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, 2018
or

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

For the transition period from _____ to _____

Commission file number **001-15771**

ABEONA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer 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.

Large accelerated filer ☐
Non-accelerated filer ☐
Emerging growth company ☐

Accelerated filer ☑
Smaller reporting company ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company ☐

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

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

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 9, 2018 was 47,943,285 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 on Form 10-Q, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission (the "SEC"), include, without limitation, statements relating to uncertainties associated with research and development activities; clinical trials; our ability to raise capital; future cash flows; the future success of our marketed products and products in development; our sales projections and the sales projections of our licensing partners; anticipated product launches and our commercialization strategies; 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 expectation that we will continue to incur losses; our belief that we will expend substantial funds to conduct research and development programs, preclinical studies and clinical trials of potential products; our belief that we have a rich pipeline of products and product candidates; our ability to achieve profitability at all or on a sustained basis; our expected cash burn rate; our belief that 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; and our belief that the data from the expansion cohort of our Phase 1/2 clinical trial in ABO-102 (AAV-SGSH) for MPS IIIA, together with the data generated in the program to date, will allow us to submit a BLA. These statements relate to management's current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact.. In some cases, you can identify forward-looking statements by terminology such as "may," "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 Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 17.

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 a clinical-stage biopharmaceutical company developing cell and gene therapies for life-threatening rare genetic diseases. Our lead programs include EB-101 (gene-corrected skin grafts) for recessive dystrophic epidermolysis bullosa ("RDEB"), ABO-102 (AAV-SGSH), an adeno-associated virus ("AAV") based gene therapy for Sanfilippo syndrome type A (MPS IIIA) and ABO-101 (AAV NAGLU), an AAV based gene therapy for Sanfilippo syndrome type B ("MPS IIIB"). We are also developing ABO-201 (AAV-CLN3) gene therapy for juvenile Batten disease (JNCL), ABO-202 (AAV-CLN1) for treatment of infantile Batten disease (INCL), EB-201 for epidermolysis bullosa (EB), ABO-301 (AAV-FANCC) for Fanconi anemia (FA) disorder and ABO-302 using a novel CRISPR/Cas9-based gene editing approach to gene therapy for rare blood diseases. In addition, we are developing a proprietary vector platform, AIM™, for next generation product candidates. Our principal executive office is located at 1330 Avenue of the Americas, 33 rd Floor, New York, New York 10019. Our website address is www.abeonatherapeutics.com.

Recent Developments

Since our May 18, 2018 update on the Phase 1/2 trial for ABO-102 (AAV-SGSH), the Company's clinical gene therapy for the treatment of Sanfilippo syndrome type A (MPS IIIA) two additional patients have been dosed with a single intravenous injection of ABO-102 bringing the total to 13 patients dosed. Also, since our May 18, 2018 update ABO-102 was well-tolerated with no drug-related serious adverse events reported through over 5,200 cumulative days post-injection.

On July 26, 2018, we announced the appointment of our Max Colao as Chief Commercial Officer. Mr. Colao has more than 20 years of global pharmaceutical and biotechnology experience, having most recently served as the Senior Vice President of US Commercial Operations at Alexion Pharmaceuticals, Inc. We also announced that Jeffrey B. Davis, in order to ensure a smooth transition, will be stepping down from his role as Chief Operating Officer at the end of the quarter, effective September 30, 2018. Additionally, in an ongoing commitment to enhance the capabilities of our senior team, we appointed Kristina Maximenko as Global Head of Human Resources.

On May 31, 2018, we announced the opening of The Elisa Linton Center for Rare Disease Therapies, the commercial GMP manufacturing facility for gene and cell therapies in Cleveland, Ohio. The GMP facility will have the capability to manufacture clinical and commercial grade products over Abeona's multiple programs, including RDEB and Sanfilippo syndrome.

On May 18, 2018, we announced updated clinical data from the Phase 1/2 trial for ABO-102 (AAV-SGSH), the Company's clinical gene therapy for the treatment of Sanfilippo syndrome type A (MPS IIIA) during the 21st Annual Meeting of the ASGCT (American Society for Gene and Cell Therapy) in Chicago, IL. The ongoing ABO-102 (AAV-SGSH) trial results demonstrated robust and durable clinical effects achieved throughout various timepoints post-administration, and the clinical study was on-going as of the quarter ended June 30, 2018. Additionally, as of that time, 11 patients had been dosed with a single intravenous injection of ABO-102 for the treatment of MPS IIIA. MPS IIIA is a rare, autosomal-recessive, lysosomal storage disease that results in the accumulation of heparan sulfate. Each subject received a single intravenous infusion of the gene therapy for systemic delivery of a functional copy of the missing SGSH gene associated with onset and progression of the disease. Select data from the presentation are highlighted below:

Biopotency Assessments: ABO-102 continued to demonstrate significant dose-dependent and time-dependent responses in key biomarkers through 18-months post-injection, including sustained reductions of heparan sulfate, the sugar molecule that is the hallmark of MPS IIIA, in the cerebral spinal fluid ("CSF") and urine.

