 30, 2021, we have recorded the payable to licensor in the balance sheet based on the present value of the payments due to REGENXBIO under the Settlement Agreement. The accounting for the Settlement Agreement resulted in a $6.7 million gain on settlement with licensor in the statement of operations and comprehensive loss during the three and nine months ended September 30, 2021 and a $6.7 million non-cash gain on settlement with licensor in the statement of cash flows during the nine months ended September 30, 2021.

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:

	September 30, 2021	December 31, 2020
Licensed technology	$ 2,156,000	$ 2,156,000
Less accumulated amortization	743,000	656,000
Licensed technology, net	$ 1,413,000	$ 1,500,000

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

2021, remainder	$ 29,000
2022	117,000
2023	117,000
2024	117,000
2025	117,000

Thereafter	916,000
Total	$ 1,413,000

Amortization on licensed technology was $29,000 and $87,000 for the three and nine months ended September 30, 2021 and $43,000 and $1.4 million for the three and nine months ended September 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 loan forgiveness for all or a portion of PPP loans was determined, subject to limitations, based on the use of loan proceeds over the 24 weeks after the loan proceeds are disbursed. In July 2021, we received notice from the SBA that our PPP loan has been forgiven. In the third quarter of 2021, the extinguishment of the PPP loan payable was recorded as PPP loan payable forgiveness income in the statement of operations and comprehensive loss. The forgiveness of the PPP loan payable was recorded as non-cash PPP loan payable forgiveness income in the statement of cash flows.

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 September 30, 2021 and December 31, 2020 are summarized below:

Description	September 30, 2021	Level 1	Level 2	Level 3	Total Gains/(Losses)
Recurring					
Assets:					
Short-term investments	$ 23,217,000	$ -	$ 23,217,000	$ -	$ -
Non-recurring					
Assets:					
Licensed technology, net	$ 1,413,000	$ -	$ -	$ 1,413,000	$ -
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 nine months ended September 30, 2021 and 2020:

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Research and development	$ 432,000	$ 765,000	$ 1,649,000	$ 2,380,000
General and administrative	955,000	484,000	2,148,000	1,703,000
Stock option-based compensation expense included in operating expense	$ 1,387,000	$ 1,249,000	$ 3,797,000	$ 4,083,000

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 September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Expected volatility	92%	110%	97%	111%
Expected term	6.08 years	6.25 years	5.97 years	6.25 years
Risk-free interest rate	0.97%	0.16%	0.98%	0.29%
Expected dividend yield	0%	0%	0%	0%

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Options granted	1,028,000	342,100	4,383,308	3,415,146
Weighted-average:				
Exercise price	$ 1.25	$ 3.08	$ 1.86	$ 2.38
Grant date fair value	$ 0.94	$ 2.56	$ 1.44	$ 1.99

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Research and development	$ 256,000	$ 89,000	$ 1,286,000	$ 561,000
General and administrative	894,000	72,000	1,832,000	251,000
Restricted stock-based compensation expense included in operating expense	$ 1,150,000	$ 161,000	$ 3,118,000	$ 812,000

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Restricted common stock granted	767,934	-	2,743,668	1,083,313
Restricted common stock forfeited	(293,109)	(265,080)	(721,768)	(265,080)
Weighted-average:				
Grant date fair value-granted awards	$ 1.24	$ -	$ 1.77	$ 3.19
Grant date fair value-forfeited awards	$ 1.93	$ 3.18	$ 1.90	$ 3.18

NOTE 7 – COMMITMENTS AND CONTINGENCIES

Arbitration Proceeding

We were engaged in an arbitration proceeding with REGENXBIO regarding the former license agreement between us and REGENXBIO 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. 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 in connection with the parties' arbitration claims and counterclaims. The tribunal awarded REGENXBIO $28.0 million plus interest.

On August 9, 2021, we filed a second arbitration claim with the AAA asserting that a settlement had been reached before the tribunal's award in the first arbitration was issued. On September 14, 2021, REGENXBIO filed its answer, a counterclaim seeking attorney fees and costs, and a request for permission to file a case dispositive motion. A preliminary hearing was held on November 1, 2021, during which the AAA Tribunal set timetables for discovery and for REGENXBIO's filing of its case dispositive motion. Those timetables were formalized in a procedural order issued by the Tribunal on November 8, 2021. Under the schedule set by the Tribunal, REGENXBIO's opening brief in support of its case dispositive motion was filed on November 8, 2021, briefing was scheduled to be completed on December 29, 2021, and oral argument was scheduled for January 14, 2022. REGENXBIO had also filed suit in the New York State Supreme Court Commercial Division seeking enforcement of the original arbitration award, and we had requested that the Court stay that proceeding until the second arbitration is complete. Oral argument on our request for a stay was set for March 10, 2022.

On November 12, 2021, we entered into a settlement agreement ("Settlement Agreement") with REGENXBIO to resolve all current disputes between the parties including the aforementioned AAA arbitration and New York State Court action. In accordance with the Settlement Agreement, we agreed to pay REGENXBIO a total of $ 30 million, payable as follows: (1) $20 million payable within one business day of the execution of the Settlement Agreement, (2) $5 million on the first anniversary of the effective date of the Settlement Agreement, and (3) $5 million upon the earlier of: (i) the third anniversary of the effective date of the Settlement Agreement or (ii) the closing of a Strategic Transaction, as defined in the Settlement Agreement. Under the Settlement Agreement's terms, the prior license agreement between the parties was not reinstituted, and any future license agreement would need to be negotiated separately and require consideration in addition to the consideration set forth in the Settlement Agreement. As of September 30, 2021, we have recorded the payable to licensor in the balance sheet based on the present value of the payments due to REGENXBIO under the Settlement Agreement. The accounting for the Settlement Agreement resulted in a $6.7 million gain on settlement with licensor in the statement of operations and comprehensive loss during the three and nine months ended September 30, 2021 and a $6.7 million non-cash gain on settlement with licensor in the statement of cash flows during the nine months ended September 30, 2021.

