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, 2019
or

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

For the transition period from _____ to _____

Commission file number **001-15771**

ABEONA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

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

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

(646) 813-4712
(Registrant's telephone number, including area code)

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 ☑

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

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

The number of shares outstanding of the registrant's common stock as of May 6, 2019 was 49,162,047 shares.

ABEONA THERAPEUTICS INC.

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CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING INFORMATION FOR THE PURPOSE OF "SAFE HARBOR" PROVISIONS OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This Form 10-Q (including information incorporated by reference) contains statements that express our 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. We caution readers not to place undue reliance on any such "forward-looking statements," which speak only as of the date made, and advise readers that these forward-looking statements are not guarantees of future performance and involve certain risks, uncertainties, estimates, and assumptions by us that are difficult to predict. Various factors, some of which are beyond our control, could cause actual results to differ materially from those expressed in, or implied by, such forward-looking statements. All such forward-looking statements, whether written or oral, and whether made by us or on our behalf, are expressly qualified by these cautionary statements and any other cautionary statements that may accompany the 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 the forward-looking statements due to a number of factors. Important factors that could affect performance and cause results to differ materially from management's expectations are described in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Form 10-K for the fiscal year ended December 31, 2018, as updated from time to time in the Company's Securities and Exchange Commission filings, including this Form 10-Q. These factors include: 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 expectation that we will continue to incur losses; our belief that we will expend substantial funds to conduct research and development programs; our future ability to achieve profitability at all or on a sustained basis; our cash burn rate; 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 we have a rich pipeline of products and product candidates; our ability to continue to develop our novel adeno-associated virus ("AAV")-based gene therapy platform technology to treat neurologic disorders, cystic fibrosis and eye disorders in human subjects; our belief that EB-101 could potentially benefit patients with recessive dystrophic epidermolysis bullosa ("RDEB"); our ability to initiate 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 belief that AAV treatment could potentially benefit patients with Sanfilippo syndrome type A ("MPS IIIA") and Sanfilippo syndrome type B ("MPS IIIB"); our ability to add clinical sites and 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 therapy products and produce an adequate product supply to support clinical trials and potentially future commercialization; our ability to secure timely regulatory review related to our clinical program; our belief in the adequacy of the data from clinical trials in EB-101 and expansion cohort of 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 intellectual property position and our ability to obtain, maintain and enforce intellectual property protection and exclusivity for our proprietary assets; the rate and degree of market acceptance of our product candidates for any indication once approved; 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; our ability to meet our obligations contained in license agreements to which we are party; and the terms of future licensing arrangements or collaborations.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,924,000	$ 18,750,000
Short-term investments	42,387,000	66,218,000
Receivables	38,000	81,000
Prepaid expenses and other current assets	3,372,000	3,802,000
Total current assets	71,721,000	88,851,000
Property and equipment, net	10,356,000	9,443,000
Right-of-use lease assets	8,749,000	-
Licensed technology, net	41,697,000	43,042,000
Goodwill	32,466,000	32,466,000
Other assets and restricted cash	1,147,000	597,000
Total assets	$ 166,136,000	$ 174,399,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,189,000	$ 6,122,000
Accrued expenses	5,241,000	3,936,000
Current portion of lease liability	1,690,000	-
Current portion of payable to licensor	10,000,000	10,000,000
Deferred revenue	296,000	296,000
Total current liabilities	21,416,000	20,354,000
Long-term lease liabilities	6,927,000	-
Payable to licensor, net of current portion	20,000,000	20,000,000
Total liabilities	48,343,000	40,354,000
Commitments and contingencies		
Stockholders' equity:		
Common stock - $0.01 par value; authorized 200,000,000 shares; issued and outstanding 47,949,694 at March 31, 2019; issued and outstanding 47,944,486 at December 31, 2018	479,000	479,000
Additional paid-in capital	546,057,000	543,754,000
Accumulated deficit	(428,743,000)	(410,188,000)
Total stockholders' equity	117,793,000	134,045,000
Total liabilities and stockholders' equity	$ 166,136,000	$ 174,399,000

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Operations
(Unaudited)

	For the three months ended March 31,	
	2019	**2018**
Revenues:		
Foundation revenues	$ -	$ 481,000
Royalties	-	50,000
Total revenues	-	531,000
Expenses:		
Research and development	11,737,000	8,162,000
General and administrative	5,659,000	2,878,000
Depreciation and amortization	1,658,000	174,000
Total expenses	19,054,000	11,214,000
Loss from operations	(19,054,000)	(10,683,000)
Interest and miscellaneous income	499,000	156,000
Interest and other expense	-	(3,000)
Net loss	$ (18,555,000)	$ (10,530,000)
Basic and diluted loss per common share	$ (0.39)	$ (0.22)
Weighted average number of common shares outstanding – basic and diluted	47,948,421	47,060,523

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2017 - as reported	46,888,108	$ 469,000	$ 529,421,000	$ (359,792,000)	$ 170,098,000
Cumulative effect adjustment of ASC 606 on January 1, 2018	-	-	-	6,275,000	6,275,000
Stock-based compensation expense	-	-	1,900,000	-	1,900,000
Restricted stock-based compensation expense	-	-	172,000	-	172,000
Common stock issued for:					
- cash exercise of options	267,196	3,000	1,682,000	-	1,685,000
- exercise of $5.00 warrants	28,874	-	144,000	-	144,000
- cashless warrant exercises	48,762	-	-	-	-
Net loss	-	-	-	(10,530,000)	(10,530,000)
Balance, March 31, 2018	47,232,940	$ 472,000	$ 533,319,000	$ (364,047,000)	$ 169,744,000
Balance, December 31, 2018 - as reported	47,944,486	$ 479,000	$ 543,754,000	$ (410,188,000)	$ 134,045,000
Stock-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	47,949,694	$ 479,000	$ 546,057,000	$ (428,743,000)	$ 117,793,000

