

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

**FORM 10-Q**

(Mark one)

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

For the quarterly period ended **September 30, 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**

(State or other jurisdiction of  
incorporation or organization)

**83-0221517**

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

**1330 Avenue of the Americas, 33<sup>rd</sup> Floor, New York, NY 10019**

(Address of principal executive offices, zip code)

**(646) 813-4701**

(Registrant's telephone number, including area code)

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

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

Accelerated filer

Non-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 November 7, 2019 was 51,154,395 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. These statements include statements about the timing for Chemistry, Manufacturing and Controls ("CMC") clearance for the phase III clinical trial for patients with recessive dystrophic epidermolysis bullosa ("RDEB") and the Company's beliefs relating thereto; the Company's ability to provide additional transport stability data points in response to the Food and Drug Administration ("FDA") clinical hold letter for our RDEB phase III clinical trial and the timing thereof; the Company's belief that completion of its CMC work and the durable safety and efficacy data will ultimately be critical to support a future Biologics License Application; and the Company's plans to consider exploring a broad range of strategic alternatives, including, but not limited to, the partnering of its various clinical and pre-clinical programs, or a sale or merger of the Company. 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 plans to consider exploring a broad range of strategic alternatives, including, but not limited to, the partnering of its various clinical and pre-clinical programs, or a sale or merger of the Company; the Company's ability to obtain additional equity funding from current or new stockholders, out-licensing technology and/or other assets, deferring and/or eliminating planned expenditures, restructuring operations and/or reducing headcount, and sales of assets; 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 RDEB; the outcome of any interactions with the FDA or other regulatory agencies relating to any of our products or product candidates; whether or when the FDA will lift the clinical hold relating to the Company's planned phase III clinical trial for patients with RDEB; 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 programs; 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

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 47,923,000	\$ 18,750,000
Short-term investments	-	66,218,000
Receivables	15,000	81,000
Prepaid expenses and other current assets	1,654,000	3,802,000
Total current assets	<u>49,592,000</u>	<u>88,851,000</u>
Property and equipment, net	13,814,000	9,443,000
Right-of-use lease assets	8,286,000	-
Licensed technology, net	37,471,000	43,042,000
Goodwill	32,466,000	32,466,000
Other assets and restricted cash	1,143,000	597,000
Total assets	<u>\$ 142,772,000</u>	<u>\$ 174,399,000</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,714,000	\$ 6,122,000
Accrued expenses	5,532,000	3,936,000
Current portion of lease liability	1,696,000	-
Current portion of payable to licensor	10,000,000	10,000,000
Deferred revenue	296,000	296,000
Total current liabilities	<u>20,238,000</u>	<u>20,354,000</u>
Long-term lease liabilities	6,482,000	-
Payable to licensor, net of current portion	20,000,000	20,000,000
Total liabilities	<u>46,720,000</u>	<u>40,354,000</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock - \$0.01 par value; authorized 200,000,000 shares; issued and outstanding 51,054,395 at September 30, 2019; issued and outstanding 47,944,486 at December 31, 2018	511,000	479,000
Additional paid-in capital	565,580,000	543,754,000
Accumulated deficit	(470,039,000)	(410,188,000)
Total stockholders' equity	<u>96,052,000</u>	<u>134,045,000</u>
Total liabilities and stockholders' equity	<u>\$ 142,772,000</u>	<u>\$ 174,399,000</u>

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 September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
<b>Revenues:</b>				
Foundation revenues	\$ -	\$ 1,687,000	\$ -	\$ 2,427,000
Royalties	-	22,000	-	89,000
Total revenues	<u>-</u>	<u>1,709,000</u>	<u>-</u>	<u>2,516,000</u>
<b>Expenses:</b>				
Research and development	10,917,000	13,150,000	38,961,000	29,228,000
General and administrative	4,700,000	4,970,000	15,971,000	12,475,000
Depreciation and amortization	2,032,000	505,000	5,747,000	969,000
Total expenses	<u>17,649,000</u>	<u>18,625,000</u>	<u>60,679,000</u>	<u>42,672,000</u>
Loss from operations	(17,649,000)	(16,916,000)	(60,679,000)	(40,156,000)
Interest and miscellaneous income	277,000	500,000	828,000	973,000
Interest and other expense	-	(3,000)	-	(9,000)
Net loss	<u>\$ (17,372,000)</u>	<u>\$ (16,419,000)</u>	<u>\$ (59,851,000)</u>	<u>\$ (39,192,000)</u>
Basic and diluted loss per common share	\$ (0.35)	\$ (0.34)	\$ (1.22)	\$ (0.83)
Weighted average number of common shares outstanding – basic and diluted	<u>49,721,753</u>	<u>47,794,394</u>	<u>48,883,883</u>	<u>47,388,833</u>

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

**Abeona Therapeutics Inc. and Subsidiaries**

Condensed Consolidated Statements of Stockholders' Equity  
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
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 option-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 option-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
Stock option-based compensation expense	-	-	2,499,000	-	2,499,000
Restricted stock-based compensation expense	-	-	172,000	-	172,000
Common stock issued for:					
- cash exercise of options	16,701	1,000	78,000	-	79,000
- exercise of \$5.00 warrants	600,000	6,000	2,994,000	-	3,000,000
Net loss	-	-	-	(16,419,000)	(16,419,000)
Balance, September 30, 2018	47,944,486	\$ 480,000	\$ 542,476,000	\$ (392,709,000)	\$ 150,247,000
Balance, December 31, 2018	47,944,486	\$ 479,000	\$ 543,754,000	\$ (410,188,000)	\$ 134,045,000
Stock option-based compensation expense	-	-	2,103,000	-	2,103,000
Restricted stock-based compensation expense	-	-	172,000	-	172,000
Common stock issued for cash exercise of options	5,208	-	28,000	-	28,000
Net loss	-	-	-	(18,555,000)	(18,555,000)
Balance, March 31, 2019	47,949,694	\$ 479,000	\$ 546,057,000	\$ (428,743,000)	\$ 117,793,000
Stock option-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
Stock option-based compensation expense	-	-	1,826,000	-	1,826,000
Restricted stock-based compensation expense	-	-	98,000	-	98,000
Common stock issued for restricted share awards	376,625	4,000	(4,000)	-	-
Common stock issued for cash under open market sale agreement	1,428,273	15,000	4,325,000	-	4,340,000
Net loss	-	-	-	(17,372,000)	(17,372,000)
Balance, September 30, 2019	51,054,395	\$ 511,000	\$ 565,580,000	\$ (470,039,000)	\$ 96,052,000

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

**Abeona Therapeutics Inc. and Subsidiaries**  
Condensed Consolidated Statements of Cash Flows  
(Unaudited)

	<b>For the nine months ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (59,851,000)	\$ (39,192,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	5,747,000	969,000
Stock option-based compensation expense	5,607,000	7,072,000
Restricted stock-based compensation expense	348,000	516,000
Accretion and interest on short-term investments	(1,090,000)	-
Non-cash loss on arbitration ruling on licensing agreement	367,000	-
Change in operating assets and liabilities:		
Receivables	66,000	(245,000)
Prepaid expenses and other current assets	2,148,000	760,000
Right-of-use lease assets and other assets	623,000	40,000
Accounts payable, accrued expenses and lease liabilities	(2,539,000)	7,936,000
Net cash used in operating activities	(48,574,000)	(22,144,000)
<b>Cash flows from investing activities:</b>		
Capital expenditures	(6,187,000)	(8,580,000)
Acquisition of licensed technology	(199,000)	-
Purchases of short-term investments	-	(94,991,000)
Proceeds from maturities of short-term investments	67,308,000	16,366,000
Net cash provided by (used in) investing activities	60,922,000	(87,205,000)
<b>Cash flows from financing activities:</b>		
Proceeds from open market sales of common stock	16,962,000	-
Proceeds from exercise of \$5.00 warrants	-	3,233,000
Proceeds from exercise of stock options	413,000	2,245,000
Net cash provided by financing activities	17,375,000	5,478,000
Net increase (decrease) in cash, cash equivalents and restricted cash	29,723,000	(103,871,000)
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	\$ 49,033,000	\$ 34,159,000
<i>Supplemental cash flow information:</i>		
<i>Cash and cash equivalents</i>	\$ 47,923,000	\$ 33,599,000
<i>Restricted cash</i>	1,110,000	560,000
<i>Total cash, cash equivalents and restricted cash</i>	\$ 49,033,000	\$ 34,159,000
<i>Shares returned in connection with arbitration ruling on licensing agreement</i>	\$ 1,472,000	\$ -
<i>Cash paid for interest</i>	\$ -	\$ 9,000

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-50X for the treatment of retinal diseases. In addition, we are developing next-generation AAV-based gene therapy through our novel AIM™ capsid platform and internal AAV vector research programs. Our efforts since inception have been principally devoted to research and development, resulting in significant losses.

