UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016
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 **0-9314**

ABEONA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

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

3333 Lee Parkway, Suite 600, Dallas, TX 75219
(Address of principal executive offices)

(214) 665-9495
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☑ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☑

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

The number of shares outstanding of the registrant's common stock as of August 15, 2016 was 33,545,703 shares.

ABEONA THERAPEUTICS INC.

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PART I –FINANCIAL INFORMATION

This Quarterly Report on Form 10-Q (including the information incorporated by reference) contains "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, and that involve risks and uncertainties. These statements and other risks described below as well as those discussed elsewhere in this Quarterly Report Form 10-Q, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission ("SEC") include, without limitation, statements relating to uncertainties associated with research and development activities, clinical trials, our ability to raise capital, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations and our ability to attract licensing partners, future cash flow, the future success of our marketed products and products in development, our belief that advances in biotechnology will provide significant opportunities to develop new treatments for rare diseases, our sales projections, and the sales projections of our licensing partners, the size of the prospective markets in which we may offer products, anticipated product launches and our commercialization strategies, anticipated product approvals and timing thereof, product opportunities, clinical trials and U.S. Food and Drug Administration ("FDA") applications, as well as our drug development strategy, our clinical development organization expectations regarding our rate of technological developments and competition, our expectations regarding minimizing development risk and developing and introducing technology, the terms of future licensing arrangements, our ability to secure additional financing for our operations, our ability to establish new relationships and maintain current relationships, our ability to attract and retain key personnel, our belief that we will not pay any cash dividends in the foreseeable future, our belief that a failure to obtain necessary additional capital in the future will result in our operations being jeopardized, our belief that we have a rich pipeline of products and product candidates, our belief that recently licensed technology will enable us to provide new therapeutic applications and expand market opportunities while enhancing margins, our expectations 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, our ability to achieve profitability on a sustained basis or at all, our expected cash burn rate. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "could," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of such terms or other comparable terminology. We intend the forward-looking statements to be covered by the safe harbor for forward-looking statements in these sections. The forward-looking information is based on various factors and was derived using numerous assumptions.

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. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our judgment only as of the date of this report. We caution readers not to place undue reliance on such statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

ITEM 1. FINANCIAL STATEMENTS

The response to this Item is submitted as a separate section of this report. See page 16.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

OVERVIEW

Abeona Therapeutics Inc. (together with our subsidiaries, "we", "our", "Abeona" or the "Company") is a Delaware corporation. We are focused on developing and delivering gene therapy and plasma-based products for severe and life-threatening rare diseases. Abeona's lead programs are ABO-101 (AAV NAGLU) and ABO-102 (AAV SGSH), adeno-associated virus (AAV)-based gene therapies for Sanfilippo syndrome (MPS IIIB and IIIA, respectively). We are also developing ABO-201 (AAV CLN3) gene therapy for Juvenile Neuronal Ceroid Lipofuscinoses (JNCL), also known as juvenile Batten disease, and ABO-301 (AAV FANCC) for Fanconi anemia (FA) disorder using a novel CRISPR/Cas9-based gene editing approach to gene therapy program for rare blood diseases. In addition, we are also developing rare plasma protein therapies including PTB-101 SDF Alpha™ (alpha-1 protease inhibitor) for inherited COPD using our proprietary SDF™ (Salt Diafiltration) ethanol-free process. Our principal executive office is located at 3333 Lee Parkway, Suite 600, Dallas, Texas 75219. Our website address is *www.abeonatherapeutics.com*.

Recent Developments

On August 4, 2016 we announced European regulatory approval for Phase 1/2 Gene Therapy Clinical Trial utilizing ABO-102 for patients with MPS IIIA. The clinical study was approved by the Agencia Espanola de Medicamentos y Productos Sanitarios, and the Company is conducting the Phase 1/2 clinical study at Cruces University Hospital (Bilbao, Spain).

We entered into an agreement ("Agreement") with EB Research Partnership ("EBRP") and Epidermolysis Bullosa Medical Research Foundation ("EBMRF") to collaborate on gene therapy treatments for epidermolysis bullosa ("EB"). The Agreement became effective on the execution of two licensing agreements with The Board of Trustees of Leland Stanford Junior University ("Stanford") described below.

EBRP and EBMRF have the contractual right to license from Stanford EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)), and wishes to have Abeona exercise such rights and enter into a license with Stanford for such technology, and perform preclinical development and perform clinical trials of a gene therapy treatment for Epidermolysis Bullosa based upon such in-licensed technology. Abeona shall also enter into a license with Stanford for the AAV-based gene therapy EB-201 (AAV DJ COL7A1) technology, and Abeona shall perform preclinical development and perform clinical trials of a gene therapy treatment for EB based upon such in-licensed technology.

In connection with the Agreement Abeona will issue to EBRP and EBMRF an aggregate of 750,000 unregistered shares of Abeona Common Stock, $0.01 par value per share, 375,000 each to EBRP and EBMRF. The offer, sale, and issuance of the shares of Abeona common stock are exempt from registration pursuant to Rule 506 of Regulation D and Section 4(2) of the Securities Act of 1933, as amended. The recipients of securities under the Agreement agreed that day are acquiring the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends are to be affixed to the securities to be issued in conjunction with the Agreement. The shares will be subject to restrictions on selling, transferring or otherwise disposing of such shares. These restrictions shall lapse with respect to an aggregate 250,000 shares on the first anniversary of the issue date; and with respect to an additional aggregate 500,000 shares on the second anniversary of the issue date. We have an option to acquire an additional license in the future for an additional amount shares as set forth in the Agreement.

On August 3, 2016 we also entered into two licensing agreements between us and Stanford to develop EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)) and EB-201 (AAV DJ COL7A1). And the second agreement to license the invention “Gene Therapy for Recessive Dystrophic EB using Genetically Corrected Autologous Keratinocytes”. Under the terms of the licensing agreements, we will pay a upfront licensing fees in cash, annual license maintenance fees and subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments on annual net sales of the licensed product.

On May 24, 2016 we announced that the FDA has allowed an IND Application for our Phase 1/2 Clinical Study for ABO-101 for patients with Sanfilippo syndrome type B to be conducted at Nationwide Children’s Hospital (Columbus, Ohio).

On May 17, 2016 we announced that the first patient in a Phase 1/2 trial for ABO-102, a single treatment gene therapy strategy for patients with Sanfilippo syndrome type A, has been enrolled at Nationwide Children’s Hospital (Columbus, Ohio).

Product Development Strategy

Abeona is focused on developing and delivering gene therapy and plasma-based products for severe and life-threatening rare diseases. A rare disease is one that affects fewer than 200,000 people in the United States. There are nearly 7,000 rare diseases, which may involve chronic illness, disability, and often, premature death. More than 25 million Americans and 30 million Europeans have a severe and life-threatening disease. While rare diseases can affect any age group, about 50% of people affected are children (15 million), and rare diseases account for 35% of deaths in the first year of life. These rare diseases are often poorly diagnosed, very complex, and have no treatment or not very effective treatment—over 95% of rare diseases do not have a single FDA or EMA approved drug treatment. However, most rare diseases are often caused by changes in genes—80% are genetic in origin and can present at any stage of life. We believe emerging insights in genetics and advances in biotechnology, as well as new approaches and collaboration between researchers, industry, regulators and patient groups, provide significant opportunities to develop breakthrough treatments for rare diseases.

Developing Next Generation Gene Therapy

Gene therapy is the use of DNA as a potential therapy to treat a disease. In many disorders, particularly genetic diseases caused by a single genetic defect, gene therapy aims to treat a disease by delivering the correct copy of DNA into a patient's cells. The healthy, functional copy of the therapeutic gene then helps the cell function correctly. In gene therapy, DNA that encodes a therapeutic protein is packaged within a "vector", often a “naked” virus, which is used to transfer the DNA to the inside of cells within the body. Gene therapy can be delivered by a direct injection, either intravenously (IV) or directly into a specific tissue in the body, where it is taken up by individual cells. Once inside cells, the correct DNA is expressed by the cell machinery, resulting in the production of missing or defective protein, which in turn is proposed to treat the patient's underlying disease and can provide long-term benefit.

