UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 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) 813-4701
(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☑ No ☐

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

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

Large accelerated filer ☐
Non-accelerated filer ☐
Accelerated filer ☑
Smaller reporting company ☑
Emerging growth company ☐

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

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

The number of shares outstanding of the registrant's common stock as of August 5, 2019 was 49,315,751 shares.

ABEONA THERAPEUTICS INC.

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CAUTIONARY STATEMENT RELATED TO FORWARD-LOOKING STATEMENTS

This Form 10-Q (including information incorporated by reference) 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. 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 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. 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"); the outcome of any interactions with the FDA or other regulatory agencies relating to any of our products or product candidates; our ability to initiate a Phase III clinical trial for patients with RDEB in the fourth quarter of 2019; 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 and cell 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

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,609,000	$ 18,750,000
Short-term investments	19,903,000	66,218,000
Receivables	40,000	81,000
Prepaid expenses and other current assets	2,343,000	3,802,000
Total current assets	64,895,000	88,851,000
Property and equipment, net	13,616,000	9,443,000
Right-of-use lease assets	8,520,000	-
Licensed technology, net	38,765,000	43,042,000
Goodwill	32,466,000	32,466,000
Other assets and restricted cash	1,148,000	597,000
Total assets	$ 159,410,000	$ 174,399,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,156,000	$ 6,122,000
Accrued expenses	6,397,000	3,936,000
Current portion of lease liability	1,693,000	-
Current portion of payable to licensor	10,000,000	10,000,000
Deferred revenue	296,000	296,000
Total current liabilities	25,542,000	20,354,000
Long-term lease liabilities	6,708,000	-
Payable to licensor, net of current portion	20,000,000	20,000,000
Total liabilities	52,250,000	40,354,000
Commitments and contingencies		
Stockholders' equity:		
Common stock - $0.01 par value; authorized 200,000,000 shares; issued and outstanding 49,249,497 at June 30, 2019; issued and outstanding 47,944,486 at December 31, 2018	492,000	479,000
Additional paid-in capital	559,335,000	543,754,000
Accumulated deficit	(452,667,000)	(410,188,000)
Total stockholders' equity	107,160,000	134,045,000
Total liabilities and stockholders' equity	$ 159,410,000	$ 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 June 30,		For the six months ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Foundation revenues	$ -	$ 259,000	$ -	$ 740,000
Royalties	-	17,000	-	67,000
Total revenues	-	276,000	-	807,000
Expenses:				
Research and development	16,307,000	7,916,000	28,044,000	16,078,000
General and administrative	5,612,000	4,627,000	11,271,000	7,505,000
Depreciation and amortization	2,057,000	290,000	3,715,000	464,000
Total expenses	23,976,000	12,833,000	43,030,000	24,047,000
Loss from operations	(23,976,000)	(12,557,000)	(43,030,000)	(23,240,000)
Interest and miscellaneous income	52,000	317,000	551,000	473,000
Interest and other expense	-	(3,000)	-	(6,000)
Net loss	$ (23,924,000)	$ (12,243,000)	$ (42,479,000)	$ (22,773,000)
Basic and diluted loss per common share	$ (0.49)	$ (0.26)	$ (0.88)	$ (0.48)
Weighted average number of common shares outstanding – basic and diluted	48,961,988	47,303,518	48,458,004	47,182,691

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
Stock-based compensation expense	-	-	2,673,000	-	2,673,000
Restricted stock-based compensation expense	-	-	172,000	-	172,000
Common stock issued for:					
- cash exercise of options	76,956	1,000	480,000	-	481,000
- exercise of $5.00 warrants	17,889	-	89,000	-	89,000
Net loss	-	-	-	(12,243,000)	(12,243,000)
Balance, June 30, 2018	47,327,785	$ 473,000	$ 536,733,000	$ (376,290,000)	$ 160,916,000
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
Stock-based compensation expense	-	-	1,678,000	-	1,678,000
Restricted stock-based compensation expense	-	-	78,000	-	78,000
Common stock issued for cash exercise of options	91,126	1,000	384,000	-	385,000
Common stock issued for cash under open market sale agreement	1,658,677	17,000	12,605,000	-	12,622,000
Shares returned in connection with arbitration ruling on licensing agreement	(450,000)	(5,000)	(1,467,000)	-	(1,472,000)
Net loss	-	-	-	(23,924,000)	(23,924,000)
Balance, June 30, 2019	49,249,497	$ 492,000	$ 559,335,000	$ (452,667,000)	$ 107,160,000