##### Basis of Presentation

The condensed consolidated balance sheet as of September 30, 2019, the condensed consolidated statements of operations and stockholders’ equity for the three and nine months ended September 30, 2019 and 2018 and the condensed consolidated statements of cash flows for the nine months ended September 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 September 30, 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 September 30, 2019, we had 6,697,980 options and 1,820,686 warrants that were not included in the EPS calculation as their effect would be antidilutive. As of September 30, 2018, we had 5,999,544 options and 2,220,687 warrants that were not included in the earnings per share 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. Therefore, we believe it is appropriate to prepare the financial statements on a going concern basis.

As of September 30, 2019, we had cash, cash equivalents and short-term investments of \$47.9 million and net assets of \$96.1 million. For the nine months ended September 30, 2019, we had cash outflows from operations of \$48.6 million.



In early 2019, the Company implemented a multi-faceted program to seek sufficient liquidity through at least the end of 2020. This program considered 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. In September 2019, the Company announced that it has retained Jefferies LLC as its financial advisor to assist with the review of strategic options focused on advancing the Company's mission and maximizing stockholder value. In an effort to unlock potential additional value, the Company initiated this more formal process to explore a broad range of strategic alternatives including but not limited to the partnering of its various clinical and pre-clinical programs, or a sale or merger of the Company.

#### 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	September 30, 2019	December 31, 2018
U.S. government and agency securities and treasuries	\$ -	\$ 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 nine months ended September 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 received 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 was originally required under the agreement to 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 and payable on November 4, 2020. 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 November 1, 2019, we entered into an amendment of the original license agreement. The amended agreement replaced the \$10 million payment due on November 4, 2019 with a \$3 million payment due on November 4, 2019 and an additional \$8 million payment due on April 1, 2020.

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 recorded during the nine months ended September 30, 2019.

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

Licensed technology consists of the following:

	September 30, 2019	December 31, 2018
Licensed technology	\$ 42,606,000	\$ 44,859,000
Less accumulated amortization	5,135,000	1,817,000
Licensed technology, net	<u>\$ 37,471,000</u>	<u>\$ 43,042,000</u>

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

2019, remainder	\$ 1,293,000
2020	5,167,000
2021	5,167,000
2022	5,167,000
2023	5,167,000
Thereafter	15,510,000
Total	<u>\$ 37,471,000</u>

Amortization on licensed technology was \$1,293,000 and \$3,931,000 for the three and nine months ended September 30, 2019, respectively, and \$87,000 and \$260,000 for the three and nine months ended September 30, 2018, respectively.

#### NOTE 5 – RESTRICTED CASH

Restricted cash, which is reported within other assets and restricted cash on the condensed consolidated balance sheets, 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 September 30, 2019 and December 31, 2018 are summarized below:

Description	September 30, 2019	Level 1	Level 2	Level 3	Total Gains/(Losses)
<b>Non-recurring</b>					
Assets:					
Licensed technology, net	\$ 37,471,000	\$ -	\$ -	\$ 37,471,000	\$ (367,000)
Goodwill	32,466,000	-	-	32,466,000	-

Description	December 31, 2018	Level 1	Level 2	Level 3	Total Gains/(Losses)
<b>Recurring</b>					
Assets:					
Short-term investments	\$ 66,218,000	\$ -	\$ 66,218,000	\$ -	-
<b>Non-recurring</b>					
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 option-based compensation expense for the three and nine months ended September 30, 2019 and 2018:

	For the three months ended September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 972,000	\$ 1,012,000	\$ 3,013,000	\$ 2,756,000
General and administrative	854,000	1,487,000	2,594,000	4,316,000
Stock-based compensation expense included in operating expense	1,826,000	2,499,000	5,607,000	7,072,000
Total stock-based compensation expense	1,826,000	2,499,000	5,607,000	7,072,000
Tax benefit	-	-	-	-
Stock-based compensation expense, net of tax	\$ 1,826,000	\$ 2,499,000	\$ 5,607,000	\$ 7,072,000

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

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

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

	<u>For the three months ended September 30,</u>		<u>For the nine months ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Expected volatility	103%	109%	108%	109%
Expected term	6.25 years	5.00 years	5.09 years	5.00 years
Risk-free interest rate	1.83%	2.78%	2.21%	2.54%
Expected dividend yield	0%	0%	0%	0%

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

	<u>For the three months ended September 30,</u>		<u>For the nine months ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Options granted	105,600	157,000	1,490,490	1,026,800
Weighted-average:				
Exercise price	\$ 2.58	\$ 14.45	\$ 6.53	\$ 14.38
Grant date fair value	\$ 2.09	\$ 11.44	\$ 5.14	\$ 11.36

The following table summarizes restricted common stock-based compensation expense for the three and nine months ended September 30, 2019 and 2018:

	<u>For the three months ended September 30,</u>		<u>For the nine months ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Research and development	\$ 66,000	\$ -	\$ 66,000	\$ -
General and administrative	32,000	172,000	282,000	516,000
Stock-based compensation expense included in operating expense	98,000	172,000	348,000	516,000
Total stock-based compensation expense	98,000	172,000	348,000	516,000
Tax benefit	-	-	-	-
Stock-based compensation expense, net of tax	\$ 98,000	\$ 172,000	\$ 348,000	\$ 516,000

We granted 376,625 shares of restricted common stock to employees during the three and nine months ended September 30, 2019. We did not grant any restricted common stock to employees during the three and nine months ended September 30, 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 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:

	<b>Three months ended September 30, 2019</b>	<b>Nine months ended September 30, 2019</b>
Operating lease cost	\$ 434,000	\$ 1,157,000
Variable lease cost	\$ 82,000	\$ 241,000
Short-term lease cost	\$ 32,000	\$ 113,000

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

**Maturity of lease liabilities:**

2019, remainder	\$ 422,000
2020	1,699,000
2021	1,713,000
2022	1,727,000
2023	1,741,000
Thereafter	3,667,000
<b>Total undiscounted operating lease payments</b>	<b>10,969,000</b>
Less: imputed interest	2,791,000
<b>Present value of operating lease liabilities</b>	<b>\$ 8,178,000</b>

**Balance sheet classification:**

Current portion of lease liability	\$ 1,696,000
Long-term lease liability	6,482,000
<b>Total operating lease liabilities</b>	<b>\$ 8,178,000</b>

**Other information:**

Weighted-average remaining lease term for operating leases	76 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 alleged 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 sought 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 were substantially similar to those set forth in his Demand, as well as those in the Dos Ramos Action. Mahon generally sought 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-50X for the treatment of retinal diseases. In addition, we are developing next-generation AAV-based gene therapies through our novel AIM™ capsid platform and internal AAV vector research programs. We believe our product candidates are eligible for orphan drug designation, breakthrough therapy designation, or other expedited review processes in the U.S., Europe or Japan. Our pipeline includes five product candidates for which we hold several U.S. and EU regulatory designations:



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

**Our Mission and Strategy**

Abeona is at the forefront of gene and cell therapy research and development. We are a fully-integrated company featuring 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 develop therapies that address the underlying cause of a broad spectrum of rare genetic diseases for which no effective treatment options exist today.

Since our last fiscal year, we 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™ Capsid Technology to Develop New In-Vivo Gene Therapies.**

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

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

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

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

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

**Maintaining and Growing IP Portfolio.**

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



## RESULTS OF OPERATIONS FOR THREE MONTHS ENDED SEPTEMBER 30, 2019 COMPARED TO THREE MONTHS ENDED SEPTEMBER 30, 2018

Foundation revenues relate to a collaborative agreement between nine Sanfilippo foundations and us 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 September 30, 2019. 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. Our foundation revenue was \$0 in the third quarter of 2019 and \$1.7 million in the third quarter of 2018. We did not record foundation revenue in the third quarter of 2019 since we have previously recognized revenue up to the amount of cash received to date by installment performed.

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

Total research and development spending for the third quarter of 2019 was \$10.9 million, as compared to \$13.2 million for the same period of 2018, a decrease of \$2.3 million. The decrease in expenses was primarily due to decreased clinical and development work (\$3.0 million) as we carefully reviewed third-party services contracts and delayed activities for certain clinical programs, partially offset by increased salary and related costs (\$0.8 million) from the hiring of additional scientific staff.

