

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015
or

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

For the transition period from _____ to _____

Commission file number **0-9314**

ABEONA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware

(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)

(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 November 16, 2015 was 32,732,783 shares.

ABEONA THERAPEUTICS INC.

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PART I – FINANCIAL INFORMATION

This Quarterly Report on Form 10-Q (including the information incorporated by reference) contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and that involve risks and uncertainties. These statements and other risks described below as well as those discussed elsewhere in this Quarterly Report Form 10-Q, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission (“SEC”) include, without limitation, statements relating to uncertainties associated with research and development activities, clinical trials, our ability to raise capital, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations and our ability to attract licensing partners, future cash flow, the timing and receipt of licensing and milestone revenues, the future success of our marketed products and products in development, our belief that advances in biotechnology will provide significant opportunities to develop new treatments for rare diseases, our sales projections, and the sales projections of our licensing partners, our ability to achieve licensing milestones, the size of the prospective markets in which we may offer products, anticipated product launches and our commercialization strategies, anticipated product approvals and timing thereof, product opportunities, clinical trials and U.S. Food and Drug Administration (“FDA”) applications, as well as our drug development strategy, our clinical development organization expectations regarding our rate of technological developments and competition, our plan not to establish an internal marketing organization, our expectations regarding minimizing development risk and developing and introducing technology, the terms of future licensing arrangements, our ability to secure additional financing for our operations, our ability to establish new relationships and maintain current relationships, our ability to attract and retain key personnel, our belief that we will not pay any cash dividends in the foreseeable future, our belief that a failure to obtain necessary additional capital in the future will result in our operations being jeopardized, our 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 belief that we will continue to evaluate the most cost-effective methods to advance our programs, our ability to achieve profitability on a sustained basis or at all, and our expected cash burn rate. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “could,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of such terms or other comparable terminology. We intend the forward-looking statements to be covered by the safe harbor for forward-looking statements in these sections. The forward-looking information is based on various factors and was derived using numerous assumptions.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward-looking statements due to a number of factors. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our judgment only as of the date of this report. We caution readers not to place undue reliance on such statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

ITEM 1. FINANCIAL STATEMENTS

The response to this Item is submitted as a separate section of this report. See page 17.

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

OVERVIEW

Abeona Therapeutics Inc. ("Abeona" or the "Company") is focused on developing and delivering gene therapy and plasma-based products for severe and life-threatening rare diseases. Abeona's lead programs are ABO-101 (AAV9 NAGLU) and ABO-102 (scAAV9 SGSH), adeno-associated virus (AAV)-based gene therapies for Sanfilippo syndrome (MPS IIIB and IIIA, respectively). We are also developing ABO-201 (scAAV9 CLN3) gene therapy for juvenile Batten disease (JBD); and ABO-301 (AAV FANCC) for Fanconi anemia (FA) disorder using a novel CRISPR/Cas9-based gene editing approach to gene therapy program for rare blood diseases. In addition, we are also developing rare plasma protein therapies including PTB-101 SDF Alpha™ (alpha-1 protease inhibitor) for inherited COPD using our proprietary SDF™ (Salt Diafiltration) ethanol-free process. Our principal executive office is located at 3333 Lee Parkway, Suite 600, Dallas, Texas 75219. Our website address is www.abeonatherapeutics.com.

Recent Developments

On October 6, 2015 we announced a license with Stanford University for AAV LK19, a therapeutic gene delivery vector for the treatment of Fanconi anemia (FA) and rare blood disease platform. The license augments a previously announced license agreement with the University of Minnesota for ABO-301 (AAV-FANCC) to treat patients with FA disorder and other rare blood diseases.

On July 31, 2015 we closed a \$15.5 million direct placement of registered common stock with institutional investors, including Soros Fund Management and Perceptive Life Science Fund, and two members of the Board of Directors. The financing was comprised of 2.83 million shares of our common stock at a price of \$5.50 per share.

On July 7, 2015 we announced preliminary results of our SDF plasma protein programs, confirming that multiple batches of our two-step salt precipitation process yields resultant fractions with significantly enhanced levels of alpha-1 protease inhibitor and immunoglobulins (IVIG) relative to the industry-standard Cohn process.

On July 1, 2015 we announced additional financing of \$4.6 million through warrant exercises of out \$5.00 warrants.

Product Development Strategy

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

Developing Next Generation Gene Therapy

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

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

Lysosomal storage diseases (LSD) are a group of rare inborn errors of metabolism resulting from deficiency in normal lysosomal function. These diseases are characterized by progressive accumulation of storage material within the lysosomes of affected cells, ultimately leading to cellular dysfunction. Multiple tissues ranging from musculoskeletal and visceral to tissues of the central nervous system are typically involved in disease pathology. Since the advent of enzyme replacement therapy (ERT) to manage some LSDs, general clinical outcomes have significantly improved; however, treatment with infused protein is lifelong and continued disease progression is still evident in patients. Thus, 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. Also known as Sanfilippo syndromes type A and type B, MPS III is a progressive neuromuscular disease with profound CNS involvement. Our lead product candidates, ABO-101 and ABO-102, have been developed to replace the damaged, malfunctioning enzymes within target cells with the normal, functioning version. ABO-201 is a similar product, using an AAV9 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.

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

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

Mucopolysaccharides are long chains of sugar molecules used in the building of connective tissues in the body. There is a continuous process in the body of replacing used materials and breaking them down for disposal. Children with MPS III are missing an enzyme called heparan sulfate which is essential in breaking down the 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 (Sanfilippo syndrome), which involves a one-time delivery of a normal copy of the defective gene to cells of the central nervous system 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.

