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

**FORM 10-Q**

(Mark one)

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

For the quarterly period ended **March 31, 2020**

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**

(State or other jurisdiction of  
incorporation or organization)

**83-0221517**

(I.R.S. Employer I.D. No.)

**1330 Avenue of the Americas, 33<sup>rd</sup> 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 Market

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

Large accelerated filer

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 Act). Yes  No

The number of shares outstanding of the registrant's common stock as of May 1, 2020 was 83,697,928 shares.

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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 III 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 III clinical trial; our pipeline of product candidates; our belief that we have sufficient resources to fund operations for the next 12 months; the dilutive effect that raising additional funds by selling additional equity securities would have on the relative equity ownership of our existing investors; our belief that EB-101 could potentially benefit patients with RDEB; our belief that adeno-associated virus ("AAV") treatment 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 trials in EB-101 and our Phase I/II clinical trial in ABO-102 (AAV-SGSH) for MPS IIIA, together with the data generated in the program to date, to support regulatory approvals; 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 Company's Form 10-K for the fiscal year ended December 31, 2019, 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 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 with our existing cash and cash equivalents; 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; 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 III 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 I/II 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 capability 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; 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

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 40,155,000	\$ 129,258,000
Short-term investments	75,887,000	-
Prepaid expenses and other current assets	<u>2,716,000</u>	<u>3,132,000</u>
Total current assets	118,758,000	132,390,000
Property and equipment, net	12,865,000	13,157,000
Right-of-use lease assets	7,802,000	8,047,000
Licensed technology, net	1,968,000	36,178,000
Goodwill	32,466,000	32,466,000
Other assets and restricted cash	1,144,000	1,144,000
Total assets	<u>\$ 175,003,000</u>	<u>\$ 223,382,000</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,763,000	\$ 3,763,000
Accrued expenses	4,852,000	5,543,000
Current portion of lease liability	1,702,000	1,699,000
Current portion of payable to licensor	28,000,000	27,400,000
Deferred revenue	<u>296,000</u>	<u>296,000</u>
Total current liabilities	36,613,000	38,701,000
Long-term lease liabilities	<u>6,013,000</u>	<u>6,251,000</u>
Total liabilities	42,626,000	44,952,000
Commitments and contingencies		
Stockholders' equity:		
Common stock - \$0.01 par value; authorized 200,000,000 shares; issued and outstanding 83,622,135 at March 31, 2020 and December 31, 2019	836,000	836,000
Additional paid-in capital	665,784,000	664,064,000
Accumulated deficit	(534,629,000)	(486,470,000)
Accumulated other comprehensive income	<u>386,000</u>	<u>-</u>
Total stockholders' equity	<u>132,377,000</u>	<u>178,430,000</u>
Total liabilities and stockholders' equity	<u>\$ 175,003,000</u>	<u>\$ 223,382,000</u>

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)

	<b>For the three months ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Revenues</b>	\$ -	\$ -
<b>Expenses:</b>		
Research and development	6,818,000	11,737,000
General and administrative	6,412,000	5,659,000
Depreciation and amortization	2,065,000	1,658,000
Licensed technology impairment charge	32,916,000	-
Total expenses	<u>48,211,000</u>	<u>19,054,000</u>
Loss from operations	(48,211,000)	(19,054,000)
Interest and miscellaneous income	652,000	499,000
Interest expense	(600,000)	-
Net loss	<u>\$ (48,159,000)</u>	<u>\$ (18,555,000)</u>
Basic and diluted loss per common share	<u>\$ (0.52)</u>	<u>\$ (0.39)</u>
Weighted average number of common shares outstanding – basic and diluted	<u>92,639,190</u>	<u>47,948,421</u>
Other comprehensive income/(loss):		
Change in unrealized gains related to available-for-sale debt securities	386,000	-
Comprehensive loss	<u>\$ (47,773,000)</u>	<u>\$ (18,555,000)</u>

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

**Abeona Therapeutics Inc. and Subsidiaries**

Condensed Consolidated Statements of Stockholders' Equity  
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2018	47,944,486	\$ 479,000	\$ 543,754,000	\$ (410,188,000)	\$ -	\$ 134,045,000
Stock option-based compensation expense	-	-	2,103,000	-	-	2,103,000
Restricted stock-based compensation expense	-	-	172,000	-	-	172,000
Common stock issued for cash exercise of options	5,208	-	28,000	-	-	28,000
Net loss	-	-	-	(18,555,000)	-	(18,555,000)
Balance, March 31, 2019	<u>47,949,694</u>	<u>\$ 479,000</u>	<u>\$ 546,057,000</u>	<u>\$ (428,743,000)</u>	<u>\$ -</u>	<u>\$ 117,793,000</u>
Balance, December 31, 2019	83,622,135	\$ 836,000	\$ 664,064,000	\$ (486,470,000)	\$ -	\$ 178,430,000
Stock option-based compensation expense	-	-	1,256,000	-	-	1,256,000
Restricted stock-based compensation expense	-	-	464,000	-	-	464,000
Net loss	-	-	-	(48,159,000)	-	(48,159,000)
Other comprehensive income	-	-	-	-	386,000	386,000
Balance, March 31, 2020	<u>83,622,135</u>	<u>\$ 836,000</u>	<u>\$ 665,784,000</u>	<u>\$ (534,629,000)</u>	<u>\$ 386,000</u>	<u>\$ 132,377,000</u>

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

**Abeona Therapeutics Inc. and Subsidiaries**

Condensed Consolidated Statements of Cash Flows  
(Unaudited)

	<b>For the three months ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (48,159,000)	\$ (18,555,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Non-cash licensed technology impairment charge	32,916,000	-
Depreciation and amortization	2,065,000	1,658,000
Stock option-based compensation expense	1,256,000	2,103,000
Restricted stock-based compensation expense	464,000	172,000
Non-cash interest expense	600,000	-
Accretion and interest on short-term investments	(109,000)	(169,000)
Accretion of right-of-use lease assets	245,000	150,000
Change in operating assets and liabilities:		
Receivables	-	43,000
Prepaid expenses and other current assets	416,000	430,000
Accounts payable, accrued expenses and lease liabilities	(2,926,000)	(910,000)
Net cash used in operating activities	<u>(13,232,000)</u>	<u>(15,078,000)</u>
<b>Cash flows from investing activities:</b>		
Capital expenditures	(479,000)	(1,226,000)
Purchases of short-term investments	(75,392,000)	-
Proceeds from maturities of short-term investments	-	24,000,000
Net cash (used in) provided by investing activities	<u>(75,871,000)</u>	<u>22,774,000</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	-	28,000
Net cash provided by financing activities	<u>-</u>	<u>28,000</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(89,103,000)	7,724,000
Cash, cash equivalents and restricted cash at beginning of period	130,368,000	19,310,000
Cash, cash equivalents and restricted cash at end of period	<u>\$ 41,265,000</u>	<u>\$ 27,034,000</u>
<i>Supplemental cash flow information:</i>		
Cash and cash equivalents	\$ 40,155,000	\$ 25,924,000
Restricted cash	1,110,000	1,110,000
Total cash, cash equivalents and restricted cash	<u>\$ 41,265,000</u>	<u>\$ 27,034,000</u>
Cash paid for interest	<u>\$ -</u>	<u>\$ -</u>

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., 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 have additional AAV-based gene therapies in various developmental stages designed to treat the CLN1 and CLN3 forms of Batten Disease, cystic fibrosis and retinal diseases. In addition, we are developing next-generation AAV-based gene therapies using our novel AIM™ capsid platform and internal AAV vector research programs. Our efforts have been principally devoted to research and development, resulting in significant losses.

#### Basis of Presentation

The condensed consolidated balance sheet as of March 31, 2020 and the condensed consolidated statements of operations and comprehensive loss, stockholders’ equity and cash flows for the three months ended March 31, 2020 and 2019 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, 2019. The results of operations for the period ended March 31, 2020 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, 2019 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 March 31, 2020, we had cash, cash equivalents and short-term investments of \$116.0 million and net assets of \$132.4 million. For the three months ended March 31, 2020, we had cash outflows from operations of \$13.2 million. We have not generated any 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 upon our current operating plans, we believe that we have sufficient resources to fund operations through the next 12 months with our existing cash and cash equivalents. We will need to secure additional funding in the future, to carry out all 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 accounting principles generally accepted in the United States of America (“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 is included in Note 6.

### Restricted Cash

In November 2016, the Financial Accounting Standards Board issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, requiring restricted cash and restricted cash equivalents to be included with cash and cash equivalents on the statement of cash flows when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We adopted this standard during the first quarter of 2018. Restricted cash is now included as a component of cash, cash equivalents and restricted cash on our consolidated statements of cash flows. Restricted cash is recorded within other assets and restricted cash in the accompanying consolidated balance sheets.

### Loss Per Common Share

We have presented basic and diluted loss per common share on the statement of operations. 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 are included in the computation of basic net loss per share as the exercise price is negligible and they are fully vested and exercisable.

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 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:

	<b>For the three months ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
Warrants	70,000	1,820,686
Stock options	6,690,814	5,696,353
<b>Total</b>	<b>6,760,814</b>	<b>7,517,039</b>

## NOTE 2 – SHORT-TERM INVESTMENTS

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

<b>Description</b>	<b>March 31, 2020</b>	<b>December 31, 2019</b>
U.S. government and agency securities and treasuries	\$ 75,887,000	\$ -

The amortized cost of the available-for-sale debt securities, which is adjusted for amortization of premiums and accretion of discounts to maturity, was \$75,501,000 as of March 31, 2020. There were no material realized gains or losses recognized on the sale or maturity of available-for-sale debt securities during the three months ended March 31, 2020 or 2019.