CSF heparan sulfate:

- Day 360 assessment
  - Cohort 1 (n=2) demonstrated a reduction of 69.3%
  - Cohort 2 (n=2) demonstrated a reduction of 65.7%
- Day 180 assessment
  - Cohort 1 (n=3) demonstrated a reduction of 58.7%
  - Cohort 2 (n=3) demonstrated a reduction of 60.5%
  - Cohort 3 (n=1) demonstrated a reduction of 83.3%
- Day 30 assessment
  - Cohort 1 (n=3) demonstrated a reduction of 25.8%
  - Cohort 2 (n=3) demonstrated a reduction of 52.1%
  - Cohort 3 (n=4) demonstrated a reduction of 67.1%

Urine heparan sulfate:

- Day 540 assessment
  - Cohort 1 (n=3) demonstrated a reduction of 30.0%
- Day 360 assessment
  - Cohort 1 (n=3) demonstrated a reduction of 29.2%
  - Cohort 2 (n=2) demonstrated a reduction of 45.1%
- Day 180 assessment
  - Cohort 1 (n=3) demonstrated a reduction of 29.2%
  - Cohort 2 (n=2) demonstrated a reduction of 57.6%
  - Cohort 3 (n=1) demonstrated a reduction of 75.0%
- Day 90 assessment
  - Cohort 1 (n=3) demonstrated a reduction of 54.2%
  - Cohort 2 (n=3) demonstrated a reduction of 63.1%
  - Cohort 3 (n=4) demonstrated a reduction of 77.1%
- Day 30 assessment
  - Cohort 1 (n=3) demonstrated a reduction of 64.2%
  - Cohort 2 (n=3) demonstrated a reduction of 54.0%
  - Cohort 3 (n=3) demonstrated a reduction of 90.3%

Biophysical Assessments: A supportive natural history study (Truxal et. al., 2016, Mol. Genet. Metab.) in MPS IIIA demonstrated that subjects showed, on average, 2.2 times increased liver volumes over normal. Results from the Phase 1/2 clinical trial for ABO-102 demonstrated durable biophysical reductions of disease burden including reductions in liver volume.

Safety Assessments: ABO-102 was well-tolerated in all subjects as of May 18, 2018, with no drug-related serious adverse events reported through over 4,200 cumulative days post-injection.

On May 17, 2018, we announced updated clinical data during the ASGCT (American Society for Gene and Cell Therapy) 21st Annual Meeting in Chicago, IL. EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets [LEAES]) are gene–corrected autologous keratinocyte grafts transduced with a retroviral vector containing the COL7A1 gene for patients with severe Recessive Dystrophic Epidermolysis Bullosa (RDEB). RDEB is an ultra-rare, catastrophic genetic skin disorder and unmet medical need. RDEB is caused by loss of function mutations in COL7A1, the gene coding for type VII collagen. RDEB is characterized by generalized cutaneous and mucosal blistering and scarring associated with severe deformities and major extracutaneous involvement. These wounds are also extremely painful and uncomfortable. There is no approved therapy for this disease, and standard of care remains simple dressing changes and palliative care.

At ASGCT, we reported Phase 1/2 results for EB-101 treated subjects (n=7 patients, N=42 total treatments) with non-healing chronic wounds with an average time open prior to treatment of 8.5 years. Wound healing defined as >50% healing compared over baseline has been observed in 100% (42/42 grafts) at 3 months, 90% (38/42) at 6 months, 63% (24/38) at 12 months, and 81% (21/26) at 24 months. By comparison, untreated control wounds healing >50% have been observed in 20% (2/10) at 3 months, 10% (1/10) at 6 months, 0% (0/8) at 12 months, and 0% (0/2) at 24 months. Of note, durable EB-101 patients Type VII collagen expression was observed in biopsies of treated wounds up to 3 years post-treatment. In sum, we believe the Phase 1/2 trial met the primary endpoints for safety, tolerability and preliminary efficacy, and a Phase 3 study is planned.

The EB-101 program has been granted Regenerative Medicine Advanced Therapy, Breakthrough Therapy, Orphan Drug and Rare Pediatric Disease Designations from the US Food and Drug Administration (the “FDA”) and granted Orphan Drug Designation from the European Medicines Agency (the “EMA”).

On May 14, 2018 we announced the appointment of Messrs. Stefano Buono and Richard Van Duyne as independent Directors to our Board of Directors. Neither Mr. Buono nor Mr. Van Duyne has worked previously for the Company.

Product Development Strategy

Abeona is focused on developing and delivering gene therapy products for severe and life-threatening rare diseases. A rare disease is one that affects fewer than 200,000 people in the U.S. 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, life-threating 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. Approximately 80% of rare diseases 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 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 used to treat the patient's underlying disease and can provide long-term benefit.

Abeona is developing next-generation 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), making them attractive for addressing lysosomal storage diseases, which have severe CNS manifestations of the disease.

Lysosomal storage diseases ("LSDs") 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 CNS are typically involved in disease pathology. Since the advent of enzyme replacement therapy 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, 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") III A and IIIB. MPSIII, also known as Sanfilippo syndromes type A and type B, 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 only given once to a patient.

EB-101 for the Treatment of Recessive Dystrophic Epidermolysis Bullosa and EB-201 for the Correction of Gene Mutations in Skin Cells (Keratinocytes)

EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)), is an ex vivo gene therapy for the treatment of RDEB. EB-201 (AAVDJ-Col7A1) is a pre-clinical candidate targeting a novel, AAV-mediated gene editing and delivery approach to correct gene mutations in skin cells for patients with RDEB. On August 3, 2016, we entered into an agreement (the "EB Agreement") with EB Research Partnership ("EBRP") and Epidermolysis Bullosa Medical Research Foundation ("EBMRF") to collaborate on gene therapy treatments for EB.

