

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2017

or

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

For the transition period from _____ to _____

Commission file number 001-15771

ABEONA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

83-0221517

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

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

Smaller reporting company

(Do not check if a 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 May 15, 2017 was 40,255,082 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, future cash flow, the future success of our marketed products and products in development, 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, 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 belief that recently licensed technology will enable us to provide new therapeutic applications and expand market opportunities while enhancing margins, our ability to achieve profitability on a sustained basis or at all, our expected cash burn rate, that 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. 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 13.

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 gene therapies for life-threatening rare genetic diseases. Our lead programs are ABO-102 (AAV-SGSH), an adeno-associated virus (AAV) based gene therapies for Sanfilippo syndrome type A, and EB-101 (gene-corrected skin transplantations) for recessive dystrophic epidermolysis bullosa (RDEB). We are also developing ABO-101 (AAV NAGLU), an AAV gene therapy for Sanfilippo syndrome type B, , EB-201 for epidermolysis bullosa (EB), ABO-201 (AAV-CLN3) gene therapy for juvenile Batten disease (JNCL), ABO-202 (AAV-CLN1) gene therapy for treatment of infantile Batten disease (INCL), and 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. 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 March 8, 2017, we announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products granted Orphan Drug Designation for our EB-101 gene therapy program for patients with recessive dystrophic epidermolysis bullosa (RDEB).

On February 17, 2017, we announced an update on clinical results in the ongoing Phase 1/2 trial for ABO-102 (AAV-SGSH) at the 13th Annual *WORLDSymposium*TM 2017 lysosomal storage disorders conference in San Diego. The ongoing Phase 1/2 study is designed to evaluate safety and preliminary indications of efficacy of ABO-102 in subjects suffering from Mucopolysaccharidosis Type A (MPS IIIA or Sanfilippo syndrome type A). Observations demonstrated:

- ABO-102 gene therapy was well tolerated in 4 subjects (N=3 low dose, N=1 high dose) through 650 days follow up with no Serious Adverse Events.
- 63% +/- 0.5% central nervous system reduction of heparan sulfate GAG 6 months post-injection (N=2).
- Continued evidence of biopotency including reduced liver and spleen volumes and decreased urinary GAGs.
- Two subjects assessed at the 6-month time point showed evidence for stabilization or improvement (average 60% over 2 subjects) in several Mullen subdomains.
- Adaptive behavior ratings on the Vineland stabilized.
- Subjects showed an improved ability to complete individual items on the Leiter-R non-verbal IQ assessment resulting in improved raw scores.

On February 1, 2017, we announced that the first high-dose subject was enrolled in the ongoing Phase 1/2 trial for ABO-102 (AAV-SGSH).

On January 25, 2017, we received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") that due to the resignation of Mark J. Ahn, an independent director, the Company no longer complied with Nasdaq's majority independent director requirement as set forth in Listing Rule 5605. We have a cure period until July 10, 2017 in order to regain compliance. The Company is actively looking for an independent director and plans to submit the required Nasdaq information before compliance deadlines and regain Nasdaq compliance.

On January 3, 2017, we announced that the EMA Committee for Orphan Medicinal Products granted Orphan Drug Designation for our ABO-201 program (AAV-CLN3), the AAV-based single intravenous gene therapy program for juvenile Batten disease, a fatal lysosomal storage disease of the central nervous system caused by autosomal-recessive mutations in the CLN3 gene.

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 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-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 - approximately 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), 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 (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, 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. 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.

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 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 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 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.

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 recessive dystrophic epidermolysis bullosa (RDEB). EB-201 (AAV DJ COL7A1) is a pre-clinical candidate targeting a novel, AAV-mediated gene editing and delivery approach to correct gene mutations in skin cells (Keratinocytes). We entered into an agreement (the “EB Agreement”) with EB Research Partnership (“EBRP”) and Epidermolysis Bullosa Medical Research Foundation (“EBMRF”) to collaborate on gene therapy treatments for EB. The EB Agreement became effective August 3, 2016, on the execution of two licensing agreements with The Board of Trustees of Leland Stanford Junior University (“Stanford”) described below.

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

We also entered into a license with Stanford for the AAV-based gene therapy EB-201 (AAV DJ COL7A1) technology, and we shall 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 recessive dystrophic epidermolysis bullosa (RDEB).

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

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 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. 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-202 (AAV9 CLN1) is an AAV-based gene therapy which 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 (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.