## 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 due on the first anniversary of the effective date of the agreement in November 2019, (ii) annual fees totaling \$100 million, payable in \$20 million annual installments beginning on the second anniversary of the effective date (the first of which remains payable if the agreement is 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 is 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 includes \$1 million of interest) due no later than April 1, 2020. The payment due by April 1, 2020 and the guaranteed amount of \$20 million due on November 4, 2020 are recorded as payable to licensor on the consolidated balance sheet.

Prior to the April 1, 2020 deadline, we engaged REGENXBIO in discussions in an attempt to renegotiate the financial terms of the agreement, but we were unable to reach a mutual understanding that we believed would have been favorable for the Company or our programs, and we did not make the \$8 million payment due by April 1, 2020. On April 17, 2020, REGENXBIO sent us a written demand for the \$8 million fee, payable within a 15-day cure period after receipt of the demand letter. The license terminated on May 2, 2020, when the 15-day period expired. We are not subject to early termination penalties, but under the agreement, REGENXBIO is still due a total of \$28 million.

As of March 31, 2020, we considered the status of our discussions with REGENXBIO as a potential indicator of impairment in accordance with ASC 360-10-35-21. Since our impairment testing indicated that the carrying value of the license agreement exceeded its fair value, we recorded a \$32.9 million non-cash impairment charge in the three months ended March 31, 2020.

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:

	<b>March 31, 2020</b>	<b>December 31, 2019</b>
Licensed technology	\$ 2,606,000	\$ 42,606,000
Less accumulated amortization	638,000	6,428,000
<b>Licensed technology, net</b>	<b>\$ 1,968,000</b>	<b>\$ 36,178,000</b>

The aggregate estimated amortization expense for intangible assets remaining as of March 31, 2020 is as follows:

2020, remainder	\$	130,000
2021		174,000
2022		174,000
2023		174,000
2024		174,000
Thereafter		1,142,000
Total	\$	<u>1,968,000</u>

Amortization on licensed technology was \$1,294,000 and \$1,345,000 for the three months ended March 31, 2020 and 2019, respectively.

#### NOTE 4 – 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 receivables, prepaid expenses, other assets, accounts payable, accrued expenses, payable to licensor and deferred revenue 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 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.

The guidance requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

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 March 31, 2020 and December 31, 2019 are summarized below:

<b>Description</b>	<b>March 31, 2020</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Recurring</b>				
Assets:				
Short-term investments	\$ 75,887,000	\$ -	\$ 75,887,000	\$ -
<b>Non-recurring</b>				
Assets:				
Licensed technology, net	\$ 1,968,000	\$ -	\$ -	\$ 1,968,000
Goodwill	32,466,000	-	-	32,466,000
<b>December 31, 2019</b>				
<b>Description</b>				
<b>Non-recurring</b>				
Assets:				
Licensed technology, net	\$ 36,178,000	\$ -	\$ -	\$ 36,178,000
Goodwill	32,466,000	-	-	32,466,000

#### NOTE 5 – STOCK-BASED COMPENSATION

The following table summarizes stock option-based compensation for the three months ended March 31, 2020 and 2019:

	<b>For the three months ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
Research and development	\$ 744,000	\$ 1,032,000
General and administrative	512,000	1,071,000
Stock option-based compensation expense included in operating expense	1,256,000	2,103,000
Total stock option-based compensation expense	1,256,000	2,103,000
Tax benefit	-	-
Stock option-based compensation expense, net of tax	\$ 1,256,000	\$ 2,103,000

*Stock Options:* 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:

	<b>For the three months ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
Expected volatility	111%	109%
Expected term	6.25 years	5 years
Risk-free interest rate	0.43%	2.46%
Expected dividend yield	0%	0%

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

	For the three months ended March 31,	
	2020	2019
Options granted	1,175,927	201,000
Weighted-average:		
Exercise price	\$ 1.45	\$ 6.69
Grant date fair value	\$ 1.21	\$ 5.29

*Restricted Common Stock:* We did not grant any shares of restricted common stock to employees during the three months ended March 31, 2020 or 2019. The following table summarizes restricted common stock compensation expense for the three months ended March 31, 2020 and 2019:

	For the three months ended March 31,	
	2020	2019
Research and development	\$ 325,000	\$ -
General and administrative	139,000	172,000
Restricted stock-based compensation expense included in operating expense	464,000	172,000
Total restricted stock-based compensation expense	464,000	172,000
Tax benefit	-	-
Restricted stock-based compensation expense, net of tax	\$ 464,000	\$ 172,000

## NOTE 6 – COMMITMENTS AND CONTINGENCIES

### 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. We can terminate the operating leases for our manufacturing and laboratory facilities and administrative offices in Cleveland early at December 31, 2020 and pay for unamortized tenant improvements.

Components of lease cost are as follows:

	For the three months ended March 31,	
	2020	2019
Operating lease cost	\$ 434,000	\$ 289,000
Variable lease cost	\$ 83,000	\$ 73,000
Short-term lease cost	\$ 18,000	\$ 47,000

The following table presents information about the amount and timing of cash flows arising from operating leases as of March 31, 2020:

Maturity of lease liabilities:	
2020, remainder	\$ 1,275,000
2021	1,713,000
2022	1,727,000
2023	1,741,000
2024	1,781,000
Thereafter	1,885,000
Total undiscounted operating lease payments	10,122,000
Less: imputed interest	2,407,000
Present value of operating lease liabilities	\$ 7,715,000

### Balance sheet classification:

Current portion of lease liability	\$ 1,702,000
Long-term lease liability	6,013,000
Total operating lease liabilities	\$ 7,715,000

### Other information:

Weighted-average remaining lease term for operating leases	70 months
Weighted-average discount rate for operating leases	9.6%

We have engaged a contract manufacturer to assist us with developing and defining the processes necessary to manufacture our RDEB product candidate. We had a remaining commitment of \$6.3 million at March 31, 2020. The amount is payable based on the completion of specific activities outlined in the contracted project plan; we expect to spend the entire \$6.3 million in 2020.

We are not currently subject to any material pending legal proceedings as of March 31, 2020.

**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 have additional AAV-based gene therapies in various developmental stages designed to treat the CLN1 and CLN3 forms of Batten Disease, cystic fibrosis and retinal diseases. Moreover, we are developing next-generation AAV-based gene therapies using our novel AIM™ capsid platform and internal AAV vector research programs. We believe our product candidates are eligible for orphan drug designation, breakthrough therapy designation, or other expedited review processes in the U.S., Europe or Japan. Our pipeline includes five product candidates for which we hold several U.S. and EU regulatory designations:



Our robust and diverse pipeline features early-stage 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 innovative research, therapies in clinical development, in-house manufacturing facilities, a robust pipeline, and scientific, clinical, and commercial leadership. We see our mission as working together to create, develop, manufacture and deliver gene and cell therapies to patients impacted by serious diseases. We partner with leading academic researchers, patient advocacy organizations and caregivers to bring therapies that address the underlying cause of a broad spectrum of rare genetic diseases where no effective treatment options exist today.

Since our last fiscal year, we made significant progress toward fulfilling our goal of harnessing the promise of genetic medicine to transform the lives of people impacted by serious diseases and redefine 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 expertise in research and development, we believe we are positioned to rapidly introduce novel therapeutics to transform the standard of care in devastating diseases and establish our leadership position in the field.

**Applying Novel Next Generation AIM™ 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 aim 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, OH facility. We believe that our platform provides us with distinct advantages, including flexibility, scale, reliability, and the potential for reduced development risk, 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 rare disease 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**

The emergence of the coronavirus (“COVID-19”) pandemic has created extraordinary challenges and uncertainty across all aspects of healthcare. We are monitoring the COVID-19 pandemic and its effects and have taken a number of measures to ensure the safety of our patients and employees while sustaining our business operations during this uncertain time. We are fully focused on getting through the pandemic by working closely with our clinical trial sites to ensure that patient safety remains paramount.

We are actively assessing the impact of the COVID-19 pandemic on our business and are taking appropriate actions to manage our spending activities and preserve our cash resources. We will continue to monitor the situation and may take further actions to adjust our business operations that we determine are in the best interests of our patients, employees, suppliers and stockholders. 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 that it is important to share where we stand today, how our response to COVID-19 is progressing and how our operations and financial condition may change as the fight against COVID-19 develops.

### Clinical Program Activities

We remain committed to advancing our clinical programs, but recognize delays are inevitable in these uncertain times, especially as global healthcare resources are justly redirected to those who need them most. We are continually assessing the dynamic situation and have implemented measures to minimize disruption. We also are regularly reassessing plans along with associated processes and policies to ensure our patients and employees are safe, and that continuity in our scaled back operations remains.

While the full impact on our clinical programs cannot be quantified at this point, all current clinical trial sites remain active, providing virtual and remote follow-up to ensure compliance with safety oversight. Nonetheless, our EB-101 clinical site at Stanford University has paused patient dosing and delays are expected as the situation evolves globally. Clinical sites involved in the studies for children with MPS IIIA and MPS IIIB remain active, but rate of enrollment has slowed due to inability of patients and their families to travel to trial sites.

### Manufacturing Activities

Operations at our Cleveland manufacturing facility have been significantly scaled back to ensure that employees and those around them have the best chance to stay safe, and to accommodate reduced manufacturing and clinical development activities. Only employees deemed essential by senior management to maintaining the manufacturing operation are entering the facility under strict safety protocols to mitigate their risk.