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 September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Operating lease cost	$ 434,000	$ 434,000	$ 1,302,000	$ 1,302,000
Variable lease cost	$ 105,000	$ 81,000	$ 344,000	$ 256,000
Short-term lease cost	$ 13,000	$ 19,000	$ 23,000	$ 43,000

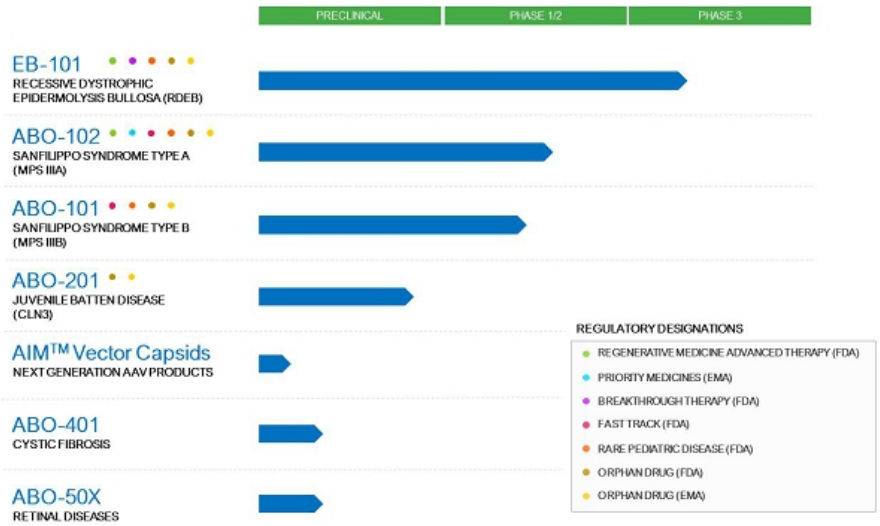
The following table presents information about the amount and timing of cash flows arising from operating leases as of September 30, 2021:

Maturity of lease liabilities:	
2021, remainder	$ 429,000
2022	1,727,000
2023	1,741,000
2024	1,781,000
2025	1,799,000
Thereafter	87,000
Total undiscounted operating lease payments	7,564,000
Less: imputed interest	1,399,000
Present value of operating lease liabilities	$ 6,165,000
Balance sheet classification:	
Current portion of lease liability	$ 1,723,000
Long-term lease liability	4,442,000
Total operating lease liabilities	$ 6,165,000
Other information:	
Weighted-average remaining lease term for operating leases	52 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 monitor the impact of the COVID-19 pandemic on our business and take appropriate actions to manage our spending activities and preserve our cash resources. While there have been vaccines developed and administered, and the spread of COVID-19 may eventually be contained or mitigated, we cannot predict the timing of vaccine adoption or roll-out globally or the efficacy of such vaccines, including against variants that emerge, and we do not yet know how businesses and our partners will operate in a post COVID-19 environment. 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 September 30, 2021 and September 30, 2020

License and other revenues for the third quarter of 2021 were nil, as compared to $7.0 million for the same period of 2020. The revenues in the third quarter of 2020 were due to the sublicense and inventory purchase agreements we entered into with Taysha Gene Therapies ("Taysha") in August 2020 for ABO-202, an AAV gene therapy for CLN1 disease (also known as infantile Batten disease). The agreements grant to Taysha worldwide exclusive rights to intellectual property developed by scientists at the University of North Carolina at Chapel Hill and us, and our know-how relating to the research, development and manufacture of the gene therapy.

Total research and development spending was $8.0 million for each of the third quarters of 2021 and 2020.

Total general and administrative spending was $6.1 million in the third quarter of 2021, as compared to $4.4 million for the same period of 2020, an increase of $1.7 million. The increase in expenses was primarily due to:

- increased stock-based compensation of $1.3 million; and
- increased professional fees of $0.7 million; partially offset by
- decreased salary and related costs of $0.3 million.

Depreciation and amortization was $0.8 million in each of the third quarters of 2021 and 2020.

Gain on settlement with licensor was $6.7 million in the third quarter of 2021, as compared to nil in the same period of 2020. On November 12, 2021, we entered into a Settlement Agreement with REGENXBIO to resolve all current disputes between us and REGENXBIO. As of September 30, 2021, we have recorded the payable to licensor in the balance sheet based on the present value of the payments due to REGENXBIO under the Settlement Agreement. The accounting for the Settlement Agreement resulted in a $6.7 million gain on settlement with REGENXBIO in the third quarter of 2021.

PPP loan payable forgiveness income was $1.8 million in the third quarter of 2021, as compared to nil in the same period of 2020. In July 2021, we received notice from the SBA that our PPP loan had been forgiven so the PPP loan payable was reversed in the third quarter of 2021.

Interest and miscellaneous income was nil for the third 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 $0.7 million for the third quarter of 2021, as compared to $1.3 million for the same period of 2020. The interest expense results from accrued interest under the prior license agreement with REGENXBIO, which is discussed in Note 3 of our Notes to Condensed Consolidated Financial Statements. The decrease results from a $0.6 million adjustment to accrued interest recorded in the third quarter of 2020 after it was determined and ordered by the American Arbitration Association ("AAA") tribunal that in accordance with the license agreement, interest should be computed without compounding.

Net loss was $7.0 million for the third quarter of 2021, or a $0.07 basic and diluted loss per common share as compared to a net loss of $7.2 million, or a $0.08 basic and diluted loss per common share, for the same period in 2020.

Comparison of Nine Months Ended September 30, 2021 and September 30, 2020

License and other revenues for the first nine months of 2021 were nil, as compared to $7.0 million for the same period of 2020. The decrease in revenue was due to the aforementioned sublicense and inventory purchase agreements we entered into with Taysha in August 2020.

Total research and development spending was $22.6 million for the first nine months of 2021, as compared to $20.9 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 and other related costs of $1.7 million.

Total general and administrative spending was $18.1 million for the first nine months of 2021, as compared to $16.4 million for the same period of 2020, an increase of $1.7 million. The increase in expenses was primarily due to:

- increased stock-based compensation of $1.9 million; and
- increased professional fees of $3.0 million; partially offset by
- decreased salary and related costs of $3.1 million resulting from severance costs of $1.3 million recorded in the first nine months of 2020 and lower compensation costs of $1.8 million due to reduced general and administrative headcount in the first nine months of 2021; and
- decreased other costs of $0.1 million.

Depreciation and amortization was $2.4 million for the first nine months of 2021, as compared to $3.7 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 nine 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.

Gain on settlement with licensor was $6.7 million in the first nine months of 2021, as compared to nil in the same period of 2020. On November 12, 2021, we entered into a Settlement Agreement with REGENXBIO to resolve all current disputes between us and REGENXBIO. As of September 30, 2021, we have recorded the payable to licensor in the balance sheet based on the present value of the payments due to REGENXBIO under the Settlement Agreement. The accounting for the Settlement Agreement resulted in a $6.7 million gain on settlement with REGENXBIO in the first nine months of 2021.

PPP loan payable forgiveness income was $1.8 million in the first nine months of 2021, as compared to nil in the same period of 2020. In July 2021, we received notice from the SBA that our PPP loan had been forgiven so the PPP loan payable was reversed in the first nine months of 2021.

Interest and miscellaneous income was nil for the first nine months of 2021, as compared to $1.3 million for the same period of 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 $3.6 million for the first nine months of 2021, as compared to $2.7 million for the same period of 2020. The increase results primarily from accrued interest under the prior license agreement with REGENXBIO, which is discussed in Note 3 of our Notes to Condensed Consolidated Financial Statements.