Total general and administrative expenses were \$4.7 million for the third quarter of 2019, as compared to \$5.0 million for the same period of 2018, a decrease of \$0.3 million. The decrease in expenses was primarily due to:

- decreased salary and related costs (\$0.6 million);
- decreased recruiting costs (\$0.4 million); and
- decreased professional fees (\$0.2 million); partially offset by
- increased office rent costs (\$0.4 million); and
- increased net other general and administrative expenses (\$0.5 million).

Depreciation and amortization were \$2.0 million for the third quarter of 2019, as compared to \$0.5 million for the same period in 2018, an increase of \$1.5 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 \$0.3 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 third quarter of 2019 was \$17.4 million, or a \$0.35 basic and diluted loss per common share as compared to a net loss of \$16.4 million, or a \$0.34 basic and diluted loss per common share, for the same period in 2018.

## RESULTS OF OPERATIONS FOR NINE MONTHS ENDED SEPTEMBER 30, 2019 COMPARED TO NINE MONTHS ENDED SEPTEMBER 30, 2018

Our foundation revenue was \$0 for the first nine months of 2019 and \$2.4 million for the same period of 2018.

We recorded royalty revenue for MuGard of \$0 for the first nine 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 nine months of 2019 was \$39.0 million, as compared to \$29.2 million for the same period of 2018, an increase of \$9.8 million. The increase in expenses was primarily due to:

- increased clinical and development work for other gene therapy products (\$6.1 million); and
- increased salary and related costs (\$4.1 million) from the hiring of additional clinical, regulatory, manufacturing and quality staff; partially offset by
- decreases in other research and development costs (\$0.4 million).

Total general and administrative expenses were \$16.0 million for the first nine months of 2019, as compared to \$12.5 million for the same period of 2018, an increase of \$3.5 million. The increase in expenses was primarily due to:

- increased professional fees (\$1.4 million);
- increased office rent costs (\$1.3 million); and
- increased net other general and administrative expenses (\$0.8 million).

Depreciation and amortization were \$5.7 million for the first nine months of 2019, as compared to \$1.0 million for the same period in 2018, an increase of \$4.7 million. The increase was driven by increased amortization expense of \$3.6 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 \$1.1 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 nine months of 2019 was \$59.9 million, or a \$1.22 basic and diluted loss per common share as compared to a net loss of \$39.2 million, or a \$0.83 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. The Company believes that it has access to sufficient resources to fund business operations for the next 12 months.

As of September 30, 2019 and December 31, 2018, our cash, cash equivalents and short-term investments were \$47.9 million and \$85.0 million, respectively. As of September 30, 2019 and December 31, 2018, our working capital was \$29.4 million and \$68.5 million, respectively. The decrease in working capital during the nine months ended September 30, 2019 resulted primarily from \$48.6 million of cash used for operating activities and \$6.2 million for capital expenditures, partially offset by \$17.0 million of proceeds from open market sales of common stock.

In early 2019, the Company implemented a multi-faceted program to seek sufficient liquidity through at least the end of 2020. This program includes 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. In September 2019, the Company announced that it has retained Jefferies LLC as its financial advisor to assist with the review of strategic options focused on advancing the Company's mission and maximizing stakeholder value. The Company initiated this more formal process to explore a broad range of strategic alternatives, including, but not limited to, the partnering of its various clinical and pre-clinical programs, or a sale or merger of the Company, in an effort to unlock the potential of those assets.

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 received 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 was originally required under the agreement to 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 and payable on November 4, 2020. 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.

On November 1, 2019, we entered into an amendment of the original license agreement. The amended agreement replaced the \$10 million payment due on November 4, 2019 with a \$3 million payment due on November 4, 2019 and an additional \$8 million payment due on April 1, 2020.

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 3,086,950 shares of our common stock under this agreement and received \$17.0 million of proceeds during the nine months ended September 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 \$470.0 million as of September 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.

In September 2019, we received a clinical hold letter from the FDA clarifying that the FDA will not provide approval for us to begin our planned phase III clinical trial for EB-101 until we submit to the FDA additional data points on transport stability of EB-101 to clinical sites. We have worked closely with the FDA to address and narrow open CMC items including this one item identified in the FDA clinical hold letter. However, we cannot predict whether or when the FDA will lift the clinical hold with respect to the Company's planned phase III clinical trial for patients with RDEB.

We plan to continue our policy of investing any available funds in certificates of deposit, money market funds, government securities and/or 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 nine months ended September 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 September 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 were effective as of September 30, 2019.

**Changes in Internal Control Over Financial Reporting** – There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 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 November 1, 2019, Sudipta Majumdar filed a putative securities class action lawsuit against the Company and certain of its current and former executive officers, in the U.S. District Court for the Southern District of New York, purportedly on behalf of purchasers of the Company's securities between May 31, 2018 and September 23, 2019. The complaint alleges, among other things, that the defendants made materially false and misleading statements regarding the Company's business, and operational and compliance policies, in violation of Sections 10(b) and 20(a) of the Exchange Act. The complaint seeks unspecified damages, fees, interest, and costs. The Company intends to defend this suit vigorously.

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 Duyn, and Todd Wider as defendants, and the Company as nominal defendant (the "Dos Ramos Defendants"). Dos Ramos generally alleged 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 sought 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 were substantially similar to those set forth in his Demand, as well as those in the Dos Ramos Action. Mahon generally sought 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 Annual Report on Form 10-K for the year ended December 31, 2018 should be carefully considered. Other than the risk factor provided below, there have been no material changes to the risk factors from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2018.

*We may encounter substantial delays in our clinical studies, such as clinical holds, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.*

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety, purity and potency, and efficacy, of the product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory agencies on study design;
- delays in obtaining required IRB or Institutional Ethics Committee approval at each clinical study site; and
- delays in recruiting suitable patients to participate in our clinical studies.

As previously reported, the Company received a clinical hold letter from the FDA in September 2019 clarifying that the FDA will not provide approval for the Company to begin its planned phase III clinical trial for EB-101 until it submits to the FDA additional data points on transport stability of EB-101 to clinical sites. Delays in launching clinical trials, such as our planned phase III clinical trial for EB-101, resulting from FDA or other regulatory actions, such as a clinical hold letter, would delay the commercialization of our product candidates and our ability to generate revenue, which would have an adverse effect on our business.

#### **ITEM 6. EXHIBITS.**

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

#### **Exhibit Index**

##### Exhibits:

- |      |  |
|------|--|
| 3.1  | <a href="#"><u>Amended and Restated Bylaws of Abeona Therapeutics Inc. (as amended and restated as of September 12, 2019).</u></a>   |
| 10.1 | <a href="#"><u>Letter Agreement, dated September 12, 2019, amending Offer Letter between the Company and João Siffert, M.D., dated February 11, 2019.</u></a>  |
| 10.2 | <a href="#"><u>Letter Agreement, dated September 12, 2019, amending Offer Letter between the Company and Christine Berni Silverstein, dated January 8, 2019.</u></a>   |
| 10.3 | <a href="#"><u>Letter Agreement, dated September 12, 2019, amending Offer Letter between the Company and Edward Carr, dated November 9, 2018.</u></a>  |
| 10.4 | <a href="#"><u>First Amendment to License Agreement, dated November 1, 2019, between the Company and REGENXBIO Inc.</u></a>  |
| 31.1 | <a href="#"><u>Principal Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.</u></a>  |
| 31.2 | <a href="#"><u>Principal Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.</u></a>  |
| 32*  | <a href="#"><u>Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>   |
| 101  | The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2019 and 2018, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2019 and 2018, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 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: November 12, 2019

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

Date: November 12, 2019

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





AMENDED RESTATED BYLAWS  
OF  
ABEONA THERAPEUTICS INC.

(As amended and restated as of September 12, 2019)

ARTICLE I.

**Offices and Agents**

1. Principal Office. The principal office of the Corporation may be located within or without the State of Delaware, as designated by the board of directors. The Corporation may have other offices and places of business at such places within or without the State of Delaware as shall be determined by the directors.
2. Registered Office. The registered office of the Corporation required by the General Corporation Law of Delaware must be maintained in the State of Delaware, and it may be, but need not be, identical with the principal office, if located in the state of Delaware. The address of the registered office of the Corporation may be changed from time to time as provided by the General Corporation Law of Delaware.
3. Registered Agent. The Corporation shall maintain a registered agent in the State of Delaware as required by the General Corporation Law of Delaware. Such registered agent may be changed from time to time as provided by the General Corporation Law of Delaware.