We have paused our manufacturing activities for EB-101 material, pending patient enrollment, as well as our AAV manufacturing and process development activities. During this pause period, we are taking the opportunity to complete maintenance and monitoring projects. We are ready to promptly resume our EB-101 manufacturing activities when patients are again ready to be treated in our phase III study as well as our AAV process development and manufacturing activities. We are expecting to resume those activities in the next few weeks but predicated on the evolution of the COVID-19 pandemic.

### Business Operations

Looking inward, the safety of our employees is a top priority. We have instituted additional protective measures since news of COVID-19 broke, and we regularly assess and improve our safety practices and policies. Aside from clinical and manufacturing operations, other business operations including regulatory, legal, finance and human resources are less impacted as remote work has continued uninterrupted.

The extent of the impact of the COVID-19 pandemic on our business, operations, and clinical trials will depend on certain developments, including: (i) the duration of the declared health emergencies; (ii) actions being taken by governmental authorities and regulators with respect to the pandemic; (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**

Total research and development spending for the first quarter of 2020 was \$6.8 million, as compared to \$11.7 million for the same period of 2019, a decrease of \$4.9 million. The decrease in expenses was primarily due to:

- decreased clinical and development work for our gene and cell therapy product candidates (\$4.5 million), partially resulting from scaled back manufacturing, clinical and non-clinical development activities following on from the effects of the COVID-19 pandemic; and
- decreased salary and related costs (\$0.4 million).

Total general and administrative expenses were \$6.4 million for the first quarter of 2020, as compared to \$5.7 million for the same period of 2019, an increase of \$0.7 million. The increase in expenses was primarily due to:

- increased salary and related costs (\$1.5 million), partially resulting from increased severance costs for certain executive positions;
- decreased professional fees (\$0.5 million);
- decreases in net other general and administrative expenses (\$0.3 million).

Depreciation and amortization were \$2.1 million for the first quarter of 2020, as compared to \$1.7 million for the same period in 2019, an increase of \$0.4 million. The increase was driven primarily by increased depreciation expense on fixed assets.

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. The cost of the license was being amortized over the life of the patent of eight years. We had been engaged in recent discussions with REGENXBIO in an attempt to renegotiate the financial terms of the agreement, but we have been unable to reach a mutual understanding that we believed would have been favorable for the Company or our programs, and we did not make an \$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 are not subject to early termination penalties, but under the Agreement, REGENXBIO is still due a total of \$28 million.

As of March 31, 2020, we considered the status of our discussions with REGENXBIO as a potential indicator of impairment in accordance with ASC 360-10-35-21. Since our impairment testing indicated that the carrying value of the license agreement exceeded its fair value, we recorded a \$32.9 million non-cash impairment charge in the first quarter of 2020.



Net loss for the first quarter of 2020 was \$48.2 million, or a \$0.52 basic and diluted loss per common share as compared to a net loss of \$18.6 million, or a \$0.39 basic and diluted loss per common share, for the same period in 2019. The increase in the net loss results primarily from a licensed technology impairment charge of \$32.9 million, partially offset by lower research and development expenses of \$4.9 million.

## 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 and cash equivalents. As of March 31, 2020 and December 31, 2019, our cash and cash equivalents were \$40.2 million and \$129.3 million, respectively.

As of March 31, 2020 and December 31, 2019, our working capital was \$82.1 million and \$93.7 million, respectively. The decrease in working capital at March 31, 2020 resulted primarily from \$13.2 million of cash used for operating activities.

On December 24, 2019, we closed an underwritten public offering of 32,382,945 shares of common stock at a public offering price of \$2.50 per share. In addition, as part of the offering, we sold to an existing investor “pre-funded” warrants to purchase up to an aggregate of 9,017,055 shares of common stock at a purchase price of \$2.4999 per pre-funded warrant, which equals the public offering price per share of the common stock less the \$0.0001 per share exercise price of each pre-funded warrant. The gross proceeds to the Company were approximately \$103.5 million, before deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company.

On August 17, 2018, we entered into an open market sale agreement with Jefferies LLC. Pursuant to the terms of this agreement, we may 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 this agreement are made under our effective “shelf” registration statement on Form S-3 that is on file with and has been declared effective by the SEC. We did not sell any shares of our common stock under this agreement during the three months ended March 31, 2020.

On November 4, 2018, we entered into a license agreement with REGENXBIO Inc. 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 due on the first anniversary of the effective date of the agreement in November 2019, (ii) annual fees totaling \$100 million, payable in \$20 million annual installments beginning on the second anniversary of the effective date (the first of which remains payable if the agreement is 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 is 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 includes \$1 million of interest) due no later than April 1, 2020. The payment due by April 1, 2020 and the guaranteed amount of \$20 million due on November 4, 2020 are recorded as payable to licensor on the consolidated balance sheet.

Prior to the April 1, 2020 deadline, we engaged REGENXBIO in discussions in an attempt to renegotiate the financial terms of the agreement, but we were unable to reach a mutual understanding that we believed would have been favorable for the Company or our programs, and we did not make the \$8 million payment due by April 1, 2020. On April 17, 2020, REGENXBIO sent us a written demand for the \$8 million fee, payable within a 15-day cure period after receipt of the demand letter. The license terminated on May 2, 2020, when the 15-day period expired. We are not subject to early termination penalties, but under the agreement, REGENXBIO is still due a total of \$28 million.

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. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit of \$534.6 million as of March 31, 2020. 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.

In light of the COVID-19 pandemic, we are carefully re-assessing key business activities and all associated spending decisions while we await clarity on the timing of re-starting our clinical trials and manufacturing activities. When those activities re-start, we expect to spend 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
- successful regulatory filings.

Due to uncertainties and certain of the risks described above, including those relating to the COVID-19 pandemic and 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, including those relating to the uncertainty of the success of our research and development activities and our ability to obtain necessary additional capital to fund operations in the future.

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

Our business and financial results are not materially affected by fluctuations in currency exchange rates or interest rates. We do not use derivative financial instruments for trading or speculative purposes.

#### *Interest Rate Risk*

Our exposure to market risk for changes in interest rates is limited to our investment portfolio. Our investment strategy has been focused on preserving capital and supporting our liquidity requirements, while earning a reasonable market return. We invest only in U.S. government, U.S. agency and U.S. treasury securities. The market value of our investments would not materially decline if current market interest rates rise given the short duration of our investments.

#### *Concentrations of Risk*

We invest excess cash in short-term, fixed-rate debt securities, and diversify the investments between financial institutions.

#### *Foreign Currency Fluctuation Risk*

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors that are located in Europe and Australia.

#### *Inflation Fluctuation Risk*

Inflation can affect us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the first quarter of 2020 or 2019.

### 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 Executive Chairman (our principal executive officer) and Chief Accounting Officer (our principal financial officer), we have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (“Disclosure Controls and Procedures”), as of March 31, 2020, 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 Executive Chairman and Chief Accounting Officer concluded that our Disclosure Controls and Procedures as of March 31, 2020 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 March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II — OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

Not Applicable.

### 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, 2019 should be carefully considered. Aside from the risk factor below, there have been no material changes in the assessment of other risk factors set forth in our 2019 Form 10-K.

***The COVID-19 pandemic and efforts to reduce its spread has affected our operations and significantly impacted worldwide economic conditions, and could have a material adverse effect on our operations, business and financial condition.***

To date, the COVID-19 pandemic has resulted in extended shutdowns of non-essential businesses throughout Europe and the United States, including in Spain and Australia, where we also conduct operations. The impact of the COVID-19 pandemic is also resulting in social, economic, and labor instability in the countries in which we, or the third parties with whom we engage, operate. Public health officials have recommended precautions to mitigate the spread of the coronavirus, including prohibitions on congregating in heavily populated areas and shelter-in-place orders. As a result, our operations at our Cleveland manufacturing facility have been significantly scaled back to ensure that our employees and those around them have the best chance to remain safe and to accommodate reduced manufacturing and clinical development activities during this uncertain time.

The COVID-19 pandemic has substantially burdened healthcare systems worldwide, delaying enrollment in and progression of many of our clinical trials. Required inspections and reviews by regulatory agencies may also be delayed due to the focus of resources on COVID-19, as well as travel and other restrictions. Significant delays in the timing of our clinical trials and in regulatory reviews could adversely affect our ability to commercialize our product candidates.

Although we remain committed to advancing our clinical programs, we recognize some delays are inevitable in light of the closure of non-essential businesses, stay at home orders, and economic impacts related to the COVID-19 pandemic, especially as healthcare resources are justly redirected to those who need them most. Many of the third parties with whom we engage, including suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, are also experiencing shutdowns or other business disruptions. We may continue to experience disruptions that could severely impact our business, supply chain, manufacturing operations, clinical trials and pre-clinical studies, including:

- continued interruption of key clinical trial activities, including continued limitations on travel imposed or recommended by federal or state governments, employers and others;
- continued delays or inability to obtain raw material or ingredients;
- continued delays or difficulties in enrolling patients in our clinical trials;
- continued delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or difficulties in manufacturing clinical drug material;
- continued diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; and
- continued limitations in employee resources that would otherwise be focused on the conduct of our manufacturing operations, clinical trials and preclinical studies, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

The ultimate impact of the COVID-19 pandemic is uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, operations, or financial condition, or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our ability to access the capital markets as needed and on our operations and business, and those of the third parties on which we rely.