Net loss was $38.3 million for the first nine months of 2021, or a $0.40 basic and diluted loss per common share as compared to a net loss of $68.4 million, or a $0.74 basic and diluted loss per common share, for the same period in 2020. The decrease in the net loss resulted primarily from a licensed technology impairment charge of $32.9 million in the first nine 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 September 30, 2021 and December 31, 2020, our cash, cash equivalents and short-term investments were $67.0 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 September 30, 2021 and December 31, 2020, our working capital was $41.4 million and $55.8 million, respectively. The decrease in working capital as of September 30, 2021 resulted primarily from $35.4 million of cash used for operating activities, partially offset by $8.5 million of cash provided by financing activities and the positive impact on working capital of the Settlement Agreement with REGENXBIO as described further below.

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 were 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 3,083,286 shares of our common stock under the 2018 ATM Agreement and received $7.7 million of net proceeds during the nine months ended September 30, 2021. Cumulatively, as of September 30, 2021, we have sold an aggregate of 6,170,236 shares of our common stock under the 2018 ATM Agreement and received $27.7 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 to 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 an agreement, 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. 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 in connection with the parties' arbitration claims and counterclaims. The tribunal awarded REGENXBIO $28.0 million plus interest.

On August 9, 2021, we filed a second arbitration claim with the AAA asserting that a settlement had been reached before the tribunal's award in the first arbitration was issued. On September 14, 2021, REGENXBIO filed its answer, a counterclaim seeking attorney fees and costs, and a request for permission to file a case dispositive motion. A preliminary hearing was held on November 1, 2021, during which the AAA Tribunal set timetables for discovery and for REGENXBIO's filing of its case dispositive motion. Those timetables were formalized in a procedural order issued by the Tribunal on November 8, 2021. Under the schedule set by the Tribunal, REGENXBIO's opening brief in support of its case dispositive motion was filed on November 8, 2021, briefing was scheduled to be completed on December 29, 2021, and oral argument was scheduled for January 14, 2022. REGENXBIO had also filed suit in the New York State Supreme Court Commercial Division seeking enforcement of the original arbitration award, and we had requested that the Court stay that proceeding until the second arbitration is complete. Oral argument on our request for a stay was set for March 10, 2022.

On November 12, 2021, we entered into a settlement agreement ("Settlement Agreement") with REGENXBIO to resolve all current disputes between the parties including the aforementioned AAA arbitration and New York State Court action. In accordance with the Settlement Agreement, we agreed to pay REGENXBIO a total of $30 million, payable as follows: (1) $20 million payable within one business day of the execution of the Settlement Agreement, (2) $5 million on the first anniversary of the effective date of the Settlement Agreement, and (3) $5 million upon the earlier of: (i) the third anniversary of the effective date of the Settlement Agreement or (ii) the closing of a Strategic Transaction, as defined in the Settlement Agreement. Under the Settlement Agreement's terms, the prior license agreement between the parties was not reinstituted, and any future license agreement would need to be negotiated separately and require consideration in addition to the consideration set forth in the Settlement Agreement. As of September 30, 2021, we have recorded the payable to licensor in the balance sheet based on the present value of the payments due to REGENXBIO under 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 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 Financial 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 September 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 Financial Officer concluded that our Disclosure Controls and Procedures as of September 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 September 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 us and REGENXBIO 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. 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 in connection with the parties' arbitration claims and counterclaims. The tribunal awarded REGENXBIO $28.0 million plus interest.

On August 9, 2021, we filed a second arbitration claim with the AAA asserting that a settlement had been reached before the tribunal's award in the first arbitration was issued. On September 14, 2021, REGENXBIO filed its answer, a counterclaim seeking attorney fees and costs, and a request for permission to file a case dispositive motion. A preliminary hearing was held on November 1, 2021, during which the AAA Tribunal set timetables for discovery and for REGENXBIO's filing of its case dispositive motion. Those timetables were formalized in a procedural order issued by the Tribunal on November 8, 2021. Under the schedule set by the Tribunal, REGENXBIO's opening brief in support of its case dispositive motion was filed on November 8, 2021, briefing was scheduled to be completed on December 29, 2021, and oral argument was scheduled for January 14, 2022. REGENXBIO had also filed suit in the New York State Supreme Court Commercial Division seeking enforcement of the original arbitration award, and we had requested that the Court stay that proceeding until the second arbitration is complete. Oral argument on our request for a stay was set for March 10, 2022.

On November 12, 2021, we entered into a settlement agreement ("Settlement Agreement") with REGENXBIO to resolve all current disputes between the parties including the aforementioned AAA arbitration and New York State Court action. In accordance with the Settlement Agreement, we agreed to pay REGENXBIO a total of $30 million, payable as follows: (1) $20 million payable within one business day of the execution of the Settlement Agreement, (2) $5 million on the first anniversary of the effective date of the Settlement Agreement, and (3) $5 million upon the earlier of: (i) the third anniversary of the effective date of the Settlement Agreement or (ii) the closing of a Strategic Transaction, as defined in the Settlement Agreement. Under the Settlement Agreement's terms, the prior license agreement between the parties was not reinstituted, and any future license agreement would need to be negotiated separately and require consideration in addition to the consideration set forth in the Settlement Agreement. As of September 30, 2021, we have recorded the payable to licensor in the balance sheet based on the present value of the payments due to REGENXBIO under the Settlement Agreement. The accounting for the Settlement Agreement resulted in a $6.7 million gain on settlement with licensor in the statement of operations and comprehensive loss during the three and nine months ended September 30, 2021 and a $6.7 million non-cash gain on settlement with licensor in the statement of cash flows during the nine months ended September 30, 2021.

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 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.

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. 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. 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 in connection with the parties' arbitration claims and counterclaims. The tribunal awarded REGENXBIO $28.0 million plus interest. On August 9, 2021, we filed a second arbitration claim with the AAA asserting that a settlement had been reached before the tribunal's award in the first arbitration was issued. On September 14, 2021, REGENXBIO filed its answer, a counterclaim seeking attorney fees and costs, and a request for permission to file a case dispositive motion. A preliminary hearing was held on November 1, 2021, during which the AAA Tribunal set timetables for discovery and for REGENXBIO's filing of its case dispositive motion. Those timetables were formalized in a procedural order issued by the Tribunal on November 8, 2021. Under the schedule set by the Tribunal, REGENXBIO's opening brief in support of its case dispositive motion was filed on November 8, 2021, briefing was scheduled to be completed on December 29, 2021, and oral argument was scheduled for January 14, 2022. REGENXBIO had also filed suit in the New York State Supreme Court Commercial Division seeking enforcement of the original arbitration award, and we had requested that the Court stay that proceeding until the second arbitration is complete. Oral argument on our request for a stay was set for March 10, 2022. On November 12, 2021, we entered into a settlement agreement ("Settlement Agreement") with REGENXBIO to resolve all current disputes between the parties including the aforementioned AAA arbitration and New York State Court action. In accordance with the Settlement Agreement, we agreed to pay REGENXBIO a total of $30 million, payable as follows: (1) $20 million payable within one business day of the execution of the Settlement Agreement, (2) $5 million on the first anniversary of the effective date of the Settlement Agreement, and (3) $5 million upon the earlier of: (i) the third anniversary of the effective date of the Settlement Agreement or (ii) the closing of a Strategic Transaction, as defined in the Settlement Agreement. Under the Settlement Agreement's terms, the prior license agreement between the parties was not reinstituted, and any future license agreement would need to be negotiated separately and require consideration in addition to the consideration set forth in 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 we believe 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:

10.1	Letter Agreement, dated August 10, 2021, between the Company and Edward Carr.
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 September 30, 2021, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2021 and December 31, 2020, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2021 and 2020, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2021 and 2020, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 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: November 15, 2021

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 15, 2021

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

Exhibit 10.1

August 10, 2021

Edward Carr

Dear Edward:

This letter agreement sets forth the terms of your employment as SVP, Chief Financial Officer, effective August 10, 2021 (the "Effective Date").