ARTICLE II.

**Stockholders Meetings**

1. Annual Meetings. Unless otherwise determined by the board of directors, the annual meeting of the stockholders of the Corporation shall be held at a reasonable hour on the second Wednesday of May unless that day be a holiday, in which case said meeting shall be held on the next business day following that day. The annual meeting of the stockholders shall be held for the purpose of electing directors and transacting such other corporate business as may come before the meeting.
  2. Special Meetings. Special meetings of the stockholders of the Corporation may be called at any time by the chairman of the board of directors, if any, by the president or by resolution of the board of directors. The notice or call of a special meeting shall state the purpose or purposes for which the meeting is called.
  3. Place of Meeting. The annual meeting of the stockholders of the Corporation may be held at any place, either within or without the State of Delaware, as may be designated by the board of directors. Except as limited by the following sentence, the person or persons calling any special meeting of the stockholders may designate any place, within or without the State of Delaware, as the place for the meeting. If no designation is made or if a special meeting shall be called other than by the board of directors, the chairman of the board of directors or the president, the place of meeting shall be the principal office of the Corporation. A waiver of notice signed by all stockholders entitled to vote at a meeting may designate any place for such meeting.
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4. Notice of Meeting. Except as otherwise provided in these Bylaws or by the laws of the State of Delaware, written or printed notice stating the place, date and hour of the meeting and, in the case of a special meeting, the purpose or purposes for which the meeting is called, shall be delivered either personally or by mail to each stockholder of record entitled to vote at such meeting not less than ten (10) nor more than sixty (60) days before the date of the meeting. If mailed, such notice shall be deemed to be delivered when deposited in the United States mail, postage prepaid, directed to the stockholder at his address as it appears on the records of the Corporation. An affidavit of the secretary, assistant secretary, if any, or transfer agent of the Corporation that notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

5. Waiver of Notice. Any stockholder, either before, at, or after any stockholders' meeting, may waive notice of the meeting, and his waiver shall be deemed the equivalent of giving notice. Attendance at a stockholders' meeting, either in person or by proxy, by a person entitled to notice thereof shall constitute a waiver of notice of the meeting unless he attends for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business on the ground that the meeting was not lawfully called or convened.

6. Fixing of Record Date. For the purpose of determining stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the board of directors of the Corporation may fix, in advance, a record date, which shall not be more than sixty (60) nor less than ten (10) days before the date of the meeting; not more than ten (10) days after the record date for determining shareholders entitled to express consent is fixed; and not more than sixty (60) days prior to the date of any other action. If no record date is fixed: (i) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting was held; (ii) the record date for determining stockholders entitled to express consent to corporate action in writing without a meeting, when no prior action by the board of directors is necessary, shall be the day on which the first written consent is delivered to the Corporation at its principal place of business or such other place as designated by the boards of directors; (iii) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto. A determination of stockholders entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, provided, however, that the board of directors may fix a new record date for the adjourned meeting.

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7. Voting List. The officer or agent who has charge of the stock ledger of the Corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, or any adjournment thereof, arranged in alphabetical order, showing the address of and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice of the meeting or, if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. The stock ledger shall be the only evidence as to who are the stockholders entitled to examine the stock ledger, the books of the Corporation or to vote in person or by proxy at any meeting of stockholders.

8. Polls. The date and time of the opening and closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting. No ballot, proxies or votes, nor any revocations thereof or changes thereto, shall be accepted by the inspectors after the closing of the polls unless the Court of Chancery upon application by a stockholder shall determine otherwise.

9. Proxies. Any stockholder entitled to vote at a meeting of the stockholders, or to express consent or dissent to corporate action in writing without meeting may authorize another person or persons to act for him by proxy. No proxy shall be voted or acted upon after three (3) years from the date of its execution unless the proxy expressly provides for a longer period. A duly executed proxy shall be irrevocable if it states that it is irrevocable and if, and only as long as, it is coupled with an interest sufficient in law to support an irrevocable power. A proxy may be irrevocable regardless of whether the interest with which it is coupled is an interest in the stock itself or an interest in the Corporation generally.

Without limiting the manner in which a stockholder may authorize another person or persons to act for him by proxy, the following shall constitute a valid means by which a stockholder may grant such authority.

A stockholder may execute a writing authorizing another person or persons to act for him as proxy. Execution may be accomplished by the stockholder or his authorized officer, director, employee or agent signing such writing or causing his signature to be affixed to such writing by any reasonable means including but not limited to, by facsimile signature.

A stockholder may authorize another person or persons to act for him as proxy by transmitting or authorizing the transmission of a telegram, cablegram or other means of electronic transmission to the person who will be the holder of the proxy or to a proxy solicitation firm, proxy support service organization or like agent duly authorized by the person who will be the holder of the proxy to receive such transmission, provided that any such telegram, cablegram or other electronic transmission must either set forth or be submitted with information from which it can be determined that the telegram, cablegram or other electronic transmission was authorized by the stockholder. If it is determined that such telegrams, cablegrams or other electronic transmission are valid, the inspectors or, if there are no inspectors, such other persons making that determination shall specify the information upon which they relied.

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Any copy facsimile telecommunication or other reliable reproduction of the writing or transmission created pursuant to this Paragraph 9 may be substituted or used in lieu of the original writing or transmission for any and all purposes for which the original writing or transmission could be used, provided that such copy, facsimile telecommunication or other reproduction shall be a complete reproduction of the entire original writing or transmission.

10. Voting Rights. Each outstanding share, regardless of class, shall be entitled to one vote, and each fractional share shall be entitled to a corresponding fractional vote on each matter submitted to a vote at a meeting of stockholders except to the extent that the voting rights of the shares of any class or classes are limited or denied by the Certificate of Incorporation.

At each election for directors every stockholder entitled to vote at such election shall have the right to vote in person or by proxy the number of shares owned by him for as many persons as there are directors to be elected and for whose election he has a right to vote, and cumulative voting in the election of such directors shall be permitted.

Persons holding stock in a fiduciary capacity shall be entitled to vote the shares so held. Persons whose stock is pledged shall be entitled to vote, unless in the transfer by the pledgor on the books of the Corporation he has expressly empowered the pledgee to vote thereon, in which case only the pledgee, or his proxy, may represent such stock and vote thereon.

The Corporation's own capital stock belonging to the Corporation or to another corporation, if a majority of the shares entitled to vote in the election or directors of such other corporation is held, directly or indirectly, by the Corporation, shall neither be entitled to vote nor be counted for quorum purposes. Nothing in this section shall be construed as limiting the right of the Corporation to vote stock, including but not limited to its own stock, held by it in a fiduciary capacity.

Shares which have been called for redemption shall not be deemed to be outstanding shares for the purpose of voting or determining the total number of shares entitled to vote on any matter on and after the date on which written notice of redemption has been sent to holders thereof and a sum sufficient to redeem such shares has been irrevocably deposited or set aside to pay the redemption price to the holders of the shares upon surrender of certificates there for.

If shares or other securities having voting power stand of record in the names of two (2) or more persons, whether fiduciaries, members of a partnership, joint tenants, tenants in common, tenants by the entirety or otherwise, or if two (2) or more persons have the same fiduciary relationship respecting the same shares, unless the secretary of the Corporation is given written notice to the contrary and is furnished with a copy of the instrument or order appointing them or creating the relationship wherein it is so provided, their acts with respect to voting shall have the following effect: (i) if only one (1) votes, his act binds all; (ii) if more than one (1) votes, the act of the majority so voting binds all; (iii) if more than one (1) votes, but the vote is evenly split on any particular matter each faction may vote the securities in question proportionally, or any person voting the shares, or a beneficiary, if any, may apply to the Court of Chancery or such other court as may have jurisdiction to appoint an additional person to act with the persons so voting the shares, which shall then be voted as determined by a majority of such persons and the person appointed by the Court. If the instrument so filed shows that any such tenancy is held in unequal interests, a majority or even split for the purpose of this subsection shall be a majority or even split in interest.

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11. Inspectors or Election. Prior to holding any meeting of stockholders, the Corporation shall appoint one or more inspectors to act at the meeting and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of his duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his ability.

The inspectors shall (i) ascertain the number of shares outstanding and the voting power of each; (ii) determine the shares represented at a meeting and the validity of proxies and ballots; (iii) count all votes and ballots; (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors, and (v) certify their determination of the number of shares represented at the meeting and their count of all votes and ballots. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of the inspectors.