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For the three months ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (18,555,000)	$ (10,530,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,658,000	174,000
Stock-based compensation expense	2,103,000	1,900,000
Restricted stock-based compensation expense	172,000	172,000
Non-cash earnings on investments	(169,000)	-
Change in operating assets and liabilities:		
Receivables	43,000	43,000
Prepaid expenses and other current assets	430,000	643,000
Right-of-use lease assets and other assets	150,000	-
Accounts payable, accrued expenses and lease liabilities	(910,000)	3,516,000
Net cash used in operating activities	(15,078,000)	(4,082,000)
Cash flows from investing activities:		
Capital expenditures	(1,226,000)	(3,502,000)
Proceeds from maturities of short-term investments	24,000,000	-
Net cash provided by (used in) investing activities	22,774,000	(3,502,000)
Cash flows from financing activities:		
Proceeds from exercise of $5.00 warrants	-	144,000
Proceeds from exercise of stock options	28,000	1,685,000
Net cash provided by financing activities	28,000	1,829,000
Net increase (decrease) in cash, cash equivalents and restricted cash	7,724,000	(5,755,000)
Cash, cash equivalents and restricted cash at beginning of period	19,310,000	138,030,000
Cash, cash equivalents and restricted cash at end of period	$ 27,034,000	$ 132,275,000
Supplemental cash flow information:		
Cash and cash equivalents	$ 25,924,000	$ 131,995,000
Restricted cash	1,110,000	280,000
Total cash, cash equivalents and restricted cash	$ 27,034,000	$ 132,275,000
Cash paid for interest	$ -	$ 3,000

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 programs include EB-101, an autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa ("RDEB"), ABO-102, an adeno-associated virus ("AAV")-based gene therapy for Sanfilippo syndrome type A ("MPS IIIA"), and ABO-101 an AAV-based gene therapy for Sanfilippo syndrome type B ("MPS IIIB"). We also are developing ABO-202 and ABO-201, which are AAV-based gene therapies for the CLN1 and CLN3 forms of Batten Disease, respectively, ABO-401 for the treatment of cystic fibrosis, and ABO-5OX for the treatment of retinal diseases. In addition, we are developing next generation AAV-based gene therapy though our novel AIM™ vector platform 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, 2019, the condensed consolidated statements of operations for the three months ended March 31, 2019 and 2018, the condensed consolidated statements of stockholders' equity for the three months ended March 31, 2019 and 2018, and the condensed consolidated statements of cash flows for the three months ended March 31, 2019 and 2018, 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, 2018. The results of operations for the period ended March 31, 2019 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, 2018 contains financial information taken from the audited Abeona consolidated financial statements as of that date.

As of March 31, 2019, we had 5,696,353 options and 1,820,686 warrants that were not included in the EPS calculation as their effect would be antidilutive. As of March 31, 2018, we had 5,807,531 options and 2,838,576 warrants that were not included in the EPS calculation as their effect would be antidilutive.

Effective January 1, 2018, we adopted Accounting Standards Update ("ASU") 2014-09,*Revenue from Contracts with Customers*, as amended (ASC 606). At year-end 2018, we determined that we should adjust the amounts originally reported for the quarters ended March 31, 2018 and June 30, 2018 to correct for an error in the determination of the cumulative effect related to the adoption of ASC 606 as of January 1, 2018. The adjusted amounts for March 31, 2018 reflect a $2,067,000 reduction in foundation revenues and corresponding increases in the loss from operations and net loss of $2,067,000 and an increase in the diluted loss per share of $0.04, as compared to the originally reported amounts. The adjusted amounts for June 30, 2018 reflect a $543,000 reduction in foundation revenues and corresponding increases in the loss from operations and net loss of $543,000 and an increase in the diluted loss per share of $0.01, as compared to the originally reported amounts

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, 2019, we had cash, cash equivalents and short-term investments of $68.3 million and net assets of $117.8 million. For the three months ended March 31, 2019, we had cash outflows from operations of $15.1 million. We believe we have sufficient resources to fund our business operations for the foreseeable future. However, we have implemented a multi-faceted program to secure sufficient liquidity through at least the end of 2020.

This program considers the possibility of accessing 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. We believe that we will be able to complete our liquidity program and will have sufficient funding to support planned expenditure commitments and our planned level of growth, and therefore we believe it is appropriate to prepare the financial statements on the going concern basis.

NOTE 2 – NEW ACCOUNTING STANDARD IMPLEMENTED

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, *Leases*, as amended ("ASC 842"), which requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous guidance. We adopted the provisions of ASC 842 effective January 1, 2019 using the cumulative-effect adjustment transition method, which applies the provisions of the standard as of the effective date without adjusting the comparative periods presented. As a result of the adoption, we recorded operating lease right-of-use assets of $8.9 million and operating lease liabilities of $8.9 million. The adoption had an immaterial impact on our net assets as of March 31, 2019. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which allowed us to carry forward the historical lease classification.

Additional information and disclosures required by this new standard are contained in Note 7.

NOTE 3 – SHORT-TERM INVESTMENTS

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

Description	March 31, 2019	December 31, 2018
U.S. government and agency securities and treasuries	$ 42,387,000	$ 66,218,000

The amortized cost of the available-for-sale investments is adjusted for amortization of premiums and accretion of discounts to maturity. There were no material realized gains or losses recognized on the sale or maturity of available-for-sale investments during the three months ended March 31, 2019.