1. Duties; Best Efforts.

As the SVP, Chief Financial Officer you shall have the duties, responsibilities and authority commensurate therewith, and shall report to the Chief Executive Officer of the Company (the "CEO"). You shall perform all duties and accept all responsibilities incident to such position as may be reasonably assigned to you. You represent you are not subject to or a party to any employment agreement, noncompetition covenant, or other agreement that would be breached by, or prohibit you from executing, this letter agreement ("Agreement") and performing fully your duties and responsibilities hereunder.

During your employment, you will devote your best efforts and full time and attention to promote the business and affairs of the Company and its affiliates, and shall be engaged in other business activities only to the extent that such activities do not materially interfere or conflict with your obligations to the Company hereunder, including, without limitation, the obligations pursuant to Section 4 below.

2. Compensation and Benefits.

(a) Base Salary. As of the Effective Date, you will receive an annual base salary of $400,000, as approved by the Compensation Committee (the "Compensation Committee") of the Board of Directors of the Company (the "Board") and payable in accordance with the regular payroll practices of the Company ("Base Salary").

(b) Annual Bonus. During your employment, you may be considered for an annual discretionary bonus ("Annual Bonus") in addition to your Base Salary, with a target of 40% of your Base Salary ("Target Annual Bonus Opportunity"). Annual Bonus compensation in any year, if any, will be determined in the Company's sole discretion, and shall be based on your performance and that of the Company, as well as market factors. Except as provided below under Section 3, to be eligible to receive an Annual Bonus as described above, you must be employed in good standing, and not have provided notice of resignation or been provided notice of termination, on the date that the Annual Bonus is paid.

(c) Equity Compensation. In connection with your employment, and subject to Compensation Committee discretion and approval, you will be entitled to receive (i) stock option grants to purchase shares of Company common stock and (ii) other long-term equity compensation grants (collectively, "Equity Awards") under the Abeona Therapeutics Inc. 2015 Equity Incentive Plan ("Plan"), subject to the terms and conditions of the Plan and the agreement memorializing the terms of the Equity Awards.

(d) Sign-On Equity. As approved by the Compensation Committee, in connection with execution of this Agreement you will be granted 238,000 Restricted Stock Units ("RSUs") and options under the Abeona Therapeutics 2015 Equity Incentive Plan to purchase 476,000 shares of the Company's Common Stock (the "Option Shares") at an exercise price per share equal to the Fair Market Value of a share of Common Stock (each term as defined in the Equity Incentive Plan) on the date of grant.

The Option Shares and RSUs will vest over a forty-eight (48) month period, with one quarter (25%) of vesting on the one-year anniversary of the Effective Date and the remaining seventy-five percent (75%) of the Option Shares vesting in equal installments thereafter over the remaining thirty-six (36) months – RSUs annually and Options monthly - commencing with the first such month following the first anniversary of the Effective Date.

Equity vesting is subject to your continued employment with the Company and/or its Affiliates through the applicable vesting dates, and subject to the terms and conditions of the Company's Equity Incentive Plan, except as provided below.

(e) If you remain continuously employed from the Effective Date through the date of a Change in Control (as defined below), notwithstanding the terms of any equity incentive plan or award agreements, as applicable, all outstanding unvested stock options granted to you during your employment with the Company shall become fully vested and exercisable and will remain exercisable for three (3) months following the date of a Change in Control, and all outstanding long-term equity compensation awards, other than stock options, shall become fully vested and the restrictions thereon shall lapse. Pursuant to the terms of the Plan, the exercise price of the stock options will be the fair market value of the Company's common stock on the date that the stock options were granted.

(f) Benefits. During your employment, you will be eligible to participate in such health and other group insurance and other employee benefit plans and programs of the Company as are in effect from time to time, on the same basis as those in commensurate positions of the Company. Your participation will be subject to the terms of the applicable plan documents and generally applicable Company policies. The Company reserves the right to amend or terminate any employee benefit plan, program and policy in its discretion at any time.

(g) Paid Time Off. You will be entitled to twenty (20) days of paid time off (vacation days plus sick time/personal time) per year, accrued at a rate in accordance with the Company's policies from time to time in effect, in addition to holidays observed by the Company. Paid Time Off may be taken at such times and intervals as you shall determine, subject to the business needs of the Company and the responsibilities of your position.

3. Employment Termination.

(a) Termination of Employment; Accrued Amounts. The Company may terminate your employment for any reason, and you may voluntarily terminate your employment hereunder for any reason, in each case at any time upon written notice to the other party (the date on which your employment terminates for any reason is herein referred to as the "Termination Date"). Upon the termination of your employment for any reason, you (or your beneficiary or estate, as applicable, in the event of your death) will be entitled to (i) payment of any Base Salary earned but unpaid through the Termination Date, (ii) any accrued unused vacation days, (iii) additional vested benefits (if any) in accordance with the applicable terms of applicable Company arrangements, and (iv) any unreimbursed expenses in accordance with the Company's business expense reimbursement policies (collectively, the "Accrued Amounts"), provided, however, that if your employment hereunder is terminated (A) by the Company without Cause (as defined below) or (B) by you for Good Reason (as defined below), then you will be eligible to receive any Annual Bonus awarded for a prior year, but not yet paid or due to be paid as of the Termination Date.