ABO-201 for Juvenile Batten Disease (JBD)

ABO-201 (scAAV9 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 central nervous system with the aim of reversing the effects of the genetic errors that cause juvenile Batten disease. Juvenile Batten disease (JBD) 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 JBD is vision impairment, which tends to progress rapidly and eventually result in blindness. As the disease progresses, children experience the loss of previously acquired skills (developmental regression). This progression usually begins with the loss of the ability to speak in complete sentences. Children then lose motor skills, such as the ability to walk or sit. They also develop movement abnormalities that include rigidity or stiffness, slow or diminished movements (hypokinesia), and stooped posture. Beginning in mid- to late childhood, affected children may have recurrent seizures (epilepsy), heart problems, behavioral problems, and difficulty sleeping. Life expectancy is greatly reduced. Most people with juvenile Batten disease live into their twenties or thirties. As yet, no specific treatment is known that can halt or reverse the symptoms of JBD disease.

JBD disease 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 JBD disease 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 JBD disease.

ABO-301 for Fanconi Anemia (FA)

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

The major function of bone marrow is to produce new blood cells. In FA, a DNA mutation renders the FANCC gene nonfunctional. Loss of FANCC causes patient 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 more precise gene modification.

Plasma-based Therapeutics using the SDF™ technology platform

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

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

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

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

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

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

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

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

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

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

Polymer Hydrogel Technology (PHT™)

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

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

ProctiGard™ (mucoadhesive oral wound rinse) approved for rectal mucositis and radiation proctitis

ProctiGard™ received 510(K) marketing clearance from the FDA on July 22, 2014 for the treatment of symptomatic management of rectal mucositis. ProctiGard is our product for the treatment of radiation proctitis, a frequent side effect of radiation treatment to the pelvic region. Radiation proctitis, or RP, is the inflammation and damage to the lower portion of the colon after exposure to x-rays or ionizing radiation as part of radiation therapy. RP is most common after treatments for cancer, such as cervical, colon and prostate cancer. RP can be acute, occurring within weeks of initiation of therapy, or can occur months or years after treatment. We intend to commercialize ProctiGard in a manner similar to the commercialization of MuGard, which may include confirmatory clinical trials, with the objective of commercialization in collaboration with marketing partners globally.

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 September 30, 2015. As of September 30, 2015, our cash and cash equivalents were \$43,282,000.

As of September 30, 2015, our working capital was \$42,120,000. Our working capital at September 30, 2015 represented an increase of \$33,463,000 as compared to our working capital as of December 31, 2014 of \$8,657,000. The net increase in the working capital at September 30, 2015 reflects financings, warrant exercises and the acquisition of Abeona Therapeutics LLC (Abeona Ohio) less nine months of net operating costs and changes in current assets and liabilities.

On July 31, 2015 we closed an upsized \$15.5 million direct placement of registered common stock with institutional investors, including Soros Fund Management and Perceptive Life Science Fund, and two members of our Board of Directors. The financing was comprised of 2.83 million shares of our common stock at a price of \$5.50 per share.

If we raise additional funds by selling 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 September 30, 2015 of \$308,260,000. 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.

THIRD QUARTER 2015 COMPARED TO THIRD QUARTER 2014

Our licensing revenue for the third quarter of 2015 and 2014 was \$151,000 and \$152,000, respectively. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We recorded royalty revenue for MuGard of \$134,000 for third quarter of 2015 and \$84,000 for the same period of 2014, an increase of \$50,000. We licensed MuGard to AMAG on June 6, 2013 and currently receive quarterly royalties from AMAG under our agreement.

Total research and development spending for the third quarter of 2015 was \$1,581,000, as compared to \$73,000 for the same period of 2014, an increase of \$1,508,000. The increase in expenses was primarily due to:

- increased development work on our products (\$526,000);
- increased salary and related costs (\$338,000) from the hiring of scientific staff;
- increased stock based compensation expense for granted restricted stock (\$213,000) and granted stock options (\$317,000); and
- other net increases in research spending (\$114,000).

Total general and administrative expenses were \$4,717,000 for the third quarter of 2015, as compared to \$795,000 for the same period of 2014, an increase of \$3,922,000. The increase in expenses was due primarily to the following:

- increased stock based compensation expense for granted restricted stock (\$1,679,000) and granted stock options (\$1,067,000);
- increased investor relations expenses (\$410,000);
- increased legal and audit fees (\$262,000);
- increased salary and related costs (\$202,000) from hiring additional general and administrative staff;
- increased director fees (\$150,000);
- increased expense for new licenses (\$80,000); and
- other net increases in general and administrative expenses (\$72,000).

Depreciation and amortization was \$151,000 for the third quarter of 2015 as compared to \$1,000 for the same period in 2014, an increase of \$150,000. We have acquired new licenses and fixed assets in 2015. We are amortizing the licenses over the life of the patents.

Total operating expenses for the third quarter of 2015 were \$6,449,000 as compared to total operating expenses of \$869,000 for the same period of 2014, an increase of \$5,580,000 for the reasons listed above.

Interest and miscellaneous income was \$92,000 for the third quarter of 2015 as compared to \$11,000 for the same period of 2014, an increase of \$81,000. Miscellaneous income is \$52,000 higher in 2015 than for the same period in 2014 due to write-offs of certain accounts payables.

Interest and other expense was \$1,000 for the third quarter of 2015 as compared to \$147,000 in the same period of 2014, a decrease of \$146,000. The interest in 2014 represents interest accrued on unpaid dividends. All dividends and accrued interest on dividends due were paid in December 2014. There are no more dividends accruing.