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 U.S. 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 in 2010; Hanmi Pharmaceutical Co. Ltd. (Hanmi) for South Korea in 2014; and Norgine B.V. (Norgine) for the European Union, Switzerland, Norway, Iceland, Lichtenstein, Australia and New Zealand in 2014.

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. Licensing payments and royalty revenues provided limited funding for operations during the period ended March 31, 2017. As of March 31, 2017, our cash and cash equivalents were \$63,212,000.

As of March 31, 2017, our working capital was \$57,758,000. Our working capital at March 31, 2017 represented a decrease of \$3,367,000 as compared to our working capital of \$61,125,000 as of December 31, 2016. The decrease in working capital at March 31, 2017 reflects three months of net operating costs and changes in current assets and liabilities.

Net cash used in operating activities for the three months ended March 31, 2017 was \$5,857,000 as compared to \$2,516,000 for the same period in 2016, an increase of \$3,341,000. The increase was primarily due to higher research and development spending for clinical trials and planned upcoming additional clinical trial centers for the first three months of 2017.

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 March 31, 2017 of \$337,720,000. 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.

FIRST QUARTER 2017 COMPARED TO FIRST QUARTER 2016

Our licensing revenue for the first quarter of 2017 and 2016 was \$151,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We recorded royalty revenue for MuGard of \$35,000 for first quarter of 2017 and \$84,000 for the same period of 2016, a decrease of \$49,000. We licensed MuGard to AMAG and Norgine and receive quarterly reports under our agreements.

Total research and development spending for the first quarter of 2017 was \$2,198,000, as compared to \$1,855,000 for the same period of 2016, an increase of \$343,000. The increase in expenses was primarily due to:

- increased clinical and development work for the manufactured product for ABO-102 and other gene therapy products (\$283,000);
- increased salary and related costs (\$88,000) from the hiring of scientific staff;
- increased rent expense for additional laboratory space (\$50,000); and
- offset by other net decreases in research spending (\$78,000).

Total general and administrative expenses were \$3,022,000 for the first quarter of 2017, as compared to \$4,366,000 for the same period of 2016, a decrease of \$1,344,000. The decrease in expenses was due primarily to the following:

- decreased restricted common stock based compensation expense (\$1,468,000) and decreased stock option compensation expense (\$115,000);
- offset by increased salary and related costs (\$84,000); and
- increases in net other general and administrative expenses (\$155,000).

Depreciation and amortization was \$250,000 for the first quarter of 2017 as compared to \$174,000 for the same period in 2016, an increase of \$76,000. We are amortizing the licenses for SDF Alpha, ABO-101 and ABO-201, and EB-102 over the life of the patents. The increase is due to amortization of licensed technology (\$58,000) and depreciation (\$18,000).

Total operating expenses for the first quarter of 2017 were \$5,470,000 as compared to total operating expenses of \$6,395,000 for the same period of 2016, a decrease of \$925,000 for the reasons listed above.

Interest and miscellaneous income was \$39,000 for the first quarter of 2017 as compared to \$618,000 for the same period of 2016, a decrease of \$579,000. Most of the decrease was due to the change in the fair value of our contingent consideration liability resulting in miscellaneous income in 2016 (\$591,000) and offset by interest and other miscellaneous income (\$12,000).

Interest and other expense for the first quarter of 2017 and 2016 was \$2,000 for each period.

Net loss for the first quarter of 2017 was \$5,247,000, or a \$0.13 basic and diluted loss per common share as compared to a net loss of \$5,544,000, or a \$0.17 basic and diluted loss per common share, for the same period in 2016, a decreased loss of \$297,000.

OFF-BALANCE SHEET ARRANGEMENTS

None.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

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 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 (the “Exchange Act”), as of March 31, 2017.

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 March 31, 2017 were effective.

Changes In Internal Control Over Financial Reporting - There were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2017 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.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 6. EXHIBITS.