(b) Severance. If your employment is terminated (i) by the Company other than for Cause or (ii) by you for Good Reason (as defined below), in addition to the Accrued Amounts and in lieu of any payments or benefits under any other Company separation policy or program, you will be entitled to: (A) a payment equal to the sum of twelve (12) months of your Base Salary plus twelve (12) months of your Target Annual Bonus Opportunity (the amount of such payment, the "Severance Amount"); and (B) a payment equal to the premiums that you would pay if you elected continued health coverage under the Company's health plan for you and your eligible dependents for the twelve (12) month period following the Termination Date, less the applicable active employee rate, which premiums will be calculated based on the rate determined under the COBRA rate in effect on the Termination Date ("Medical Benefit Payment"); provided that any delays in the settlement or payment of such awards that are set forth in the applicable award agreement and that are required under Section 409A of the Internal Revenue Code, as amended (the "Code"), and the Treasury Regulations thereunder ("Section 409A") shall remain in effect. The Company's obligations to make the payments and provide the benefits set forth in (A) and (B) in this Section 3(b) shall be conditioned upon your continued compliance with your obligations under Section 4 below and your execution and nonrevocation of a release of claims in favor of the Company and its affiliates in a form provided by the Company ("Release"). Notwithstanding any provision to the contrary herein (other than the provisions of Section 7 below), and without limitation of any remedies to which the Company may be entitled, (I) the Severance Amount shall be paid in installments in accordance with the Company's regular payroll practices during a twelve (12) month period commencing within sixty (60) days following the Termination Date (with the first such payment to include all installment amounts from the Termination Date), and (II) the Medical Benefit Payment shall be paid in a lump sum within sixty (60) days following the Termination Date; provided that the Release is effective.

(c) Change in Control Termination. Notwithstanding any other provision contained herein, if your employment hereunder is terminated by you for Good Reason (as defined below) or by the Company without Cause, in each case within twelve (12) months following a Change in Control, in addition to the Accrued Amounts and in lieu of any payments or benefits under any other Company separation policy or program, you will be entitled to receive (A) a payment equal to the sum of twelve (12) months of your Base Salary plus twelve (12) months of your Target Annual Bonus Opportunity (such amount, the "CIC Severance Amount"); and (B) a payment equal to the premiums that you would pay if you elected continued health coverage under the Company's health plan for you and your eligible dependents for the twelve (12) month period following the Termination Date, less the applicable active employee rate, which premiums will be calculated based on the rate determined under the COBRA rate in effect on the Termination Date ("CIC Medical Benefit Payment"). If the Change in Control is a "change in control event" as defined under Section 409A, (I) the CIC Severance Amount shall be paid in a lump sum within sixty (60) days following the Termination Date; and (II) the CIC Medical Benefit Payment shall be paid in a lump sum within sixty (60) days following the Termination Date. The Company's obligations to provide the payments and benefits described in this Section 3(c) shall be conditioned upon your continued compliance with your obligations under Section 4 below and your execution and delivery to the Company of an effective Release.

(d) Resignation of Positions. Upon your termination of employment with the Company for any reason, you will be deemed to have resigned, as of the Termination Date, from all positions you then hold with the Company and its affiliates, and you agree to execute all documents necessary to effectuate the same.

(e) Cooperation. Following the termination of your employment with the Company for any reason, you will reasonably cooperate with the Company upon request of the CEO, General Counsel, or the Board, and be reasonably available to the Company (taking into account your other business endeavors) with respect to matters arising out of your services to the Company and its subsidiaries, including, in connection with any legal proceeding, providing testimony and affidavits; provided, that, the Company shall make reasonable efforts to minimize disruption of your other activities. The Company shall reimburse you for reasonable expenses incurred in connection with such cooperation.

(f) Definitions. For purposes of this Agreement, the following terms have the following meanings:

(i) "Cause" shall mean: (A) your substantial failure to perform your duties (other than any such failure resulting from incapacity due to physical or mental disability) that continues for fifteen (15) calendar days after written notice from the Company; (B) your failure to comply with any valid and legal directive of the CEO or the Board (as applicable) that continues for fifteen (15) calendar days after written notice from the Company; (C) your engagement in dishonesty, illegal conduct, or misconduct (or the discovery of your having engaged in such conduct in the past), which, in each case, materially harms or is reasonably likely to materially harm, reputationally, financially or otherwise, the Company or its subsidiaries; (D) your embezzlement, misappropriation, or fraud, whether or not related to your employment with the Company; (E) your conviction of or plea of guilty or nolo contendere to a crime that constitutes a felony; (F) your willful violation of a material policy of the Company; (G) your willful or grossly negligent unauthorized disclosure of Confidential Information (as defined below); or (H) your material breach of any material obligation under this Agreement or any other written agreement between you and the Company that continues for fifteen (15) calendar days after written notice from the Company (if such breach is reasonably curable); or (I) any willful material failure by you to comply with the Company's written policies or written rules, as they may be in effect from time to time.

(ii) "Change in Control" shall have the meaning defined in subparagraph (ii) of the definition of such term under the Appendix in the Plan as in effect on the date hereof.

(iii) "Good Reason" shall mean the occurrence of any of the following, in each case without your written consent: (A) a material reduction of at least ten percent (10%) of your Base Salary other than a general reduction in Base Salary that affects all similarly situated executives; (B) a material reduction of at least thirty percent (30%) of the Target Annual Bonus Opportunity other than a general reduction in the Target Annual Bonus Opportunity that affects all similarly situated executives; (C) a permanent and material relocation of your principal place of employment, which for purposes of this Agreement, means a relocation of more than fifty (50) miles; (D) any material breach by the Company of any material provision of this Agreement; or (E) a material adverse change in your title, authority, duties, or responsibilities (including the reporting structure applicable to you, other than temporarily while you are physically or mentally incapacitated); provided, however, that you cannot terminate your employment for Good Reason unless you have provided written notice to the Company of the existence of the circumstances providing grounds for termination for Good Reason within sixty (60) calendar days following the initial existence of such grounds and the Company has had thirty (30) calendar days from the date on which such notice is provided to cure such circumstances. If you do not terminate your employment for Good Reason within sixty (60) calendar days after expiration of the cure period (in which the Company shall not have so cured such grounds), then you will be deemed to have waived your right to terminate for Good Reason with respect to such grounds.

4. Restrictive Covenants.

This offer of employment is contingent on your signing the Company's Policy on Insider Trading, Whistle Blower Policy, Code of Ethics, and the standard Employee Confidentiality, Non-competition and Proprietary Information Agreement attached hereto as Exhibit A, the terms of which are incorporated herein by reference in its entirety.

5. Conditions of Employment

This offer of employment is contingent upon your providing an I-9 Employment Verification Form. You will be required to submit documentation that establishes your identity and employment eligibility in accordance with the U.S. Immigration and Naturalization requirements, if appropriate. The offer of employment contained in this Agreement, and your continued employment, are contingent upon and subject to a satisfactory background and reference check (which you hereby authorize), including but not limited to confirmation of your stated credentials. It will be in the Company's sole discretion at any time to determine the scope of the background and reference check, whether and when to conduct or update such background check and reference check, and whether such check is satisfactory.

6. At-Will Employment.

Your employment with the Company is at-will. This means that you will have the right to terminate your employment relationship with the Company at any time for any reason. Similarly, the Company will have the right to terminate its employment relationship with you at any time for any reason.

7. Section 409A.

(a) To the extent applicable, it is intended that this Agreement (including all amendments hereto, if any) either meets the requirements for exclusion from coverage under Section 409A, or alternatively complies with the requirements of Section 409A, so that the income inclusion provisions of Section 409A(a)(1) of the Code do not apply to you. This Agreement shall be interpreted and administered in a manner consistent with this intent.