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For the six months ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (42,479,000)	$ (22,773,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	3,715,000	464,000
Stock-based compensation expense	3,781,000	4,573,000
Restricted stock-based compensation expense	250,000	344,000
Non-cash earnings on investments	(829,000)	-
Non-cash loss on arbitration ruling on licensing agreement	367,000	-
Change in operating assets and liabilities:		
Receivables	41,000	60,000
Prepaid expenses and other current assets	1,459,000	798,000
Right-of-use lease assets and other assets	381,000	42,000
Accounts payable, accrued expenses and lease liabilities	2,994,000	3,388,000
Net cash used in operating activities	(30,320,000)	(13,104,000)
Cash flows from investing activities:		
Capital expenditures	(5,250,000)	(6,923,000)
Acquisition of licensed technology	(200,000)	-
Proceeds from maturities of short-term investments	47,144,000	(69,852,000)
Net cash provided by (used in) investing activities	41,694,000	(76,775,000)
Cash flows from financing activities:		
Proceeds from open market sales of common stock	12,622,000	-
Proceeds from exercise of $5.00 warrants	-	233,000
Proceeds from exercise of stock options	413,000	2,166,000
Net cash provided by financing activities	13,035,000	2,399,000
Net increase (decrease) in cash, cash equivalents and restricted cash	24,409,000	(87,480,000)
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	$ 43,719,000	$ 50,550,000
Supplemental cash flow information:		
Cash and cash equivalents	$ 42,609,000	$ 49,990,000
Restricted cash	1,110,000	560,000
Total cash, cash equivalents and restricted cash	$ 43,719,000	$ 50,550,000
Shares returned in connection with arbitration ruling on licensing agreement	$ 1,472,000	$ -
Cash paid for interest	$ -	$ 6,000

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

NOTE 1 – NATURE OF OPERATIONS AND SIGNIFICANT ACCOUNTING POLICIES

Background

Abeona Therapeutics Inc., 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 since inception have been principally devoted to research and development, resulting in significant losses.

Basis of Presentation

The condensed consolidated balance sheets as of June 30, 2019, the condensed consolidated statements of operations and stockholders' equity for the three and six months ended June 30, 2019 and 2018 and the condensed consolidated statements of cash flows for the six months ended June 30, 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 periods ended June 30, 2019 are not necessarily indicative of the operating results that may be expected for a full year. The condensed consolidated balance sheets as of December 31, 2018 contain financial information taken from the audited Abeona consolidated financial statements as of that date.

As of June 30, 2019, we had 6,926,781 options and 1,820,686 warrants that were not included in the EPS calculation as their effect would be antidilutive. As of June 30, 2018, we had 5,895,135 options and 2,820,687 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 a going concern basis, which assumes the Company will have sufficient cash to pay its operating expenses, as and when they become payable, for a period of at least 12 months from the date the financial report was issued.

As of June 30, 2019, we had cash, cash equivalents and short-term investments of $62.5 million and net assets of $107.2 million. For the six months ended June 30, 2019, we had cash outflows from operations of $30.3 million. We believe we have sufficient resources to fund our business operations for the next 12 months. However, we have implemented a multi-faceted program to seek 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 a 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 January 1, 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 8.

NOTE 3 – SHORT-TERM INVESTMENTS

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

Description	June 30, 2019	December 31, 2018
U.S. government and agency securities and treasuries	$ 19,903,000	$ 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 and six months ended June 30, 2019 and 2018.

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 royalties payable in the low double digits to low teens 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"). On August 3, 2016, we recorded the issuance of 375,000 of our common shares to each of EBRP and EBMRF and recorded licensed technology of $2.45 million, which was being amortized over 20 years. In connection with an arbitration proceeding relating to the EB Agreement, on May 15, 2019, the arbitrator issued a decision in favor of the Company requiring the Company to cancel any and all shares of its common stock issued to EBRP and EBMRF that were still in their possession. As a result, we have recorded the return of 450,000 shares of our common stock and the reversal of the licensed technology from our financial statements. The net of these transactions resulted in a non-cash charge to expense of $367,000.