*If we fail to comply with our obligations under existing license agreements, the licensor may have the right to terminate such license, in which event we would not be able to develop, manufacture, or market products covered by the license or may face other penalties under the agreements, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.*

If we fail to comply with our obligations under these license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we may face challenges for patent infringement if we continue to develop, manufacture, or market products covered by the license, or may face other penalties under the agreements. 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.

On May 2, 2020, our 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 was terminated. The Company had an \$8 million payment due on April 1, 2020 pursuant to such agreement. Prior to the April 1, 2020 deadline, the Company engaged REGENXBIO in discussions in an attempt to renegotiate the financial terms of the agreement, but the parties were unable to reach a mutual understanding that the Company believed would have been favorable for the Company or its programs, and the Company did not make the \$8 million payment due by April 1, 2020. On April 17, 2020, REGENXBIO sent the Company 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. As a result, the Company no longer has an exclusive worldwide license to REGENXBIO's NAV AAV9 vector for the development and commercialization of gene therapies for the treatment of MPS IIIA, MPS IIIB, CLN1 Disease and CLN3 Disease.

#### **ITEM 5. OTHER INFORMATION**

On November 4, 2018, the Company entered into a license agreement (as amended on November 4, 2019, "Agreement") with REGENXBIO. Under the Agreement, REGENXBIO granted the Company an exclusive worldwide license to use the NAV AAV9 vector for gene therapies for treating Sanfilippo Syndrome Type A (also known as MPS IIIA), Sanfilippo Syndrome Type B (also known as MPS IIIB), Infantile Batten Disease (also known as CLN1 disease) and Juvenile Batten Disease (also known as 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 due on the first anniversary of the effective date of the Agreement in November 2019, (ii) annual fees totaling \$100 million, payable in \$20 million annual installments beginning on the second anniversary of the effective date (the first of which remains payable if the Agreement is 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.

As previously reported, on November 4, 2019, the Company and REGENXBIO amended the Agreement to replace the \$10 million payment due to REGENXBIO on the first anniversary of the effective date with a provision under which REGENXBIO received \$3 million in 2019 and was to receive an additional \$8 million no later than April 1, 2020 (including \$1 million in interest).

Prior to the April 1, 2020 deadline, the Company engaged REGENXBIO in discussions in an attempt to renegotiate the financial terms of the agreement, but the parties were unable to reach a mutual understanding that the Company believed would have been favorable for the Company or its programs, and the Company did not make the \$8 million payment due by April 1, 2020. On April 17, 2020, REGENXBIO sent the Company 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. The Company is not subject to early termination penalties, but under the Agreement, REGENXBIO is due a total of \$28 million, including one \$20 million installment referenced in clause (ii) above, and the \$8 million payment that was due on April 1, 2020.

A description of the terms and conditions of the Agreement is set forth under Item 1.01 of the Company's Current Report on Form 8-K filed with the SEC on November 6, 2018 and is incorporated herein by reference.

## ITEM 6. EXHIBITS

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

### Exhibit Index

<u>Exhibits:</u>	
10.1	<a href="#">Letter Agreement, dated January 2, 2020, between the Company and Steven H. Rouhandeh.</a>
10.2	<a href="#">Amendment No. 1, dated March 6, 2020, to Letter Agreement, dated January 2, 2020, between the Company and Steven H. Rouhandeh.</a>
10.3	<a href="#">Letter Agreement, dated March 13, 2020, between the Company and Christine Berni Silverstein.</a>
10.4	<a href="#">Amendment No. 2, dated March 31, 2020, to Letter Agreement, dated January 2, 2020, between the Company and Steven H. Rouhandeh.</a>
31.1	<a href="#">Principal Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.</a>
31.2	<a href="#">Principal Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.</a>
32*	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101	The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at March 31, 2020 and December 31, 2019, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2020 and 2019, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2020 and 2019, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2020 and 2019, and (v) Notes to Condensed Consolidated Financial Statements.

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\* 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: May 6, 2020

By: /s/ Brian Pereira

Brian Pereira  
Executive Chairman  
(Principal Executive Officer)

Date: May 6, 2020

By: /s/ Edward Carr

Edward Carr  
Chief Accounting Officer  
(Principal Financial Officer)



**VIA ELECTRONIC MAIL AND HAND DELIVERY**

January 2, 2020

Steven H. Rouhandeh

Dear Steven:

This letter of agreement and general release ("Agreement") confirms our mutual agreement regarding the terms and conditions of your separation from employment with Abeona Therapeutics, Inc. (the "Company"). You and the Company agree as follows:

1. **Separation Date; Transition Period** - Provided you sign this Agreement, your effective date of separation from the Company will be March 31, 2020 (the "Separation Date"), unless your employment is terminated earlier as addressed below. The period between the date of this Agreement and the Separation Date will be a transition period (the "Transition Period"), during which time you agree to reasonably assist the Company with the transition of your job duties and to perform any other transition duties as may be reasonably requested by the Company (it being understood and agreed that such assistance will not require any travel or a material amount of your time) (collectively, the "Transition Duties"). The Company shall maintain, at the Company's cost and expense, your current level of benefits (health/medical and any other applicable benefits) and salary at all times during the Transition Period.
  2. **Compensation/Severance Benefits**
    - (a) On the Separation Date, the Company will pay you any unpaid base salary through the Separation Date, any accrued unused vacation days, additional vested benefits (if any) in accordance with the applicable terms of applicable Company arrangements, and any unreimbursed expenses in accordance with the Company's business expense reimbursement policies (collectively, the "Accrued Amounts").
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- (b) In addition to the Accrued Amounts, you will be entitled to: (i) a payment equal to the sum of your current base salary plus your target annual bonus for the year ended December 31, 2019, which is fifty percent (50%) of your current base salary (such amount, the "Severance Amount"); (ii) 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 twenty four (24) month period following the Separation 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 Separation Date ("Medical Benefit Payment"); (iii) an annual bonus for the year ended December 31, 2019 in an amount equal to any annual bonus payable to the Company's Chief Executive Officer for such year, (iv) a pro-rata annual bonus for the year ending December 31, 2020 in an amount equal to the annual bonus amount payable to the Chief Executive Officer for such year, multiplied by a fraction, the numerator of which is the number of days during which you were employed by the Company in the year in which the Separation Date occurs and the denominator of which is three hundred sixty-five (365); (v) an option grant prior to the Separation Date in an amount, and with the same terms, as any option granted to the Company's Chief Executive Officer prior to the Separation Date, and (vi) accelerated vesting equivalent to twenty-four (24) months of continued service to the Company, whether as an employee, a member of the Board of Directors or, at the discretion of the Company, as a consultant, from the date you are no longer providing any such service to the Company (disregarding such termination for such purpose), with respect to all unvested equity and any other long-term incentive awards granted to you and then outstanding on such date, including any awards made on or after January 1, 2020; 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 (i) – (vi) in this Paragraph shall be conditioned upon your continued compliance with your obligations under Section 3 below and your execution and nonrevocation of a release of claims in favor of the Company and its affiliates in the form substantially similar to Attachment A (the "Final Release").

Notwithstanding any provision to the contrary herein, and without limitation of any remedies to which the Company may be entitled, (A) 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 Separation Date (with the first such payment to include all installment amounts from the Separation Date), (B) the Medical Benefit Payment will be made in a lump sum within sixty (60) days following the Separation Date, (C) the annual bonus for the year ended December 31, 2019 shall be paid to you in the ordinary course at the same time annual bonuses are paid to other senior executives, but in no event later than March 15, 2020, and (D) the pro-rated annual bonus for the year ending December 31, 2020 shall be paid to you in the ordinary course at the same time annual bonuses are paid to other senior executives, but in no event later than March 15, 2021; provided, that, the Release is effective.