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 March 31, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at March 31, 2017 and December 31, 2016, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2017 and March 31, 2016, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2017, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2017 and March 31, 2016, 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: May 15, 2017

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

Date: May 15, 2017

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 63,212,000	\$ 69,142,000
Receivables	148,000	124,000
Prepaid expenses and other current assets	463,000	155,000
Total current assets	<u>63,823,000</u>	<u>69,421,000</u>
Property and equipment, net	748,000	721,000
Licensed technology, net	8,181,000	8,384,000
Goodwill	32,466,000	32,466,000
Other assets	66,000	66,000
Total assets	<u>\$ 105,284,000</u>	<u>\$ 111,058,000</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,463,000	\$ 3,694,000
Payable due to Plasma Technologies, LLC	4,000,000	4,000,000
Current portion of deferred revenue	602,000	602,000
Total current liabilities	<u>6,065,000</u>	<u>8,296,000</u>
Deferred revenue, net of current portion	3,513,000	3,664,000
Total liabilities	<u>9,578,000</u>	<u>11,960,000</u>
Commitments and contingencies		
Stockholders' equity		
Common stock - \$.01 par value; authorized 200,000,000 shares; issued, 40,255,082 at March 31, 2017 and 40,254,457 at December 31, 2016	403,000	403,000
Additional paid-in capital	433,023,000	431,168,000
Accumulated deficit	(337,720,000)	(332,473,000)
Total stockholders' equity	<u>95,706,000</u>	<u>99,098,000</u>
Total liabilities and stockholders' equity	<u>\$ 105,284,000</u>	<u>\$ 111,058,000</u>

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Operations
(unaudited)

	Three Months ended March 31,	
	2017	2016
Revenues		
License revenues	\$ 151,000	\$ 151,000
Royalties	35,000	84,000
Total revenues	186,000	235,000
Expenses		
Research and development	2,198,000	1,855,000
General and administrative	3,022,000	4,366,000
Depreciation and amortization	250,000	174,000
Total expenses	5,470,000	6,395,000
Loss from operations	(5,284,000)	(6,160,000)
Interest and miscellaneous income	39,000	618,000
Interest and other expense	(2,000)	(2,000)
	37,000	616,000
Net loss	\$ (5,247,000)	\$ (5,544,000)
Basic and diluted loss per common share	\$ (0.13)	\$ (0.17)
Weighted average number of common shares outstanding	40,254,679	32,743,013

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity
(unaudited)

	<u>Common Stock</u>		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	<u>Shares</u>	<u>Amount</u>			
Balance, December 31, 2016	40,254,457	\$ 403,000	\$431,168,000	\$(332,473,000)	\$ 99,098,000
Restricted common stock issued to employees and directors	-	-	362,000	-	362,000
Stock based compensation expense	-	-	1,492,000	-	1,492,000
Common stock issued for cash exercise of options	625	-	1,000	-	1,000
Net loss	-	-	-	(5,247,000)	(5,247,000)
Balance, March 31, 2017	<u>40,255,082</u>	<u>\$ 403,000</u>	<u>\$433,023,000</u>	<u>\$(337,720,000)</u>	<u>\$ 95,706,000</u>

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows
(unaudited)

	Three Months ended March 31,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (5,247,000)	\$ (5,544,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	250,000	174,000
Stock option compensation expense	1,492,000	1,592,000
Restricted common stock expense issued to directors, employees and consultants	362,000	1,892,000
Change in operating assets and liabilities:		
Receivables	(24,000)	(129,000)
Prepaid expenses and other current assets	(308,000)	114,000
Other assets	-	(40,000)
Accounts payable	(2,231,000)	167,000
Contingent consideration liability	-	(591,000)
Deferred revenue	(151,000)	(151,000)
Net cash used in operating activities	(5,857,000)	(2,516,000)
Cash flows from investing activities:		
Capital expenditures	(74,000)	(227,000)
Net cash used in investing activities	(74,000)	(227,000)
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,000	-
Net cash provided by financing activities	1,000	-
Net decrease in cash and cash equivalents	(5,930,000)	(2,743,000)
Cash and cash equivalents at beginning of period	69,142,000	40,138,000
Cash and cash equivalents at end of period	\$ 63,212,000	\$ 37,395,000

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

Abeona Therapeutics Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements Three Months Ended March 31, 2017 and 2016 (unaudited)

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 gene therapies for life-threatening rare genetic diseases. Our lead programs are ABO-102 (AAV-SGSH), an adeno-associated virus (AAV) based gene therapies for Sanfilippo syndrome type A, and EB-101 (gene-corrected skin transplantations) for recessive dystrophic epidermolysis bullosa (RDEB). We are also developing ABO-101 (AAV NAGLU), an AAV gene therapy for Sanfilippo syndrome type B, , EB-201 for epidermolysis bullosa (EB), ABO-201 (AAV-CLN3) gene therapy for juvenile Batten disease (JNCL), ABO-202 (AAV-CLN1) gene therapy for treatment of infantile Batten disease (INCL), and 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. 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 March 31, 2017, the condensed consolidated statements of operations for the three months ended March 31, 2017 and 2016, the condensed consolidated statements of stockholders’ equity for the three months ended March 31, 2017, and the condensed consolidated statements of cash flows for the three months ended March 31, 2017 and 2016, 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, 2016. The results of operations for the period ended March 31, 2017 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, 2016 contains financial information taken from the audited Abeona consolidated financial statements as of that date.