We recorded a loss for the derivative liability related to preferred stock of \$700,000 for the third quarter of 2014. The preferred stock related to the dividends was converted into common stock in December 2014.

Preferred stock dividends of \$740,000 were accrued for the third quarter of 2014. The preferred stock related to the dividends was converted into common stock in December 2014.

Net loss allocable to common stockholders for the third quarter of 2015 was \$6,073,000, or a \$0.19 basic and diluted loss per common share as compared to a net loss of \$2,209,000, or a \$4.15 basic and diluted loss per common share, for the same period in 2014, an increased loss of \$3,864,000.

NINE MONTHS ENDED SEPTEMBER 30, 2015 COMPARED TO NINE MONTHS ENDED SEPTEMBER 30, 2014

Our licensing revenue for the first nine months of 2015 was \$452,000 and \$448,000 for the same period of 2014. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We recorded royalty revenue for MuGard of \$373,000 for first nine months of 2015 as compared to \$243,000 for the same period of 2014, an increase of \$130,000. We licensed MuGard to AMAG on June 6, 2013 and currently receive quarterly royalties from AMAG under our agreement.

Total research and development spending for the first nine months of 2015 was \$2,644,000, as compared to \$298,000 for the same period of 2014, an increase of \$2,346,000. The increase in research and development expenses was primarily due to:

- increased development work on our products (\$1,157,000);
- increased salary and related costs (\$513,000) from increased scientific staff;
- increased stock based compensation expense for granted restricted stock (\$213,000) and granted stock options (\$315,000); and
- other net increases in research spending (\$148,000).

Total general and administrative expenses were \$10,073,000 for the first nine months of 2015, as compared to \$3,055,000 for the same period of 2014, an increase of \$7,018,000. The increase in expenses was due primarily to the following:

- increased stock based compensation expense for granted restricted stock (\$2,717,000) and granted options (\$1,039,000);
- increased legal and audit fees (\$957,000);
- increased salary and related costs (\$842,000) from hiring additional general and administrative staff;
- increased investor relations expenses (\$761,000);
- increased director fees (\$340,000); and
- net increase other general and administrative expenses (\$362,000).

Depreciation and amortization was \$401,000 for the first nine months of 2015 as compared to \$2,000 for the same period in 2014. We have acquired new licenses and fixed assets in 2015.

Total operating expenses for the first nine months of 2015 were \$13,118,000 as compared to total operating expenses of \$3,355,000 for the same period of 2014, an increase of \$9,763,000 for the reasons listed above.

Interest and miscellaneous income was \$111,000 for the first nine months of 2015 as compared to \$45,000 for the same period of 2014, an increase of \$66,000. Miscellaneous income is \$52,000 higher in 2015 than for the same period in 2014 due to write-offs of certain accounts payables.

Interest and other expense was \$4,000 for the first nine months of 2015 as compared to \$406,000 in the same period of 2014, a decrease of \$402,000. The interest in 2014 represents interest accrued on unpaid dividends. All dividends and accrued interest on dividends due were paid in December 2014. There are no more dividends accruing.

We recorded a loss for the derivative liability related to preferred stock of \$11,810,000 for the first nine months of 2014. The preferred stock related to the dividends was converted into common stock in December 2014.

Preferred stock dividends of \$2,191,000 were accrued for the first nine months of 2014. The preferred stock related to the dividends was converted into common stock in December 2014.

Net loss allocable to common stockholders for the first nine months of 2015 was \$12,186,000, or a \$0.47 basic and diluted loss per common share as compared to a net loss of \$17,026,000, or a \$32.46 basic and diluted loss per common share, for the same period in 2014, a decreased loss of \$4,840,000.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

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

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

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

Based on our evaluation, our management concluded in our Annual Report on Form 10-K for the year ended December 31, 2014 that there was a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness identified in our Annual Report on Form 10-K for the year ended December 31, 2014 related to the monitoring and review of work performed by our Chief Accounting Officer and our then accounting consultant in the preparation of audit and financial statements, footnotes and financial data provided to the Company's registered public accounting firm in connection with the annual audit. All of our financial reporting was carried out by our Chief Accounting Officer. This lack of accounting staff resulted in a lack of segregation of duties. The material weakness identified did not result in the restatement of any previously reported financial statements or any related financial disclosure

As of the date of this Quarterly Report on Form 10-Q, we are making changes to alleviate such material weakness. As of the end of the period covered by this Quarterly Report on Form 10-Q we have not completed our review that our disclosure controls and procedures were effective based on the criteria established in Internal Control—Integrated Framework issued by COSO.