We entered into a license with Stanford, effective August 3, 2016, for the EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)) technology, and we have performed certain preclinical development work and, as of June 30, 2018, were performing clinical trials of a gene therapy treatment for EB based upon such in-licensed technology.

We also entered into a license with Stanford, effective August 3, 2016, for the EB-201 (AAV DJ COL7A1) technology, and we plan to perform preclinical development and clinical trials of a gene therapy treatment for EB based upon such in-licensed technology.

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

MPS 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. At June 30, 2018, the incidence of MPS III (all four types combined) was 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 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 CNS, including the brain and spinal cord, resulting in cognitive decline, motor dysfunction, and eventual death. At June 30, 2018, there was no cure for MPS III and treatments were largely supportive.

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

After a single dose in MPS III 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 MPS III 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 MPS III A and B. In addition, safety studies conducted in animal models of MPS III have demonstrated that delivery of ABO-101 or ABO-102 were well tolerated with minimal side effects.

ABO-201 for juvenile Batten disease (or Juvenile Neuronal Ceroid Lipofuscinoses) (JNCL) and ABO-202 (AAV-CLN1) gene therapy for treatment of infantile Batten disease (or Infantile Neuronal Ceroid Lipofuscinoses) (INCL)

ABO-201 (AAV CLN3) is an AAV-based gene therapy that has shown promising preclinical efficacy in delivery of a normal copy of the defective CLN3 gene to cells of the CNS with the aim 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 regression 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. At June 30, 2018, 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 were affected at June 30, 2018, 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-202 (AAV9 CLN1) is an AAV-based gene therapy that has shown promising preclinical efficacy in delivery of a normal copy of the defective CLN1 gene to cells of the central nervous system with the aim of reversing the effects of the genetic errors that cause an infantile form of Batten disease (also known as infantile neuronal ceroid lipofuscinosis).

ABO-301 for Fanconi Anemia (FA) and ABO-302 for rare blood diseases using a novel CRISPR/Cas9-based gene editing approach to gene therapy for rare blood diseases

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 aim of reversing the effects of the genetic errors that cause 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 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, 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.

LIQUIDITY AND CAPITAL RESOURCES

We have historically 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. Foundation grants and royalty revenues provided limited funding for operations during the period ended June 30, 2018. As of June 30, 2018, our cash and cash equivalents and marketable securities were $119,842,000, as compared to $137,750,000 as of December 31, 2017. The decrease in cash and cash equivalents was primarily attributable to the decrease in working capital discussed below.

As of June 30, 2018, our working capital was $116,043,000. Our working capital as of June 30, 2018 represented a decrease of $18,942,000 as compared to our working capital of $134,985,000 as of December 31, 2017. The decrease in working capital as of June 30, 2018 reflects six months of net operating costs and changes in current assets and liabilities and capital expenditures, partially offset by proceeds from the exercise of stock options and warrants.

On October 16, 2017, we announced a collaborative agreement between nine Sanfilippo foundations to provide up to approximately $13.85 million of grants to Abeona in installments for the advancement of the Company's clinical stage gene therapies for Sanfilippo Syndrome Type A (MPS IIIA) and Sanfilippo Syndrome Type B (MPS IIIB), subject to the achievement of certain milestones. As of June 30, 2018, we received $3.4 million in grants ($2.6 million in the quarter ended December 31, 2017 and $0.8 million in the six months ended June 30, 2018) and recorded them first as deferred revenue. $2.6 million of the $3.4 million in grants were recorded as revenue in the quarter ended March 31, 2018 and $0.8 million were recorded as revenue in the quarter ended June 30, 2018.

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, 2018 of $376,292,000. 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, as of June 30, 2018, had 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 2018 COMPARED TO SECOND QUARTER 2017

Our licensing revenue for the second quarter of 2017 was $150,000. In 2017, we recognized licensing revenue over the period of the performance obligation under our licensing agreements under the Financial Accounting Standards Board's Accounting Standards Codification ("ASC") 605, *Revenue Recognition (Topic 605)*. Effective January 1, 2018, we adopted Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*, as amended (commonly referred to as ASC 606) using the modified retrospective transition method. The cumulative effect of applying the standard was an increase of $3.7 million to stockholders' equity as of January 1, 2018. There was no licensing revenue for the second quarter of 2018 due to ASC 606.

We recorded revenue for Foundation Grants of $802,000 for the second quarter of 2018 and no revenues for the same period of 2017, an increase of $802,000. We recorded revenue to match expenses for the advancement of the Company's clinical stage gene therapies for Sanfilippo Syndrome Type A (MPS IIIA) and Sanfilippo Syndrome Type B (MPS IIIB).

We recorded royalty revenue for MuGard of $17,000 for second quarter of 2018 and $67,000 for the same period of 2018, a decrease of $50,000. We licensed MuGard to AMAG and Norgine and received quarterly reports under our agreement.