Abeona is developing next generation adeno-associated virus (AAV) gene therapies. Viruses such as AAV are utilized because they have evolved a way of encapsulating and delivering one or more genes of the size needed for clinical application, and can be purified in large quantities at high concentration. Unlike AAV vectors found in nature, the AAV vectors used by Abeona have been genetically-modified such that they do not replicate. Although the preclinical studies in animal models of disease demonstrate the promising impact of AAV-mediated gene expression to affected tissues such as the heart, liver and muscle, our programs use a specific virus that is capable of delivering therapeutic DNA across the blood-brain barrier and into the central nervous system (CNS) and the somatic system (body), which we believe make them attractive for addressing lysosomal storage diseases which have severe CNS manifestations of the disease.

Lysosomal storage diseases (LSD) are a group of rare inborn errors of metabolism resulting from deficiency in normal lysosomal function. These diseases are characterized by progressive accumulation of storage material within the lysosomes of affected cells, ultimately leading to cellular dysfunction. Multiple tissues ranging from musculoskeletal and visceral to tissues of the central nervous system are typically involved in disease pathology. Since the advent of enzyme replacement therapy (ERT) to manage some LSDs, general clinical outcomes have significantly improved; however, treatment with infused protein is lifelong and continued disease progression is still evident in patients. Thus, we believe that AAV-based gene therapy may provide a viable alternative or adjunctive therapy to current management strategies for LSDs.

Our initial programs are focused on LSDs such as Mucopolysaccharidosis (MPS) IIIA and IIIB. MPS III, also known as Sanfilippo syndromes type A and type B, MPS III is a progressive neuromuscular disease with profound CNS involvement. Our lead product candidates, ABO-101 and ABO-102, have been developed to replace the damaged, malfunctioning enzymes within target cells with the normal, functioning version. ABO-201 is a similar product, using an AAV to deliver the correct lysosomal gene that is defective in juvenile neuronal ceroid lipofuscinosis. Delivered via a single injection, these drugs are expected to be given only once.

ABO-101 for MPS III B and ABO-102 for MPS III A (Sanfilippo syndrome)

MPS type III (Sanfilippo syndrome) is a group of four inherited genetic diseases, described as type A, B, C or D, which cause enzyme deficiencies that result in the abnormal accumulation of glycosaminoglycans (sugars) in body tissues. MPS III is a lysosomal storage disease, a group of rare inborn errors of metabolism resulting from deficiency in normal lysosomal function. The incidence of MPS III (all four types combined) is estimated to be 1 in 70,000 births.

Mucopolysaccharides are long chains of sugar molecules used in the building of connective tissues in the body. There is a continuous process in the body of replacing used materials and breaking them down for disposal. Children with MPS III are missing an enzyme called heparan sulfate, which is essential in breaking down used mucopolysaccharides. The partially broken down mucopolysaccharides remain stored in cells in the body causing progressive damage. Babies may show little sign of the disease, but as more and more cells become damaged, symptoms start to appear.

In MPS III, the predominant symptoms occur due to accumulation within the central nervous system (CNS), including the brain and spinal cord, resulting in cognitive decline, motor dysfunction, and eventual death. To date, there is no cure for MPS III and treatments are largely supportive.

Abeona is developing next generation AAV-based gene therapies for MPS III, which will involve a one-time delivery of a normal copy of the defective gene to cells of the CNS with the goal of reversing the effects of the genetic errors that cause the disease.

After a single dose in Sanfilippo preclinical models, ABO-101 and ABO-102 induced cells in the CNS and peripheral organs to produce the missing enzymes which helped repair the damage caused to the cells. Preclinical *in vivo* efficacy studies in Sanfilippo syndrome have demonstrated functional benefits that remain for months after treatment. A single dose of ABO-101 or ABO-102 significantly restored normal cell and organ function, corrected cognitive defects that remained months after drug administration, increased neuromuscular control and increased the lifespan of animals with MPS III over 100% one year after treatment compared to untreated control animals. These results are consistent with studies from several laboratories suggesting AAV treatment could potentially benefit patients with Sanfilippo Syndrome Type A and B. In addition, safety studies conducted in animal models of Sanfilippo syndromes have demonstrated that delivery of ABO-101 or ABO-102 are well tolerated with minimal side effects.

On August 4, 2016 we announced European regulatory approval for Phase 1/2 Gene Therapy Clinical Trial utilizing ABO-102 for patients with MPS IIIA. The clinical study was approved by the Agencia Espanola de Medicamentos y Productos Sanitarios, and the Company is conducting the Phase 1/2 clinical study at Cruces University Hospital (Bilbao, Spain).

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ABO-201 for Juvenile Neuronal Ceroid Lipofuscinoses (JNCL) (or Juvenile Batten Disease (JBD))

ABO-201 (AAV CLN3) is an AAV-based gene therapy which has shown promising preclinical efficacy in delivery of a normal copy of the defective CLN3 gene to cells of the CNS with the goal of reversing the effects of the genetic errors that cause JNCL. JNCL is a rare, fatal, autosomal recessive (inherited) disorder of the nervous system that typically begins in children between 4 and 8 years of age. Often the first noticeable sign of JNCL is vision impairment, which tends to progress rapidly and eventually result in blindness. As the disease progresses, children experience loss of previously acquired skills (developmental regression). This progression usually begins with the loss of the ability to speak in complete sentences. Children then lose motor skills, such as the ability to walk or sit. They also develop movement abnormalities that include rigidity or stiffness, slow or diminished movements (hypokinesia), and stooped posture. Beginning in mid- to late childhood, affected children may have recurrent seizures (epilepsy), heart problems, behavioral problems, and difficulty sleeping. Life expectancy is greatly reduced. Most people with juvenile Batten disease live into their twenties or thirties. As yet, no specific treatment is known that can halt or reverse the symptoms of JNCL.

JNCL is the most common form of a group of disorders known as neuronal ceroid lipofuscinoses (NCLs). Collectively, all forms of NCL affect an estimated 2 to 4 in 100,000 live births in the United States. NCLs are more common in Finland, where approximately 1 in 12,500 individuals are affected, as well as Sweden, other parts of northern Europe, and Newfoundland, Canada.

Most cases of JNCL are caused by mutations in the CLN3 gene, which is the focus of our AAV-based gene therapy approach. These mutations disrupt the function of cellular structures called lysosomes. Lysosomes are compartments in the cell that normally digest and recycle different types of molecules. Lysosome malfunction leads to a buildup of fatty substances called lipopigments and proteins within these cell structures. These accumulations occur in cells throughout the body, but neurons in the brain seem to be particularly vulnerable to damage. The progressive death of cells, especially in the brain, leads to vision loss, seizures, and intellectual decline in children with JNCL.

ABO-301 for Fanconi Anemia (FA)

ABO-301 (AAV FANCC) is an AAV-based gene therapy which has shown promising preclinical efficacy in delivery of a normal copy of the defective gene to cells of the hematopoietic or blood system with the goal of reversing the effects of the genetic errors that cause Fanconi anemia (FA). FA is a rare (1 in 160,000) pediatric, autosomal recessive (inherited) disease characterized by multiple physical abnormalities, organ defects, bone marrow failure, and a higher than normal risk of cancer. The average lifespan for people with FA is 20 to 30 years.