Changes In Internal Control Over Financial Reporting

There were changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2015 that have materially affected, or are reasonable likely to materially affect, our internal control over financial reporting. We hired a Director of Finance and Operations and an Accounting Assistant to segregate duties.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Alan Schmidt (“Schmidt”), a former shareholder of Genaera Corporation (“Genaera”), and a former unitholder of the Genaera Liquidating Trust (the “Trust”), filed a purported class action in the United States District Court for the Eastern District of Pennsylvania in June 2012. The lawsuit named thirty defendants, including Abeona, MacroChem Corporation, which was acquired by us in February 2009, Jeffrey Davis, the then-CEO and currently a director of Abeona, and Steven H. Rouhandeh and Mark Alvino, both of whom are our directors (the “Abeona Defendants”). With respect to the Abeona Defendants, the complaint alleged direct and derivative claims asserting that directors of Genaera and the Trustee of the Trust breached their fiduciary duties to Genaera, Genaera’s shareholders and the Trust’s unitholders in connection with the licensing and disposition of certain assets, aided and abetted by numerous defendants including the Abeona Defendants. Schmidt seeks monetary damages, disgorgement of any distributions received from the Trust, rescission of sales made by the Trust, attorneys’ and expert fees, and costs. On December 19, 2012, Schmidt filed an amended complaint (the “Amended Complaint”) which asserted substantially the same allegations with respect to the Abeona Defendants. On February 4, 2013, the Abeona Defendants moved to dismiss all claims asserted against them. On August 12, 2013 the court granted the Abeona Defendants’ motions to dismiss and entered judgment in favor of the Abeona Defendants on all claims. On August 26, 2013, Schmidt filed a motion for reconsideration. On September 10, 2013 Schmidt filed a Notice of Appeal with the District Court. On September 17, 2013, Schmidt filed his appeal with the U.S. Third Circuit Court of Appeals (the “Third Circuit”). On September 25, 2013, the District Court denied Schmidt’s motion for reconsideration. On October 17, 2013, Schmidt amended his appeal to include the District Court’s denial of his motion for reconsideration. On March 20, 2014, Schmidt filed his Brief and Joint Appendix. On May 22, 2014, the Abeona Defendants filed their Oppositions to Schmidt’s Brief. On May 29, 2014, Schmidt was granted an extension of time until June 23, 2014 to file his Reply Brief and filed his Reply Brief on that date. The Third Circuit held oral argument on September 12, 2014. On October 17, 2014, in a split decision, the Third Circuit reversed the District Court’s decision holding, among other things, that the District Court’s determination that the Amended Complaint was time-barred on statute of limitations grounds was premature. The Third Circuit did not rule upon any of the other grounds for dismissal advanced in the District Court and on appeal. The Third Circuit remanded the case to the District Court for further proceedings. On January 6, 2015, the District Court ordered the parties to file supplemental briefs on all remaining arguments for dismissal, and further ordered that a hearing on the motions to dismiss would be held on February 3, 2015. On January 23, 2015, the Abeona Defendants filed their Supplemental Brief. At the February 3, 2015 hearing, Schmidt sought and was granted leave to amend his complaint for a second time. Schmidt filed his Second Amended Complaint on February 3, 2015. The Second Amended Complaint asserts substantially the same factual allegations with respect to the Abeona Defendants, but eliminates all causes of action against the Abeona Defendants except for aiding and abetting the Genaera directors’ and officers’ purported breaches of fiduciary duties, a claim for “punitive damages” and a claim for rescission of a settlement agreement between the Trust and the Abeona Defendants. On March 20, 2015, the Abeona Defendants filed a motion to dismiss the Second Amended Complaint. On November 10, 2015, the District Court granted the Abeona Defendant’s motion and dismissed the action in its entirety. On November 11, 2015, Schmidt filed a Notice of Appeal with the District Court. We intend to continue contesting the claims vigorously.

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

ITEM 1A. RISK FACTORS

Our products could infringe on the intellectual property rights of others, and we may be required to license technology from third parties in the future in order to market our products. Companies in the biotechnology and pharmaceutical industries steadfastly pursue and protect intellectual property rights. This can result in considerable and costly litigation to determine the validity of patents and claims by third parties of infringement of patents or other intellectual property. Our gene therapy products could be found to infringe on the intellectual property rights of others. Other companies may hold or obtain patents or inventions or other proprietary rights in technology necessary for our business. We have or may be required to obtain licenses from other companies to use such proprietary rights. We may be unable to obtain licenses to use such proprietary rights. Furthermore, should we violate the terms of a license, that license could be cancelled. Our ability to achieve profitability and positive cash flow may be negatively affected by our inability to procure such a license, the cancellation of any such license, any new license fees arising out of any new license, or any increases in license fees we currently pay. Periodically companies inquire about our products and technology in their attempts to assess whether we violate their intellectual property rights. If we are forced to defend against infringement claims, we may face costly litigation and diversion of technical and management personnel, even if the allegations of infringement are unwarranted. In addition, as a result of potential infringement claims, we may be required to obtain one or more licenses from other companies to use the infringed technology, and the license fees we pay may negatively affect our ability to achieve profitability and positive cash flow. If there is a successful claim of infringement against us and we are unable to develop non-infringing technology or license the infringed or similar technology on a timely basis, our business, and our ability to grow revenue and achieve profitability and positive cash flow, could be adversely affected.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 6. EXHIBITS.

Exhibits:

| | |
|--------|--|
| 10.1** | Employment Agreement dated May 6, 2015 between Registrant and Timothy J. Miller |
| 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 formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets at September 30, 2015 and December 31, 2014, (ii) Consolidated Statements of Operations for the three and nine months ended September 30, 2015 and September 30, 2014, (iii) Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2015, (iv) Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and September 30, 2014, and (v) Notes to 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.

** Management contract or compensatory plan.

SIGNATURES

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

ABEONA THERAPEUTICS INC.