3. **Release** – In consideration of your continued employment with the Company through the Transition Period and your eligibility to receive payment of the severance benefits described in Paragraph 2, both of which you acknowledge you would not otherwise be entitled to receive, you waive, subject to Paragraph 3a below, all claims available under federal, state or local law against the Company and the directors, officers, employees, employee benefit plans and agents of the Company arising out of your employment with the Company or the termination of that employment, including but not limited to all claims arising under the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Civil Rights Act of 1991, the Employee Retirement Income Security Act ("ERISA"), the Equal Pay Act, the Genetic Information Non-discrimination Act, the Family and Medical Leave Act, Section 1981 of U.S.C, Title VII of the Civil Rights Act; the New York State Human Rights Law, the New York State Executive Law, the New York State Civil Rights Law, the retaliation provisions of the New York State Workers' Compensation Law, the New York Labor Law, the New York City Human Rights Law, and the New York City Administrative Code; as well as wrongful termination claims, breach of contract claims, discrimination claims, harassment claims, retaliation claims, whistleblower claims (to the fullest extent they may be released under applicable law), defamation or other tort claims, and claims for attorneys' fees and costs.
- a. The only claims not being waived, released and discharged by this Agreement are (i) those that relate to your rights and remedies under this Agreement, (ii) any rights to indemnification exculpation and/or contribution to which you are entitled as of the date hereof pursuant to the Company's and its affiliates organizational documents, any indemnification or similar agreement or applicable law (and any rights under any insurance policies of the Company or its affiliates), and (iii) those that cannot be waived as a matter of applicable law; any claims you may have to government-sponsored and administered benefits such as unemployment insurance, workers' compensation insurance (excluding claims for retaliation under workers' compensation laws), state disability insurance and paid family leave insurance benefits; and any benefits that vested on or prior to the Separation Date pursuant to a written benefit plan sponsored by the Company and governed by the ERISA.
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- b. Nothing in this Agreement prevents you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits or personal relief in connection with any such claim, charge or proceeding).
  - c. You hereby represent that you have not instituted, assisted or otherwise participated in connection with, any action, complaint, claim, charge, grievance, arbitration, lawsuit or administrative agency proceeding, or action at law or otherwise against the Company or any other member of the Company or any of their respective shareholders, officers, employees, directors, shareholders or agents.
4. **Post-Separation Obligations/Non-Disparagement** - Subject to Paragraph 5, you acknowledge and reaffirm your obligation to keep confidential and not to disclose any and all non-public information concerning the Company that you acquired during the course of your employment with the Company, including, but not limited to, any non-public information concerning the Company's business affairs, business prospects and financial condition. You agree that you will not make any public statement intended to disparage the Company. The Company agrees that it will not issue or authorize any public statement intended to disparage you.
5. **Disclosure Exceptions** - Nothing in this Agreement or the Final Release shall prohibit or restrict you 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 official(s) (collectively, "Governmental Authorities") regarding a possible violation of any law; (B) responding to any inquiry or legal process directed to you individually (and not directed to the Company and/or its subsidiaries) 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. Additionally, pursuant to the federal Defend Trade Secrets Act of 2016, you shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made to your attorney in relation to a lawsuit for retaliation against you for reporting a suspected violation of law; or (c) 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 you 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.
6. **Amendment** - This Agreement and the Final Release shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by the parties hereto or their duly authorized representatives. This Agreement and the Final Release are binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators.
7. **Confidentiality of this Agreement** - Subject to Paragraph 5, you understand and agree that in exchange for the consideration set forth above, both during the Transition Period and thereafter, the terms and conditions of this Agreement, the Final Release, and the contents of any negotiations and discussions resulting in this Agreement and the Final Release, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed to any third party except (i) to the extent required by federal or state law or otherwise agreed to in writing by the Company or (ii) in connection with the enforcement of your rights under this Agreement; provided that you and the Company shall be entitled to make third parties (including your prospective employers) aware of this Agreement and your obligations under this Agreement (including those set forth in Paragraph 14 hereof).
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8. **Nature of Agreement** - You understand and agree that this Agreement and the Final Release represent a severance agreement and do not constitute an admission of liability or wrongdoing on the part of the Company.
  9. **Acknowledgments**- You acknowledge that you are being provided at least twenty-one (21) days to consider this Agreement, including all attachments hereto, and that the Company hereby advises you to consult with an attorney of your own choosing prior to signing this Agreement. You understand that you may revoke this Agreement for a period of seven (7) days after execution, and the Agreement shall not be effective or enforceable until the expiration of this seven (7) day period. You understand and agree that by entering into this Agreement you are waiving any and all rights or claims you may have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled. You agree that changes to this Agreement, whether material or immaterial, do not restart the running of the 21-day consideration period.
  10. **Taxes** – All payments hereunder will be subject to applicable deductions and withholdings. You shall bear all expense of, and be solely responsible for, all federal, state and local taxes due with respect to any payment received under this Agreement. This Agreement shall be interpreted to avoid any penalty sanctions under Section 409A. If any payment or benefit cannot be provided or made at the time specified herein without incurring sanctions under Section 409A, then such benefit or payment shall be provided in full (to extent not paid in part at earlier date) at the earliest time thereafter when such sanctions will not be imposed. For purposes of Section 409A, all payments to be made upon a termination of employment under this Agreement may only be made upon the your “separation from service” (within the meaning of such term under Section 409A) and each payment made under this Agreement shall be treated as a separate payment. In no event shall you, directly or indirectly, designate the calendar year of payment, except as permitted under Section 409A. The Company will assist you by preparing an analysis under IRS Code Section 1202 to determine which, if any, of your shares qualify for tax treatment under Section 1202.
  11. **Further Cooperation** – You agree that, during and after the term of this Agreement, you will make yourself available, upon reasonable notice and under reasonable conditions, to assist the Company in any capacity with respect to matters of which you were involved or had knowledge while employed by the Company. To that end, you agree to cooperate with the Company in connection with any pending or future investigation or pending or threatened litigation matters, lawsuits or administrative proceedings in which the Company believes you are an individual with knowledge concerning the subject thereof. In particular, but without limitation, you agree to make yourself available for meetings, interviews, depositions, and court appearances, as reasonably requested by the Company, and to otherwise reasonably assist the Company in connection with any such investigation or litigation, or other proceedings. You also agree to provide the Company with any and all documents which may be in your possession that may concern the subject matter of any pending or future investigation or litigation. You understand that the Company will reimburse you for all reasonable, documented out-of-pocket expenses incurred as a result of my obligations under this paragraph in accordance with the Company’s then-applicable Expense Guidelines.
  12. **Exercise of Stock Options** – You understand that you are not entitled to any future grants of stock or stock options. In accordance with the Stock Option Agreement and Prospectus, you understand that up to and including the Separation Date, all stock options that have vested as of the Separation Date, if any, must be exercised by the earlier of 24 months of the Separation Date or the expiration of the option. You further understand that following the Separation Date, all stock options that vested as of the Separation Date, if any, must be exercised within 24 months of the Separation Date. You further understand that upon death or disability, all stock options that have vested as of the Separation Date, if any, must be exercised within twenty-four months of said death or disability.
  13. **Agreement Not to Seek Rehire** – You agree that, without prior written Company approval, you will not seek or accept employment with the Company (including all subsidiaries and affiliates), including assignment to or on behalf of the Company as an independent contractor or through any third party, and the Company has no obligation to consider you for any future employment or assignment.
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14. **Restrictive Covenants**

- (a) **Non-Competition** – In consideration for the promises made by the Company herein, you agree that you shall not, during the 47 week period after the Separation Date (the “Restriction Period”), directly or indirectly, own, manage, operate, join, control, be employed by, or participate in the ownership, management, operation or control of, or be connected in any manner with, including, without limitation, holding any position as a stockholder, director, officer, consultant, independent contractor, employee, partner, or investor in, any Restricted Enterprise (as defined below); provided, that in no event shall ownership by you of two percent (2%) or less of the outstanding securities of any class of any issuer whose securities are registered under the Securities Exchange Act of 1934, as amended, standing alone, be prohibited by this Paragraph 14, so long as you do not have, or exercise, any rights to manage or operate the business of such issuer other than rights as a stockholder thereof. For purposes of this paragraph, “Restricted Enterprise” shall mean any person or entity that, on the Separation Date, is engaged, directly or indirectly, in a business of developing or commercializing biopharmaceutical therapies for those therapeutic indications that the Company or its subsidiaries has either commercialized products or programs in pre-clinical or clinical development or has undertaken material efforts to so engage on the Separation Date, in any country or territory in which on the Separation Date the Company or any of its affiliates markets any of its services or products or has material plans to begin marketing any of its services or products in such country or territory; provided, that if such business of any such person or entity which otherwise would be a Restricted Enterprise is immaterial to the other businesses of such person or entity and part of a separate division or subsidiary from that which you are then employed, then such person or entity shall not be deemed to be a Restricted Enterprise.
- (b) **Non-Solicitation of Employees** – During the Restriction Period, you shall not directly or indirectly, hire, contact, recruit, induce or solicit (or assist any person to hire, contact, induce or solicit) for employment or other services any person who is, or within twelve (12) months prior to the date of such hiring, contacting, inducing or solicitation was, an employee, independent contractor, or consultant of the Company or any of its subsidiaries. For purposes of this Paragraph 14, independent contractors and consultants refer to such persons, companies, or entities that on or prior to the Separation Date performed services related to the business of the Company.
- (c) **Non-Solicitation of Customers** – During the Restriction Period, you shall not directly or indirectly, solicit, contact (including but not limited to e-mail, regular mail, express mail, telephone, fax, and instant message), attempt to contact, or meet with the Company’s current, former, or prospective customers for purposes of offering or accepting goods or services for Restricted Enterprises or cause any such customer to terminate or diminish their commercial relationship with the Company. For purposes of this Agreement, a “prospective customer” is any person or entity with whom the Company is or was engaged in material communications with respect to potential business transactions at the time of employment termination or six (6) months prior to date of the Termination Date.

15. **Entire Agreement** – This Agreement sets forth the entire agreement and understanding of the parties hereto with respect to the matters covered hereby and supersedes and replaces any express or implied prior agreement with respect to the terms of your employment and the termination thereof which you may have had with the Company (including, without limitation, the Retention Agreement (other than Section 3 thereof, which will remain in full force and effect)). This Agreement may be amended only by a written document signed by the parties hereto.

16. **Voluntary Assent** – You affirm that you have read this Agreement, and understand all of its terms, including the full and final release of claims set forth in Paragraph 3. You further acknowledge that you have voluntarily entered into this Agreement; that you have not relied upon any representation or statement, written or oral, not set forth in this Agreement; that the only consideration for signing this Agreement is as set forth herein; and that this document gives you the opportunity and encourages you to have this Agreement reviewed by your attorney and/or tax advisor.