The major function of bone marrow is to produce new blood cells. In FA, a DNA mutation renders the FANCC gene nonfunctional. Loss of FANCC causes skeletal abnormalities and leads to bone marrow failure. FA patients also have much higher rates of hematological diseases, such as acute myeloid leukemia (AML) or tumors of the head, neck, skin, gastrointestinal system, or genital tract. The likelihood of developing one of these cancers in people with FA is between 10 and 30 percent. Aside from bone marrow transplantation (BMT) there are no specific treatments known that can halt or reverse the symptoms of FA. Repairing fibroblast cells in FA patients with a functional FANCC gene is the focus of our AAV-based gene therapy approach.

Using a novel CRISPR (clustered, regularly interspaced short palindromic repeats)-Cas9 (CRISPR associated protein 9) system, researchers used a protein-RNA complex composed of an enzyme known as Cas9 bound to a guide RNA molecule that has been designed to recognize a particular DNA sequence. The RNA molecules guide the Cas9 complex to the location in the genome that requires repair. CRISPR-Cas9 uniquely enables surgically efficient knock-out, knock-down or selective editing of defective genes in the context of their natural promoters, unlocking the potential to treat both recessive and dominant forms of genetic diseases. Most importantly, this approach has the potential to allow for more precise gene modification.

Plasma-based Therapeutics using the SDF™ technology platform

Abeona's proprietary patented Salt Diafiltration Process™ (SDF™) focuses on ethanol-free extraction of therapeutic biologics from human plasma. Plasma biologics are biopharmaceutical proteins extracted, purified, and formulated from human blood plasma by the use of biotechnological processing techniques including precipitation, diafiltration, affinity chromatography, and ion-exchange chromatography. These products are rendered virus-safe by means of chemical treatment, nanofiltration, and pasteurization. Plasma biologics primarily address indications arising from genetic deficiencies, which are increasingly being identified by means of newly available rapid and low-cost diagnostic genetic tests. Examples of plasma biologics include Alpha-1 Antitrypsin (also known as alpha-1 proteinase inhibitor, A1PI), Intravenous Immune Globulin (IVIG), Anti-Hemophilic Factor VIII (AHF) and Albumin.

Plasma biologics are currently obtained from human plasma by a fractionation process known as the Cohn Cold Ethanol Fractionation Process (Cohn Process), which was developed prior to World War II to provide a stable solution of human albumin for the rapid treatment of hemorrhagic shock on the battlefield. This process employs various concentrations of ethanol combined with adjustments of pH, ionic strength, and temperature to bring about the necessary separations by precipitation. Ethanol can inactivate many of the plasma proteins.

In contrast to the highly denaturing Cohn Process, Abeona's SDF method involves a short two-step, ethanol-free salt precipitation process optimized to extract a wide range of therapeutically useful biologic proteins from human blood plasma. SDF enables the production of higher yields of these proteins compared with the Cohn Process.

PTB-101 SDF Alpha™ (alpha-1 protease inhibitor) for emphysema or chronic obstructive pulmonary disease (COPD) due to severe congenital deficiency of A1PI (alpha-1-antitrypsin deficiency)

Alpha-1 antitrypsin deficiency is a rare (1 in 1,500 to 3,500) genetic (inherited) autosomal disorder that may cause lung disease from an inability to neutralize the enzyme neutrophil elastase and liver disease from retained misfolded protein. Alpha-1 antitrypsin deficiency occurs worldwide, but its prevalence varies by population. Alpha-1 antitrypsin is also known as alpha-1 proteinase inhibitor (A1PI).

About 10% of infants with alpha-1 antitrypsin deficiency develop liver disease, which often causes yellowing of the skin and whites of the eyes (jaundice). Approximately 15% of adults with alpha-1 antitrypsin deficiency develop liver damage (cirrhosis) due to the formation of scar tissue in the liver. Signs of cirrhosis include a swollen abdomen, swollen feet or legs, and jaundice. Individuals with alpha-1 antitrypsin deficiency are also at risk of developing a type of liver cancer called hepatocellular carcinoma.

Alpha-1 antitrypsin deficiency is inherited with an autosomal codominant pattern, which means that two different versions of the gene may be active (expressed), and both versions contribute to the genetic trait. The most common version (allele) of the SERPINA1 gene, called M, produces normal levels of alpha-1 antitrypsin. Most people in the general population have two copies of the M allele (MM) in each cell. Other versions of the SERPINA1 gene lead to reduced levels of alpha-1 antitrypsin. For example, the S allele produces moderately low levels of this protein, and the Z allele produces very little alpha-1 antitrypsin. Individuals with two copies of the Z allele (ZZ) in each cell are likely to have alpha-1 antitrypsin deficiency. Those with the SZ combination have an increased risk of developing liver and lung diseases such as chronic obstructive pulmonary disease (COPD).

It is estimated that about 200,000 individuals in the United States and Europe have severe alpha-1 antitrypsin deficiency. However, only about 5% of such individuals have been diagnosed as symptoms caused by this deficiency are very similar to those of asthma and chronic obstructive pulmonary disease (COPD) from non-genetic causes. Only about 1–2% of COPD patients have severe alpha-1 antitrypsin deficiency. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines COPD as group of airflow-limited diseases including emphysema and chronic bronchitis. While severe alpha-1 antitrypsin deficiency can lead to or exacerbate all forms of COPD, it is considered to be the dominant cause of Panacinar Emphysema, a form of emphysema which causes gradual destruction of all lung aveolii.

PTB-101 SDF Alpha™ (alpha1-proteinase inhibitor) for Alpha-1 Antitrypsin Deficiency (Alpha-1)

Abeona is developing PTB-101 SDF Alpha™ (alpha-1-proteinase inhibitor) for chronic augmentation and maintenance therapy in adults with clinically evident panacinar emphysema and other forms of COPD due to severe deficiency of alpha-1-proteinase inhibitor.

Polymer Hydrogel Technology (PHT™)

MuGard® (mucoadhesive oral wound rinse) approved for mucositis, stomatitis, aphthous ulcers, and traumatic ulcers

MuGard® is our marketed product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no other established treatment. MuGard, a proprietary nanopolymer formulation, received marketing clearance from the FDA in the US as well as Europe, China, Australia, New Zealand and Korea. We launched MuGard in the U.S. in 2010 and licensed MuGard for commercialization in the U.S. to AMAG Pharmaceuticals, Inc. (AMAG) in 2013. We licensed MuGard to RHEI Pharmaceuticals, N.V. (RHEI) for China and other Southeast Asian countries; Hanmi Pharmaceutical Co. Ltd. (Hanmi) for South Korea; and Norgine B.V. (Norgine) for the European Union, Switzerland, Norway, Iceland, Lichtenstein, Australia and New Zealand.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through public and private sales of common stock, preferred stock, convertible notes and through licensing agreements. Our principal source of liquidity is cash and cash equivalents. Licensing payments and royalty revenues provided limited funding for operations during the period ended June 30, 2016. As of June 30, 2016, our cash and cash equivalents were $34,303,000.

As of June 30, 2016, our working capital was $25,914,000. Our working capital at June 30, 2016 represented a decrease of $13,177,000 as compared to our working capital of $39,091,000 as of December 31, 2015. The decrease in working capital at June 30, 2016 reflects six months of net operating costs and changes in current assets and liabilities and the classification of contingent consideration liability ($2,000,000) and payable to Licensor ($4,000,000) from long-term liabilities to current liabilities. The contingent consideration liability will be paid in Abeona common stock if the milestone is met. The payable to Licensor may be paid in cash or stock at our discretion.

Net cash used in operating activities for the six months ended June 30, 2016 was $5,632,000 as compared to $5,034,000 for the same period in 2015, an increase of $598,000. The increase was primarily due to higher research and development spending in the first six months of 2016 offset by a $1.0 million license payment made in the first quarter of 2015.

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.

We have incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of June 30, 2016 of $322,847,000. We 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.

Since our inception, we have devoted our resources primarily to fund our research and development programs. We have been unprofitable 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.