Total research and development spending for the second quarter of 2018 was $7,916,000, as compared to $5,808,000 for the same period of 2017, an increase of $2,108,000. The increase in expenses was primarily due to:

- increased clinical and development work for the manufactured product for EB-101, ABO-102, ABO-101 and other gene therapy products ($614,000);
- increased salary and related costs ($647,000) from the hiring of scientific staff;
- increased stock option compensation expense ($532,000); and
- other net increases in research spending ($315,000).

Total general and administrative expenses were $4,627,000 for the second quarter of 2018, as compared to $2,642,000 for the same period of 2017, an increase of $1,985,000. The increase in expenses was due primarily to the following:

- increased stock option compensation expense ($908,000);
- increased salary and related costs ($309,000);
- increased expense for search firms for new executives ($278,000);
- increased legal and audit fees ($238,000) and
- by increases in net other general and administrative expenses ($252,000).

Depreciation and amortization was $290,000 for the second quarter of 2018, as compared to $207,000 for the same period in 2017, an increase of $83,000. We are amortizing the licenses for ABO-101 and ABO-201, and EB-102 over the life of the patents. The decrease was primarily due to lower amortization of licensed technology ($71,000), partially offset by an increase in depreciation ($154,000). SDF Alpha was amortized through May 26, 2017. The license was returned to the licensor, Plasma Technologies, LLC in 2017.

Total operating expenses for the second quarter of 2018 were $12,833,000, as compared to total operating expenses of $8,657,000 for the same period of 2017, an increase of $4,176,000 for the reasons listed above.

Interest and miscellaneous income was $317,000 for the second quarter of 2018 as compared to $164,000 for the same period of 2017, an increase of $153,000. Most of the increase was due to increased interest income due to higher cash balances and marketable securities ($282,000) offset by decreased miscellaneous income ($129,000).

Interest and other expense was $3,000 for the second quarter of 2018, as compared to $3,000 in the same period of 2017.

Net loss for the second quarter of 2018 was $11,700,000, or a $0.25 basic and diluted loss per common share as compared to a net loss of $8,279,000, or a $0.21 basic and diluted loss per common share, for the same period in 2017, an increased loss of $3,421,000.

SIX MONTHS ENDED JUNE 30, 2018 COMPARED TO SIX MONTHS ENDED JUNE 30, 2017

Our licensing revenue for the first six months of 2017 was $301,000. In 2017, we recognized licensing revenue over the period of the performance obligation under our licensing agreements under ASC 605. Effective January 1, 2018, we adopted ASC 606 using the modified retrospective transition method. The cumulative effect of applying the standard was an increase of $3.7 million to stockholders' equity as of January 1, 2018. There was no licensing revenue for the first six months of 2018 due to ASC 606.

We recorded revenue for Foundation Grants of $3,350,000 for first six months of 2018 and no revenues for the same period of 2017, an increase of $3,350,000. We recorded revenue to match expenses for the advancement of the Company's clinical stage gene therapies for Sanfilippo Syndrome Type A (MPS IIIA) and Sanfilippo Syndrome Type B (MPS IIIB).

We recorded royalty revenue for MuGard of $67,000 for first six months of 2018 and $102,000 for the same period of 2017, a decrease of $35,000. We licensed MuGard to AMAG and Norgine and received quarterly reports under our agreement.

Total research and development spending for the first six months of 2018? was $16,078,000, as compared to $8,006,000 for the same period of 2017, an increase of $8,072,000. The increase in expenses was primarily due to:

- increased clinical and development work for the manufactured product for EB-101, ABO-102, ABO-101 and other gene therapy products ($5,553,000);
- increased salary and related costs ($1,115,000) from the hiring of scientific staff;
- increased stock option compensation expense ($976,000); and
- other net increases in research spending ($428,000).

Total general and administrative expenses were $7,505,000 for the first six months of 2018, as compared to $5,664,000 for the same period of 2017, an increase of $1,841,000. The increase in expenses was due primarily to the following:

- increased stock option compensation expense ($838,000) offset by decreased restricted common stock expense ($342,000);
- increased salary and related costs ($300,000);
- increased expense for search firms for new executives ($278,000);
- increased legal and audit fees ($242,000) and
- by increases in net other general and administrative expenses ($526,000).

Depreciation and amortization was $464,000 for the first six months of 2018, as compared to $457,000 for the same period in 2017, an increase of $7,000. We amortize the licenses for ABO-101 and ABO-201, and EB-102 over the life of the patents. We amortize the licenses for ABO-101 and ABO-201, and EB-102 over the life of the patents. The decrease was primarily due to lower amortization of licensed technology ($187,000), partially offset by an increase in depreciation ($194,000). SDF Alpha was amortized through May 26, 2017. The license was returned to the licensor, Plasma Technologies, LLC in 2017.

Total operating expenses for the first six months of 2018 were $24,047,000, as compared to total operating expenses of $14,127,000 for the same period of 2017, an increase of $9,920,000 for the reasons listed above.

Interest and miscellaneous income was $473,000 for the first six months of 2018, as compared to $203,000 for the same period of 2017, an increase of $270,000. Most of the increase was due to increased interest income due to higher cash balances ($391,000), partially offset by decreased miscellaneous income ($121,000).

Interest and other expense was $6,000 for the six months of 2018, as compared to $5,000 in the same period of 2017.