In determining the validity and counting of proxies and ballots, the inspectors shall be limited to an examination of the proxies, any envelopes submitted with those proxies, any information provided in accordance with Article II, Paragraph 9 of these Bylaws, any records of the Corporation, except that the inspectors may consider other reliable information for the limited purpose of reconciling proxies and ballots submitted by or on behalf of banks, brokers, their nominees or similar persons which represent more votes than the holder of a proxy is authorized by the record owner to cast or more votes than the stockholder holds of record. If the inspectors consider other reliable information for the limited purpose permitted herein, the inspectors at the time they make their certification shall specify the precise information considered by them including the person or persons from whom they obtained the information, when the information was obtained, the means by which the information was obtained and the basis for the inspectors' belief that such information is accurate and reliable.

12. Quorum. Except as otherwise provided in the Certificate of Incorporation, the presence, in person or by proxy, of the holders of a majority of the shares outstanding and entitled to vote shall constitute a quorum at meetings of the stockholders. In all matters, other than the election of directors, the affirmative vote of a majority of the shares present in person or represented by proxy at the meeting and actually voting on the subject matter shall be the act of the stockholders. Directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. In the event any stockholders withdraw from a duly organized meeting at which a quorum was initially present, the remaining shares represented shall constitute a quorum for the purpose of continuing to do business, and the affirmative vote of the majority of the remaining shares represented at the meeting and entitled to vote on the subject matter shall be the act of the stockholders unless the vote of a greater number or voting by classes is required by the General Corporation Law of Delaware or the Certificate of Incorporation.

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13. Adjournments. If less than a quorum of the outstanding shares entitled to vote is represented at any meeting of the stockholders, a majority of the shares so represented may adjourn the meeting from time to time for a period not to exceed thirty (30) days at any one adjournment, without further notice, provided the time and place thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. Any meeting of the stockholders may adjourn from time to time until its business is completed. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

14. Informal Act by Shareholders. Any action required to be taken at a meeting of shareholders, or any action which may be taken at a meeting of shareholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted shall be delivered to the Corporation by said consent or consents delivered at its principal place of business or such other place as designated by the board of directors. Delivery made to the Corporation shall be by hand or by certified or registered mail, return receipt requested.

### ARTICLE III.

#### **Board of Directors**

1. Number, Qualifications and Term of Office. Except as otherwise provided in the Certificate of Incorporation or the General Corporation Law of Delaware, the business and affairs of the Corporation shall be managed under the direction of a board of directors consisting of from three to fifteen members. Each director shall be a natural person of the age of fifteen years or older, but does not need to be a resident of the state of Delaware or a stockholder of the Corporation. The board of directors, by resolution, may increase or decrease the number of directors from time to time. Except as otherwise provided in these Bylaws or in the Certificate of Incorporation, the board of directors shall be divided into three (3) classes as nearly equal in number as possible. Each director in each class shall be elected at the appropriate annual meeting of stockholders, as determined by the Certificate of Incorporation, and shall hold office for a term of three (3) years and until his successor is elected and qualified or until his earlier resignation or removal. No decrease in the number of directors shall have the effect of shortening the term of any incumbent director.

2. Vacancies and Newly Created Directorships. Vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class shall be filled solely by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. Any directors so chosen shall hold office until the next election of the class for which such director shall have been chosen, and until their successors shall be elected and qualified. No decrease in the number of directors constituting the board of directors shall shorten the term of any incumbent director.

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If at any time of filling any vacancy or newly created directorship, the directors then in office shall constitute less than a majority of the whole board, the Court of Chancery may, upon application of any stockholder or stockholders holding at least ten percent (10%) of the total number of shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by Section 211 of the General Corporation Law of Delaware.

Any director may resign at any time by giving written notice to the president or to the secretary of the Corporation. Such resignation shall take effect at the future time specified therein; and unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective. Any vacancy occurring on the board of directors created by the resignation of a director, may be filled by the affirmative vote of a majority of directors then in office, including those who have so resigned. The vote thereon shall take effect when such resignation or resignations shall become effective. A director elected to fill a vacancy shall be elected for the unexpired term of his predecessor in office.

3. Removal. Any director or the entire board of directors may be removed in accordance with the provisions of Article VII Subparagraph D of the Certificate of Incorporation.

4. Compensation. Any director may be paid any one or more of the following: his expenses, if any, of attendance at meetings; a fixed sum for attendance at each meeting; or a stated salary as director. No such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor. A director shall also be entitled to receive options for the acquisition of shares of stock of the corporation.

#### ARTICLE IV.

##### **Meetings of the Board**

1. Place of Meetings. The regular or special meetings of the board of directors or any committee designated by the board may be held at the principal office of the Corporation or at any other place within or without the State of Delaware that a majority of the board of directors or any such committee, as the case may be, may designate from time to time by resolution.

2. Regular Meetings. The board of directors shall meet each year immediately after the annual meeting of the stockholders for the purpose of electing officers and transacting such other business as may come before the meeting. The board of directors or any committee designated by the board may provide, by resolution, for the holding of additional regular meetings without other notice than such resolution.

3. Special Meetings. Special meetings of the board of directors or any committee designated by the board may be called at any time by the chairman of the board, if any, by the president or by a majority of the members of the board of directors or any such committee, as the case may be.

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4. Notice of Meetings. Notice of the regular meetings of the board of directors or any committee designated by the board need not be given. Except as otherwise provided by these Bylaws or the laws of the State of Delaware, written notice of each special meeting of the board of directors or any such committee setting forth the time and the place of the meeting shall be given to each director not less than two (2) days prior to the time fixed for the meeting. Notice of special meetings may be either given personally, personally by telephone, or by sending a copy of the notice through the United States mail or by telegram, telex or telecopy, charges prepaid, to the address of each director appearing on the books of the Corporation. If mailed, such notice shall be deemed to be delivered when deposited in the United States mail so addressed, with postage prepaid thereon. If notice is given by telegram, telex or telecopy, such notice shall be deemed to be delivered when the telegram is delivered to the telegraph, telex or telecopy operator. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the board of directors need be specified in the notice or waiver of notice of such meeting.

5. Waiver of Notice. A director may in writing waive notice of any special meeting of the board of directors or any committee, either before, at, or after the meeting; and his waiver shall be deemed the equivalent of giving notice. Attendance of a director at a meeting shall constitute waiver of notice of that meeting unless he attends for the express purpose of objecting to the transaction of business because the meeting has not been lawfully called or convened.

6. Quorum. At meetings of the board of directors or any committee designated by the board a majority of the number of directors fixed by these Bylaws or a majority of the members of any such committee, as the case may be, shall be necessary to constitute a quorum for the transaction of business. If a quorum is present, the act of the majority of directors in attendance shall be the act of the board of directors or any such committee, as the case may be, unless the act of a greater number is required by these Bylaws, the Certificate of Incorporation or the General Corporation Law of Delaware. One or more directors may participate in meetings of the board of directors as authorized by Subparagraph 11 of this Article IV by conference telephone, while the remaining director or directors are physically present at the meeting.

7. Presumption of Assent. A director who is present at a meeting of the board or committee designated by the board when corporate action is taken is deemed to have assented to the action taken unless: (i) he objects at the beginning of such meeting to the holding of the meeting or the transacting of business at the meeting; (ii) he contemporaneously requests that his dissent from the action taken be entered in the minutes of such meeting; or (iii) he gives written notice of his dissent to the presiding officer of such meeting before its adjournment or to the secretary of the Corporation immediately after adjournment of such meeting. The right of dissent as to a specific action taken in a meeting of a board or committee thereof is not available to a director who votes in favor of such action.

8. Reliance on Books of Account or Reports. Any member of the board of directors or any committee designated by the board of directors shall, in the performance of his duties, be fully protected in relying in good faith upon the records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of its officers, or employees, or committees of the board of directors, or by any other person as to matters the members reasonably believes are within such other persons professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation, or in relying in good faith upon other records of the Corporation.

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9. Committees. The board of directors may, by a resolution passed by a majority of the whole board designate one (1) or more committees, each committee to consist of one (1) or more directors of the corporation. The board may designate one or more directors as alternate members of any committee who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the board of directors to act at the meeting in the place of any such absent or disqualified member.