SECOND QUARTER 2016 COMPARED TO SECOND QUARTER 2015

Our licensing revenue for the second quarter of each of 2016 and 2015 was $150,000 for each period. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We recorded royalty revenue for MuGard of $64,000 for second quarter of 2016 and $132,000 for the same period of 2015, a decrease of $68,000. We licensed MuGard to AMAG on June 6, 2013 and currently receive quarterly royalties from AMAG under our agreement.

Total research and development spending for the second quarter of 2016 was $3,018,000, as compared to $610,000 for the same period of 2015, an increase of $2,408,000. The increase in expenses was primarily due to:

- increased development work for the manufactured product for ABO-102 and other gene therapy products ($1,068,000);
- increased salary and related costs ($605,000) from the hiring of scientific staff and annual bonus payments;
- increased stock based compensation expense for granted stock options ($231,000) and granted stock ($62,000);
- increased clinical costs for our clinical trial for ABO-102 and preparation for other clinical trials ($223,000); and
- other net increases in research spending ($219,000).

Total general and administrative expenses were $3,730,000 for the second quarter of 2016, as compared to $3,667,000 for the same period of 2015, an increase of $63,000. The increase in expenses was due primarily to the following:

- increased salary and related costs and annual bonus payments ($376,000);
- increased stock based compensation expense for granted stock options ($346,000) offset by lower granted stock expense ($113,000);
- offset by decreased legal fees ($299,000);
- offset by decreased investor relations fees ($219,000); and
- offset by decreased net other general and administrative expenses ($28,000).

Depreciation and amortization was $181,000 for the second quarter of 2016 as compared to $132,000 for the same period in 2015, an increase of $49,000. We are amortizing the licenses for SDF Alpha and ABO-101 and ABO-201 over the life of the patents. The increase is due to amortization of licensed technology of $15,000 and depreciation of $34,000.

Total operating expenses for the second quarter of 2016 were $6,929,000 as compared to total operating expenses of $4,409,000 for the same period of 2015, an increase of $2,520,000 for the reasons listed above.

Interest and miscellaneous income was $13,000 for the second quarter of 2016 as compared to $16,000 for the same period of 2015, a decrease of $3,000.

Interest and other expense was $1,000 for the second quarter of 2016 as compared to $2,000 in the same period of 2015, a decrease of $1,000.

Net loss for the second quarter of 2016 was $6,703,000, or a $0.20 basic and diluted loss per common share as compared to a net loss of $4,113,000, or a $0.16 basic and diluted loss per common share, for the same period in 2015, an increased loss of $2,590,000.

SIX MONTHS ENDED JUNE 30, 2016 COMPARED TO SIX MONTHS ENDED JUNE 30, 2015

Our licensing revenue for the first six months of 2016 and 2015 was $301,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We recorded royalty revenue for MuGard of $148,000 for the first six months of 2016 and $239,000 for the same period of 2015, a decrease of $91,000. We licensed MuGard to AMAG on June 6, 2013 and currently receive quarterly royalties from AMAG under our agreement.

Total research and development spending for the first six months of 2016 was $4,873,000, as compared to $1,063,000 for the same period of 2015, an increase of $3,810,000. The increase in expenses was primarily due to:

- increased development work for the manufactured product for ABO-102 and other gene therapy products ($1,393,000);
- increased salary and related costs ($963,000) from the hiring of scientific staff and annual bonus payments;
- increased stock based compensation expense for granted stock options ($553,000) and granted stock ($200,000);
- increased clinical costs for our clinical trial for ABO-102 and preparation for other clinical trials ($252,000); and
- other net increases in research spending ($449,000).

Total general and administrative expenses were $8,096,000 for the first six months of 2016, as compared to $5,356,000 for the same period of 2015, an increase of $2,740,000. The increase in expenses was due primarily to the following:

- increased stock based compensation expense for granted stock options ($1,338,000) and granted stock ($1,642,000);
- increased salary and related costs and annual bonus payments ($314,000);

- increased net other general and administrative expense ($73,000).
- offset by decreased investor relations fees ($397,000); and
- offset by decreased legal fees ($230,000).

Depreciation and amortization was $355,000 for the first six months of 2016 as compared to $250,000 for the same period in 2015, an increase of $105,000. We are amortizing the licenses for SDF Alpha and ABO-101 and ABO-201 over the life of the patents. The increase is due to amortization of licensed technology of $44,000 and depreciation of $61,000.

Total operating expenses for the first six months of 2016 were $13,324,000 as compared to total operating expenses of $6,669,000 for the same period of 2015, an increase of $6,655,000 for the reasons listed above.

Interest and miscellaneous income was $631,000 for the first six months of 2016 as compared to $19,000 for the same period of 2015, an increase of $612,000. Miscellaneous income is higher in 2016 than for the same period in 2015 due to the change in the fair value of our contingent consideration liability ($591,000) related to the acquisition of Abeona Therapeutics LLC and interest income and other income ($21,000).

Interest and other expense was $3,000 for the six months of 2016 as compared to $3,000 in the same period of 2015.

Net loss for the six months of 2016 was $12,247,000, or a $0.37 basic and diluted loss per common share as compared to a net loss of $6,113,000, or a $0.27 basic and diluted loss per common share, for the same period in 2015, an increased loss of $6,134,000.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management and consultants, including the Executive Chairman (our principal executive officer) and Vice President Finance (our principal accounting officer), we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control system was designed 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. Because of inherent limitations, a system of internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to change in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our principal executive officer and principal accounting officer, conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework.

Based on such evaluation, our management concluded in our Annual Report on Form 10-K for the year ended December 31, 2015 that there is no material weakness in our internal control as defined under the standards established by the Public Company Accounting Oversight Board (United States). A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Changes In Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2016 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.

None.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

On April 2016, we issued 52,690 shares of restricted common stock, at a price of $2.85 per share to a foundation per a previous agreement.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 6. EXHIBITS.

Exhibits:

10.1 Form of Indemnification Agreement, between us and directors and officers of the Company

31.1 Principal Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Principal Financial Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1* Principal Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2* Principal Financial Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101 The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at June 30, 2016 and December 31, 2015, (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2016 and June 30, 2015, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2016, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and June 30, 2015, and (v) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

* 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 and Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ABEONA THERAPEUTICS INC.

Date: August 15, 2016

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

Date: August 15, 2016

By: /s/ Stephen B. Thompson
Stephen B Thompson
Vice President Finance
(Principal Accounting Officer)

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	June 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	$ 34,303,000	$ 40,138,000
Receivables	112,000	115,000
Prepaid expenses and other current assets	206,000	315,000
Total current assets	34,621,000	40,568,000
Property and equipment, net	639,000	350,000
Licensed technology, net	6,318,000	6,609,000
Goodwill	32,466,000	32,466,000
Other assets	108,000	62,000
Total assets	$ 74,152,000	$ 80,055,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,105,000	$ 875,000
Current portion of deferred revenue	602,000	602,000
Contingent consideration liability	2,000,000	-
Payable due Licensor	4,000,000	-
Total current liabilities	8,707,000	1,477,000
Contingent consideration liability	-	2,591,000
Payable due Licensor	-	4,000,000
Long-term deferred revenue	3,965,000	4,266,000
Total liabilities	12,672,000	12,334,000
Commitments and contingencies		
Stockholders' equity		
Common stock - $.01 par value; authorized 200,000,000 shares;		
issued, 32,795,703 at June 30, 2016 and 32,743,013 at	328,000	328,000
December 31, 2015	383,999,000	377,993,000
Additional paid-in capital	(322,847,000)	(310,600,000)
Accumulated deficit	61,480,000	67,721,000
Total stockholders' equity		
Total liabilities and stockholders' equity	$ 74,152,000	$ 80,055,000