NOTE 4 – LICENSED TECHNOLOGY

On November 4, 2018, we entered into a license agreement with REGENXBIO to obtain rights to an exclusive worldwide license (subject to certain non-exclusive rights previously granted for MPS IIIA), with rights to sublicense, to REGENXBIO's NAV AAV9 vector for the development and commercialization of gene therapies for the treatment of MPS IIIA, MPS IIIB, CLN1 Disease and CLN3 Disease. In return for these rights, REGENXBIO will receive a guaranteed $20 million upfront payment, $10 million of which was paid on signing of the agreement on November 4, 2018 and $10 million of which will be paid by November 4, 2019. In addition, REGENXBIO will receive a total of $100 million in annual fees, payable upon the second through sixth anniversaries of the agreement, $20 million of which is guaranteed. REGENXBIO is also eligible to receive potential commercial milestone payments of up to $60 million as well as low double-digit royalties on net sales of products incorporating the licensed intellectual property. The license is amortized over the life of the patent of eight years.

On August 3, 2016, we announced that we entered into an agreement (the "EB Agreement") with EB Research Partnership ("EBRP") and Epidermolysis Bullosa Medical Research Foundation ("EBMRF") to collaborate on gene therapy treatments for EB. The EB Agreement became effective August 3, 2016, on the execution of two licensing agreements with The Board of Trustees of Leland Stanford Junior University ("Stanford"). We also entered into a license with Stanford for the AAV-based gene therapy EB-201 (AAV DJ COL7A1) technology and are performing preclinical development and clinical trials of a gene therapy treatment for EB based upon such in-licensed technology. EB-201 (AAV DJ COL7A1) is a preclinical candidate targeting a novel, AAV-mediated gene editing and delivery approach (known as homologous recombination) to correct gene mutations in skin cells (keratinocytes) for patients with RDEB. The licenses are amortized over the life of the license of 20 years.

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:

	March 31, 2019	December 31, 2018
Licensed technology	$ 44,859,000	$ 44,859,000
Less accumulated amortization	3,162,000	1,817,000
Licensed technology, net	$ 41,697,000	$ 43,042,000

The aggregate estimated amortization expense for intangible assets remaining as of March 31, 2019 is as follows:

2019, remainder	$ 4,033,000
2020	5,378,000
2021	5,378,000
2022	5,378,000
2023	5,378,000
Thereafter	16,152,000
Total	$ 41,697,000

Amortization on licensed technology was $1,345,000 and $87,000 for the three months ended March 31, 2019 and 2018, respectively.

NOTE 5 – FAIR VALUE MEASUREMENTS

We calculate the fair value of our assets and liabilities that qualify as financial instruments and include additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of 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, 2019 and December 31, 2018 are summarized below:

Description	March 31, 2019	Level 1	Level 2	Level 3	Total Gains/(Losses)
Recurring					
Assets:					
Short-term investments	$ 42,387,000	$ -	$ 42,387,000	$ -	$ -
Non-recurring					
Assets:					
Licensed technology, net	$ 41,697,000	$ -	$ -	$ 41,697,000	$ -
Goodwill	32,466,000	-	-	32,466,000	-

Description	December 31, 2018	Level 1	Level 2	Level 3	Total Gains/(Losses)
Recurring					
Assets:					
Short-term investments	$ 66,218,000	$ -	$ 66,218,000	$ -	$ -
Non-recurring					
Assets:					
Licensed technology, net	$ 43,042,000	$ -	$ -	$ 43,042,000	$ -
Goodwill	32,466,000	-	-	32,466,000	-

NOTE 6 – STOCK-BASED COMPENSATION

The following table summarizes stock-based option compensation for the three months ended March 31, 2019 and 2018:

	For the three months ended March 31,	
	2019	2018
Research and development	$ 1,032,000	$ 1,056,000
General and administrative	1,071,000	844,000
Stock-based compensation expense included in operating expense	2,103,000	1,900,000
Total stock-based compensation expense	2,103,000	1,900,000
Tax benefit	-	-
Stock-based compensation expense, net of tax	$ 2,103,000	$ 1,900,000

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

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

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

	For the three months ended March 31,	
	2019	2018
Expected volatility	109%	109%
Expected term	5 years	5 years
Risk-free interest rate	2.46%	2.37%
Expected dividend yield	0%	0%

For the three months ended March 31, 2019, we granted 201,000 stock options and the weighted-average fair value was $5.29 and the weighted-average exercise price was $6.69. For the three months ended March 31, 2018, we granted 645,000 stock options and the weighted-average fair value was $10.83 and the weighted-average exercise price was $13.72.

The following table summarizes restricted common stock compensation expense for the three months ended March 31, 2019 and 2018:

	For the three months ended March 31,	
	2019	2018
Research and development	$ -	$ -
General and administrative	172,000	172,000
Stock-based compensation expense included in operating expense	172,000	172,000
Total stock-based compensation expense	172,000	172,000
Tax benefit	-	-
Stock-based compensation expense, net of tax	$ 172,000	$ 172,000

We did not grant any common stock to directors or employees during the three months ended March 31, 2019 and 2018.

NOTE 7 – OPERATING LEASES

We lease space under non-cancelable operating leases for manufacturing and laboratory facilities and administrative offices in Cleveland as well as administrative offices in New York. The 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. We also lease office space in Dallas and 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.

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.

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 the lease payments.

Components of lease cost are as follows:

	Three months ended March 31, 2019
Operating lease cost	$ 289,000
Variable lease cost	$ 73,000
Short-term lease cost	$ 47,000

The following table presents information about the amount and timing of cash flows arising from operating leases as of March 31, 2019:

Maturity of lease liabilities:	
2019, remainder	$ 1,266,000
2020	1,699,000
2021	1,713,000
2022	1,727,000
2023	1,741,000
Thereafter	3,667,000
Total undiscounted operating lease payments	11,813,000
Less: imputed interest	3,196,000
Present value of operating lease liabilities	$ 8,617,000
Balance sheet classification:	
Current portion of lease liability	$ 1,690,000
Long-term lease liability	6,927,000
Total operating lease liabilities	$ 8,617,000
Other information:	
Weighted-average remaining lease term for operating leases	82 months
Weighted-average discount rate for operating leases	9.6%