Date: November 16, 2015

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

Date: November 16, 2015

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

| | <u>September 30, 2015</u> | <u>December 31, 2014</u> |
|---|---------------------------|--------------------------|
| | (unaudited) | |
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$ 43,282,000 | \$ 11,520,000 |
| Receivables | 271,000 | 35,000 |
| Prepaid expenses and other current assets | 137,000 | - |
| Total current assets | <u>43,690,000</u> | <u>11,555,000</u> |
| Property and equipment, net | 87,000 | 4,000 |
| Licensed technology, net | 6,755,000 | 4,991,000 |
| Goodwill | 38,955,000 | - |
| Other assets | 62,000 | 32,000 |
| Total assets | <u>\$ 89,549,000</u> | <u>\$ 16,582,000</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$ 968,000 | \$ 1,896,000 |
| Short-term notes payable | - | 400,000 |
| Current portion of deferred revenue | 602,000 | 602,000 |
| Total current liabilities | <u>1,570,000</u> | <u>2,898,000</u> |
| Contingent consideration liability | 6,489,000 | - |
| Payable due Licensor | 4,000,000 | 4,000,000 |
| Long-term deferred revenue | 4,417,000 | 4,868,000 |
| Total liabilities | <u>16,476,000</u> | <u>11,766,000</u> |
| Commitments and contingencies | | |
| Stockholders' equity | | |
| Common stock - \$.01 par value; authorized 200,000,000 shares; issued, 32,728,106 at September 30, 2015 and 19,960,801 at December 31, 2014 | 327,000 | 200,000 |
| Additional paid-in capital | 381,006,000 | 300,690,000 |
| Accumulated deficit | <u>(308,260,000)</u> | <u>(296,074,000)</u> |
| Total stockholders' equity | <u>73,073,000</u> | <u>4,816,000</u> |
| Total liabilities and stockholders' equity | <u>\$ 89,549,000</u> | <u>\$ 16,582,000</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 September 30, | | Nine months ended September 30, | |
|--|-------------------------------------|-----------------------|------------------------------------|------------------------|
| | 2015 | 2014 | 2015 | 2014 |
| Revenues | | | | |
| License revenues | \$ 151,000 | \$ 152,000 | \$ 452,000 | \$ 448,000 |
| Royalties | 134,000 | 84,000 | 373,000 | 243,000 |
| Total revenues | <u>285,000</u> | <u>236,000</u> | <u>825,000</u> | <u>691,000</u> |
| Expenses | | | | |
| Research and development | 1,581,000 | 73,000 | 2,644,000 | 298,000 |
| General and administrative | 4,717,000 | 795,000 | 10,073,000 | 3,055,000 |
| Depreciation and amortization | 151,000 | 1,000 | 401,000 | 2,000 |
| Total expenses | <u>6,449,000</u> | <u>869,000</u> | <u>13,118,000</u> | <u>3,355,000</u> |
| Loss from operations | (6,164,000) | (633,000) | (12,293,000) | (2,664,000) |
| Interest and miscellaneous income | 92,000 | 11,000 | 111,000 | 45,000 |
| Interest and other expense | (1,000) | (147,000) | (4,000) | (406,000) |
| Loss on change in fair value of derivative - preferred stock | - | (700,000) | - | (11,810,000) |
| | <u>91,000</u> | <u>(836,000)</u> | <u>107,000</u> | <u>(12,171,000)</u> |
| Net loss | (6,073,000) | (1,469,000) | (12,186,000) | (14,835,000) |
| Less preferred stock dividends | - | 740,000 | - | 2,191,000 |
| Net loss allocable to common stockholders | <u>\$ (6,073,000)</u> | <u>\$ (2,209,000)</u> | <u>\$ (12,186,000)</u> | <u>\$ (17,026,000)</u> |
| Basic and diluted loss per common share | <u>\$ (0.19)</u> | <u>\$ (4.15)</u> | <u>\$ (0.47)</u> | <u>\$ (32.46)</u> |
| Weighted average number of common shares outstanding | <u>31,787,777</u> | <u>532,258</u> | <u>25,865,739</u> | <u>524,595</u> |

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity
(unaudited)

| | Common Stock | | Additional paid-in capital | Accumulated deficit | Total stockholders' equity |
|---|--------------|------------|----------------------------------|------------------------|----------------------------------|
| | Shares | Amount | | | |
| Balance December 31, 2014 | 19,960,801 | \$ 200,000 | \$ 300,690,000 | \$ (296,074,000) | \$ 4,816,000 |
| Common stock issued to employees | 10,000 | - | 32,000 | - | 32,000 |
| Common stock issued for services | 28,000 | - | 87,000 | - | 87,000 |
| Stock option compensation expense | - | - | 224,000 | - | 224,000 |
| Net loss | - | - | - | (2,000,000) | (2,000,000) |
| Balance March 31, 2015 | 19,998,801 | \$ 200,000 | \$ 301,033,000 | \$ (298,074,000) | \$ 3,159,000 |
| Restricted common stock issued to employees | 1,350,000 | 13,000 | 1,023,000 | - | 1,036,000 |
| Common stock issued for services | 22,500 | - | 75,000 | - | 75,000 |
| Exercise of \$5.00 warrants | 927,119 | 9,000 | 4,626,000 | - | 4,635,000 |
| Common stock issued for \$3.00 share net of costs | 2,333,334 | 24,000 | 6,977,000 | - | 7,001,000 |
| Common stock issued for \$8.00 share net of costs | 1,250,000 | 13,000 | 8,992,000 | - | 9,005,000 |
| Common stock issued to Abeona Ohio holders | 3,979,761 | 40,000 | 38,207,000 | - | 38,247,000 |
| Stock option compensation expense | - | - | 904,000 | - | 904,000 |
| Net loss | - | - | - | (4,113,000) | (4,113,000) |
| Balance June 30, 2015 | 29,861,515 | \$ 299,000 | \$ 361,837,000 | \$ (302,187,000) | \$ 59,949,000 |
| Restricted common stock issued to employees | - | - | 1,892,000 | - | 1,892,000 |
| Common stock issued for services | 37,500 | - | 442,000 | - | 442,000 |
| Common stock issued for \$5.50 share net of costs | 2,829,091 | 28,000 | 15,383,000 | - | 15,411,000 |
| Stock option compensation expense | - | - | 1,452,000 | - | 1,452,000 |
| Net loss | - | - | - | (6,073,000) | (6,073,000) |
| Balance September 30, 2015 | 32,728,106 | \$ 327,000 | \$ 381,006,000 | \$ (308,260,000) | \$ 73,073,000 |