Any such committee to the extent provided in the resolution of the board of directors shall have and may exercise all of the powers and authority of the board of directors in the management of the business and affairs of the Corporation and may authorize the seal of the Corporation to be affixed to all papers which it may acquire. No such committee shall have the power or authority of the board of directors to: (i) amend the Certificate of Incorporation; (ii) adopt an agreement of merger or consolidation; (iii) recommend to the stockholders the sale, lease or exchange of all or substantially all of the Corporation's property and assets; (iv) recommend to the stockholders a dissolution of the Corporation or a revocation of a dissolution; (v) amend the Bylaws of the Corporation; (vi) or unless expressly provided for by resolution, or in the Certificate of Incorporation, declare a dividend, authorize the issuance of stock or to adopt a certificate of ownership and merger. To the extent authorized by resolution or resolutions providing for the issuance of shares of stock, adopted by the board, a committee may: (i) fix the designations and any of the preferences or rights of such shares relating to dividends, redemption, dissolution, any distribution of assets of the Corporation or the conversion into, or the exchange of such shares for, shares of any other class or classes or any other series of the same or any other class or classes of stock of the Corporation; or (ii) fix the number of shares of any series of stock or authorize the increase or decrease of the shares of any series. If any such delegation of the authority of the board of directors is made as provided herein, all references to the board of directors contained in these Bylaws, the Certificate of Incorporation, the General Corporation Law of Delaware or any other applicable law or regulation relating to the authority so delegated shall be deemed to refer to such committee.

10. Informal Action by Directors. Any action required or permitted to be taken at a meeting of the board of directors or any committee thereof, may be taken without a meeting if all the members of the board or committee, as the case may be, consent thereto in writing, and the writing or writings are filed with the minutes of proceedings of the board or committee. Such consent shall have the same force and effect as a unanimous vote of the directors and may be stated as such in any articles or documents filed with the Secretary of State of Delaware under the General Corporation Law of Delaware.

11. Telephonic Meetings. Members of the board of directors or any committee designated by the board may participate in meeting of such board or committee by means of a conference telephone or similar communications equipment by which all persons participating in the meeting can hear each other at the same time. Participation in such a meeting shall constitute presence in person at the meeting.

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ARTICLE V.

**Officers and Agents**

1. General. The executive officers of the Corporation shall be elected annually by the board of directors at the first meeting of the board held after each annual meeting of the stockholders. If the election of such officers shall not be held at such meeting, such election shall take place as soon thereafter as a meeting may conveniently be held. The officers of the Corporation shall consist of a president, a secretary and a treasurer, or a secretary/treasurer; in addition, one or more vice presidents, a chairman of the board of directors and such other officers, assistant officers, agents and employees that the board of directors may from time to time deem necessary may be elected by the board of directors or be appointed in a manner prescribed by the board.

Two or more offices may be held by the same person. Officers shall hold office until their successors are elected and qualified, unless they are sooner removed from office as provided in these Bylaws. All officers of the Corporation shall be natural persons of the age of eighteen years or older. Officers of the Corporation need not be residents of the State of Delaware or directors or stockholders of the Corporation.

2. General Duties. All officers and agents of the Corporation, as between themselves and the Corporation, shall have such authority and shall perform such duties in the management of the Corporation as may be provided in these Bylaws or as may be determined by resolution of the board of directors not inconsistent with these Bylaws. In all cases where the duties of any officer, agent or employee are not prescribed by the Bylaws or by the board of directors, such officer, agent or employee shall follow the orders and instructions of the president.

Any officer shall have the power to execute and deliver on behalf of and in the name of the Corporation any instrument requiring the signature of an officer of the Corporation, except as otherwise provided in these Bylaws or where the execution and delivery thereof shall be expressly delegated by the board of directors to some other officer or agent of the Corporation. Unless authorized to do so by these Bylaws or by the board of directors, no officer, agent or employee shall have any power or authority to bind the Corporation in any way, to pledge its credit or to render it liable pecuniarily for any purpose or in any amount.

3. Vacancies. When a vacancy occurs in one of the executive offices by reason of death, resignation or otherwise, it shall be filled by a resolution of the board of directors. The officer so selected shall hold office until his successor is chosen and qualified.

4. Salaries. The board of directors shall fix the salaries of the officers of the Corporation. The salaries of other agents and employees of the Corporation may be fixed by the board of directors, or by any committee designated by the board or by an officer to whom that function has been delegated by the board. No officer shall be prevented from receiving such salary by reason of the fact that he is also a director of the Corporation.

5. Removal. Any officer or agent of this Corporation may be removed by the board of directors whenever in its judgment the best interests of the Corporation may be served thereby, but such removal shall be without prejudice to the contract rights, if any, of the person so removed. Election or appointment of an officer or an agent shall not of itself create contract rights.

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6. Chairman of the Board. The chairman of the board, if any, shall preside as chairman at meetings of the stockholders and the board of directors. He shall, in addition, have such other duties as the board may prescribe that he perform. At the request of the president, the chairman of the board may, in the case of the president's absence or inability to act, temporarily act in his place. In the case of death of the president or in the case of his absence or inability to act without having designated the chairman of the board to act temporarily in his place, the chairman of the board shall perform the duties of the president, unless the board of directors, by resolution, provides otherwise. If the chairman of the board shall be unable to act in place of the president, any vice president may exercise such powers and perform such duties as provided in section 8 below.

6a. Executive Chairman. The board of directors may from time to time elect or appoint the chairman of the board, if any, to serve as executive chairman. To the extent such position is filled, all other executive officers shall report to the executive chairman, unless delegated otherwise by the executive chairman. The executive chairman shall have general and active management and supervision of the business and affairs of the Corporation.

7. President. The president shall be the chief executive officer of the Corporation (unless the board of directors appoints another executive to be the chief executive officer of the Corporation with such duties and responsibilities as the board of directors shall delegate from time to time), and, subject to the control of the board of directors, shall have general supervision of the business and affairs of the Corporation. In the event the position of chairman of the board shall not be occupied or the chairman shall be absent or otherwise unable to act, the president shall preside at meetings of the stockholders and directors and shall discharge the duties of the presiding officer. At each annual meeting of the stockholders the president shall give a report of the business of the Corporation for the preceding fiscal year and shall perform whatever other duties the board of directors may from time to time prescribe. The president may sign, with the secretary or any other proper officer of the Corporation thereunto authorized by the board of directors, certificates for shares of the Corporation, any deeds, mortgages, bonds, contracts, or other instruments which the board of directors has authorized to be executed, except in cases where the signing and execution thereof shall be expressly delegated by the board of directors or by these Bylaws to some other officer or agent of the Corporation, or shall be required by law to be otherwise signed or executed.

8. Vice Presidents. Each vice president shall have such powers and perform such duties as the board of directors may from time to time prescribe or as the president may from time to time delegate to him. At the request of the president, in the case of the president's absence or inability to act, any vice president may temporarily act in his place. In the case of the death of the president, or in the case of his absence or inability to act without having designated a vice president or vice presidents to act temporarily in his place, the board of directors, by resolution, may designate a vice president or vice presidents, to perform the duties of the president. If no such designation shall be made, the chairman of the board of directors, if any, shall exercise such powers and perform such duties, as provided in Section 6 above, but if the Corporation has no chairman of the board of directors, or if the chairman is unable to act in place of the president, all the vice presidents may exercise such powers and perform such duties.

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9. Secretary. The secretary shall keep or cause to be kept in books provided for that purpose the minutes of the meetings of the stockholders, executive committee, if any, and any other committees, and of the board of directors; shall see that all notices are duly given in accordance with the provisions of these Bylaws and as required by law; shall be custodian of the records and of the seal of the Corporation and see that the seal is affixed to all documents, the execution of which on behalf of the Corporation under its seal is duly authorized and in accordance with the provisions of these Bylaws; keep a register of the post office address of each stockholder which shall be furnished to the secretary by such stockholder, sign with the president certificates for shares of the Corporation, the issuance of which shall have been authorized by resolution of the board of directors; have a general charge of the stock transfer books of the Corporation; and, in general, shall perform all duties incident to the office of secretary and such other duties as may, from time to time, be assigned to him by the board of directors or by the president. In the absence of the secretary or his inability to act, the assistant secretaries, if any, shall act with the same powers and shall be subject to the same restrictions as are applicable to the secretary.