NOTE 8 – COMMITMENTS AND CONTINGENCIES

On January 18, 2018, William Mahon, a Company stockholder, served a demand upon the Company's board of directors (the "Board") pursuant to Section 220 of the Delaware General Corporation Law (the "Demand") seeking to inspect certain of the Company's books and records. Generally, the Demand's stated purpose was to investigate allegedly excessive compensation awarded to non-employee Board members for the fiscal years 2015–2017. The Board denied the allegations in the Demand, and agreed to provide limited books and records to Mahon. On September 17, 2018, another Company stockholder, Francisco Dos Ramos, filed a stockholder derivative complaint in the Delaware Chancery Court (the "Dos Ramos Action") against Steven Rouhandeh, Frank Carsten Thiel, Mark Alvino, Stefano Buono, Stephen Howell, Richard Van Duyne, and Todd Wider as defendants, and the Company as nominal defendant (the "Dos Ramos Defendants"). Dos Ramos generally alleges that the Board breached its fiduciary duties, were unjustly enriched, and committed corporate waste by approving allegedly excessive compensation to non-employee Board members for the fiscal years 2015–2017. Dos Ramos generally seeks disgorgement of the allegedly improper payments to the Board, money damages, an order requiring corporate governance reforms, costs and attorneys' fees. On November 28, 2018, Mahon filed a stockholder derivative complaint (the "Mahon Action") in the United States District Court for the District of Delaware (the "District Court") against Mark Ahn, Mark Alvino, Jeffrey Davis, Stephen Howell, Todd Wider, and Steven Rouhandeh, as defendants, and the Company as a nominal defendant ("Mahon Defendants"). The allegations in the Mahon Action are substantially similar to those set forth in his Demand, as well as those in the Dos Ramos Action. Mahon generally seeks the disgorgement of the allegedly improper payments to the Board, a constructive trust, money damages, costs and attorneys' fees. On December 6, 2018, Mahon and the Mahon Defendants filed a joint motion for preliminary approval of settlement, along with a stipulation of settlement (the "Stipulation") intending to settle all claims asserted in the Mahon Action.

On January 8, 2019, the District Court approved the parties' notice of settlement, enjoining all Company stockholders from commencing or further prosecuting any claims asserted in the Mahon Action, and scheduled a settlement approval hearing for May 1, 2019. On January 25, 2019, the Chancery Court entered an order staying the Dos Ramos Action until May 8, 2019—one week after the May 1, 2019 settlement hearing in the Mahon Action. On May 2, 2019 the District Court entered an Order and Final Judgment approving the Stipulation.

On October 22, 2018, EB Research Partnership, Inc. ("EBRP") served upon the Company a Request for Arbitration (the "Request"), alleging that the Company is in breach of an Agreement executed in July 2016 (the "Agreement") between and among the Company, EBRP, and Epidermolysis Bullosa Medical Research Foundation ("EBMRF"). EBRP alleges that Abeona has refused to lift trading restrictions on certain shares of Abeona common stock issued to EBRP, purportedly in breach of the Agreement. On November 21, 2018, the Company filed an action in the United States District Court for the Southern District of New York seeking a declaration that it is not required to arbitrate its dispute with EBRP on the basis that the Agreement is void for lack of consideration. On February 4, 2019, the court granted EBRP and EBMRF's motion to compel arbitration. EBMRF was subsequently joined as a party to the arbitration. The parties submitted briefs to the arbitrator on March 18 and April 18, 2019. The dispute is pending before the arbitrator and a decision is expected on or before May 20, 2019.

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 programs include EB-101, an autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa ("RDEB"), ABO-102, an adeno-associated virus ("AAV")-based gene therapy for Sanfilippo syndrome type A ("MPS IIIA"), and ABO-101 an AAV-based gene therapy for Sanfilippo syndrome type B ("MPS IIIB"). We also are developing ABO-202 and ABO-201, which are AAV-based gene therapies for the CLN1 and CLN3 forms of Batten Disease, respectively, ABO-401 for the treatment of cystic fibrosis, and ABO-5OX for the treatment of retinal diseases. In addition, we are developing next generation AAV-based gene therapies though our novel AIM™ vector platform 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. We hold several U.S. and EU regulatory designations for five product candidates as follows:

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 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 for people 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. Our programs are focused on rare serious diseases. Through our gene and cell therapy expertise in research and development, we are positioned to rapidly introduce meaningful therapeutics to transform the standard of care in devastating diseases and establish our leadership position in the field.

Applying Novel Next Generation AIM™ Vector Technology to Develop New In-Vivo Gene Therapies.

We are researching and developing the next generation of AAV gene therapy using our novel capsids developed from the AIM™ Vector Technology Platform. 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.

RESULTS OF OPERATIONS

Foundation revenues relate to a collaborative agreement between us and nine Sanfilippo foundations to provide up to approximately $13.9 million of grants to us in installments for the advancement of our clinical stage gene therapies for MPS IIIA and MPS IIIB, subject to the achievement of certain milestones. We have received $5.7 million of such grants as of March 31, 2019. Our foundation revenue was $0 in the first quarter of 2019 and $0.5 million in the first quarter of 2018. The cash received upfront from the foundations is deferred on the condensed consolidated balance sheet until the costs of the activities as outlined in the manufacturing and clinical work plan are incurred by installment as outlined in the agreement with the foundations. As a result, we record foundation revenues to match the costs of the activities by installment performed under the collaborative agreement.

We recorded royalty revenue for MuGard of $0 in the first quarter of 2019 and $0.1 million in the first quarter of 2018. We licensed MuGard to AMAG Pharmaceuticals, Inc. ("AMAG") and Norgine B.V. ("Norgine").

Total research and development spending for the first quarter of 2019 was $11.7 million, as compared to $8.2 million for the same period of 2018, an increase of $3.5 million. The increase in expenses was primarily due to:

- increased clinical and development work for EB-101, ABO-102, ABO-101 and other gene therapy products ($1.8 million); and
- increased salary and related costs ($1.7 million) from the hiring of additional scientific staff.