As of March 31, 2017, we had 4,770,935 options and 3,736,617 warrants that were not included in the EPS calculation as their effect would be antidilutive.

(2) Intangible Assets

Intangible assets consist of the following (in thousands):

	<u>March 31, 2017</u>		<u>December 31, 2016</u>	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated Amortization
Amortizable intangible assets Licensed technology	\$ 9,608	\$ 1,427	\$ 9,608	\$ 1,224

Amortization expense related to intangible assets totaled \$203,000 for the three months ended March 31, 2017 and totaled \$145,000 for the three ended March 31, 2016. The aggregate estimated amortization expense for intangible assets remaining as of March 31, 2017 is as follows (in thousands):

2017	\$	610
2018		812
2019		812
2020		812
2021		812
over 5 years		4,323
Total	\$	<u>8,181</u>

(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 condensed 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, accounts payable and payable due to Plasma Technologies, LLC 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 March 31, 2017 and December 31, 2016 are summarized below:

(in thousands)

Description	As of March 31, 2017	Level 1	Level 2	Level 3	Total Gains (Losses)
<u>Non-recurring</u>					
Assets:					
Licensed technology (net)	\$ 8,181	\$ -	\$ -	\$ 8,181	\$ -
Goodwill	32,466	-	-	32,466	-

(in thousands)

Description	As of December 31, 2016	Level 1	Level 2	Level 3	Total Gains (Losses)
<u>Non-recurring</u>					
Assets:					
Licensed technology (net)	\$ 8,384	\$ -	\$ -	\$ 8,384	\$ -
Goodwill	32,466	-	-	32,466	-
<u>Recurring</u>					
Liabilities:					
Contingent consideration	\$ -	\$ -	\$ -	\$ -	\$ 1,391

(4) Stock Based Compensation and Restricted Stock Compensation

For the three months ended March 31, 2017, we recognized stock-based compensation expense of \$1,492,000 for granted options. For the three months ended March 31, 2016 we recognized stock-based compensation expense of \$1,592,000.

The following table summarizes stock-based compensation for the three months ended March 31, 2017 and 2016:

	Three months ended March 31,	
	2017	2016
Research and development	\$ 356,000	\$ 341,000
General and administrative	1,136,000	1,251,000
Stock-based compensation expense included in operating expense	<u>\$1,492,000</u>	<u>\$1,592,000</u>

For the three months ended March 31, 2017, we granted no stock options and for the three months ended March 31, 2016 we granted 1,315,000 stock options.

For the three months ended March 31, 2017, we recognized restricted common stock compensation expense of \$362,000 for granted restricted common stock. For the three months ended March 31, 2016, we recognized restricted stock compensation expense of \$1,892,000 for granted restricted common stock compensation expense.

The following table summarizes restricted common stock compensation expense for the three months ended March 31, 2017 and 2016:

	Three months ended March 31,	
	2017	2016
Research and development	\$ -	\$ 62,000
General and administrative	362,000	1,830,000
Stock-based compensation expense included in operating expense	<u>\$ 362,000</u>	<u>\$1,892,000</u>

For the three months ended March 31, 2017 and 2016 no stock was granted to directors or officers.

(5) Litigation

We are not currently subject to any material pending proceeding.

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: May 15, 2017

/s/ Steven H. Rouhandeh

Steven H. Rouhandeh
Executive Chairman
Principal Executive Officer

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: May 15, 2017

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

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 March 31, 2017 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 May, 2017.

/s/ Steven H. Rouhandeh

Steven H. Rouhandeh
Executive Chairman
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

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 March 31, 2017 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 May, 2017.

/s/ Stephen B. Thompson

Stephen B. Thompson

Vice President Finance

Principal Financial and Accounting Officer