Net loss for the six months of 2018 was $20,163,000, or a $0.43 basic and diluted loss per common share as compared to a net loss of $13,526,000, or a $0.34 basic and diluted loss per common share, for the same period in 2017, an increased loss of $6,637,000.

OFF-BALANCE SHEET ARRANGEMENTS

None.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to a variety of financial risks in the normal course of our business, including market risk (including currency and price risk), credit risk and liquidity risk. Our overall risk management program focuses on preservation of capital and the unpredictability of financial markets and has sought to minimize potential adverse effects on our financial performance and position.

Market Risk

Currency risk
We are exposed to foreign exchange risk arising from various currencies, primarily with respect to the U.S. dollar and to a lesser extent to the euro, Australian dollar and British pound. As our U.S. operating entity primarily conducts its operations in U.S. dollars, its exposure to changes in foreign currency is insignificant.

Price risk
The market prices for the provision of preclinical and clinical materials and services, as well as external contracted research, may vary over time.

The commercial prices of any of our products or product candidates are currently uncertain.

We are not exposed to commodity price risk.

We do hold investments classified as available-for-sale or at fair value through profit or loss; therefore, we are exposed to equity securities price risk.

Credit Risk

Credit risk is managed on a consolidated basis. Credit risk arises from cash and cash equivalents and deposits with banks and financial institutions, outstanding receivables and committed transactions with collaboration partners and security deposits paid to landlords. We currently have no wholesale debtors.

We deposited funds as security to our landlords related to our facility in Cleveland, Ohio and our facility in Dallas, Texas.

Our cash and cash equivalents include bank balances, demand deposits and other short-term highly liquid investments (with maturities of less than three months at the time of purchase) that are readily convertible into a known amount of cash and are subject to an insignificant risk of fluctuation in value. Restricted cash includes deposits made in relation to facility leases. Cash, cash equivalents and restricted cash were placed at Comerica Bank.

Liquidity Risk

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We manage liquidity through a rolling forecast of our liquidity reserve on the basis of expected cash flow and raise cash if and when needed through the issuance of shares.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management and consultants, including the Executive Chairman (our principal executive officer) and Senior Vice President Finance (our principal accounting officer), we have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures ("Disclosure Controls and Procedures"), as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of June 30, 2018.

Conclusion of Evaluation – Based on this Disclosure Controls and Procedures evaluation, the Executive Chairman and Chief Accounting Officer concluded that our Disclosure Controls and Procedures as of June 30, 2018 were effective.

Changes In Internal Control Over Financial Reporting – There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2018 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.

We are not currently subject to any material legal proceedings.

ITEM 1A. RISK FACTORS.

As of the date of this filing, there have been no material changes to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 16, 2018.

ITEM 6. EXHIBITS.

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

Exhibit Index

Exhibits:

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, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of June 30, 2018 and December 31, 2017, (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2018 and June 30, 2017, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2018, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2018 and June 30, 2017, and (v) Notes to Condensed Consolidated Financial Statements.

* 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 9, 2018

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

Date: August 9, 2018

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	June 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 49,990,000	$ 137,750,000
Marketable securities	69,852,000	-
Receivables	47,000	107,000
Prepaid expenses and other current assets	1,937,000	2,735,000
Total current assets	121,826,000	140,592,000
Property and equipment, net	8,007,000	1,374,000
Licensed technology, net	3,803,000	3,977,000
Goodwill	32,466,000	32,466,000
Other assets and restricted cash	595,000	357,000
Total assets	$ 166,697,000	$ 178,766,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 5,783,000	$ 2,393,000
Current portion of deferred revenue	-	3,214,000
Total current liabilities	5,783,000	5,607,000
Deferred revenue, net of current portion	-	3,061,000
Total liabilities	5,783,000	8,668,000
Commitments and contingencies		
Stockholders' equity		
Common stock – $.01 par value; authorized 200,000,000 shares; issued, 47,327,785 at June 30, 2018 and 46,888,108 at December 31, 2017	473,000	469,000
Additional paid-in capital	536,733,000	529,421,000
Accumulated deficit	(376,292,000)	(359,792,000)
Total stockholders' equity	160,914,000	170,098,000
Total liabilities and stockholders' equity	$ 166,697,000	$ 178,766,000

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,	
	2018	**2017**	**2018**	**2017**
Revenues				
Foundation grants	$ 802,000	$ -	$ 3,350,000	$ -
Royalties	17,000	67,000	67,000	102,000
License revenues	-	150,000	-	301,000
Total revenues	819,000	217,000	3,417,000	403,000
Expenses				
Research and development	7,916,000	5,808,000	16,078,000	8,006,000
General and administrative	4,627,000	2,642,000	7,505,000	5,664,000
Depreciation and amortization	290,000	207,000	464,000	457,000
Total expenses	12,833,000	8,657,000	24,047,000	14,127,000
Loss from operations	(12,014,000)	(8,440,000)	(20,630,000)	(13,724,000)
Interest and miscellaneous income	317,000	164,000	473,000	203,000
Interest and other expense	(3,000)	(3,000)	(6,000)	(5,000)
	314,000	161,000	467,000	198,000
Net loss	$ (11,700,000)	$ (8,279,000)	$ (20,163,000)	$ (13,526,000)
Basic and diluted loss per common share	$ (0.25)	$ (0.21)	$ (0.43)	$ (0.34)
Weighted average number of common shares outstanding	47,303,518	40,270,879	47,182,691	40,262,824