Total general and administrative expenses were $5.7 million for the first quarter of 2019, as compared to $2.9 million for the same period of 2018, an increase of $2.8 million. The increase in expenses was primarily due to:

- increased salary and related costs ($0.9 million);
- increased professional fees ($1.0 million);
- increased office rent costs ($0.5 million); and
- increases in net other general and administrative expenses ($0.4 million).

Depreciation and amortization were $1.7 million for the first quarter of 2019, as compared to $0.2 million for the same period in 2018, an increase of $1.5 million. The increase was driven primarily by increased amortization expense resulting from the REGENXBIO license, which we entered into in November 2018.

Net loss for the first quarter of 2019 was $18.6 million, or a $0.39 basic and diluted loss per common share as compared to a net loss of $10.5 million, or a $0.22 basic and diluted loss per common share, for the same period in 2018.

LIQUIDITY AND CAPITAL RESOURCES

We have historically funded our operations primarily through sales of common stock and, to a significantly lesser extent, foundation grants and licensing agreements. Our principal source of liquidity is cash, cash equivalents and short-term investments. As of March 31, 2019 and December 31, 2018, our cash, cash equivalents and short-term investments were $68.3 million and $85.0 million, respectively.

As of March 31, 2019 and December 31, 2018, our working capital was $50.3 million and $68.5 million, respectively. The decrease in working capital at March 31, 2019 resulted primarily from $15.1 million of cash used for operating activities and $1.2 million for capital expenditures during the three months ended March 31, 2019.

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 will be 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, 2019.

On October 16, 2017, we announced a collaborative agreement between us and nine Sanfilippo foundations to provide up to approximately $13.9 million of grants to us in installments for the advancement of our clinical stage gene therapies for MPS IIIA and MPS IIIB, subject to the achievement of certain milestones. As of March 31, 2019, we had received $5.7 million of such grants. We did not receive any cash from such grants during the three months ended March 31, 2019.

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 $429 million as of March 31, 2019. We have not been profitable since inception and to date have received limited revenues from the sale of products. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials and regulatory compliance and cannot provide assurance that we will ever be able to generate sufficient product sales or royalty revenue to achieve profitability on a sustained basis, or at all.

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

We plan to expend substantial funds to conduct research and development programs, expand our manufacturing capabilities and conduct 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 will depend on many factors, including:

- 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 risks described in our most recent Form 10-K, including those relating to our ability to successfully commercialize 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 risk factors in our most recent Form 10-K, 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. As discussed in such risk factors, delays in our research and development efforts and any inability to raise additional funds could cause us to eliminate one or more of our research and development programs.

We plan to continue our policy of investing any available funds in 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 relates to our investment portfolio. Our investment strategy is 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 2019 or 2018.

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 Financial Officer (our principal financial officer), we have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures ("Disclosure Controls and Procedures"), as of March 31, 2019, 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 Financial Officer concluded that our Disclosure Controls and Procedures as of March 31, 2019 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, 2019 that have materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

PART II -- OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

On January 18, 2018, William Mahon, a Company stockholder, served a demand upon the Company's board of directors (the "Board") pursuant to Section 220 of the Delaware General Corporation Law (the "Demand") seeking to inspect certain of the Company's books and records. Generally, the Demand's stated purpose was to investigate allegedly excessive compensation awarded to non-employee Board members for the fiscal years 2015–2017. The Board denied the allegations in the Demand, and agreed to provide limited books and records to Mahon. On September 17, 2018, another Company stockholder, Francisco Dos Ramos, filed a stockholder derivative complaint in the Delaware Chancery Court (the "Dos Ramos Action") against Steven Rouhandeh, Frank Carsten Thiel, Mark Alvino, Stefano Buono, Stephen Howell, Richard Van Duyne, and Todd Wider as defendants, and the Company as nominal defendant (the "Dos Ramos Defendants"). Dos Ramos generally alleges that the Board breached its fiduciary duties, were unjustly enriched, and committed corporate waste by approving allegedly excessive compensation to non-employee Board members for the fiscal years 2015–2017. Dos Ramos generally seeks disgorgement of the allegedly improper payments to the Board, money damages, an order requiring corporate governance reforms, costs and attorneys' fees. On November 28, 2018, Mahon filed a stockholder derivative complaint (the "Mahon Action") in the United States District Court for the District of Delaware (the "District Court") against Mark Ahn, Mark Alvino, Jeffrey Davis, Stephen Howell, Todd Wider, and Steven Rouhandeh, as defendants, and the Company as a nominal defendant ("Mahon Defendants"). The allegations in the Mahon Action are substantially similar to those set forth in his Demand, as well as those in the Dos Ramos Action. Mahon generally seeks the disgorgement of the allegedly improper payments to the Board, a constructive trust, money damages, costs and attorneys' fees. On December 6, 2018, Mahon and the Mahon Defendants filed a joint motion for preliminary approval of settlement, along with a stipulation of settlement (the "Stipulation") intending to settle all claims asserted in the Mahon Action.

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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, 2018 should be carefully considered. There have been no material changes in the assessment of our risk factors from those set forth in our 2018 Form 10-K.

ITEM 6. EXHIBITS.

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

Exhibit Index

Exhibits:

3.1	Restated Certificate of Incorporation of Abeona Therapeutics Inc.
3.2	Amended and Restated Bylaws of Abeona Therapeutics Inc. (incorporated by reference to our Form 10-K filed on March 18, 2019)
10.1+	Offer Letter, dated January 8, 2019, by and between Abeona Therapeutics Inc. and Christine Berni Silverstein (incorporated by reference to our Form 8-K filed on January 10, 2019)
10.2+	Offer Letter, dated January 8, 2019, by and between Abeona Therapeutics Inc. and João Siffert, M.D. (incorporated by reference to our Form 8-K filed on February 13, 2019)
31.1	Principal Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Principal Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2019 and December 31, 2018, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2019 and 2018, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2019 and 2018, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2019 and 2018, and (v) Notes to Condensed Consolidated Financial Statements.