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

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

| | Nine Months ended September 30, | |
|--|---------------------------------|-------------------|
| | 2015 | 2014 |
| Cash flows from operating activities: | | |
| Net loss | \$ (12,186,000) | \$ (14,835,000) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Loss on change in fair value of derivative – preferred stock | - | 11,810,000 |
| Depreciation and amortization | 401,000 | 2,000 |
| Stock option compensation expense | 2,851,000 | 1,159,000 |
| Stock issued to directors, employees and consultants | 2,960,000 | - |
| Stock issued for services | 333,000 | 291,000 |
| Change in operating assets and liabilities: | | |
| Receivables | (235,000) | 71,000 |
| Prepaid expenses and other current assets | (109,000) | 1,000 |
| Other assets | (29,000) | - |
| Accounts payable and accrued expenses | (1,081,000) | 767,000 |
| Interest payable on dividends | - | 423,000 |
| Deferred revenue | (451,000) | (198,000) |
| Net cash used in operating activities | <u>(7,546,000)</u> | <u>(509,000)</u> |
| Cash flows from investing activities: | | |
| Capital expenditures | (41,000) | - |
| Cash from Abeona Ohio | 3,697,000 | - |
| Net cash provided by investing activities | <u>3,656,000</u> | <u>-</u> |
| Cash flows from financing activities: | | |
| Proceeds from \$3.00 common stock issuances net of costs | 7,001,000 | - |
| Proceeds from \$8.00 common stock issuances net of costs | 9,005,000 | - |
| Proceeds from \$5.50 common stock issuances net of costs | 15,411,000 | - |
| Proceeds from exercise of \$5.00 warrants | 4,635,000 | - |
| Payment of short-term debt | (400,000) | 250,000 |
| Net cash provided by financing activities | <u>35,652,000</u> | <u>250,000</u> |
| Net increase (decrease) in cash and cash equivalents | 31,762,000 | (259,000) |
| Cash and cash equivalents at beginning of period | 11,520,000 | 424,000 |
| Cash and cash equivalents at end of period | <u>\$ 43,282,000</u> | <u>\$ 165,000</u> |
| Supplemental cash flow information: | | |
| Cash paid for interest | \$ - | \$ - |
| Supplemental disclosure of noncash transactions: | | |
| Shares issued to holders of Abeona Ohio for acquisition | \$ 31,758,000 | \$ - |
| Contingent milestones to Abeona Ohio members | 6,489,000 | - |
| Licensed technology from Abeona Ohio | 2,156,000 | - |
| Preferred stock dividends in dividends payable | - | 2,191,000 |

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

Abeona Therapeutics Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements Three and Nine Months Ended September 30, 2015 and 2014 (unaudited)

Abeona Therapeutics Inc. (together with our subsidiaries, “we”, “our”, “Abeona” or the “Company”) is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing and delivering gene therapy and plasma-based products for severe and life-threatening rare diseases. Abeona's lead programs are ABO-101 (AAV9 NAGLU) and ABO-102 (scAAV9 SG), adeno-associated virus (AAV)-based gene therapies for Sanfilippo syndrome (MPS IIIB and IIIA, respectively). We are also developing ABO-201 (scAAV9 CLN3) gene therapy for juvenile Batten disease (JBD); and ABO-301 (AAV FANCC) for Fanconi anemia (FA) disorder using a novel CRISPR/Cas9-based gene editing approach to gene therapy program for rare blood diseases. In addition, we are also developing rare plasma protein therapies including PTB-101 SDF Alpha™ (alpha-1 protease inhibitor) for inherited COPD using our proprietary SDF™ (Salt Diafiltration) ethanol-free process. Our efforts have been principally devoted to research and development, resulting in significant losses.

(1) Interim Financial Statements

The condensed consolidated balance sheet as of September 30, 2015, the condensed consolidated statements of operations for the three and nine months ended September 30, 2015 and 2014, the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2015, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014, 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, 2014. The results of operations for the period ended September 30, 2015 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, 2014 contains financial information taken from the audited Abeona financial statements as of that date.

Certain reclassifications to the consolidated financial statements for all periods presented have been made to conform to the September 30, 2015 presentation.

On June 19, 2015 we changed our name from PlasmaTech Biopharmaceuticals, Inc. to Abeona Therapeutics Inc.

(2) Intangible Assets

Intangible assets consist of the following (in thousands):

| | September 30, 2015 | | December 31, 2014 | |
|-------------------------------|----------------------|--------------------------|----------------------|--------------------------|
| | Gross carrying value | Accumulated amortization | Gross carrying value | Accumulated Amortization |
| Amortizable intangible assets | | | | |
| Licensed technology | \$ 7,156 | \$ 401 | \$ 5,000 | \$ 9 |

Amortization expense related to intangible assets totaled \$145,000 and \$392,000 for the three and nine months ended September 30, 2015, respectively, and totaled \$0 for the three and nine months ended September 30, 2014. The aggregate estimated amortization expense for intangible assets remaining as of September 30, 2015 is as follows (in thousands):

| | |
|--------------|----------|
| 2015 | \$ 145 |
| 2016 | 582 |
| 2017 | 582 |
| 2018 | 582 |
| 2019 | 582 |
| 2020 | 582 |
| over 5 years | 3,700 |
| Total | \$ 6,755 |

(3) Stock Based Compensation

For the three and nine months ended September 30, 2015, we recognized stock-based compensation expense of \$1,452,000 and \$2,580,000, respectively. For the three and nine months ended September 30, 2014 we recognized stock-based compensation expense of \$172,000 and \$1,159,000, respectively.