(b) To the extent that payment of amounts under this Agreement that are subject to Section 409A are payable upon termination of your employment, such amounts shall only be payable if such termination also constitutes a "separation from service," within the meaning of Section 409A, from the Company and its affiliates. If you are deemed on the date of your separation from service to be a "specified employee" (within the meaning of Section 409A(a)(2)(B) of the Code) of the Company, then, notwithstanding any other provision herein, with regard to any payment that is "nonqualified deferred compensation" subject to Section 409A and that is payable on account of your "separation from service," such payment shall not be made prior to six (6) months from the date of your separation from service, following which all payments so delayed shall be paid to you in a lump sum without interest.

(c) Any taxable reimbursement of business or other expenses provided for under this Agreement that is subject to Section 409A shall be subject to the following conditions: (i) the expenses eligible for reimbursement in one taxable year shall not affect the expenses eligible for reimbursement in any other taxable year; (ii) the reimbursement of an eligible expense shall be made no later than the end of the year after the year in which such expense was incurred; and (iii) the right to reimbursement shall not be subject to liquidation or exchange for another benefit.

(d) In applying Section 409A to amounts paid pursuant to this Agreement, each payment shall be treated as a separate payment and any right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments. Whenever a payment under this Agreement specifies a payment period within a specified number of days, the actual date of payment within the specified period shall be within the sole discretion of the Company. If the consideration and revocation period for the Release spans two taxable years and any amount hereunder is "nonqualified deferred compensation" subject to Section 409A and payable on account of your separation from service, such payment shall not be made or commence until the second taxable year.

8. Section 280G.

In the event of a change in ownership or control under Section 280G of the Code, if it shall be determined that any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to or for your benefit, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "Payment"), would constitute an "excess parachute payment" within the meaning of Section 280G of the Code, the aggregate present value of the Payments under this Agreement shall be reduced (but not below zero) to the Reduced Amount (defined below) if and only if the Accounting Firm (described below) determines that the reduction will provide you with a greater net after-tax benefit than would no reduction. No reduction shall be made unless the reduction would provide you with a greater net after-tax benefit. The determinations under this Section 8 shall be made as follows:

(i) The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Payments under this Agreement without causing any Payment under this Agreement to be subject to the Excise Tax (defined below), determined in accordance with Section 280G(d)(4) of the Code. The term "Excise Tax" means the excise tax imposed under Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(ii) Payments under this Agreement shall be reduced on a nondiscretionary basis in such a way as to minimize the reduction in the economic value deliverable to you. Where more than one payment has the same value for this purpose and they are payable at different times, they will be reduced on a pro-rata basis. Only amounts payable under the Agreement shall be reduced pursuant to this Section.

(iii) All determinations to be made under this Section shall be made by an independent certified public accounting firm selected by the Company and agreed to by you immediately prior to the change in ownership or control transaction (the "Accounting Firm"). The Accounting Firm shall provide its determinations and any supporting calculations both to the Company and you within ten (10) days of the transaction. Any such determination by the Accounting Firm shall be binding upon the Company and you. All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section shall be borne solely by the Company.

9. Miscellaneous.

(a) All amounts paid to you under this Agreement during or following your employment shall be subject to withholding and other employment taxes imposed by applicable law, and the Company shall withhold from any payments under this Agreement all federal, state and local taxes that the Company is required to withhold pursuant to any law or governmental rule or regulation. You shall be solely responsible for the payment of all taxes imposed on you relating to the payment or provision of any amounts or benefits hereunder.

(b) This Agreement may be executed by PDF or facsimile signatures in any number of counterparts, each of which shall be deemed an original, but all such counterparts shall together constitute one and the same instrument.

(c) From and after the Effective Date, this Agreement (including Exhibit A hereto) constitutes the entire agreement between you and the Company, and supersedes all prior representations, agreements and understandings (including any prior course of dealings), both written and oral, between you and the Company with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and any other plan, program, practice or agreement in which you are a participant or a party, this Agreement shall control unless such other plan, program, practice or agreement is more favorable to you (term by term) or specifically refers to this Agreement as not controlling.

(d) This Agreement and any of the provisions hereof may be amended, waived (either generally or in a particular instance and either retroactively or prospectively), modified or supplemented, in whole or in part, only by written agreement signed by you and the Company. This Agreement and your rights and obligations hereunder may not be assigned by you, and any purported assignment by you in violation hereof shall be null and void. The Company is authorized to assign this Agreement to a successor to substantially all of its assets or business. Nothing in this Agreement shall confer upon any person not a party hereto, or the legal representatives of such person, any rights or remedies of any nature or kind whatsoever under or by reason of this Agreement, except the personal representative of the deceased. This Agreement shall inure to the benefit of, and be binding on, the successors and assigns of each of the parties, including, without limitation, your heirs and the personal representatives of your estate and any successor to all or substantially all of the business and/or assets of the Company.

(e) No remedy conferred upon a party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given under this Agreement or now or hereafter existing at law or in equity. Except as explicitly provided herein, no delay or omission by a party in exercising any right, remedy or power under this Agreement or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in its sole discretion.

(f) This Agreement shall be construed and enforced in accordance with the laws of the State of New York, without giving effect to the conflicts of law principles thereof.

(g) Any reference to a Section of the Code shall be deemed to include any successor to such Section.

(h) This Agreement and the compensation payable hereunder shall be subject to any applicable clawback or recoupment policies, share trading policies, and other policies that may be implemented by the Board from time to time with respect to officers of the Company.

(i) Any notices required or permitted hereunder or necessary or convenient in connection herewith shall be in writing and shall be deemed to have been given (a) when hand delivered, (b) when emailed to the email address stated below, or (c) when actually received, if notice is mailed by registered or certified mail to the physical address stated below.

If to Edward Carr:

Edward Carr
Email:

If to Company:

Abeona Therapeutics Inc.
c/o Chief Executive Officer
1330 Avenue of the Americas, 33rd Floor
New York, NY 10019
Email: legalnotice@abeonatherapeutics.com

(j) Please acknowledge your acceptance of this offer by returning a signed copy of this Agreement. If there are any other agreements of any type that you are aware of that may impact or limit your ability to perform your job at the Company, please let us know as soon as possible. In accepting this offer, you represent and warrant to the Company that you are not subject to any legal or contractual restrictions that would in any way impair your ability to perform your duties and responsibilities to the Company, and that all information you provided to the Company is accurate and complete in all respects.

Very truly yours,

/s/ Michael Amoroso
Michael Amoroso
Chief Executive Officer
Abeona Therapeutics Inc.

I accept this offer of employment with Abeona Therapeutics.