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

+ Management contract or compensation plans or arrangements in which directors or executive officers are eligible to participate.

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 10, 2019

By: /s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
(Principal Executive Officer)

Date: May 10, 2019

By: /s/ Christine Silverstein
Christine Silverstein
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 3.1

RESTATED

CERTIFICATE OF INCORPORATION
OF
ABEONA THERAPEUTICS INC.

Abeona Therapeutics Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), does hereby certify:

1. The original Certificate of Incorporation of the Corporation was filed with the Secretary of State of Delaware on June 22, 1989 (the "Original Certificate"), and the original name of the corporation was Chemex-Delaware, Inc.

2. Pursuant to Section 245 of the General Corporation Law of the State of Delaware (the "DGCL"), this Restated Certificate of Incorporation restates and integrates the provisions of the Original Certificate of the Corporation, as previously amended or supplemented.

3. This Restated Certificate of Incorporation does not amend the provisions of the Corporation's Original Certificate, as previously amended or supplemented, and there is no discrepancy between the provisions in this Restated Certificate of Incorporation and the provisions in the Corporation's Original Restated Certificate, as previously amended or supplemented.

4. This Restated Certificate of Incorporation has been duly approved by the Board of Directors of the Corporation in accordance with Sections 245 of the DGCL.

ARTICLE I.

The name of the Corporation is:
Abeona Therapeutics Inc.

ARTICLE II.

A. The address of the initial registered office of the Corporation is 1209 Orange Street, County of New Castle, Wilmington, Delaware 19801.

B. The name of the initial registered agent for the Corporation at such address is the Corporation Trust Company.

ARTICLE III.

The nature of the business of the Corporation and the objects and purposes to be transacted, promoted, and carried on by it are to generally engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of Delaware.

ARTICLE IV.

This Corporation shall have perpetual existence, which existence shall commence upon the filing by the Secretary of State of Delaware of this Certificate of Incorporation.

ARTICLE V.

A. The aggregate number of shares of Common Stock which the Corporation shall have authority to issue is Two Hundred Million (200,000,000) shares with a par value of one cent ($0.01) per share.

B. The aggregate number of shares of preferred stock which the Corporation shall have authority to issue is Two Million (2,000,000) shares with a par value of one cent ($0.01) per share in one or more series. Each series of preferred stock shall be designated by the board of directors so as to distinguish the shares thereof and the shares of all other series and classes. The board of directors may, by resolution, from time to time divide shares of the preferred stock into series and fix and determine the number of shares and the relative rights and preferences of any series so established, which relative rights and preferences of any series so established may be greater or lesser than those granted to the common stock as provided herein. Notwithstanding the foregoing, all shares of preferred stock shall be identical, except as to the following relative rights and preferences, in respect of any or all of which there may be variations between different series, namely the rate of dividends (including the date from which dividends shall be cumulative), the price at, and the terms and conditions on which, shares may be redeemed, the amounts payable on shares in the event of voluntary or involuntary liquidation or dissolution, sinking fund provisions for the redemption or purchase of shares in the event shares of any series or issue with sinking fund provisions, and the terms and conditions on which shares of any series may be converted in the event shares of any series are issued a privilege of conversion. Each share of any series of preferred stock shall be identical with all the shares of such series. The consideration for the issuance of shares may be paid in whole or in part in money and other property, tangible or intangible, or in labor or in services actually performed for the Corporation. When payment of the consideration for which shares are to be issued has been received or, when payment of the capital consideration has been received and the Corporation has received a binding obligation from the purchaser to pay the balance of the purchase price; such shares shall be deemed to be fully paid and not liable for any further call or assessment thereon.

C. Each stockholder of record of the common stock shall have one vote for each share of stock standing in his name on the books of the Corporation and entitled to vote. In the election of directors, cumulative voting shall be allowed. The voting rights, if any, of the shareholders of any series, if any, of preferred stock, shall be designated, by resolution, of the board of directors.

D. Stockholders of the common or preferred stock, regardless of the series of the preferred stock shall not have the preemptive right to acquire unissued or treasury shares or securities convertible into such shares or carrying a right to subscribe to or acquire shares. Such provision shall apply to both shares outstanding and to newly issued shares.

ARTICLE VI.

A. Any purchase or other acquisition, directly or indirectly, in one or more transactions, by the Corporation of any shares of the Corporation's Voting Stock or any Voting Stock Right known by the Corporation to be beneficially owned by any Interested Shareholder who has beneficially owned such security or right for less than two years prior to the date of such purchase shall, except as hereinafter expressly provided, require the affirmative vote of the holders of not less than 66 2/3% of all shares entitled to vote. Such affirmative vote shall be required notwithstanding the fact that no vote may be required, or that a lesser percentage may be specified, by law or any agreement with any national securities exchange, or otherwise, but no such affirmative vote shall be required with respect to any purchase or other acquisition by the Corporation of Voting Stock or Voting Stock Right purchased at or below Fair Market Value or made as part of a tender or exchange offer made on the same terms to all holders of such securities and complying with the applicable requirements of the Securities Exchange Act of 1934 (the "Exchange Act") and the rules and regulations thereunder or in a Public Transaction.

B. A majority of the Board of Directors shall have the power and duty to determine for the purposes of this Article VI, on the basis of information known to it after reasonable inquiry, all facts necessary to determine compliance with this Article VI, including without limitation: (i) if (1) a person is an Interested Shareholder; (2) any Voting Stock and Voting Stock Right is beneficially owned by any person; (3) a person is an Affiliate or Associate of another; (4) a transaction is a Public Transaction; and (ii) the Fair Market Value of any Voting Stock or Voting Stock Right.

C. For the purposes of this Article VI, the following terms shall mean:

(i) An "Affiliate" of, or a person "Affiliated" with, a specified person, is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified.