The following table summarizes stock-based compensation for the three and nine months ended September 30, 2015 and 2014:

| | Three months ended September 30, | | Nine months ended September 30, | |
|--|-------------------------------------|------------|------------------------------------|--------------|
| | 2015 | 2014 | 2015 | 2014 |
| Research and development | \$ 142,000 | \$ 18,000 | \$ 246,000 | \$ 113,000 |
| General and administrative | 1,310,000 | 154,000 | 2,334,000 | 1,046,000 |
| Stock-based compensation expense included in operating expense | \$ 1,452,000 | \$ 172,000 | \$ 2,580,000 | \$ 1,159,000 |

For the three and nine months ended September 30, 2015 we granted no stock options and 1,815,000 stock options, respectively, and for the three and nine months ended September 30, 2014 we granted no stock options and 210,000 stock options, respectively.

For the three and nine months ended September 30, 2015 stock valued at \$1,892,000 and \$2,960,000, respectively, was recorded to our directors, employees and consultants. For the three and nine months ended September 30, 2014 stock valued at \$84,000 and \$291,000, respectively, was granted to consultants.

(4) Litigation

Alan Schmidt (“Schmidt”), a former shareholder of Genaera Corporation (“Genaera”), and a former unitholder of the Genaera Liquidating Trust (the “Trust”), filed a purported class action in the United States District Court for the Eastern District of Pennsylvania in June 2012. The lawsuit named thirty defendants, including Abeona, MacroChem Corporation, which was acquired by us in February 2009, Jeffrey Davis, the then-CEO and currently a director of Abeona, and Steven H. Rouhandeh and Mark Alvino, both of whom are our directors (the “Abeona Defendants”). With respect to the Abeona Defendants, the complaint alleged direct and derivative claims asserting that directors of Genaera and the Trustee of the Trust breached their fiduciary duties to Genaera, Genaera’s shareholders and the Trust’s unitholders in connection with the licensing and disposition of certain assets, aided and abetted by numerous defendants including the Abeona Defendants. Schmidt seeks monetary damages, disgorgement of any distributions received from the Trust, rescission of sales made by the Trust, attorneys’ and expert fees, and costs. On December 19, 2012, Schmidt filed an amended complaint (the “Amended Complaint”) which asserted substantially the same allegations with respect to the Abeona Defendants. On February 4, 2013, the Abeona Defendants moved to dismiss all claims asserted against them. On August 12, 2013 the court granted the Abeona Defendants’ motions to dismiss and entered judgment in favor of the Abeona Defendants on all claims. On August 26, 2013, Schmidt filed a motion for reconsideration. On September 10, 2013 Schmidt filed a Notice of Appeal with the District Court. On September 17, 2013, Schmidt filed his appeal with the U.S. Third Circuit Court of Appeals (the “Third Circuit”). On September 25, 2013, the District Court denied Schmidt’s motion for reconsideration. On October 17, 2013, Schmidt amended his appeal to include the District Court’s denial of his motion for reconsideration. On March 20, 2014, Schmidt filed his Brief and Joint Appendix. On May 22, 2014, the Abeona Defendants filed their Oppositions to Schmidt’s Brief. On May 29, 2014, Schmidt was granted an extension of time until June 23, 2014 to file his Reply Brief and filed his Reply Brief on that date. The Third Circuit held oral argument on September 12, 2014. On October 17, 2014, in a split decision, the Third Circuit reversed the District Court’s decision holding, among other things, that the District Court’s determination that the Amended Complaint was time-barred on statute of limitations grounds was premature. The Third Circuit did not rule upon any of the other grounds for dismissal advanced in the District Court and on appeal. The Third Circuit remanded the case to the District Court for further proceedings. On January 6, 2015, the District Court ordered the parties to file supplemental briefs on all remaining arguments for dismissal, and further ordered that a hearing on the motions to dismiss would be held on February 3, 2015. On January 23, 2015, the Abeona Defendants filed their Supplemental Brief. At the February 3, 2015 hearing, Schmidt sought and was granted leave to amend his complaint for a second time. Schmidt filed his Second Amended Complaint on February 3, 2015. The Second Amended Complaint asserts substantially the same factual allegations with respect to the Abeona Defendants, but eliminates all causes of action against the Abeona Defendants except for aiding and abetting the Genaera directors’ and officers’ purported breaches of fiduciary duties, a claim for “punitive damages” and a claim for rescission of a settlement agreement between the Trust and the Abeona Defendants. On March 20, 2015, the Abeona Defendants filed a motion to dismiss the Second Amended Complaint. On November 10, 2015, the District Court granted the Abeona Defendant’s motion and dismissed the action in its entirety. On November 11, 2015, Schmidt filed a Notice of Appeal with the District Court. We intend to continue contesting the claims vigorously.

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

(5) Abeona Therapeutics LLC Acquisition

On May 15, 2015, we agreed to issue an aggregate of 3,979,761 unregistered shares of our common stock to the members of Abeona Therapeutics LLC (Abeona Ohio). Abeona Ohio's principal activities were focused on developing and delivering gene therapy products for severe and life-threatening rare diseases. Abeona Ohio's lead program is ABO-101 (AA9 NAGLU) and ABO-102 (scAAV9 SGHG), adeno-associated virus (AAV)-based gene therapies for Sanfilippo syndrome (MPS IIIA and IIIB) in collaboration with patient advocate groups, researchers and clinicians, anticipated to commence clinical trials in 2015.