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity
(unaudited)

	Common Stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	capital	deficit	equity
Balance, December 31, 2017 – as reported	46,888,108	$ 469,000	$529,421,000	$(359,792,000)	$ 170,098,000
Cumulative effect adjustment of ASC 606 on January 1, 2018	-	-	-	3,663,000	3,663,000
Stock based compensation expense	-	-	1,900,000	-	1,900,000
Vesting of restricted common stock issued to employees	-	-	172,000	-	172,000
Common stock issued for cash exercise of options	267,196	3,000	1,682,000	-	1,685,000
Exercise of $5.00 warrants	28,874	-	144,000	-	144,000
Cashless warrant exercises	48,762	-	-	-	-
Net loss	-	-	-	(8,463,000)	(8,463,000)
Balance, March 31, 2018	47,232,940	472,000	533,319,000	(364,592,000)	169,199,000
Stock based compensation expense	-	-	2,673,000	-	2,673,000
Vesting of restricted common stock issued to employees	-	-	172,000	-	172,000
Common stock issued for cash exercise of options	76,956	1,000	480,000	-	481,000
Exercise of $5.00 warrants	17,889	-	89,000	-	89,000
Net loss	-	-	-	(11,700,000)	(11,700,000)
Balance, June 30, 2018	47,327,785	$ 473,000	$536,733,000	$(376,292,000)	$ 160,914,000

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,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (20,163,000)	$ (13,526,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	464,000	457,000
Stock option compensation expense	4,573,000	2,735,000
Restricted common stock expense issued to directors and employees	344,000	686,000
Net gain on write off of licensed technology	-	(127,000)
Change in operating assets and liabilities:		
Receivables	60,000	27,000
Prepaid expenses and other current assets	798,000	(712,000)
Other assets	42,000	-
Accounts payable and accrued expenses	3,390,000	(77,000)
Deferred revenue	(2,612,000)	(302,000)
Net cash used in operating activities	(13,104,000)	(10,839,000)
Cash flows from investing activities:		
Capital expenditures	(6,923,000)	(84,000)
Short term investments	(69,852,000)	-
Net cash used in investing activities	(76,775,000)	(84,000)
Cash flows from financing activities:		
Proceeds from exercise of $5.00 warrants	233,000	-
Proceeds from exercise of stock options	2,166,000	85,000
Net cash provided by financing activities	2,399,000	85,000
Net decrease in cash, cash equivalents and restricted cash	(87,480,000)	(10,838,000)
Cash, cash equivalents and restricted cash at beginning of period	138,030,000	69,142,000
Cash, cash equivalents and restricted cash at end of period	$ 50,550,000	$ 58,304,000
Supplemental disclosure:		
Cash and cash equivalents	*$ 49,990,000*	*$ 58,304,000*
Restricted cash	*560,000*	-
Total cash, cash equivalents and restricted cash	*$ 50,550,000*	*$ 58,304,000*
Write off of licensed asset and corresponding liability	*$ -*	*$ 4,000,000*
Cash paid for interest	*$ 6,000*	*$ 5,000*

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 a clinical-stage biopharmaceutical company developing cell and gene therapies for life-threatening rare genetic diseases. Our lead programs include EB-101 (gene-corrected skin grafts) for RDEB, ABO-102 (AAV-SGSH), an AAV based gene therapy for Sanfilippo syndrome type A (MPS IIIA) and ABO-101 (AAV NAGLU), an AAV based gene therapy for MPS IIIB. We are also developing ABO-201 (AAV-CLN3) gene therapy for juvenile Batten disease (JNCL), ABO-202 (AAV-CLN1) for treatment of infantile Batten disease (INCL), EB-201 for epidermolysis bullosa ("EB"), ABO-301 (AAV-FANCC) for Fanconi anemia ("FA") disorder and ABO-302 using a novel CRISPR/Cas9-based gene editing approach to gene therapy for rare blood diseases. In addition, we are developing a proprietary vector platform, AIM™, for next generation product candidates. 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, 2018, the condensed consolidated statements of operations for the three and six months ended June 30, 2018 and 2017, the condensed consolidated statements of stockholders' equity for the three and six months ended June 30, 2018, and the condensed consolidated statements of cash flows for the six months ended June 30, 2018 and 2017, were prepared by management without audit. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted. 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, 2017. The results of operations for the period ended June 30, 2018 are not necessarily indicative of the operating results that may be expected for a full year. The condensed consolidated balance sheet as of December 31, 2017 contains financial information taken from the audited Abeona consolidated financial statements as of that date.

As of June 30, 2018, we had 5,895,135 options and 2,820,687 warrants that were not included in the EPS calculation as their effect would be antidilutive.

(2) New Accounting Standards Implemented

Revenue Recognition

Effective January 1, 2018, we adopted ASC 606 using the modified retrospective transition method. The cumulative effect of applying the standard was an increase of $3.7 million to stockholders' equity as of January 1, 2018. Our statement of operations for the quarterly period ended June 30, 2018 and our balance sheet as of June 30, 2018 are presented under ASC 606, while our statement of operations for the second quarter and six months ended June 30, 2017 and our balance sheet as of December 31, 2017 are presented under ASC 605. See below for disclosure of the impact of the adoption of ASC 606 on our statement of operations and balance sheet for the quarterly period ended June 30, 2018, and the effect of changes made to our consolidated balance sheet as of January 1, 2018.