(ii) The term "Associate" used to indicate a relationship with any person, means: (1) any corporation or organization (other than the Corporation or a Subsidiary of the Corporation) of which such person is an officer, director or partner or is, directly or indirectly, the beneficial owner of 20% or more of any class of voting stock; (2) any trust or other estate in which such person has at least a 20% beneficial interest or as to which such person serves as trustee or in a similar fiduciary capacity; and (3) any relative or spouse of such person, or any relative of such spouse, who has the same residence as such person.

(iii) A person shall "beneficially own" any Voting Stock or Voting Stock Right: (1) which such person or any of its Affiliates or Associates beneficially owns, directly or indirectly; (2) which such person or any of its Affiliates or Associates has (a) the right to acquire (whether such right is exercisable immediately or only after the passage of time), pursuant to any agreement, arrangement or understanding or upon the exercise of conversion rights, exchange rights, warrants or options, or otherwise, or (b) any right to vote pursuant to any agreement, arrangement or understanding; or (3) which is beneficially owned, directly or indirectly, by any other person with which such person or any of its Affiliates or Associates has any agreement, arrangement or understanding for the purpose of acquiring, holding, voting or disposing of any security of any class of the Corporation or any of its Subsidiaries. For the purposes of determining whether a person is an Interested Shareholder, the relevant class of securities outstanding shall be deemed to include all such securities of which such person is deemed to be the "beneficial owner" through application of this subparagraph (iii), but shall not include any other securities of such class which may be issuable pursuant to any agreement, arrangement or understanding, or upon exercise of conversion rights, warrants or options, or otherwise, but are not yet issued.

(iv) "Fair Market Value" means, for any share of Voting Stock or any Voting Stock Right, the average of the closing sale prices during the 90-day period immediately preceding the repurchase of such Voting Stock or any Voting Stock Right, as the case may be, on the Composite Tape for New York Stock Exchange-Listed Stocks, or, if such Voting Stock or any Voting Stock Right is not quoted on the Composite Tape, on the New York Stock Exchange, or, if such Voting Stock or any Voting Stock Right, is not listed on such Exchange, on the principal United States securities exchange registered under the Exchange Act on which such Voting Stock or any Voting Stock Right is listed, or if such Voting Stock or any Voting Stock Right is not listed on any such exchange, the average of the closing bid quotations with respect to a share of such Voting Stock or any Voting Stock Right during the 90-day period immediately preceding the date in question of a share of such Voting Stock or any Voting Stock Right quoted by a registered national securities association, or if none of the preceding shall be applicable as determined by the Board of Directors in good faith.

(v) "Interested Shareholder" shall mean any person or group of persons (other than (1) the Corporation, (2) any of its Subsidiaries, (3) any benefit plan or trust of or for the benefit of the Corporation or any of its Subsidiaries, or (4) any trustee, agent or other representative of any of the foregoing) who or which is the beneficial owner, directly or indirectly, of more than 5% of any class of Voting Stock or any Voting Stock Rights.

(vi) A "Public Transaction" shall mean any (1) purchase of shares offered pursuant to an effective registration statement under the Securities Act of 1933, as amended (2) open market purchases of shares if, in either such case, the price and other terms of sale are not negotiated by the purchaser and seller of the beneficial interest in the shares.

(vii) The term "Voting Stock" shall mean stock of any class or series of the Corporation entitled to vote generally in the election of directors.

(viii) The term "Voting Stock Right" shall mean any security convertible into, and any warrant, option or other right of any kind to acquire beneficial ownership of, any Voting Stock, other than securities issued pursuant to any of the Corporation's employee benefit plans.

D. Notwithstanding anything contained in this Certificate to the contrary, the affirmative vote of the holders of at least 66 2/3% of the shares entitled to vote shall be required to alter, amend, repeal or to adopt any provision inconsistent with this Article VI.

ARTICLE VII.

A. The number of persons constituting the board of directors of the Corporation shall be fixed by the Bylaws of the Corporation. Directors need not be residents of the State of Delaware or stockholders of the Corporation and shall exercise all the powers conferred on the Corporation by this Certificate of Incorporation and by the laws of the State of Delaware. The initial board of directors shall consist of nine (9) members. The use of a written ballot in connection with the election of directors shall not be required.

B. The board of directors shall be divided into three classes as nearly equal in number as possible. At each Annual Meeting of Stockholders the directors whose terms expire shall be elected for a term of office to expire at the third succeeding Annual Meeting of Stockholders.

C. Nominations for the election of directors may be made by the board of directors or by any record owner of capital stock of the Corporation entitled to vote in the election of directors. However, a stockholder may nominate one or more persons for election as a director at a meeting, only if written notice of such stockholder's intent to make such nomination or nominations has been given, either by personal delivery or by United States mail, postage prepaid, to the Secretary of the Corporation not later than: (i) with respect to an election to be held at an annual meeting of stockholders, one hundred twenty (120) days in advance of such meeting; and (ii) with respect to an election to be held at a special meeting of stockholders for the election of directors, the close of business on the seventh day following the earlier of: (1) the date on which notice of such meeting is first given to stockholders; and (2) the date on which a public announcement of such meeting is first made. Each notice shall include: (i) the name and address of each stockholder of record who intends to appear in person or by proxy to make the nomination and of the person or persons to be nominated; (ii) a description of all arrangements or understandings between the stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nomination or nominations are made by the stockholder; (iii) such other information regarding each nominee proposed by such stockholder as would have been required to be included in a proxy statement filed pursuant to the proxy rules of the Securities and Exchange Commission; and (iv) the consent of each nominee to serve as a director of the Corporation if so elected. The chairman of the meeting may refuse to acknowledge the nomination of any person not made in compliance with the foregoing procedure.

D. Any director, or the entire board of directors, may be removed from office at any time, but only for cause and only upon the affirmative vote of the holders of at least 66 2/3% of the shares entitled to vote in the election of directors.