10. Treasurer. The treasurer shall have custody of corporate funds and securities. He shall keep full and accurate accounts of receipts and disbursements and shall deposit all corporate monies and other valuable effects in the name and to the credit of the Corporation in the depository or depositories of the Corporation selected by the board of directors, and shall render an account of his transactions as treasurer and of the financial condition of the Corporation to the president and/or the board of directors upon request. Such power given to the treasurer to deposit and disburse funds shall not, however, preclude any other officer or employee of the Corporation from also depositing and disbursing funds when authorized to do so by the board of directors. The treasurer shall, if required by the board of directors, give the Corporation a bond in such amount and with such surety or sureties as may be ordered by the board of directors for the faithful performance of duties of his office. The treasurer shall have such other duties as may be from time to time prescribed by the board of directors or the president. In the absence of the treasurer or his inability to act, the assistant treasurers, if any, shall act with the same authority and shall be subject to the same restrictions as are applicable to the treasurer.

11. Delegation of Duties. Whenever an officer is absent, or whenever, for any reason, the board of directors may deem it desirable, the board may delegate the powers and duties of an officer to any other officer or officers or to any director or directors.

12. Bond of Officers. The board of directors may require any officer to give the Corporation a bond in such sum and with such surety or sureties as shall be satisfactory to the board of directors for such terms and conditions as the board of directors may specify, including without limitation for the faithful performance of his duties and for the restoration to the Corporation of all property in his possession or under his control belong to the Corporation.

13. Loans to Director, Officers, Employees. The Corporation may lend money to, guarantee the obligations of and otherwise assist directors, officers and employees of the Corporation, or directors of another corporation of which the Corporation owns a majority of the voting stock to the extent of and in compliance with the General Corporation Laws of Delaware.

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ARTICLE VI.

**Stock Certificates and the Transfer of Shares**

1. Stock Certificates; Uncertificated Shares. The shares of the Corporation shall be represented by certificates, provided that the board of directors of the Corporation may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Notwithstanding the adoption of such a resolution by the board of directors, every holder of stock represented by certificates and upon request every holder of uncertificated shares shall be entitled to have a certificate signed by, or in the name of the Corporation by the chairman or vice-chairman of the board of directors, or the president or vice-president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the Corporation representing the number of shares registered in certificate form. Any or all the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he were such officer, transfer agent or registrar at the date of issue.

2. Consideration for Shares. Shares shall be issued for such consideration as shall be fixed from time to time by the board of directors. Consideration for shares shall be expressed in dollars, and shall not be less than the par value or stated value therefor, as the case may be. The par value for shares, if any, shall be stated in the Certificate of Incorporation, and the stated value for shares, if any, shall be fixed from time to time by the board of directors. Treasury shares may be disposed of by the Corporation for such consideration expressed in dollars as may be fixed from time to time by the board. Consideration for shares may consist, in whole or in part, of money, other property whether tangible, intangible or both, or in labor or services actually performed for the Corporation, but the promise of future services of a subscriber or direct purchaser of shares from the Corporation shall not constitute payment or part payment for shares.

3. Lost Certificates. The board of directors may direct a new certificate of stock or uncertificated share in place of any certificate issued by it, alleged to have been lost, stolen or destroyed if the owner makes an affidavit or affirmation of that fact and produces such evidence of loss or destruction as the board may require. The board, in its discretion, may as a condition precedent to the issuance of a new certificate require the owner to give the Corporation a bond sufficient to indemnify it against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of the certificate or the issuance of such new certificate.

4. Transfer of Shares. Shares of the Corporation shall only be transferred on its books upon the surrender to the Corporation of the share certificates duly endorsed or accompanied by proper evidence of succession, assignment or authority to transfer and such documentary stamps as may be required by law. In that event, the surrendered certificates shall be cancelled, new certificates issued to the persons entitled to them, and the transaction recorded on the books or the Corporation.

5. Registered Stockholders. The Corporation shall be entitled to treat the holder of record of shares as the holder in fact and, except as otherwise provided by the laws of Delaware, shall not be bound to recognize any equitable or other claim to or interest in the shares.

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The board of directors may adopt by resolution a procedure whereby a stockholder may certify in writing to the Corporation that all or a portion of the shares registered in the name of such stockholder are held for the account of a specified person or persons. Such resolution shall set forth: (i) the classification of stockholder who may certify; (ii) the purpose or purposes for which the certification may be made; (iii) the form of certification and information to be contained therein; (iv) if the certification is with respect to a record date or closing of the stock transfer books within which the certification must be received by the Corporation; and (v) such other provisions with respect to the procedure as are deemed necessary or desirable.

Upon receipt by the Corporation of a certification complying with the procedure, the persons specified in the certification shall be deemed, for the purpose or purposes set forth in the certification, to be the holders of record of the number of shares specified in place of the stockholder making the certification.

6. Stock Ledger. An appropriate stock journal and ledger shall be kept by the secretary or such registrars or transfer agents as the directors by resolution may appoint in which all transactions in the shares of stock of the Corporation shall be recorded.

7. Location. The books, accounts and records of the Corporation may be kept at such place or places within or outside the State of Delaware as the board of directors may from time to time determine.

8. Inspection. The books, accounts and records of the Corporation shall be open for inspection by any member of the board of directors at all times, and open to inspection by the stockholders at such times, and subject to such regulations as the board of directors may prescribe, except as otherwise provided by statute.

#### ARTICLE VII.

##### **Seal and Fiscal Year**

1. Seal. The Corporation shall have a seal in the form impressed to the left of this paragraph of the Bylaws.

2. Fiscal Year. The fiscal year of the Corporation shall be determined by the board of directors and set forth in the minutes of the directors. Said fiscal year may be changed from time to time by the board of directors in its discretion.

#### ARTICLE VIII.

##### **Dividends**

Dividends shall be declared and paid out of the surplus or net profits for the fiscal year in which the dividend is declared, and/or the preceding fiscal year as often and at such times as the board of directors may determine. If the capital of the Corporation, computed in accordance with the General Corporation Law of Delaware, shall have been diminished by depreciation in the value of its property, or by losses, or otherwise, to an amount less than the aggregate amount of the capital represented by the issued and outstanding stock; the board of directors shall not declare and pay out of net profits any dividends upon any shares of its capital stock until the deficiency in the amount of capital represented by issued and outstanding stock shall have been repaired. No unclaimed dividend shall bear interest against the Corporation.

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ARTICLE IX.

**Amendments**

Subject to repeal or change by action of the stockholders in accordance with the Certificate of Incorporation, the board of directors may amend, supplement or repeal these Bylaws or adopt new Bylaws, and all such changes shall affect and be binding upon the holders of all shares heretofore as well as hereafter authorized, subscribed for or offered.

ARTICLE X.

**Miscellaneous**

1. Gender. Whenever required by the context, the singular shall include the plural, the plural the singular, and one gender shall include all genders.
2. Invalid Provision. The invalidity or unenforceability of any particular provision of these Bylaws shall not affect the other provisions herein, and these Bylaws shall be construed in all respects as if such invalid or unenforceable provision was omitted.
3. Governing Law. These Bylaws shall be governed by and construed in accordance with the laws of the State of Delaware.
4. Severability. If any provision (or any part thereof) or provisions of these Bylaws shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever: (i) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of these Bylaws (including, without limitation, each portion of any section of these Bylaws containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and (ii) to the fullest extent possible, the provisions of these Bylaws (including, without limitation, each such portion containing any such provision held to be invalid, illegal or unenforceable) shall be construed for the benefit of the Corporation to the fullest extent permitted by law so as to (a) give effect to the intent manifested by the provision held invalid, illegal or unenforceable, and (b) permit the Corporation to protect its directors, officers, employees and agents from personal liability in respect of their good faith service. Reference herein to laws, regulations or agencies shall be deemed to include all amendments thereof, substitutions therefor and successors thereto, as the case may be.

ARTICLE XI.

**Exclusive Jurisdiction for Certain Actions**

1. Forum for Adjudication of Disputes. Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Corporation, (b) any action asserting a claim of breach of fiduciary duty owed by, or other wrongdoing by, any director, officer, employee or agent of the Corporation to the Corporation or the Corporation's stockholders, creditors or other constituents, (c) any action asserting a claim arising pursuant to any provision of the General Corporation Law of Delaware or the Certificate of Incorporation or these Bylaws of the Corporation, (d) any action to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or these Bylaws of the Corporation or (e) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein; provided that if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. To the fullest extent permitted by applicable law, any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article XI of these Bylaws.
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AMENDMENT TO THE  
EMPLOYMENT AGREEMENT BY AND BETWEEN  
JOÃO SIFFERT, M.D. AND ABEONA THERAPEUTICS INC.