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Operations
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Revenues				
License revenues	$ 150,000	$ 150,000	$ 301,000	$ 301,000
Royalties	64,000	132,000	148,000	239,000
Total revenues	214,000	282,000	449,000	540,000
Expenses				
Research and development	3,018,000	610,000	4,873,000	1,063,000
General and administrative	3,730,000	3,667,000	8,096,000	5,356,000
Depreciation and amortization	181,000	132,000	355,000	250,000
Total expenses	6,929,000	4,409,000	13,324,000	6,669,000
Loss from operations	(6,715,000)	(4,127,000)	(12,875,000)	(6,129,000)
Interest and miscellaneous income	13,000	16,000	631,000	19,000
Interest and other expense	(1,000)	(2,000)	(3,000)	(3,000)
	12,000	14,000	628,000	16,000
Net loss	$ (6,703,000)	$ (4,113,000)	$ (12,247,000)	$ (6,113,000)
Basic and diluted loss per common share	$ (0.20)	$ (0.16)	$ (0.37)	$ (0.27)
Weighted average number of common shares outstanding	32,784,123	25,695,973	32,763,568	22,855,642

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, 2015	32,743,013	$ 328,000	$ 377,993,000	$ (310,600,000)	$ 67,721,000
Restricted common stock issued to employees and directors	-	-	1,892,000	-	1,892,000
Stock option compensation expense	-	-	1,592,000	-	1,592,000
Net loss	-	-	-	(5,544,000)	(5,544,000)
Balance March 31, 2016	32,743,013	$ 328,000	$ 381,477,000	$ (316,144,000)	$ 65,661,000
Restricted common stock issued to employees and directors	-	-	987,000	-	987,000
Restricted common stock issued for $2.85	52,690	-	150,000	-	150,000
Stock option compensation expense	-	-	1,385,000	-	1,385,000
Net loss	-	-	-	(6,703,000)	(6,703,000)
Balance June 30, 2016	32,795,703	$ 328,000	$ 383,999,000	$ (322,847,000)	$ 61,480,000

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows
(unaudited)

	Six Months ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (12,247,000)	$ (6,113,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	355,000	250,000
Stock option compensation expense	2,977,000	1,128,000
Stock issued to directors, employees and consultants	2,879,000	1,068,000
Stock issued for services	-	162,000
Change in operating assets and liabilities:		
Receivables	3,000	(294,000)
Prepaid expenses and other current assets	109,000	(194,000)
Other assets	(46,000)	(9,000)
Accounts payable	1,230,000	(731,000)
Contingent consideration liability	(591,000)	-
Deferred revenue	(301,000)	(301,000)
Net cash used in operating activities	(5,632,000)	(5,034,000)
Cash flows from investing activities:		
Capital expenditures	(353,000)	(14,000)
Cash from Abeona Ohio	-	3,697,000
Net cash (used in) provided by investing activities	(353,000)	3,683,000
Cash flows from financing activities:		
Proceeds from $3.00 common stock issuances net of costs	-	7,001,000
Proceeds from $8.00 common stock issuances net of costs	-	9,005,000
Proceeds from exercise of $5.00 warrants	-	4,635,000
Proceeds from $2.85 restricted common stock issuance	150,000	-
Payment of short-term debt	-	(400,000)
Net cash provided by financing activities	150,000	20,241,000
Net increase (decrease) in cash and cash equivalents	(5,835,000)	18,890,000
Cash and cash equivalents at beginning of period	40,138,000	11,520,000
Cash and cash equivalents at end of period	$ 34,303,000	$ 30,410,000
Supplemental disclosure of noncash transactions:		
Shares issued to holders of Abeona Ohio for acquisition	*$ -*	*$ 31,758,000*
Contingent milestones to Abeona Ohio members	*-*	*6,489,000*
Licensed technology from Abeona Ohio	*-*	*2,156,000*

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

Abeona Therapeutics Inc. (together with our subsidiaries, "we", "our", "Abeona" or the "Company") is a Delaware corporation. We are focused on developing and delivering gene therapy and plasma-based products for severe and life-threatening rare diseases. Abeona's lead programs are ABO-101 (AAV NAGLU) and ABO-102 (AAV SGSH), adeno-associated virus (AAV)-based gene therapies for Sanfilippo syndrome (MPS IIIB and IIIA, respectively). We are also developing ABO-201 (AAV CLN3) gene therapy for Juvenile Neuronal Ceroid Lipofuscinoses (JNCL), also known as juvenile Batten disease, and ABO-301 (AAV FANCC) for Fanconi anemia (FA) disorder using a novel CRISPR/Cas9-based gene editing approach to gene therapy program for rare blood diseases. In addition, we are also developing rare plasma protein therapies including PTB-101 SDF Alpha™ (alpha-1 protease inhibitor) for inherited COPD using our proprietary SDF™ (Salt Diafiltration) ethanol-free process. Our efforts have been principally devoted to research and development, resulting in significant losses.

(1) Interim Financial Statements

The condensed consolidated balance sheet as of June 30, 2016, the condensed consolidated statements of operations for the three and six months ended June 30, 2016 and 2015, the condensed consolidated statements of stockholders' equity for the three and six months ended June 30, 2016, and the condensed consolidated statements of cash flows for the six months ended June 30, 2016 and 2015, 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 have been condensed or omitted. It is suggested that these interim financial statements be read in conjunction with the consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2015. The results of operations for the period ended June 30, 2016 are not necessarily indicative of the operating results which may be expected for a full year. The condensed consolidated balance sheet as of December 31, 2015 contains financial information taken from the audited Abeona financial statements as of that date.

(2) Intangible Assets

Intangible assets consist of the following (in thousands):

	June 30, 2016		December 31, 2015	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated Amortization
Amortizable intangible assets Licensed technology	$ 7,156	$ 838	$ 7,156	$ 547

Amortization expense related to intangible assets totaled $146,000 and $291,000 for the three and six months ended June 30, 2016, respectively, and totaled $116,000 and $232,000 for the three and six months ended June 30, 2015, respectively. The aggregate estimated amortization expense for intangible assets remaining as of June 30, 2016 is as follows (in thousands):

2016	$ 290
2017	582
2018	582
2019	582
2020	582
over 5 years	3,700
Total	$ 6,318

(3) Fair Value Measurements

We calculate the fair value of our assets and liabilities which 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, accounts payable, short-term notes payable and payable to licensor approximate their carrying amounts due to the relatively short maturity of these instruments.

U.S. GAAP define's 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 basis as of June 30, 2016 and December 31, 2015 are summarized below:

(in thousands)

Description	As of June 30, 2016	Level 1	Level 2	Level 3	Total Gains (Losses)
Assets:					
Licensed technology (net)	$ 6,318	$ -	$ -	$ 6,318	$ -
Goodwill	32,466	-	-	32,466	-
Liabilities:					
Contingent consideration	$ 2,000	$ -	$ -	$ 2,000	$ 591

(in thousands)

Description	As of December 31, 2015	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Contingent consideration	$ 2,591	$ -	$ -	$ 2,591	$ 3,898

(4) Stock Based Compensation and Restricted Stock Compensation

For the three and six months ended June 30, 2016, we recognized stock-based compensation expense of $1,385,000 and $2,977,000, respectively. For the three and six months ended June 30, 2015 we recognized stock-based compensation expense of $904,000 and $1,128,000, respectively.

The following table summarizes stock-based compensation for the three and six months ended June 30, 2016 and 2015:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Research and development	$ 314,000	$ 86,000	$ 664,000	$ 104,000
Selling, general and administrative	1,071,000	818,000	2,313,000	1,024,000
Stock-based compensation expense included in operating expense	$ 1,385,000	$ 904,000	$ 2,977,000	$ 1,128,000

For the three and six months ended June 30, 2016 we granted 125,000 and 1,440,000 stock options, respectively, and for the three and six months ended June 30, 2015 we granted 1,695,000 and 1,815,000 stock options.

For the three and six months ended June 30, 2016, we recognized restricted stock compensation expense of $987,000 and $2,879,000, respectively. For the three and six months ended June 30, 2015 we recognized stock-based compensation expense of $1,036,000 and $1,036,000, respectively.