The table below presents the cumulative effect of the changes made to the consolidated January 1, 2018 balance sheet due to the adoption of ASC 606.

Balance Sheet (in thousands)	**December 31, 2017, As Reported Under ASC 605**	**Adjustments Due to ASC 606**	**January 1, 2018 As Adjusted Under ASC 606**
Liabilities			
Current liabilities			
Current portion of deferred revenue	$ 3,214	$ (602)	$ 2,612
Total current liabilities	3,214	(602)	2,612
Deferred revenue, net of current portion	3,061	(3,061)	-
Total liabilities	8,668	(3,663)	5,005
Stockholders' Equity			
Accumulated deficit	(359,792)	3,663	(356,129)
Total equity	$ 170,098	$ -	$ 170,098

The table below presents the impact of the adoption of ASC 606 on our statement of operations.

	Second Quarter Ended June 30, 2018		
STATEMENT OF OPERATIONS (in thousands except per share amounts)	**Under ASC 605**	**Effect of ASC 606**	**As Reported Under ASC 606**
Revenues			
License revenues	$ 150	$ (150)	$ -
Total revenues	969	(150)	819
Loss from operations	$ (11,864)	$ (150)	$ (12,014)
Net loss	$ (11,550)	$ (150)	$ (11,700)
Basic and diluted loss per common share	$ (0.25)	$ 0.00	$ (0.25)

STATEMENT OF OPERATIONS (in thousands except per share amounts)	Six Months Ended June 30, 2018		
	Under ASC 605	Effect of ASC 606	As Reported Under ASC 606
Revenues			
License revenues	$ 301	$ (301)	$ -
Total revenues	3,718	(301)	3,417
Loss from operations	$ (20,329)	$ (301)	$ (20,630)
Net loss	$ (19,862)	$ (301)	$ (20,163)
Basic and diluted loss per common share	$ (0.42)	$ (0.01)	$ (0.43)

The table below presents the impact of the adoption of ASC 606 on our balance sheet.

Balance Sheet (in thousands)	June 30, 2018		
	Under ASC 605	Effect of ASC 606	As Reported Under ASC 606
Liabilities and Stockholders' Equity			
Current liabilities			
Current portion of deferred revenue	$ 602	$ (602)	$ -
Total current liabilities	6,385	(602)	5,783
Deferred revenue, net of current portion	2,760	(2,760)	-
Total liabilities	9,145	(3,362)	5,783
Stockholders' Equity			
Accumulated deficit	(379,254)	3,662	(375,829)
Total stockholders' equity	$ 164,256	$ (3,662)	$ 160,914

We received upfront cash payments for licenses of our technology in years 2008-2014. The revenue was recognized straight-line over the life of the patent. Our obligation was performed at the time the license was granted. Following the revenue recognition policies in accordance with ASC 606, we decreased the accumulated deficit by $3,663,000 as of January 1, 2018 and decreased deferred revenue by the same amount.

Royalty revenues will continue to be recognized in the period of sales. Royalties recognized in the second quarter of 2018 are $17,000 and for the first six months of 2018 are $67,000.

On October 16, 2017, we announced a collaborative agreement between nine Sanfilippo foundations to provide up to approximately $13.85 million of grants to Abeona in installments for the advancement of the Company's clinical stage gene therapies for MPS IIIA and MPS IIIB, subject to the achievement of certain milestones. As of June 30, 2018, we received $3.4 million in grants ($2.6 million in the fourth quarter 2017 and $0.8 million in the six months of 2018) and recorded them first as deferred revenue. We recorded $2.6 million of the $3.4 million in grants as revenue in the first quarter of 2018, and we recorded $0.8 million in grants as revenue in the second quarter of 2018.

We recorded revenue for Foundation Grants of $802,000 in the second quarter of 2018 and no revenues for the same period of 2017, an increase of $802,000. We recorded revenue for Foundation Grants of $3,350,000 in the first six months of 2018 and no revenues for the same period of 2017, an increase of $3,350,000. We record revenue to match expenses for the advancement of the Company's clinical stage gene therapies for MPS IIIA and MPS IIIB.

Restricted cash disclosure

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, requiring restricted cash and restricted cash equivalents to be included with cash and cash equivalents on the statement of cash flows when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The guidance is effective for interim and annual periods beginning after December 15, 2017, with early adoption permitted. We adopted this standard during the first quarter of 2018. Restricted cash is now included as a component of cash, cash equivalents, and restricted cash on our unaudited condensed consolidated statements of cash flows. Restricted cash is recorded within other non-current assets in the accompanying unaudited condensed consolidated balance sheets. The inclusion of restricted cash increased beginning balances of the unaudited condensed consolidated statements of cash flows by $560,000 and $0, respectively, and the ending balances by $560,000 and $0, respectively, for the six months ended June 30, 2018 and 2017.

(3) Short Term Investments

The following table summarizes the available-for-sale investments held as of June 30, 2018. There were no available-for-sale investments in prior periods.