This AMENDMENT, dated as of the 12<sup>th</sup> day of September, 2019, is made by and between ABEONA THERAPEUTICS INC. (“Abeona”) and João Siffert, M.D. (“Siffert”).

WITNESSETH:

WHEREAS, Abeona and Siffert entered into that certain Employment Agreement, dated as of February 11, 2019 (“Agreement”);

WHEREAS, Abeona and Siffert desire to amend the Agreement.

NOW, THEREFORE, Abeona and Siffert hereby agree to amend the Agreement as follows:

1. The third sentence of the first paragraph of Section 4 of the Agreement is hereby amended to read in its entirety as follows:

*“If you remain continuously employed from the Effective Date through the date of a Change in Control (as defined below), notwithstanding the terms of any equity incentive plan or award agreements, as applicable, all outstanding invested stock options/stock appreciation rights granted to you during your employment with the Company shall become fully vested and exercisable immediately prior to the date of the Change in Control.”*

2. From and after the execution of this Amendment, all references in the Agreement to “this Agreement,” “hereof,” “herein,” and similar words or phrases shall mean and refer to the Agreement as amended, including this Amendment. This Amendment shall not be modified, supplemented, amended, or terminated in any manner whatsoever, except by a written instrument signed by the party against which such modification, supplement, amendment, or termination is sought to be enforced.

3. Except as expressly modified by this Amendment, all other terms and conditions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Abeona and Siffert have caused this Amendment to be executed by their respective duly authorized officers as of the date first above written.

/s/ João Siffert, M.D.  
João Siffert, M.D.

ABEONA THERAPEUTICS INC.  
By: /s/ Steven H. Rouhandeh  
Name: Steven H. Rouhandeh  
Title: Executive Chairman



**AMENDMENT TO THE  
EMPLOYMENT AGREEMENT BY AND BETWEEN  
CHRISTINE BERNI SILVERSTEIN AND ABEONA THERAPEUTICS INC.**

This AMENDMENT, dated as of the 12<sup>th</sup> day of September, 2019, is made by and between ABEONA THERAPEUTICS INC. (“Abeona”) and Christine Berni Silverstein (“Silverstein”).

WITNESSETH:

WHEREAS, Abeona and Silverstein entered into that certain Employment Agreement, dated as of January 8, 2019 (“Agreement”);

WHEREAS, Abeona and Silverstein desire to amend the Agreement.

NOW, THEREFORE, Abeona and Silverstein hereby agree to amend the Agreement as follows:

1. The third sentence of the first paragraph of Section 4 of the Agreement is hereby amended to read in its entirety as follows:

*“If you remain continuously employed from the Effective Date through the date of a Change in Control (as defined below), notwithstanding the terms of any equity incentive plan or award agreements, as applicable, all outstanding unvested stock options/stock appreciation rights granted to you during your employment with the Company, including, without limitation, the Options, shall become fully vested and exercisable immediately prior to the date of the Change in Control.”*

2. From and after the execution of this Amendment, all references in the Agreement to “this Agreement,” “hereof,” “herein,” and similar words or phrases shall mean and refer to the Agreement as amended, including this Amendment. This Amendment shall not be modified, supplemented, amended, or terminated in any manner whatsoever, except by a written instrument signed by the party against which such modification, supplement, amendment, or termination is sought to be enforced.

3. Except as expressly modified by this Amendment, all other terms and conditions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, Abeona and Silverstein have caused this Amendment to be executed by their respective duly authorized officers as of the date first above written.

/s/ Christine Berni Silverstein  
Christine Berni Silverstein

ABEONA THERAPEUTICS INC.  
By: /s/ Steven H. Rouhandeh  
Name: Steven H. Rouhandeh  
Title: Executive Chairman

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September 12, 2019

C/O Edward Carr

Dear Ed:

You previously executed a letter offer of employment setting forth the terms of your employment as Chief Accounting Officer for Abeona Therapeutics Inc. (the "Corporation") dated as of October 17, 2018 (the "Offer"). We are hereby revising the terms of your employment as follows:

1. The following section entitled "Severance" shall be added as the third section of the Offer:

*"If your employment is terminated by the Company other than for cause, in addition to any other amounts to which you may be entitled, you will be entitled to a payment equal to the sum of fifty percent (50%) of your Base Salary plus fifty percent (50%) of your target performance bonus."*

2. From and after the execution of this Amendment, all references in the Offer to "this offer," "hereof," "herein," and similar words or phrases shall mean and refer to the Offer as amended, including this Amendment. This Amendment shall not be modified, supplemented, amended, or terminated in any manner whatsoever, except by a written instrument signed by the party against which such modification, supplement, amendment, or termination is sought to be enforced.
3. Except as expressly modified by this Amendment, all other terms and conditions of the Offer shall remain in full force and effect.

Please acknowledge your acceptance of this offer by returning a signed copy of this letter.

Very truly yours,

/s/ Kristina Maximenko  
VP, Human Resources  
Abeona Therapeutics Inc.

AGREED AND ACCEPTED:

/s/ Edward Carr  
Edward Carr



Certain identified information has been excluded from this exhibit pursuant to Item 601(b)(10)(iv) of Regulation S-K because such information both (i) is not material and (ii) would likely cause competitive harm if publicly disclosed. Excluded information is indicated with brackets and asterisks.

#### FIRST AMENDMENT TO LICENSE AGREEMENT

This First Amendment to License Agreement (the "First Amendment") is made as of November 4, 2019 (the "First Amendment Effective Date") by and between REGENXBIO Inc., a corporation organized under the laws of the State of Delaware, with offices at 9600 Blackwell Road, Suite 210, Rockville, MD 20850 ("Licensor"), and Abeona Therapeutics Inc., a corporation organized under the laws of the State of Delaware, with offices at 1330 Avenue of the Americas, 33rd Floor, New York, NY 10019 ("Licensee"). Licensor and Licensee are hereinafter referred to individually as a "Party" and collectively as the "Parties."

**WHEREAS**, the Parties entered into that certain License Agreement dated November 4, 2018 (the "License Agreement");

**WHEREAS**, the Parties desire to amend certain provisions of the License Agreement relating to the timing of certain fees Licensee shall pay Licensor under the License Agreement; and

**WHEREAS**, pursuant to Section 10.9 of the License Agreement, the License Agreement may be amended, provided that such amendment is in writing and signed by duly authorized representatives of both Parties.

**NOW, THEREFORE**, in consideration of the promises and covenants contained in this First Amendment, and intending to be legally bound, the Parties hereby agree as follows:

1. Section 3.1 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"3.1 Initial Fee. In partial consideration of the rights and licenses granted to Licensee under this Agreement, Licensee shall pay Licensor an initial fee of \$21,000,000, which shall be payable as follows: (a) \$10,000,000 within [\*\*\*\*] after the Effective Date; (b) \$3,000,000 within twelve (12) months of the Effective Date; and (c) \$8,000,000 no later than April 1, 2020, provided that any unpaid portion of the initial fee (including (a), (b) and (c)) shall be immediately payable upon termination of this Agreement or a Change of Control."

2. This First Amendment amends the terms of the License Agreement and is deemed incorporated into, and governed by all other terms of, the License Agreement. To the extent that the License Agreement is explicitly amended by this First Amendment, the terms of this First Amendment will control where the terms of the License Agreement are contrary to, or conflict with, the terms of this First Amendment. All other terms and conditions of the License Agreement not explicitly amended by this First Amendment shall remain in full force and effect. The License Agreement, shall, together with this First Amendment, be read and construed as a single instrument.

3. Signatures on this First Amendment may be communicated by facsimile or e-mail transmission and shall be binding upon the Parties upon receipt by transmitting the same by facsimile or e-mail transmission, which signatures shall be deemed originals. If executed in counterparts, this First Amendment shall be effective as if simultaneously executed.

*[Remainder of page intentionally left blank.]*

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IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this First Amendment to be executed by their duly authorized representatives.

**REGENXBIO INC.**

By: /s/ Kenneth T. Mills  
Name: Kenneth T. Mills  
Title: President and Chief Executive Officer  
Date: November 1, 2019

**ABEONA THERAPEUTICS INC.**

By: /s/ Joao Siffert  
Name: Joao Siffert  
Title: CEO  
Date: 1-Nov-2019





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: November 12, 2019

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

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

I, 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: November 12, 2019

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

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

In connection with the Quarterly Report of Abeona Therapeutics Inc. (the "Company") on Form 10-Q for the three months ended September 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: November 12, 2019

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

Date: November 12, 2019

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

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