The following table summarizes restricted stock compensation expense for the three and six months ended June 30, 2016 and 2015:

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Research and development	$ 62,000	$ 75,000	$ 200,000	$ 91,000
Selling, general and administrative	925,000	961,000	2,679,000	977,000
Restricted stock compensation expense included in operating expense	$ 987,000	$ 1,036,000	$ 2,879,000	$ 1,068,000

For the three and six months ended June 30, 2016 no shares were granted to directors and employees. For the three and six months ended June 30, 2015 we granted 1,350,000 and 1,360,000 shares, respectively of our common stock to directors and employees.

(5) Litigation

We are not currently subject to any material legal proceedings.

(6) Subsequent Events

We entered into an agreement ("Agreement") with EB Research Partnership ("EBRP") and Epidermolysis Bullosa Medical Research Foundation ("EBMRF") to collaborate on gene therapy treatments for epidermolysis bullosa ("EB"). The Agreement became effective on the execution of two licensing agreements with The Board of Trustees of Leland Stanford Junior University ("Stanford") described below.

EBRP and EBMRF have the contractual right to license from Stanford EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)), and wishes to have Abeona exercise such rights and enter into a license with Stanford for such technology, and perform preclinical development and perform clinical trials of a gene therapy treatment for Epidermolysis Bullosa based upon such in-licensed technology. Abeona shall also enter into a license with Stanford for the AAV-based gene therapy EB-201 (AAV DJ COL7A1) technology, and Abeona shall perform preclinical development and perform clinical trials of a gene therapy treatment for EB based upon such in-licensed technology.

In connection with the Agreement Abeona will issue to EBRP and EBMRF an aggregate of 750,000 unregistered shares of Abeona Common Stock, $0.01 par value per share, 375,000 each to EBRP and EBMRF. The offer, sale, and issuance of the shares of Abeona common stock are exempt from registration pursuant to Rule 506 of Regulation D and Section 4(2) of the Securities Act of 1933, as amended. The recipients of securities under the Agreement agreed that day are acquiring the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends are to be affixed to the securities to be issued in conjunction with the Agreement. The shares will be subject to restrictions on selling, transferring or otherwise disposing of such shares. These restrictions shall lapse with respect to an aggregate 250,000 shares on the first anniversary of the issue date; and with respect to an additional aggregate 500,000 shares on the second anniversary of the issue date. We have an option to acquire an additional license in the future for an additional amount shares as set forth in the Agreement.

On August 3, 2016 we also entered into two licensing agreements between us and Stanford to develop EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)) and EB-201 (AAV DJ COL7A1). And the second agreement to license the invention “Gene Therapy for Recessive Dystrophic EB using Genetically Corrected Autologous Keratinocytes”. Under the terms of the licensing agreements, we will pay a upfront licensing fees in cash, annual license maintenance fees and subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments on annual net sales of the licensed product.

EXHIBIT 10.1

INDEMNIFICATION AGREEMENT

This Agreement is made as of the __ day of ___ 201_, by and between Abeona Therapeutics Inc., a Delaware corporation (the "Corporation), and _____ (the "Indemnitee"), a director or officer of the Corporation.

WHEREAS, it is essential to the Corporation to retain and attract as directors and officers the most capable persons available, and

WHEREAS, the substantial increase in corporate litigation subjects directors and officers to expensive litigation risks at the same time that the availability of directors' and officers' liability insurance has been severely limited, and

WHEREAS, it is now and has always been the express policy of the Corporation to indemnify its directors and officers, and

WHEREAS, the Indemnitee does not regard the protection available under the Corporation's Certificate of Incorporation and insurance as adequate in the present circumstances, and may not be willing to serve or continue to serve as a director or officer without adequate protection, and

WHEREAS, the Corporation desires the Indemnitee to serve, or continue to serve, as a director or officer of the Corporation.

NOW THEREFORE, the Corporation and the Indemnitee do hereby agree as follows:

1 . Agreement to Serve. The Indemnitee agrees to serve or continue to serve as a director or officer of the Corporation for so long as the Indemnitee is duly elected or appointed or until such time as the Indemnitee tenders a resignation in writing.

2. Definitions. As used in this Agreement:

(a) The term "Proceeding" shall include any threatened, pending or completed action, suit, arbitration, alternative dispute resolution proceeding, administrative hearing or other proceeding, whether brought by or in the right of the Corporation or otherwise and whether of a civil, criminal, administrative or investigative nature, and any appeal therefrom.

(b) The term "Corporate Status" shall mean the status of a person who is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, fiduciary, partner, trustee, member, employee or agent of, or in a similar capacity with, another corporation, partnership, joint venture, trust, limited liability company or other enterprise.

(c) The term "Expenses" shall include, without limitation, attorneys' fees, retainers, court costs, transcript costs, fees and expenses of experts, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees and other disbursements or expenses of the types customarily incurred in connection with investigations, judicial or administrative proceedings or appeals, but shall not include the amount of judgments, fines or penalties against Indemnitee or amounts paid in settlement in connection with such matters.

(d) References to "other enterprise" shall include employee benefit plans; references to "fines" shall include any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of the Corporation" shall include any service as a director, officer, employee or agent of the Corporation which imposes duties on, or involves services by, such director, officer, employee, or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the Corporation" as referred to in this Agreement.

3. Indemnity of Indemnitee. Subject to Sections 6, 7 and 9, the Corporation shall indemnify the Indemnitee in connection with any Proceeding as to which the Indemnitee is, was or is threatened to be made a party (or is otherwise involved) by reason of the Indemnitee's Corporate Status, to the fullest extent permitted by law (as such may be amended from time to time). In furtherance of the foregoing and without limiting the generality thereof:

(a) Indemnification in Third-Party Proceedings. The Corporation shall indemnify the Indemnitee in accordance with the provisions of this Section 3(a) if the Indemnitee was or is a party to or threatened to be made a party to or otherwise involved in any Proceeding (other than a Proceeding by or in the right of the Corporation to procure a judgment in its favor or a Proceeding referred to in Section 6 below) by reason of the Indemnitee's Corporate Status or by reason of any action alleged to have been taken or omitted in connection therewith, against all Expenses, judgments, fines, penalties and amounts paid in settlement actually and reasonably incurred by or on behalf of the Indemnitee in connection with such Proceeding, if the Indemnitee acted in good faith and in a manner which the Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation and, with respect to any criminal Proceeding, had no reasonable cause to believe that his or her conduct was unlawful.

(b) Indemnification in Proceedings by or in the Right of the Corporation. The Corporation shall indemnify the Indemnitee in accordance with the provisions of this Section 3(b) if the Indemnitee was or is a party to or threatened to be made a party to or otherwise involved in any Proceeding by or in the right of the Corporation to procure a judgment in its favor by reason of the Indemnitee's Corporate Status or by reason of any action alleged to have been taken or omitted in connection therewith, against all Expenses and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred by or on behalf of the Indemnitee in connection with such Proceeding, if the Indemnitee acted in good faith and in a manner which the Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that, if applicable law so provides, no indemnification shall be made under this Section 3(b) in respect of any claim, issue, or matter as to which the Indemnitee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, the Indemnitee is fairly and reasonably entitled to indemnity for such Expenses as the Court of Chancery or such other court shall deem proper.

4 . Indemnification of Expenses of Successful Party. Notwithstanding any other provision of this Agreement, to the extent that the Indemnitee has been successful, on the merits or otherwise, in defense of any Proceeding or in defense of any claim, issue or matter therein (other than a Proceeding referred to in Section 6), the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by or on behalf of the Indemnitee in connection therewith. Without limiting the foregoing, if any Proceeding or any claim, issue or matter therein is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to the Indemnitee, (ii) an adjudication that the Indemnitee was liable to the Corporation, (iii) a plea of guilty or nolo contendereby the Indemnitee, (iv) an adjudication that the Indemnitee did not act in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Corporation, and (v) with respect to any criminal proceeding, an adjudication that the Indemnitee had reasonable cause to believe his or her conduct was unlawful, the Indemnitee shall be considered for the purposes hereof to have been wholly successful with respect thereto.