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

Licensed technology consists of the following:

	June 30, 2019	December 31, 2018
Licensed technology	$ 42,606,000	$ 44,859,000
Less accumulated amortization	3,841,000	1,817,000
Licensed technology, net	$ 38,765,000	$ 43,042,000

The aggregate estimated amortization expense for intangible assets remaining as of June 30, 2019 is as follows:

2019, remainder	$ 2,587,000
2020	5,167,000
2021	5,167,000
2022	5,167,000
2023	5,167,000
Thereafter	15,510,000
Total	$ 38,765,000

Amortization on licensed technology was $1,293,000 and $2,638,000 for the three and six months ended June 30, 2019, respectively, and $87,000 and$174,000 for the three and six months ended June 30, 2018, respectively.

NOTE 5 – RESTRICTED CASH

Restricted cash, which is reported within other assets and restricted cash on the condensed consolidated balance sheet, consists of cash and cash equivalents held as collateral for a corporate credit card and office space in New York. As such, the cash and cash equivalents are restricted in use.

NOTE 6 – 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 June 30, 2019 and December 31, 2018 are summarized below:

Description	June 30, 2019	Level 1	Level 2	Level 3	Total Gains/(Losses)
Recurring					
Assets:					
Short-term investments	$ 19,903,000	$ -	$ 19,903,000	$ -	$ -
Non-recurring					
Assets:					
Licensed technology, net	$ 38,765,000	$ -	$ -	$ 38,765,000	$ (367,000)
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 7 – STOCK-BASED COMPENSATION

The following table summarizes stock-based option compensation for the three and six months ended June 30, 2019 and 2018:

	For the three months ended June 30,		For the six months ended June 30,	
	2019	2018	2019	2018
Research and development	$ 1,009,000	$ 900,000	$ 2,041,000	$ 1,744,000
General and administrative	669,000	1,773,000	1,740,000	2,829,000
Stock-based compensation expense included in operating expense	1,678,000	2,673,000	3,781,000	4,573,000
Total stock-based compensation expense	1,678,000	2,673,000	3,781,000	4,573,000
Tax benefit	-	-	-	-
Stock-based compensation expense, net of tax	$ 1,678,000	$ 2,673,000	$ 3,781,000	$ 4,573,000

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 June 30,		For the six months ended June 30,	
	2019	2018	2019	2018
Expected volatility	108%	109%	108%	109%
Expected term	5 years	5 years	5 years	5 years
Risk-free interest rate	2.21%	2.65%	2.24%	2.44%
Expected dividend yield	0%	0%	0%	0%

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

	For the three months ended June 30,		For the six months ended June 30,	
	2019	2018	2019	2018
Options granted	1,183,890	224,800	1,384,890	869,800
Weighted-average:				
Exercise price	$ 6.86	$ 16.27	$ 6.84	$ 14.38
Grant date fair value	$ 5.39	$ 12.87	$ 5.37	$ 11.36

The following table summarizes restricted common stock compensation expense for the three and six months ended June 30, 2019 and 2018:

	For the three months ended June 30,		For the six months ended June 30,	
	2019	2018	2019	2018
Research and development	$ -	$ -	$ -	$ -
General and administrative	78,000	172,000	250,000	344,000
Stock-based compensation expense included in operating expense	78,000	172,000	250,000	344,000
Total stock-based compensation expense	78,000	172,000	250,000	344,000
Tax benefit	-	-	-	-
Stock-based compensation expense, net of tax	$ 78,000	$ 172,000	$ 250,000	$ 344,000

We did not grant any common stock to directors or employees during the three and six months ended June 30, 2019 or 2018.