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17. **Waiver** – The failure of either party to this Agreement to enforce any of its terms, provisions or covenants will not be construed as a waiver of the same or of the right of such party to enforce the same. Waiver by either party hereto of any breach or default by the other party of any term or provision of this Agreement will not operate as a waiver of any other breach or default.
18. **Severability** – In the event that any provision of this Agreement is held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remainder of this Agreement will not in any way be affected or impaired thereby. If any provision of this Agreement is held to be excessively broad as to duration, activity or subject, such provision will be construed by limiting and reducing it so as to be enforceable to the maximum extent allowed by applicable law.
19. **Counterparts** – This Agreement may be executed in one or more counterparts, which together will constitute one and the same agreement.
20. **Notices** – All notices, demands, requests or other communications which may be or are required to be given, served, or sent by a party pursuant to this Agreement shall be in writing and shall be hand delivered (including delivery by courier), mailed by first-class, registered or certified mail, return-receipt requested, postage prepaid, or transmitted by telegram, telex or facsimile transmission, addressed as follows:

If to the Company:

Abeona Therapeutics  
1330 Avenue of the Americas  
New York, NY 10019  
Attention: Kristina Maximenko, HR  
Telephone: (781) 267-4056  
Email: kmaximenko@abeonatherapeutics.com

If to you:

At your address on file with the Company.

Each party may designate by notice in writing a new address to which any notice, demand, request or communication may thereafter be so given, served or sent

21. **Applicable Law** - This Agreement shall be governed by the laws of New York without reference to that jurisdiction's choice of law rules.

If you have any questions about the matters covered in this Agreement, please contact me at (203) 747 0604.

Very truly yours,

Abeona Therapeutics, Inc.

By: /s/ Mark J. Alvino

Name: Mark J. Alvino

Title: Chair, Compensation Committee

I hereby agree to the terms and conditions set forth above. I intend that this Agreement become a binding agreement between me and the Company. I further understand that payment of the consideration and other benefits described herein is conditioned upon my timely execution, return and non-revocation of this Agreement and the Final Release.

By: /s/ Steven H. Rouhandeh  
Steven H. Rouhandeh

Date: January 2, 2020

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**ATTACHMENT A**

**FINAL RELEASE OF CLAIMS**

1. **Release** - In consideration of the severance benefits set forth in the Agreement to which this Final Release of Claims (the "Final Release") is attached, which you acknowledge you would not otherwise be entitled to receive, you waive, subject to the exceptions specified below, all claims available under federal, state or local law against the Company and the directors, officers, employees, employee benefit plans and agents of the Company arising out of your employment with the Company or the termination of that employment, including but not limited to all claims arising under the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Civil Rights Act of 1991, the Employee Retirement Income Security Act ("ERISA"), the Equal Pay Act, the Genetic Information Non-discrimination Act, the Family and Medical Leave Act, Section 1981 of U.S.C. Title VII of the Civil Rights Act; the New York State Human Rights Law, the New York State Executive Law, the New York State Civil Rights Law, the retaliation provisions of the New York State Workers' Compensation Law, the New York Labor Law, the New York City Human Rights Law, and the New York City Administrative Code; as well as wrongful termination claims, breach of contract claims, discrimination claims, harassment claims, retaliation claims, whistleblower claims (to the fullest extent they may be released under applicable law), defamation or other tort claims, and claims for attorneys' fees and costs.

The only claims not being waived, released and discharged by this Final Release are (i) those that relate to your rights and remedies under this Agreement, (ii) any rights to the indemnification exculpation and/or contribution to which you are entitled as of the date hereof pursuant to the Company's and its affiliates organizational documents, any indemnification or similar agreement or applicable law (and any rights under the insurance policies of the Company or its affiliates) and (iii) those that cannot be waived as a matter of applicable law; any claims you may have to government-sponsored and administered benefits such as unemployment insurance, workers' compensation insurance (excluding claims for retaliation under workers' compensation laws), state disability insurance and paid family leave insurance benefits; and any benefits that vested on or prior to the Separation Date pursuant to a written benefit plan sponsored by the Company and governed by ERISA.

Nothing in this Final Release prevents you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such claim, charge or proceeding).

2. **Business Expenses and Compensation** - You acknowledge that you have been reimbursed by the Company for all business expenses incurred in conjunction with the performance of your employment and that no other reimbursements are owed to you. You further acknowledge that you have received payment in full for all services rendered in conjunction with your employment by the Company and that no other compensation is owed to you except as provided in the Agreement.
  3. **Return of Company Property** - You agree that you have returned all Company property, including but not limited to keys, ID card, cell phone, PDA, thumb drive, and Company documents and information (either hard copy or electronic) other than records related solely to your own compensation or benefits. To the extent you have any Company material or information stored on any personal electronic devices, you represent and warrant that you have destroyed all such information currently known to you (subject to any litigation preservation directive then in effect) and that you will cooperate with the Company to ensure the return and permanent deletion of all such material and information discovered in the future.
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4. **Acknowledgments** - You acknowledge that you are being provided twenty-one (21) days to consider this Final Release and that the Company hereby advises you to consult with an attorney of your own choosing prior to signing this Final Release. You understand that you may revoke this Final Release for a period of seven (7) days after you sign it by notifying me in writing, and the Final Release shall not be effective or enforceable until the expiration of this seven (7) day revocation period. You understand and agree that by entering into this Final Release, you are waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled.
  
5. **Incorporation by Reference** - This Final Release incorporates by reference, as if set forth fully herein, all terms and conditions of the January 2, 2020 Agreement between you and the Company, including the recitation of consideration provided by the Company. By signing this Final Release, you hereby waive, release and forever discharge any and all claims that may have arisen through the date of your execution of this Final Release. You acknowledge that this Final Release is not intended to otherwise change, alter or amend any of the terms and conditions of the January 2, 2020 Agreement, for which you received adequate consideration, and which Agreement remains in full force and effect. You acknowledge and agree that you continue to be bound by the terms and conditions of the January 2, 2020 Agreement.

*I hereby provide this Final Release as of the current date and acknowledge that the execution of this Final Release is in further consideration of the severance benefits to which I acknowledge I would not be entitled if I did not sign this Final Release. I intend that this Final Release become a binding agreement between the Company and me if I do not revoke my acceptance in seven (7) days.*

\*\* /s/ \*\*

\_\_\_\_\_

\*\*NAME\*\*

\_\_\_\_\_

Date

To be signed and returned within 21 days after the Separation Date, ***but not before*** the Separation Date.

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**Amendment No. 1  
to  
Separation Agreement**

**March 6, 2020**

Reference is hereby made to that certain Separation Agreement between Abeona Therapeutics, Inc. (the “**Company**”) and Steven Rouhandeh (the “**Executive**”), dated January 2, 2020 (the “**Separation Agreement**”).

WHEREAS, the Company and the Executive desire to amend the Separation Agreement,

NOW THEREFORE, the parties hereby agree as follows:

1. Section 2(b)(ii) is hereby replaced in its entirety with the following:

(ii) The Company shall, at its expense, continue your current level of health coverage under the Company’s health plan for the twenty-four (24) month period following the Separation Date (“**Medical Benefit Payment**”).

2. A new Section 2(c) is hereby added to the Separation Agreement:

(c) The parties hereby agree that the Company shall provide to the Executive the exclusive use of his current office at 1330 Avenue of the Americas, New York, NY (or, if the Company relocates its executive offices, a reasonably similar office) and continued use of his Company computer and email address, company phone, filing space and office services at the same level as currently in place until the later of (i) two years from the date that the Executive is no longer a Director of the Company and (ii) April 1, 2022.

ACCEPTED AND AGREED:

Abeona Therapeutics, Inc.

*/s/ Mark J. Alvino*

By: Mark J. Alvino  
Title: Chair Comp. Comm

*/s/ Steven H. Rouhandeh*

Steven H. Rouhandeh







**VIA ELECTRONIC MAIL AND HAND DELIVERY**

March 13, 2020

Christine Silverstein

Dear Christine:

This letter of agreement and general release ("Agreement") confirms our mutual agreement regarding the terms and conditions of your transition period with Abeona Therapeutics, Inc. (the "Company"). You and the Company agree as follows:

1. **Transition Date; Transition Period** – Given your effective date of resignation of March 31, 2020, should you sign this Agreement, your effective date of transition from the Company will be June 30, 2020 (the "Transition Date"). The period between the date of this Agreement and the Transition Date will be a transition period (the "Transition Period"), during which time you agree to reasonably assist the Company with the transition of your job duties and to perform any other transition duties as may be reasonably requested by the Company (it being understood and agreed that such assistance will not require any travel or a material amount of your time) (collectively, the "Transition Duties"). The Company shall maintain, at the Company's cost and expense, your current level of benefits (health/medical and any other applicable benefits) and salary at all times during the Transition Period.
  2. **Compensation/Transition Period Benefits**
    - (a) The Company will pay your current annual base salary through the Transition Date in accordance with the Company's usual payroll guidelines and practices.
    - (b) On the next payroll date following the Transition Date, you will be paid an amount equal to \$80,000 in respect of to your prorated target bonus for 2020.
    - (c) You will further be paid for any accrued but unused vacation days, and will be reimbursed for previously submitted, but un-reimbursed, business expenses in accordance with the Company's usual guidelines and practices.
    - (d) Following your Transition Date, provided that: (i) you have satisfactorily performed the Transition Duties set forth in Paragraph 1 in all material respects and complied with your other obligations under this Agreement in all material respects, including your obligations under Section 4 below (it being understood and agreed that the Company will provide you written notice of any such non-compliance and that you will be deemed to have complied with any such obligations if you cure such non-compliance, if curable, within five (5) days following the receipt of such notice); (ii) you have executed this Agreement on or before March 31, 2020, and you did not exercise your right to revoke during the 7-day revocation period specified in Paragraph 9; and (iii) you execute a formal release in a form substantially similar to Attachment A (the "Final Release") on, and not before, the Transition Date, and you do not exercise your right to revoke during the 7-day revocation period specified in Attachment A, in consideration for your release and waiver of claims and other commitments set forth herein and in Attachment A:
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- (i) The Company will pay you transition pay in the form of a twelve (12) week continuation of your base salary, less all applicable state and federal taxes and withholdings (such twelve (12) week period, the "Transition Period"). The transition pay will be paid as salary continuation in accordance with the Company's normal payroll practices.
- (ii) The Company shall make a lump-sum payment within 30 days following the Transition Date equal to the COBRA premiums that you would pay if you elected continued health coverage under the Company's health plan for you and your dependents for the three-month period following the Transition Date, based on the COBRA rates in effect at the Transition Date.
- (e) You will be entitled to receive your vested accrued benefits, if any, under the Company's 401(k) plan in accordance with the terms and conditions of such plan.