5 . Indemnification for Expenses of a Witness. To the extent that the Indemnitee is, by reason of the Indemnitee's Corporate Status, a witness in any Proceeding to which the Indemnitee is not a party, the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by or on behalf of the Indemnitee in connection therewith.

6. Exceptions to Right of Indemnification.

(a) Notwithstanding anything to the contrary in this Agreement, except as set forth in Section 10, the Corporation shall not indemnify the Indemnitee in connection with a Proceeding (or part thereof) initiated by the Indemnitee unless the initiation thereof was approved by the Board of Directors of the Corporation.

(b) The Company shall not be liable under this Agreement to indemnify any Indemnitee to the extent Indemnitee has otherwise actually received payment (under any insurance policy, Certificate of Incorporation, Bylaw, or otherwise) of the amounts otherwise indemnifiable hereunder. To the extent the Indemnitee has been indemnified by the Company hereunder and later receives payments under any insurance policy covering the same Expenses so indemnified by the Company hereunder, the Indemnitee shall immediately reimburse the Company hereunder for all such amounts received from the insurer. Notwithstanding anything contained herein to the contrary, the Indemnitee shall not be entitled to recover amounts under this Agreement, which, when added to the amount of indemnification payments made to, or on behalf of, the Indemnitee under the Certificate of Incorporation or By-laws of the Company, in the aggregate exceed the Expenses actually and reasonably incurred by the Indemnitee ("*Excess Amounts"*). To the extent the Company has paid Excess Amounts to the Indemnitee, the Indemnitee shall be obligated to reimburse the Company immediately for such Excess Amounts.

(c) The Company and Indemnitee acknowledge that in certain instances, Federal law or applicable public policy may prohibit the Company from indemnifying its directors, officers, employees, controlling persons, agents, or fiduciaries under this Agreement or otherwise. Each Indemnitee understands and acknowledges that the Company has undertaken or may be required in the future to undertake with the Securities and Exchange Commission to submit the question or indemnification to a court in certain circumstances for a determination of the Company's rights under public policy to indemnify Indemnitee. No such undertaking or submission to a court shall be a breach of this Agreement.

(d) Any other provision herein to the contrary notwithstanding, the Company shall not be obligated pursuant to the terms of this Agreement:

(i) Claims Initiated by Indemnitee. To indemnify or advance Expenses to any Indemnitee with respect to Claims initiated or brought voluntarily by Indemnitee and not by way of defense, except (i) with respect to successful actions or proceedings to establish or enforce a right to indemnify under this Agreement or any other agreement or insurance policy or under the Company's Certificate of Incorporation or Bylaws now or hereafter in effect relating to Claims for Indemnifiable Events, (ii) in specific cases if the Board of Directors has approved the initiation or bringing of such Claim, or (ii) as otherwise required under Section 145 of the Delaware General Corporation Laws.

(ii) Claims Under Section 16(b). To indemnify Indemnitee for expenses and the payment of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 16(b) of the Exchange Act or any similar successor statute.

7 . Notification and Defense of Claim. As a condition precedent to the Indemnitee's right to be indemnified, the Indemnitee must notify the Corporation in writing as soon as practicable of any Proceeding for which indemnity will or could be sought. With respect to any Proceeding of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to the Indemnitee. After notice from the Corporation to the Indemnitee of its election so to assume such defense, the Corporation shall not be liable to the Indemnitee for any legal or other expenses subsequently incurred by the Indemnitee in connection with such Proceeding, other than as provided below in this Section 7. The Indemnitee shall have the right to employ his or her own counsel in connection with such Proceeding, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of the Indemnitee unless (i) the employment of counsel by the Indemnitee has been authorized by the Corporation, (ii) counsel to the Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and the Indemnitee in the conduct of the defense of such Proceeding or (iii) the Corporation shall not in fact have employed counsel to assume the defense of such Proceeding, in each of which cases the fees and expenses of counsel for the Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Agreement, and provided that Indemnitee's counsel shall cooperate reasonably with the Corporation's counsel to minimize the cost of defending claims against the Corporation and the Indemnitee. The Corporation shall not be entitled, without the consent of the Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for the Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above. The Corporation shall not be required to indemnify the Indemnitee under this Agreement for any amounts paid in settlement of any Proceeding effected without its written consent. The Corporation shall not settle any Proceeding in any manner that would impose any penalty or limitation on the Indemnitee without the Indemnitee's written consent unless, in the case of a monetary penalty, the Corporation agrees to pay such monetary penalty. Neither the Corporation nor the Indemnitee will unreasonably withhold or delay their consent to any proposed settlement.

8. Advancement of Expenses. In the event that the Corporation does not assume the defense pursuant to Section 7 of any Proceeding of which the Corporation receives notice under this Agreement, any Expenses actually and reasonably incurred by or on behalf of the Indemnitee in defending such Proceeding shall be paid by the Corporation in advance of the final disposition of such Proceeding; provided, however, that the payment of such Expenses incurred by or on behalf of the Indemnitee in advance of the final disposition of such Proceeding shall be made only upon receipt of an undertaking by or on behalf of the Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined that the Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Agreement. Such undertaking shall be accepted without reference to the financial ability of the Indemnitee to make repayment. Any advances and undertakings to repay pursuant to this Section 8 shall be unsecured and interest-free. Notwithstanding the foregoing, no advancement of Expenses shall be made if it is determined that (i) the Indemnitee did not act in good faith and in a manner he reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, the Indemnitee had reasonable cause to believe his conduct was unlawful.

9. Procedures.

(a) In order to obtain indemnification or advancement of Expenses pursuant to this Agreement, the Indemnitee shall submit to the Corporation a written request, including in such request such documentation and information as is reasonably available to the Indemnitee and is reasonably necessary to determine whether and to what extent the Indemnitee is entitled to indemnification or advancement of Expenses. Any such indemnification or advancement of Expenses shall be made promptly, and in any event within (i) in the case of indemnification under Sections 4, 5, or 9(c) or advancement of Expenses, 30 days after receipt by the Corporation of the written request of the Indemnitee, or (ii) in the case of all other indemnification, 60 days after receipt by the Corporation of the written request of the Indemnitee, unless with respect to requests under this clause (ii) the Corporation determines, by clear and convincing evidence, within the 60-day period referred to above that the Indemnitee did not meet the applicable standard of conduct. Such determination, and any determination that advanced Expenses must be repaid to the Corporation, shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the Proceeding ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by a majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by applicable law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

(b) The termination of any Proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the Indemnitee did not act in good faith and in a manner that the Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal Proceeding, had reasonable cause to believe that his or her conduct was unlawful.

(c) The Indemnitee shall cooperate with the person, persons or entity making such determination with respect to the Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to the Indemnitee and reasonably necessary to such determination. Any Expenses actually and reasonably incurred by the Indemnitee in so cooperating shall be borne by the Corporation (irrespective of the determination as to the Indemnitee's entitlement to indemnification) and the Corporation hereby indemnifies the Indemnitee therefrom.

10. Remedies. The right to indemnification or advancement of Expenses as provided by this Agreement shall be enforceable by the Indemnitee in any court of competent jurisdiction if the Corporation denies such request, in whole or in part, or if no disposition thereof is made within the applicable period referred to in Section 9. Unless otherwise required by law, the burden of proving that indemnification or advancement of Expenses is not appropriate shall be on the Corporation. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because the Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation that the Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that the Indemnitee has not met the applicable standard of conduct. The Indemnitee's Expenses actually and reasonably incurred in connection with successfully establishing the Indemnitee's right to indemnification, in whole or in part, in any such Proceeding shall also be indemnified by the Corporation.