NOTE 8 – 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 June 30, 2019	Six months ended June 30, 2019
Operating lease cost	$ 434,000	$ 723,000
Variable lease cost	$ 86,000	$ 159,000
Short-term lease cost	$ 34,000	$ 81,000

The following table presents information about the amount and timing of cash flows arising from operating leases as of June 30, 2019:

Maturity of lease liabilities:	
2019, remainder	$ 845,000
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	11,392,000
Less: imputed interest	2,991,000
Present value of operating lease liabilities	$ 8,401,000
Balance sheet classification:	
Current portion of lease liability	$ 1,693,000
Long-term lease liability	6,708,000
Total operating lease liabilities	$ 8,401,000
Other information:	
Weighted-average remaining lease term for operating leases	79 months
Weighted-average discount rate for operating leases	9.6%

NOTE 9 – 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 August 6, 2019, the plaintiff in the Dos Ramos Action filed a voluntary notice of dismissal. On August 7, 2019, the Chancery Court entered an order of dismissal.

On October 22, 2018, EB Research Partnership, Inc. ("EBRP") served upon the Company a Request for Arbitration (the "Request"), alleging that the Company was in breach of an Agreement executed in July 2016 (the "Agreement") between and among the Company, EBRP, and Epidermolysis Bullosa Medical Research Foundation ("EBMRF" and together with EBRP, "Claimants"). EBRP alleged that Abeona had 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 was not required to arbitrate its dispute with EBRP on the basis that the Agreement was void for lack of consideration. On February 4, 2019, the court granted Claimants' 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. On May 15, 2019, the arbitrator issued a decision in favor of the Company (the "Final Award"). Specifically, the Final Award provides that the Agreement is void for lack of consideration; that Claimants fraudulently induced Abeona to enter into the Agreement; that Claimants cannot enforce the Agreement; that Claimants are not entitled to any relief under the Agreement; that, in view of their status as charitable organizations, Claimants would not be required to repay to Abeona the value of Abeona common stock they already sold; that the Company shall cancel any and all shares of Abeona common stock issued to Claimants that were still in Claimants' possession; and that, as the losing parties, Claimants must bear the costs and expenses of the arbitration and Abeona's costs and expenses.

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 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 for which no effective treatment options exist today.

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

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

We have four programs in clinical development—EB-101, ABO-101, ABO-102 and ABO-202—and a pipeline of additional earlier stage programs. Through our gene and cell therapy expertise in research and development, we are positioned to 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-based 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 FOR THREE MONTHS ENDED JUNE 30, 2019 COMPARED TO THREE MONTHS ENDED JUNE 30, 2018

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 cumulatively as of June 30, 2019. Our foundation revenue was $0 in the second quarter of 2019 and $0.3 million in the second 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 second quarter of 2019 and $0.1 million in the second quarter of 2018. We licensed MuGard to AMAG Pharmaceuticals, Inc. ("AMAG") and Norgine B.V. ("Norgine").

Total research and development spending for the second quarter of 2019 was $16.3 million, as compared to $7.9 million for the same period of 2018, an increase of $8.4 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 ($7.2 million); and
- increased salary and related costs ($1.2 million) from the hiring of additional scientific staff.

Total general and administrative expenses were $5.6 million for the second quarter of 2019, as compared to $4.6 million for the same period of 2018, an increase of $1.0 million. The increase in expenses was primarily due to:

- increased salary and related costs ($0.6 million);
- increased professional fees ($0.6 million); and
- increased office rent costs ($0.5 million); partially offset by
- decreases in net other general and administrative expenses ($0.7 million).

Depreciation and amortization were $2.1 million for the second quarter of 2019, as compared to $0.3 million for the same period in 2018, an increase of $1.8 million. The increase was driven by increased amortization expense of $1.2 million resulting primarily from the amortization of the cost of the REGENXBIO license, which we entered into in November 2018, and increased depreciation expense of $0.6 million resulting primarily from the build-out of our production facility in Cleveland, Ohio and, to a much lesser extent, the build-out of our corporate offices in New York, New York.

Net loss for the second quarter of 2019 was $23.9 million, or a $0.49 basic and diluted loss per common share as compared to a net loss of $12.2 million, or a $0.26 basic and diluted loss per common share, for the same period in 2018.

RESULTS OF OPERATIONS FOR SIX MONTHS ENDED JUNE 30, 2019 COMPARED TO SIX MONTHS ENDED JUNE 30, 2018

Our foundation revenue was $0 for the first six months of 2019 and $0.7 million for the same period of 2018.

We recorded royalty revenue for MuGard of $0 for the first six months of 2019 and $0.1 million for the same period of 2018. We licensed MuGard to AMAG and Norgine.