Description		Fair Value
June 30, 2018		
U.S. government agency securities and treasuries	$	69,852,000

The amortized cost of the available-for-sale investments is adjusted for amortization of premiums and accretion of discounts to maturity. There were no material realized gains or losses recognized on the sale or maturity of available-for-sale investments during the three or six months ended June 30, 2018.

(4) Licensed Technology

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

On August 3, 2016, we announced we entered into the EB Agreement with EBRP and EBMRF to collaborate on gene therapy treatments for EB.

We also entered into a license with Stanford University for the AAV-based gene therapy EB-201 (AAV DJ COL7A1) technology, and we intend to perform preclinical development and perform clinical trials of a gene therapy treatment for EB based upon such in-licensed technology. EB-201 (AAV DJ COL7A1) is a pre-clinical candidate targeting a novel, AAV-mediated gene editing and delivery approach (known as homologous recombination) to correct gene mutations in skin cells (keratinocytes) for patients with RDEB. The licenses are amortized over the life of the license of 20 years.

Licensed technology consists of the following (in thousands):

	June 30, 2018		December 31, 2017	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated Amortization
Amortizable intangible assets Licensed technology	$ 4,608	$ 805	$ 4,608	$ 631

Amortization expense related to intangible assets totaled $87,000 and $174,000 for the three and six months ended June 30, 2018, respectively, and totaled $158,000 and $361,000 for the three and six months ended June 30, 2017, respectively. The aggregate estimated amortization expense for intangible assets remaining as of June 30, 2018 is as follows (in thousands):

2018	$ 172
2019	346
2020	346
2021	346
2022	346
over 5 years	2,247
Total	$ 3,803

(5) Fair Value Measurements

We calculate the fair value of our assets and liabilities that qualify as financial instruments and include additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of receivables, prepaids and other and accounts payable approximate their carrying amounts due to the relatively short maturity of these instruments.

U.S. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. This guidance establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

· Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

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

We have segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below.

Financial assets and liabilities measured at fair value on a non-recurring and recurring basis as of June 30, 2018 and December 31, 2017 are summarized below:

(in thousands)

Description	As of June 30, 2018	Level 1	Level 2	Level 3	Total Gains (Losses)
Non-recurring					
Assets:					
Licensed technology (net)	$ 3,803	$ -	$ -	$ 3,803	$ 174
Goodwill	32,466	-	-	32,466	-
Recurring					
Marketable securities	-	-	69,852	-	-

(in thousands)

Description	As of December 31, 2017	Level 1	Level 2	Level 3	Total Gains (Losses)
Non-recurring					
Assets:					
Licensed technology (net)	$ 3,977	$ -	$ -	$ 3,977	$ 127
Goodwill	32,466	-	-	32,466	-
Recurring					
Liabilities:					
Contingent consideration	$ -	$ -	$ -	$ -	$ 1,391

(6) Stock Based Option Compensation and Restricted Stock Compensation

For the three and six months ended June 30, 2018, we recognized stock-based option compensation expense of $2,673,000 and $4,573,000, respectively. For the three and six months ended June 30, 2017, we recognized stock-based option compensation expense of $1,243,000 and $2,735,000, respectively.

The following table summarizes stock-based option compensation for the three and six months ended June 30, 2018 and 2017:

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Research and development	$ 900,000	$ 368,000	$ 1,744,000	$ 724,000
General and administrative	1,773,000	875,000	2,829,000	2,011,000
Stock-based option compensation expense included in operating expense	$ 2,673,000	$ 1,243,000	$ 4,573,000	$ 2,735,000

For the three and six months ended June 30, 2018, we granted 224,800 and 869,800 stock options, respectively, and for the three and six months ended June 30, 2017 we granted 185,000 and 185,000 stock options, respectively.

For the three and six months ended June 30, 2018, the fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

For the three months ended June 30, 2018, the fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions: dividend yield of 0%; volatility of 109%; risk-free interest rate of 2.65%; and expected lives of 5.0 years. The weighted average fair value of options granted was $12.87 per share. The weighted average grant date fair value is $12.87 and the weighted average exercise price is $16.27.

For the six months ended June 30, 2018, the fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions: dividend yield of 0%; volatility of 109%; risk-free interest rate of 2.44%; and expected lives of 5.0 years. The weighted average fair value of options granted was $11.36 per share. The weighted average grant date fair value is $11.36 and the weighted average exercise price is $14.38.

For the three and six months ended June 30, 2018, we recognized restricted common stock compensation expense of $172,000 and $344,000, respectively. For the three and six months ended June 30, 2017, we recognized restricted stock compensation expense of $324,000 and $686,000, respectively.

The following table summarizes restricted common stock compensation expense for the three and six months ended June 30, 2018 and 2017:

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Research and development	$ -	$ -	$ -	$ -
General and administrative	172,000	324,000	344,000	686,000
Restricted stock compensation expense included in operating expense	$ 172,000	$ 324,000	$ 344,000	$ 686,000

For the three and six months ended June 30, 2018 and June 30, 2017 no common stock was granted to directors or employees.

(7) Commitments and Contingencies

We are not currently subject to any material pending legal proceedings.

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 9, 2018

/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 9, 2018

/s/ Stephen B. Thompson
Stephen B. Thompson
Sr. 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, 2018 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 New York, in the State of New York, this 9th day of August, 2018.

/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, 2018 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 New York, in the State of New York, this 9th day of August, 2018.

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