Signature: */s/ Edward Carr* Date: August 10, 2021
Edward Carr

Exhibit A

EMPLOYEE CONFIDENTIALITY, NON-COMPETITION, AND PROPRIETARY INFORMATION AGREEMENT

THIS AGREEMENT, effective as of August 10, 2021 between Abeona Therapeutics Inc., a Delaware corporation (the "Company"), and Edward Carr (the "Employee").

1. Employee will make full and prompt disclosure to the Company of all inventions, improvements, modifications, discoveries, methods, technologies, biological materials, and developments, and all other materials, items, techniques, and ideas related directly or indirectly to the business of the Company (collectively, "Intellectual Property"), whether patentable or not, made or conceived by Employee or under Employee's direction during Employee's employment with the Company, whether or not made or conceived during normal working hours, or on the premises of the Company.

2. Employee agrees that all Intellectual Property, as defined above, shall be the sole property of the Company and its assigns, and the Company and its assigns shall be the sole owner of all patents and other rights in connection therewith. Employee hereby assigns to the Company any rights Employee may have or acquire in all Intellectual Property and all related patents, copyrights, trademarks, trade names, and other industrial and intellectual property rights and applications therefore, in the United States and elsewhere. Employee further agrees that with regard to all future developments of Intellectual Property, Employee will assist the Company in every way that may be reasonably required by the Company (and at the Company's expense) to obtain and, from time to time, enforce patents on Intellectual Property in any and all countries that the Company may require, and to that end, Employee will execute all documents for use in applying for and obtaining such patents thereon and enforcing the same, as the Company may desire, together with any assignment thereof to the Company or persons designated by the Company, and Employee hereby appoints the Company as Employee's attorney to execute and deliver any such documents or assignments requested by the Company. Employee's obligation to assist the Company in obtaining and enforcing patents for Intellectual Property in any and all countries shall continue beyond the termination of Employee's employment with the Company, but the Company shall compensate Employee at a reasonable, standard hourly rate following such termination for time directly spent by Employee at the Company's request for such assistance.

3. Employee hereby represents that Employee has no continuing obligation to assign to any former employer or any other person, corporation, institution, or firm any Intellectual Property as described above. Employee represents that Employee's performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement to keep in confidence proprietary information acquired by Employee, in confidence or in trust, prior to Employee's employment by the Company. Employee has not entered into, and Employee agrees not to enter into, any agreement (either written or oral), which would put Employee in conflict with this Agreement.

4. Employee agrees to assign to the Company any and all copyrights and reproduction rights to any material prepared by Employee in connection with this Agreement and/or developed during the term of Employee's employment with the Company.

5. Employee understands and agrees that a condition of Employee's employment and continued employment with the Company is that Employee has not brought and will not bring to the Company or use in the performance of Employee's duties at the Company any materials or documents rightfully belonging to a former employer which are not generally available to the public.

6. Employee recognizes that the services to be performed by Employee hereunder are special, unique, and extraordinary and that, by reason of Employee's employment with the Company, Employee may acquire Confidential Information (as hereinafter defined) concerning the operation of the Company, the use or disclosure of which would cause the Company substantial loss and damage which could not be readily calculated and for which no remedy at law would be adequate. Accordingly, except as provided in the last Paragraph in this Section 6, Employee agrees that Employee will not (directly or indirectly) at any time, whether during or after Employee's employment with the Company:

(i) knowingly use for personal benefit or for any other reason not authorized by the Company any Confidential Information that Employee may acquire or has acquired by reason of Employee's employment with the Company, or;

(ii) disclose any such Confidential Information to any person or entity except (A) in the performance of Employee obligations to the Company hereunder, (B) as required by a court of competent jurisdiction or as permitted below, or (C) with the prior written consent of the Chief Executive Officer of the Company.

As used herein, "Confidential Information" includes, for example and without limitation, information with respect to the facilities and methods of the Company, reagents, chemical compounds, cell lines or subcellular constituents, organisms, or other biological materials, trade secrets, and other Intellectual Property, systems, patents and patent applications, procedures, manuals, confidential reports, financial information, business plans, prospects, or opportunities, personnel information, or lists of customers and suppliers; provided, however, that Confidential Information shall not include any information that is known or becomes generally known or available publicly (a) other than as a result of disclosure by Employee which is not permitted as described in clause (ii) above, (b) as a result of wrongful conduct of a third party, or (c) because the Company discloses such Confidential Information to others without obtaining an agreement of confidentiality.

Nothing in this Agreement shall prohibit or restrict Employee from lawfully (a) initiating communications directly with, cooperating with, providing information to, causing information to be provided to, or otherwise assisting in an investigation by any governmental or regulatory agency, entity, or officials, including, without limitation, the United States Food and Drug Administration (FDA), the United States Securities and Exchange Commission (SEC), or the United States Equal Employment Opportunity Commission (EEOC) (collectively, "Governmental Authorities") regarding a possible violation of any law; (b) responding to any inquiry or legal process directed to Employee individually (and not directed to the Company) from any such Governmental Authorities; (c) testifying, participating or otherwise assisting in an action or proceeding by any such Governmental Authorities relating to a possible violation of law; or (d) making any other disclosures that are protected under the whistleblower provisions of any applicable law. Notwithstanding the foregoing, Employee agrees that in making any such disclosures or communications, Employee will take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Company Confidential Information to any parties other than any Governmental Authority. Employee further understands that Employee is not permitted to disclose the Company's attorney-client privileged communications or attorney work product unless required by applicable law. Additionally, pursuant to the federal Defend Trade Secrets Act of 2016, Employee shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (i) is made (A) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made to Employee's attorney in relation to a lawsuit for retaliation against Employee for reporting a suspected violation of law; or (iii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nor does this Agreement require Employee to obtain prior authorization from the Company before engaging in any conduct described in this Paragraph, or to notify the Company that you have engaged in any such conduct.

7. During the term of Employee's employment with the Company and for one (1) year thereafter (the "Restricted Period"), the Employee shall not, without the Company's written consent, directly or indirectly, for Employee's own account or for the account of others, act as an officer, director, stockholder (other than as the holder of less than 1% of the outstanding stock of any publicly traded company), owner, partner, employee, promoter, investor, consultant, manager or otherwise participate in the promotion, financing, ownership, operation, or management of, or assist in or carry on through proprietorship, a corporation, partnership, or other form of business entity which is in competition with the Company, within the United States or any other country, in the fields of gene and cell therapy (a) that the Company is engaged in or has engaged in within one (1) year prior to the Employee's separation from the Company, or (b) in which the Company is actively seeking or planning to conduct Company Business as of the date of such termination (the "Company Business"), and (c) about which the Employee possesses or has had access to Confidential Information.

During the Restricted Period, the Employee shall not, whether for Employee's own account or for the account of any other person (excluding the Company): (i) solicit or contact in an effort to do business with any person who was or is a customer or prospective customer (i.e., any individual or entity with whom the Company was actively engaged in soliciting to do business) of the Company, or any affiliate of the Company, at the time of Employee's termination or at any time during the two (2) year period prior to Employee's termination, if such solicitation or contact is for the purpose of competition with the Company; or (ii) solicit or induce any of the Company's employees to leave their employment with the Company or accept employment with anyone else, or hire any such employees or persons who were employed by the Company during the preceding twelve (12) months.