You will not be eligible for, nor shall you have a right to receive, any payments from the Company following the Transition Date other than, as applicable, the amounts set forth in subparagraphs (a), (b), (c), (d) and (e) above or except as otherwise agreed upon in writing by the Company and except as set forth in paragraph 4 below.

3. Release — In consideration of your continued employment with the Company through the Transition Period and your eligibility to receive payment of the severance benefits described in Paragraph 2, both of which you acknowledge you would not otherwise be entitled to receive, you waive, subject to Paragraph 3a below, all claims available under federal, state or local law against the Company and the directors, officers, employees, employee benefit plans and agents of the Company arising out of your employment with the Company or the termination of that employment, including but not limited to all claims arising under the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Civil Rights Act of 1991, the Employee Retirement Income Security Act ("ERISA"), the Equal Pay Act, the Genetic Information Non-discrimination Act, the Family and Medical Leave Act, Section 1981 of U.S.C, Title VII of the Civil Rights Act; the New York State Human Rights Law, the New York State Executive Law, the New York State Civil Rights Law, the retaliation provisions of the New York State Workers' Compensation Law, the New York Labor Law, the New York City Human Rights Law, and the New York City Administrative Code; as well as wrongful termination claims, breach of contract claims, discrimination claims, harassment claims, retaliation claims, whistleblower claims (to the fullest extent they may be released under applicable law), defamation or other tort claims, and claims for attorneys' fees and costs.
- a. The only claims not being waived, released and discharged by this Agreement are (i) those that relate to your rights and remedies under this Agreement, (ii) any rights to indemnification exculpation and/or contribution to which you are entitled as of the date hereof pursuant to the Company's and its affiliates organizational documents, any indemnification or similar agreement or applicable law (and any rights under any insurance policies of the Company or its affiliates), and (iii) those that cannot be waived as a matter of applicable law; any claims you may have to government-sponsored and administered benefits such as unemployment insurance, workers' compensation insurance (excluding claims for retaliation under workers' compensation laws), state disability insurance and paid family leave insurance benefits; and any benefits that vested on or prior to the Transition Date pursuant to a written benefit plan sponsored by the Company and governed by the ERISA.
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- b. Nothing in this Agreement prevents you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits or personal relief in connection with any such claim, charge or proceeding).
- c. You hereby represent that you have not instituted, assisted or otherwise participated in connection with, any action, complaint, claim, charge, grievance, arbitration, lawsuit or administrative agency proceeding, or action at law or otherwise against the Company or any other member of the Company or any of their respective shareholders, officers, employees, directors, shareholders or agents.

4. **Post-Separation Obligations/Non-Disparagement**

(a) Subject to Paragraph 5, you acknowledge and reaffirm your obligation to keep confidential and not to disclose any and all non-public information concerning the Company that you acquired during the course of your employment with the Company, including, but not limited to, any nonpublic information concerning the Company's business affairs, business prospects and financial condition. You agree that you will not make any public statement intended to disparage the Company. The Company agrees that it will not issue or authorize any public statement intended to disparage you.

5. **Disclosure Exceptions** - Nothing in this Agreement or the Final Release shall prohibit or restrict you 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 official(s) (collectively, "Governmental Authorities") regarding a possible violation of any law; (B) responding to any inquiry or legal process directed to you individually (and not directed to the Company and/or its subsidiaries) 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. Additionally, pursuant to the federal Defend Trade Secrets Act of 2016, you shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made to your attorney in relation to a lawsuit for retaliation against you for reporting a suspected violation of law; or (c) 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 you 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.

6. **Amendment**- This Agreement and the Final Release shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by the parties hereto or their duly authorized representatives. This Agreement and the Final Release are binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators.
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7. **Confidentiality of this Agreement** - Subject to Paragraph 5, you understand and agree that in exchange for the consideration set forth above, both during the Transition Period and thereafter, the terms and conditions of this Agreement, the Final Release, and the contents of any negotiations and discussions resulting in this Agreement and the Final Release, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed to any third party except (i) to the extent required by federal or state law or otherwise agreed to in writing by the Company or (ii) in connection with the enforcement of your rights under this Agreement; provided that you and the Company shall be entitled to make third parties (including your prospective employers) aware of this Agreement and your obligations under this Agreement (including those set forth in Paragraph 14 hereof).
  8. **Nature of Agreement** - You understand and agree that this Agreement and the Final Release represent a severance agreement and do not constitute an admission of liability or wrongdoing on the part of the Company.
  9. **Acknowledgments** - You acknowledge that you are being provided at least twenty one (21) days to consider this Agreement, including all attachments hereto, and that the Company hereby advises you to consult with an attorney of your own choosing prior to signing this Agreement. You understand that you may revoke this Agreement for a period of seven (7) days after execution, and the Agreement shall not be effective or enforceable until the expiration of this seven (7) day period. You understand and agree that by entering into this Agreement you are waiving any and all rights or claims you may have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled. You agree that changes to this Agreement, whether material or immaterial, do not restart the running of the 21-day consideration period.
  10. **Taxes** — All payments hereunder will be subject to applicable deductions and withholdings. You shall bear all expense of, and be solely responsible for, all federal, state and local taxes due with respect to any payment received under this Agreement. This Agreement shall be interpreted to avoid any penalty sanctions under Section 409A of the Internal Revenue Code (the "Code"). If any payment or benefit cannot be provided or made at the time specified herein without incurring sanctions under Section 409A of the Code, then such benefit or payment shall be provided in full (to extent not paid in part at earlier date) at the earliest time thereafter when such sanctions will not be imposed. For purposes of Section 409A of the Code, all payments to be made upon a termination of employment under this Agreement may only be made upon the your "separation from service" (within the meaning of such term under Section 409A of the Code) and each payment made under this Agreement shall be treated as a separate payment. In no event shall you, directly or indirectly, designate the calendar year of payment, except as permitted under Section 409A of the Code.
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11. **Further Cooperation** — You agree that, during and after the term of this Agreement, you will make yourself available, upon reasonable notice and under reasonable conditions, to assist the Company in any capacity with respect to matters of which you were involved or had knowledge while employed by the Company. To that end, you agree to cooperate with the Company in connection with any pending or future investigation or pending or threatened litigation matters, lawsuits or administrative proceedings in which the Company believes you are an individual with knowledge concerning the subject thereof. In particular, but without limitation, you agree to make yourself available for meetings, interviews, depositions, and court appearances, as reasonably requested by the Company, and to otherwise reasonably assist the Company in connection with any such investigation or litigation, or other proceedings. You also *agree* to provide the Company with any and all documents which may be in your possession that may concern the subject matter of any pending or future investigation or litigation. You understand that the Company will reimburse you for all reasonable, documented out-of-pocket expenses incurred as a result of my obligations under this paragraph in accordance with the Company's then-applicable Expense Guidelines.
  12. **Exercise of Stock Options** — You understand that you are not entitled to any future grants of stock or stock options. In accordance with the Stock Option Agreements and Prospectus, you understand that all stock options will continue to vest only during the time that you are an officer, director or advisor to the Company (including during the 3 month period that you assisting with the transition of duties to the Company under Section 4(b) of this Agreement). After such time, any options will cease to vest and must be exercised by the earlier of (a) 12 months after you are no longer an officer, director or advisor to the Company (the "Exercise Period") or (b) the expiration of the option. You further understand that upon death or disability, all stock options that have vested as of such date, if any, must be exercised within twelve months of said death or disability.
  13. **Agreement Not to Seek Rehire** — You agree that, without prior written Company approval, you will not seek or accept employment with the Company (including all subsidiaries and affiliates), including assignment to or on behalf of the Company as an independent contractor or through any third party, and the Company has no obligation to consider you for any future employment or assignment.
  14. **Restrictive Covenants** – The below are the only restrictive covenants that are applicable to you.
    - (a) **Non-Competition** — In consideration for the promises made by the Company herein, you agree that you shall not, during the 12 week period after the Transition Date (the "Restriction Period"), directly or indirectly, own, manage, operate, join, control, be employed by, or participate in the ownership, management, operation or control of, or be connected in any manner with, including, without limitation, holding any position as a stockholder, director, officer, advisor, independent contractor, employee, partner, or investor in, any Restricted Enterprise (as defined below); provided, that in no event shall ownership by you of two percent (2%) or less of the outstanding securities of any class of any issuer whose securities are registered under the Securities Exchange Act of 1934, as amended, standing alone, be prohibited by this Paragraph 14, so long as you do not have, or exercise, any rights to manage or operate the business of such issuer other than rights as a stockholder thereof. For purposes of this paragraph, "Restricted Enterprise" shall mean any person or entity that, on the Transition Date, is engaged, directly or indirectly, in a business of developing or commercializing biopharmaceutical therapies for those therapeutic indications that the Company or its subsidiaries has either commercialized products or programs in clinical development or has undertaken material efforts to so engage on the date of this agreement, in any country or territory in which on the date of this agreement the Company or any of its affiliates markets any of its services or products or has material plans to begin marketing any of its services or products in such country or territory; provided, that if such business of any such person or entity which otherwise would be a Restricted Enterprise is immaterial to the other businesses of such person or entity and part of a separate division or subsidiary from that which you are then employed, then such person or entity shall not be deemed to be a Restricted Enterprise.
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- (b) **Non-Solicitation of Employees** — During the Restriction Period, you shall not directly or indirectly, hire, contact, recruit, induce or solicit (or assist any person to hire, contact, induce or solicit) for employment or other services any person who is, or within twelve (12) months prior to the date of such hiring, contacting, inducing or solicitation was, an employee, independent contractor, or consultant of the Company or any of its subsidiaries. For purposes of this Paragraph 14, independent contractors and consultants refer to such persons, companies, or entities that on or prior to the Transition Date performed services related to the business of the Company.
- (c) **Non-Solicitation of Customers** — During the Restriction Period, you shall not directly or indirectly, solicit, contact (including but not limited to e-mail, regular mail, express mail, telephone, fax, and instant message), attempt to contact, or meet with the Company’s current, former, or prospective customers for purposes of offering or accepting goods or services for Restricted Enterprises or cause any such customer to terminate or diminish their commercial relationship with the Company. For purposes of this Agreement, a “prospective customer” is any person or entity with whom the Company is or was engaged in material communications with respect to potential business transactions at the time of employment termination or six (6) months prior to date of the Transition Date.
15. **Entire Agreement** — This Agreement sets forth the entire agreement and understanding of the parties hereto with respect to the matters covered hereby and supersedes and replaces any express or implied prior agreement with respect to the terms of your employment and the termination thereof which you may have had with the Company (including, without limitation, the Retention Agreement (other than Section 3 thereof, which will remain in full force and effect)). This Agreement may be amended only by a written document signed by the parties hereto.
16. **Voluntary Assent** — You affirm that you have read this Agreement, and understand all of its terms, including the full and final release of claims set forth in Paragraph 3. You further acknowledge that you have voluntarily entered into this Agreement; that you have not relied upon any representation or statement, written or oral, not set forth in this Agreement; that the only consideration for signing this Agreement is as set forth herein; and that this document gives you the opportunity and encourages you to have this Agreement reviewed by your attorney and/or tax advisor.
17. **Waiver**— The failure of either party to this Agreement to enforce any of its terms, provisions or covenants will not be construed as a waiver of the same or of the right of such party to enforce the same. Waiver by either party hereto of any breach or default by the other party of any term or provision of this Agreement will not operate as a waiver of any other breach or default.
18. **Severability** — In the event that any provision of this Agreement is held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remainder of this Agreement will not in any way be affected or impaired thereby. If any provision of this Agreement is held to be excessively broad as to duration, activity or subject, such provision will be construed by limiting and reducing it so as to be enforceable to the maximum extent allowed by applicable law.
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19. **Counterparts**— This Agreement may be executed in one or more counterparts, which together will constitute one and the same agreement.
20. **Notices**— All notices, demands, requests or other communications which may be or are required to be given, served, or sent by a party pursuant to this Agreement shall be in writing and shall be hand delivered (including delivery by courier), mailed by first-class, registered or certified mail, return-receipt requested, postage prepaid, or transmitted by telegram, telex or facsimile transmission, addressed as follows:

If to the Company:

Abeona Therapeutics  
1330 Avenue of the Americas  
New York, NY 10019  
Attention: Kristina Maximenko, HR  
Telephone: (781) 267-4056  
Email: [lcmaximenko@abeonatherapeutics.com](mailto:lcmaximenko@abeonatherapeutics.com)

If to you:

At your address on file with the Company.

Each party may designate by notice in writing a new address to which any notice, demand, request or communication may thereafter be so given, served or sent

21. **Applicable Law** - This Agreement shall be governed by the laws of New York without reference to that jurisdiction's choice of law rules.

Very truly yours,

Abeona Therapeutics, Inc.

By: /s/ Steven H. Rouhandeh  
Steven H. Rouhandeh  
Executive Chairman

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I hereby agree to the terms and conditions set forth above. I intend that this Agreement become a binding agreement between me and the Company. I further understand that payment of the consideration and other benefits described herein is conditioned upon my timely execution, return and non-revocation of this Agreement and the Final Release.

/s/ Christine Silverstein

Date: March 14, 2020

Christine Silverstein

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**ATTACHMENT A**

**FINAL RELEASE OF CLAIMS**

1. **Release** - In consideration of the transition benefits set forth in the Agreement to which this Final Release of Claims (the "Final Release") is attached, which you acknowledge you would not otherwise be entitled to receive, you waive, subject to the exceptions specified below, all claims available under federal, state or local law against the Company and the directors, officers, employees, employee benefit plans and agents of the Company arising out of your employment with the Company or the termination of that employment, including but not limited to all claims arising under the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Civil Rights Act of 1991, the Employee Retirement Income Security Act ("ERISA"), the Equal Pay Act, the Genetic Information Non-discrimination Act, the Family and Medical Leave Act, Section 1981 of U.S.C, Title VII of the Civil Rights Act; the New York State Human Rights Law, the New York State Executive Law, the New York State Civil Rights Law, the retaliation provisions of the New York State Workers' Compensation Law, the New York Labor Law, the New York City Human Rights Law, and the New York City Administrative Code; as well as wrongful termination claims, breach of contract claims, discrimination claims, harassment claims, retaliation claims, whistleblower claims (to the fullest extent they may be released under applicable law), defamation or other tort claims, and claims for attorneys' fees and costs.

The only claims not being waived, released and discharged by this Final Release are (i) those that relate to your rights and remedies under this Agreement, (ii) any rights to the indemnification exculpation and/or contribution to which you are entitled as of the date hereof pursuant to the Company's and its affiliates organizational documents, any indemnification or similar agreement or applicable law (and any rights under the insurance policies of the Company or its affiliates) and (iii) those that cannot be waived as a matter of applicable law; any claims you may have to government-sponsored and administered benefits such as unemployment insurance, workers' compensation insurance (excluding claims for retaliation under workers' compensation laws), state disability insurance and paid family leave insurance benefits; and any benefits that vested on or prior to the Transition Date pursuant to a written benefit plan sponsored by the Company and governed by ERISA.

Nothing in this Final Release prevents you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such claim, charge or proceeding).

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2. **Business Expenses and Compensation** - You acknowledge that you have been reimbursed by the Company for all business expenses incurred in conjunction with the performance of your employment and that no other reimbursements are owed to you. You further acknowledge that you have received payment in full for all services rendered in conjunction with your employment by the Company and that no other compensation is owed to you except as provided in the Agreement.
3. **Return of Company Property** - You agree that you have returned all Company property, including but not limited to keys, **ID** card, cell phone, PDA, thumb drive, and Company documents and information (either hard copy or electronic) other than records related solely to your own compensation or benefits. To the extent you have any Company material or information stored on any personal electronic devices, you represent and warrant that you have destroyed all such information currently known to you (subject to any litigation preservation directive then in effect) and that you will cooperate with the Company to ensure the return and permanent deletion of all such material and information discovered in the future.
4. **Acknowledgments** - You acknowledge that you are being provided twenty-one (21) days to consider this Final Release and that the Company hereby advises you to consult with an attorney of your own choosing prior to signing this Final Release. You understand that you may revoke this Final Release for a period of seven (7) days after you sign it by notifying me in writing, and the Final Release shall not be effective or enforceable until the expiration of this seven (7) day revocation period. You understand and agree that by entering into this Final Release, you are waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled.

*I hereby provide this Final Release as of the current date and acknowledge that the execution of this Final Release is in further consideration of the severance benefits to which I acknowledge I would not be entitled if I did not sign this Final Release. I intend that this Final Release become a binding agreement between the Company and me if I do not revoke my acceptance in seven (7) days.*

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Christine Silverstein

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Date

To be signed and returned within 21 days after the Transition Date, but not before the Transition Date

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**Amendment No. 2  
to  
Separation Agreement**

**March 31, 2020**

Reference is hereby made to that certain Separation Agreement between Abeona Therapeutics, Inc. (the “**Company**”) and Steven Rouhandeh (the “**Executive**”), dated January 2, 2020 (the “**Separation Agreement**”).

WHEREAS, the Company and the Executive desire to amend the Separation Agreement, as amended

NOW THEREFORE, the parties hereby agree as follows:

1. The first sentence of Section 1 is hereby amended with the following:

“Your effective date of separation from the Company will be the earlier of (a) June 30, 2020 or (b) the date that the Board appoints a new Executive Chairman of the Company (the “Separation Date”).

ACCEPTED AND AGREED:

Abeona Therapeutics, Inc.

*/s/ Mark J. Alvino*

By: Mark J. Alvino  
Title: Chair Comp. Comm

*/s/ Steven H. Rouhandeh*

Steven H. Rouhandeh

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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, Brian Pereira, 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: May 6, 2020

By: /s/ Brian Pereira  
Brian Pereira  
Executive Chairman  
(Principal Executive Officer)

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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: May 6, 2020

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

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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 March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Brian Pereira, Executive Chairman of the Company, and Edward Carr, Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: May 6, 2020

By: /s/ Brian Pereira  
Brian Pereira  
Executive Chairman  
(Principal Executive Officer)

Date: May 6, 2020

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

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