Total research and development spending for the first six months of 2019 was $28.0 million, as compared to $16.1 million for the same period of 2018, an increase of $11.9 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 ($9.1 million); and
- increased salary and related costs ($3.0 million) from the hiring of additional scientific staff.

Total general and administrative expenses were $11.3 million for the first six months of 2019, as compared to $7.5 million for the same period of 2018, an increase of $3.8 million. The increase in expenses was primarily due to:

- increased salary and related costs ($1.5 million);
- increased professional fees ($1.5 million); and
- increased office rent costs ($0.9 million); partially offset by
- decreases in net other general and administrative expenses ($0.1 million).

Depreciation and amortization were $3.7 million for the first six months of 2019, as compared to $0.5 million for the same period in 2018, an increase of $3.2 million. The increase was driven by increased amortization expense of $2.5 million resulting primarily from the amortization of the cost of the REGENXBIO license, which we entered into in November 2018, and increased depreciation expense of $0.7 million resulting primarily from the build-out of our production facility in Cleveland, Ohio and, to a much lesser extent, the build-out of our corporate offices in New York, New York.

Net loss for the first six months of 2019 was $42.5 million, or a $0.88 basic and diluted loss per common share as compared to a net loss of $22.8 million, or a $0.48 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 equity securities and, to a significantly lesser extent, foundation grants and licensing agreements. Our principal sources of liquidity are cash, cash equivalents and short-term investments.

As of June 30, 2019 and December 31, 2018, our cash, cash equivalents and short-term investments were $62.5 million and $85.0 million, respectively. We believe we have sufficient resources to fund our business operations for the next 12 months. However, we have implemented a multi-faceted program to seek sufficient liquidity through at least the end of 2020.

As of June 30, 2019 and December 31, 2018, our working capital was $39.4 million and $68.5 million, respectively. The decrease in working capital during the six months ended June 30, 2019 resulted primarily from $30.3 million of cash used for operating activities.

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 sold 1,658,677 shares of our common stock under this agreement and received $12.6 million of proceeds during the three and six months ended June 30, 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 $452.7 million as of June 30, 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 three and six months ended June 30, 2019 and 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 June 30, 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 June 30, 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 June 30, 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.

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 August 6, 2019, the plaintiff in the Dos Ramos Action filed a voluntary notice of dismissal. On August 7, 2019, the Chancery Court entered an order of dismissal.

On October 22, 2018, EB Research Partnership, Inc. ("EBRP") served upon the Company a Request for Arbitration (the "Request"), alleging that the Company was in breach of an Agreement executed in July 2016 (the "Agreement") between and among the Company, EBRP, and Epidermolysis Bullosa Medical Research Foundation ("EBMRF" and together with EBRP, "Claimants"). EBRP alleged that Abeona had 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 was not required to arbitrate its dispute with EBRP on the basis that the Agreement was void for lack of consideration. On February 4, 2019, the court granted Claimants' 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. On May 15, 2019, the arbitrator issued a decision in favor of the Company (the "Final Award"). Specifically, the Final Award provides that the Agreement is void for lack of consideration; that Claimants fraudulently induced Abeona to enter into the Agreement; that Claimants cannot enforce the Agreement; that Claimants are not entitled to any relief under the Agreement; that, in view of their status as charitable organizations, Claimants would not be required to repay to Abeona the value of Abeona common stock they already sold; that the Company shall cancel any and all shares of Abeona common stock issued to Claimants that were still in Claimants' possession; and that, as the losing parties, Claimants must bear the costs and expenses of the arbitration and Abeona's costs and expenses.

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 to the 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:

31.1	Principal Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Principal Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of June 30, 2019 and December 31, 2018, (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2019 and 2018, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2019 and 2018, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 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.

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:	August 9, 2019	By:	/s/ Steven H. Rouhandeh Steven H. Rouhandeh Executive Chairman (Principal Executive Officer)
Date:	August 9, 2019	By:	/s/ Christine Silverstein Christine Silverstein Chief Financial Officer (Principal Financial Officer)

EXHIBIT 31.1

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

I, 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: August 9, 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: August 9, 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 June 30, 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: August 9, 2019

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

Date: August 9, 2019

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