Nothing herein shall prohibit or preclude the Employee from performing any other types of services that are not precluded by this Section 7 for any other person.

Employee has carefully read and considered the provisions of this Section 7 (including the Restricted Period, scope of activity to be restrained, and the restriction's geographical scope) and concluded them to be fair, appropriate and reasonably required for the protection of the legitimate business interests of the Company, its officers, directors, employees, creditors, and shareholders. Employee understands that the restrictions contained in this Section 7 may limit Employee's ability to engage in a business similar to the Company's business, but acknowledges that Employee will receive adequate and affluent remuneration and other benefits from the Company hereunder to justify such restrictions.

The Employee shall give prompt notice to the Company of the Employee's acceptance of employment or other fees for services relationship during the Restricted Period, which notice shall include the name of, the business of, and the position that Employee shall hold with such other employer. Employee also agrees to inform any prospective employer or business entity or person of the restrictions set forth in this Agreement prior to accepting employment or entering into any business relationship.

8. In the event that Employee's employment is transferred by the Company to a subsidiary, affiliated company, or acquiring company (as the case may be), Employee's employment by such company will, for the purpose of this Agreement, be considered as continued employment with the Company, unless Employee executes an agreement, substantially similar in substance to this Agreement, and until the effective date of said agreement in any such company for which Employee becomes employed Employee agrees to be bound by and comply with Employee's obligations under this Agreement. It is likewise agreed that no changes in Employee's position or title will operate to terminate the provisions of this Agreement unless expressly agreed to in writing.

9. Employee confirms that all Confidential Information is the exclusive property of the Company. All business records, papers, documents and electronic materials kept or made by Employee relating to the business of the Company which comprise Confidential Information shall be and remain the property of the Company during the Employee's employment and at all times thereafter. Upon the termination, for any reason, of Employee's employment with the Company, or upon the request of the Company at any time, Employee shall deliver to the Company, and shall retain no copies of any written or electronic materials, records and documents made by Employee or coming into Employee's possession concerning the business or affairs of the Company and which comprise Confidential Information. To the extent that, upon termination, Employee has any Confidential Information or other proprietary material of the Company stored within any smart phone or personal computer, email account, thumb drive or other storage device or cloud storage, Employee agrees to fully cooperate with the Company to return such information and material and subsequently permanently delete and remove such information and material from such devices (subject to any litigation preservation directive in effect), including, as necessary, providing access by the Company to such devices to ensure compliance with this Paragraph. Employee further agrees, upon termination of Employee's employment for any reason, unless such employment is transferred to a subsidiary, affiliated or acquiring company of the Company, Employee agrees to return to the Company all equipment, tools or other devices owned by the Company, that are then in Employee's possession, however such items were obtained, and Employee agrees not to reproduce or otherwise retain any document or data relating thereto.

10. Subject to Section 6 with respect to disclosure to Governmental Authorities, Employee agrees and covenants that s/he will not at any time make, publish or communicate to any person or entity or in any public forum any defamatory or disparaging remarks, comments, or statements concerning the Company or its businesses, or any of its employees, officers, and existing and prospective customers, suppliers, investors and other associated third parties.

11. Employee's obligations under this Agreement shall survive the termination of Employee's employment with the Company regardless of the manner of, and reason for, such termination or resignation, and shall be binding upon Employee's heirs, executors, and administrators.

12. Prior to entering the employ of the Company, Employee has lawfully terminated employment with all previous employers. Employee acknowledges that this Agreement does not constitute a contract of employment for a term and does not otherwise imply that the Company will continue his or her employment for any period of time, and the nature of Employee's employment with the Company is at-will.

13. Employee agrees that there is no Intellectual Property relevant to the subject matter of Employee's employment with the Company, which has been made or conceived or first reduced to practice by Employee alone or jointly with others prior to Employee's employment with the Company, which Employee desires to exclude from Employee's obligations under this Agreement.

14. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

15. Employee agrees that in addition to any other rights and remedies available to the Company for any breach or threatened breach by Employee of Employee's obligations hereunder, the Company shall be entitled to enforcement of Employee's obligations hereunder by whatever means are at the Company's disposal, including court injunction, without having to post a bond or other security. In the event of any such breach or threatened breach by Employee, the Company shall be entitled to recover all damages permitted by law in addition to its reasonably incurred costs and attorney's fees in enforcing its rights hereunder, and the Restricted Period shall be extended by the period of any such breach.

16. The Company may assign this Agreement to any other corporation or entity which acquires (whether by purchase, merger, consolidation or otherwise) all or substantially all of the business and/or assets of the Company. Employee shall have no rights of assignment.

17. If any provision of this Agreement shall be declared invalid, illegal, or unenforceable, then such provision shall be enforceable to the extent that a court deems it reasonable to enforce such provision. If such provision shall be unreasonable to enforce to any extent, such provision shall be severed and all remaining provisions shall continue in full force and effect.

18. Employee hereby acknowledges receipt of the Company's Confidentiality Policy.

19. This Agreement shall be effective as of the date set forth below next to Employee's signature.

20. This Agreement and the employment offer letter constitute the entire contract between the parties hereto with regard to the subject matter hereof. They supersede any other agreements, representations or understandings (whether oral or written and whether express or implied) which relate to the subject matter hereof.

21. This Agreement shall be governed in all respects by the laws of the State of New York. Each of the Company and Employee (a) hereby irrevocably submits to the exclusive jurisdiction of the state courts of the State of New York or the United States District Court for the Southern District of New York for the purpose of any action between the Company and Employee arising in whole or in part under or in connection with this Agreement, (b) hereby waives, to the extent not prohibited by applicable law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such action brought in one of the above-named courts should be dismissed on grounds of forum non conveniens, should be transferred or removed to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (c) hereby agrees not to commence any such action other than before one of the above-named courts. Notwithstanding the previous sentence, the Company or Employee may commence any action in a court other than the above-named courts solely for the purpose of enforcing an order or judgment issued by one of the above-named courts.

IN WITNESS WHEREOF, Employee has executed this Agreement as of the date set forth above:

EMPLOYEE

By: */s/ Edward Carr*
Name: **Edward Carr**

ACCEPTED AND AGREED TO BY THE COMPANY:

By: */s/ Michael Amoroso*
Name: **Michael Amoroso**
Title: Chief Executive 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, Vishwas Seshadri, 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: November 15, 2021

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
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: November 15, 2021

By: */s/ Edward Carr*
Edward Carr
Chief Financial 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 September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Vishwas Seshadri, President and Chief Executive Officer of the Company, and Edward Carr, Chief Financial 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: November 15, 2021

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 15, 2021

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