E. Notwithstanding any other provisions of this Certificate of Incorporation or the Bylaws of the Corporation, the affirmative vote of the holders of at least 66 2/3% of the shares entitled to vote shall be required to amend, repeal, or adopt any provisions inconsistent with this Article VII.

ARTICLE VIII.

No contract or transaction between the Corporation and one or more of its directors or officers, or between the Corporation and any other corporation, partnership, association, or other organization in which one or more of its directors or officers have any interest, shall be void or voidable solely for that reason or solely because the director or officer is present at or participates in the meeting of the board or committee thereof which authorizes, approves, or ratifies the contract or transaction or solely because his or their votes are counted for such purpose if: (i) The material facts as to his relationship or interest and as to the contract or transaction are disclosed or are known to the board of directors or the committee, and the board or committee in good faith authorizes, approves, or ratifies the contract or transaction by the affirmative vote of a majority of the disinterested directors, even though the disinterested directors are less than a quorum; (ii) The material facts as to his relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction is specifically authorized, approved, or ratified in good faith by vote of the stockholders; or (iii) The contract or transaction is fair as to the Corporation as of the time it is authorized, approved, or ratified by the board of directors, a committee thereof, or the stockholders.

Common or interested directors may be counted in determining the presence of a quorum at a meeting of the board of directors or a committee thereof which authorizes, approves, or ratifies such contract or transaction.

ARTICLE IX.

The officers of the Corporation shall be subject to the doctrine of corporate opportunities only insofar as it applies to business opportunities in which this Corporation has expressed an interest as determined from time to time by the Corporation's board of directors, as evidenced by resolutions appearing in its minutes. When so delineated, opportunities within such areas of interest shall be disclosed promptly to the board of directors. Until such time as this Corporation, through its board of directors, has designated an area of interest, the officers shall be free to engage in such areas and to continue a business existing prior to the time that such an area of interest has been designated.

ARTICLE X.

A. The Corporation shall indemnify all persons to the extent and in the manner permitted by the provisions of the General Corporation Law of Delaware, as amended from time to time, subject to any permissible expansion or limitation of such indemnification as may be set forth in the Bylaws of the Corporation or any stockholders' or directors' resolution or by contract. The provisions of this Article shall also be applicable to the personal representative and heirs of all persons who may be indemnified pursuant to the General Corporation Law of Delaware.

B. No director of the Corporation shall be liable to the Corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except for liability for: (i) any breach of the director's duty of loyalty to the Corporation or its stockholders; (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) unlawful payment of dividends or unlawful repurchases or redemptions as more fully described in Section 174 of the General Corporation Law of Delaware; or (iv) any transaction from which the directors derived an improper personal benefit. If the General Corporation Law of Delaware is amended after the filing of this Certificate of Incorporation to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of Delaware. Any repeal or modification of the foregoing by the shareholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification.

C. Notwithstanding any other provision of this Certificate of Incorporation, the affirmative vote of at least 66 2/3% of the shares entitled to vote shall be required to alter, amend, repeal or adopt any provision inconsistent with this Article X.

ARTICLE XI.

The Corporation shall be entitled to treat the registered holder of any shares of the Corporation as the owner thereof for all purposes, including all rights derived from such shares, and shall not be bound to recognize any equitable or other claim to or interest in such shares or rights deriving from such shares, on the part of any other persons, including but without limiting the generality thereof, a purchaser, assignee or transferee of such shares or rights deriving from such shares, unless and until such purchaser, assignee or transferee or other person becomes a registered holder of such shares, whether or not the Corporation shall have either actual or constructive notice of the interest of such purchaser, assignee, transferee, or any other person. The purchaser, assignee, or transferee of any of the shares of the Corporation shall not be entitled: (i) To receive notice of the meetings of the stockholders; (ii) To vote at such meetings; (iii) To examine a list of the stockholders; (iv) To be paid dividends or other sums payable to stockholders; or (v) To own, enjoy, and exercise any other privilege or right derived from such shares against the Corporation, until such purchaser, assignee, or transferee has become the registered holder of such shares.

ARTICLE XII.

A. The Corporation's Bylaws may contain any provisions for the regulation and management of the affairs of the Corporation not inconsistent with the laws of Delaware or this Certificate of Incorporation. In furtherance and not in limitation of the powers conferred by statute, the board of directors is expressly authorized to adopt, amend or repeal the Bylaws of the Corporation. Notwithstanding the foregoing or any other provisions of this Certificate of Incorporation, and except as otherwise provided by law, the Bylaws may be altered, amended or repealed by the affirmative vote of the holders of at least 66 2/3% of the shares entitled to vote.

B. Notwithstanding any other provision of this Certificate of Incorporation, the affirmative vote of at least 66 2/3% of the shares entitled to vote shall be required to alter, amend, repeal or adopt any provision inconsistent with this Article XII.

ARTICLE XIII.

The right is expressly reserved to amend, alter, change or repeal any provision or provisions contained in this Certificate of Incorporation or any Article herein in any manner or respect now or hereafter permitted or provided by the General Corporation Law of Delaware or by this Certificate of Incorporation, and the rights of all officers, directors and stockholders are expressly made subject to such reservation.

EXHIBIT 31.1

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

I, Steven H. Rouhandeh, 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 10, 2019

By: /s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
(Principal Executive Officer)

EXHIBIT 31.2

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

I, Christine Silverstein, 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 10, 2019

By: /s/ Christine Silverstein
Christine Silverstein
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32

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

In connection with the Quarterly Report of Abeona Therapeutics Inc. (the "Company") on Form 10-Q for the three months ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Steven H. Rouhandeh, Executive Chairman of the Company, and Christine Silverstein, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2019

By: /s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
(Principal Executive Officer)

Date: May 10, 2019

By: /s/ Christine Silverstein
Christine Silverstein
Chief Financial Officer
(Principal Financial Officer)