11. Partial Indemnification. If the Indemnitee is entitled under any provision of this Agreement to indemnification by the Corporation for some or a portion of the Expenses, judgments, fines, penalties or amounts paid in settlement actually and reasonably incurred by or on behalf of the Indemnitee in connection with any Proceeding but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify the Indemnitee for the portion of such Expenses, judgments, fines, penalties or amounts paid in settlement to which the Indemnitee is entitled.

12. Subrogation. In the event of any payment under this Agreement, the Corporation shall be subrogated to the extent of such payment to all of the rights of recovery of the Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Corporation to bring suit to enforce such rights.

13. Term of Agreement. This Agreement shall continue until and terminate upon the later of (a) six years after the date that the Indemnitee shall have ceased to serve as a director or officer of the Corporation or, at the request of the Corporation, as a director, officer, partner, trustee, member, employee or agent of another corporation, partnership, joint venture, trust, limited liability company or other enterprise or (b) the final termination of all Proceedings pending on the date set forth in clause (a) in respect of which the Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by the Indemnitee pursuant to Section 10 of this Agreement relating thereto.

14. Indemnification Hereunder Not Exclusive. The indemnification and advancement of Expenses provided by this Agreement shall not be deemed exclusive of any other rights to which the Indemnitee may be entitled under the Certification of Incorporation, the By-Laws, any other agreement, any vote of stockholders or disinterested directors, the General Corporation Law of Delaware, any other law (common or statutory), or otherwise, both as to action in the Indemnitee's official capacity and as to action in another capacity while holding office for the Corporation. Nothing contained in this Agreement shall be deemed to prohibit the Corporation from purchasing and maintaining insurance, at its expense, to protect itself or the Indemnitee against any expense, liability or loss incurred by it or the Indemnitee in any such capacity, or arising out of the Indemnitee's status as such, whether or not the Indemnitee would be indemnified against such expense, liability or loss under this Agreement; provided that the Corporation shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder if and to the extent that the Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

15. No Special Rights. Nothing herein shall confer upon the Indemnitee any right to continue to serve as an officer or director of the Corporation for any period of time or at any particular rate of compensation.

16. Savings Clause. If this Agreement or any portion thereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify the Indemnitee as to Expenses, judgments, fines, penalties and amounts paid in settlement with respect to any Proceeding to the full extent permitted by any applicable portion of this Agreement that shall not have been invalidated and to the fullest extent permitted by applicable law.

17. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall constitute the original.

18. Successors and Assigns. This Agreement shall be binding upon the Corporation and its successors and assigns and shall inure to the benefit of the estate, heirs, executors, administrators and personal representatives of the Indemnitee.

19. Headings. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

20. Modification and Waiver. This Agreement may be amended from time to time to reflect changes in Delaware law or for other reasons. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision hereof nor shall any such waiver constitute a continuing waiver.

21. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been given (i) when delivered by hand or (ii) if mailed by certified or registered mail with postage prepaid, on the third day after the date on which it is so mailed:

(a) if to the Indemnitee, to: _____
_____
_____

(b) if to the Corporation, to: Abeona Therapeutics Inc.
3333 Lee Parkway
Suite 600
Dallas, TX 75219
Attn: Executive Chairman

or to such other address as may have been furnished to the Indemnitee by the Corporation or to the Corporation by the Indemnitee, as the case may be.

22. Applicable Law. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware. The Indemnitee may elect to have the right to indemnification or reimbursement or advancement of Expenses interpreted on the basis of the applicable law in effect at the time of the occurrence of the event or events giving rise to the applicable Proceeding, to the extent permitted by law, or on the basis of the applicable law in effect at the time such indemnification or reimbursement or advancement of Expenses is sought. Such election shall be made, by a notice in writing to the Corporation, at the time indemnification or reimbursement or advancement of Expenses is sought; provided, however, that if no such notice is given, and if the General Corporation Law of Delaware is amended, or other Delaware law is enacted, to permit further indemnification of the directors and officers, then the Indemnitee shall be indemnified to the fullest extent permitted under the General Corporation Law, as so amended, or by such other Delaware law, as so enacted.

23. Enforcement. The Corporation expressly confirms and agrees that it has entered into this Agreement in order to induce the Indemnitee to continue to serve as an officer or director of the Corporation, and acknowledges that the Indemnitee is relying upon this Agreement in continuing in such capacity.

24. Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto in respect of the subject matter contained herein and supercedes all prior agreements, whether oral or written, by any officer, employee or representative of any party hereto in respect of the subject matter contained herein; and any prior agreement of the parties hereto in respect of the subject matter contained herein is hereby terminated and cancelled. For avoidance of doubt, the parties confirm that the foregoing does not apply to or limit the Indemnitee's rights under Delaware law or the Corporation's Certificate of Incorporation or By-Laws.

25. Consent to Suit. In the case of any dispute under or in connection with this Agreement, the Indemnitee may only bring suit against the Corporation in the Court of Chancery of the State of Delaware. The Indemnitee hereby consents to the exclusive jurisdiction and venue of the courts of the State of Delaware, and the Indemnitee hereby waives any claim the Indemnitee may have at any time as to forum non conveniens with respect to such venue. The Corporation shall have the right to institute any legal action arising out of or relating to this Agreement in any court of competent jurisdiction. Any judgment entered against either of the parties in any proceeding hereunder may be entered and enforced by any court of competent jurisdiction.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

Abeona Therapeutics Inc.

Attest: _____ By: _____

By: _____ Name: _____

Name: _____ Title: _____

INDEMNITEE:

_____

EXHIBIT 31.1

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

I, Steven H. Rouhandeh, certify that:

1. I have reviewed this report on Form 10-Q of Abeona Therapeutics Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) 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 first 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(s) 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.

Dated: August 15, 2016

/s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
Principal Executive Officer

EXHIBIT 31.2

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

I, Stephen B. Thompson, 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(s) 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 first 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(s) 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.

Dated: August 15, 2016

/s/ Stephen B. Thompson
Stephen B. Thompson
Vice President Finance
Principal Financial and
Accounting Officer

EXHIBIT 32.1

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

This certification set forth below is hereby made solely for the purposes of satisfying the requirements of Section 906 of the Sarbanes-Oxley Act of 2002 and may not be relied upon or used for any other purposes.

A signed original of this written statement required by Section 906 has been provided to Abeona Therapeutics Inc. and will be retained by Abeona Therapeutics Inc. and furnished to the SEC or its staff upon its request.

Pursuant to Section 906 of the Public Company Accounting Reform and Investor Act of 2002 (18 U.S.C. 1350, as adopted, the “Sarbanes-Oxley Act”), Steven H. Rouhandeh, Executive Chairman of Abeona Therapeutics Inc. (the "Company") hereby certifies that to his knowledge the report on Form 10-Q for the period ended June 30, 2016 of the Company filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period specified.

Signed at the City of Dallas, in the State of Texas, this 15th day of August, 2016.

/s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
Principal Executive Officer

EXHIBIT 32.2

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

This certification set forth below is hereby made solely for the purposes of satisfying the requirements of Section 906 of the Sarbanes-Oxley Act of 2002 and may not be relied upon or used for any other purposes.

A signed original of this written statement required by Section 906 has been provided to Abeona Therapeutics Inc. and will be retained by Abeona Therapeutics Inc. and furnished to the SEC or its staff upon its request.

Pursuant to Section 906 of the Public Company Accounting Reform and Investor Act of 2002 (18 U.S.C. 1350, as adopted, the "Sarbanes-Oxley Act"), Stephen B. Thompson, Vice President Finance of the Company hereby certifies that to his knowledge the report on Form 10-Q for the period ended June 30, 2016 of the Company filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period specified.

Signed at the City of Dallas, in the State of Texas, this 15th day of August, 2016.

/s/ Stephen B. Thompson
Stephen B. Thompson
Vice President Finance
Principal Financial and Accounting Officer