The initial consideration of \$31,758,000 was calculated using the Company's stock price on date of the closing, May 15, 2015 of \$7.98 times the number of the Company shares (3,979,761) issued to Abeona Ohio members.

There is a contingent valuation on three milestones. Per the merger agreement with Abeona Ohio each milestone would consist of either cash, our stock or a combination of both, at the Company's election, equivalent to a stated dollar amount. The fair value of the probability of achieving all three milestones is estimated at \$6,489,000.

The following preliminary purchase price allocation is based on information we have to date and is unaudited.

| | |
|---|----------------------|
| Total purchase price | |
| Initial consideration | \$ 31,758,000 |
| Contingent consideration | 6,489,000 |
| Total purchase price | <u>\$ 38,247,000</u> |
| Allocation of the purchase price | |
| Cash | \$ 3,697,000 |
| Accounts receivable | 1,000 |
| Prepaid expenses | 28,000 |
| Property and equipment | 51,000 |
| Other assets | 1,000 |
| Accounts payable | (153,000) |
| Total tangible assets | <u>3,625,000</u> |
| Licensing agreement | 2,156,000 |
| Goodwill | 38,955,000 |
| Contingent consideration liability | <u>(6,489,000)</u> |
| Total net asset value | <u>\$ 38,247,000</u> |

In connection with the acquisition \$375,000 in merger costs were expensed.

EMPLOYMENT AGREEMENT

This AGREEMENT (the "Agreement"), dated as of May ____, 2015, is made between PlasmaTech Biopharmaceuticals, Inc., a Delaware corporation located at 4848 Lemmon Avenue, Suite 517, Dallas, Texas 75219, ("PlasmaTech" or the "Company"), and Timothy J. Miller, an individual residing at 2240 Delaware Drive, Cleveland Heights, OH 44106 (the "Executive").

WITNESSETH:

WHEREAS, in connection with that certain Agreement and Plan of Merger by and among the Company, PlasmaTech Merger Sub, Inc., Abeona Therapeutics LLC, and Member Representative dated as of even date herewith (the "Merger Agreement"), the Company desires that Executive serve as the Company's President and Chief Executive Officer ("CEO");

WHEREAS, in order to induce Executive to agree to serve in such capacity, the Company hereby offers Executive certain compensation and benefits of employment, as described herein; and

WHEREAS, Executive is willing to serve in this position on the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the premises and of the mutual covenants contained herein, the Company and Executive hereby agree as follows:

1. Employment

The Company hereby agrees to employ Executive and Executive hereby agrees to be employed upon the terms and conditions hereinafter set forth. During the Term (as defined below), Executive shall serve as the President and CEO of the Company. Executive shall be responsible to the Board of Directors of the Company, rendering the services and performing the duties consistent with Executive's position and title, and such other reasonable duties as the Board of Directors of the Company (together with any applicable sub-committee or sub-committees thereof, the "Board") may request. The Executive shall also be nominated to serve as a voting member on the Board of Directors for the Term (as defined below). If the Executive is no longer the CEO of the Company, he shall immediately tender his resignation as a member of the Board to the Board.

The Executive agrees, while employed hereunder, to perform his duties faithfully and to the best of his ability. The Executive shall be employed at the Company's offices in Cleveland, OH, and his principal duties shall be performed primarily in Cleveland, OH, except for business trips reasonable in number and duration.

2. Term

The employment of the Executive hereunder shall begin on the Closing Date (as such term is defined in the Merger Agreement) of the Merger Agreement (the “Effective Date”) and shall continue in full force and effect for a period of three (3) years, and thereafter shall be automatically renewed for successive one-year periods unless the Company gives the Executive written notice of termination within six (6) months prior to the end of any such period or until the occurrence of a Termination Date, as defined in Section 5 (the “Term”). If the Company provides written notice of termination as described above, then the last day of the Term will be considered the Termination Date by General Discharge (as defined in Section 5.1.6), and the Executive will be entitled to all benefits attributable to General Discharge as defined in Section 5.2. Notwithstanding anything contained herein to the contrary, if there is no Closing (as defined in the Merger Agreement) for any reason or the Merger Agreement is otherwise terminated prior to the Closing Date, this Agreement shall immediately terminate and shall become null and void.

3. Compensation

3.1. As compensation for the Executive's services during the Term, the Company shall pay the Executive an annual base salary at the rate of \$350,000 (the “Base Salary”), payable monthly on the last day of each month during the Term. Prior to the end of each calendar year during the Term, the Compensation Committee of the Company shall undertake an evaluation of the services of the Executive during the calendar year then ended in accordance with the Company's compensation program then in effect (the “Program”). The Company shall consider the performance of the Executive, his contribution to the success of the Company and entities under common control with the Company (collectively, “Affiliates”), and such other factors as the Compensation Committee considers relevant in its sole discretion and shall fix an annual base salary not less than \$350,000 per year to be paid to the Executive during the ensuing calendar year.

3.2 Notwithstanding the foregoing, the Company may change the Program from time to time or institute a successor to the Program, but the Executive's Base Salary shall in no event be less than his Base Salary in effect on the date of change, adjusted regularly to reflect increases in the cost of living and comparable compensation for like positions.

3.3. The executive shall be eligible to participate in the Company incentive compensation programs in accordance with the following subparagraphs (i) and (ii):

(i) Incentive Plan - The executive shall be covered by any cash bonus plan maintained by the Company, as in effect from time to time, and shall be afforded the opportunity thereunder to receive a target award of up to 30% of annual Base Salary (an “Annual Bonus”) payable in cash, as well as an allocation of options to purchase shares of PlasmaTech's Common Stock or restricted shares of Common Stock, as applicable, at the sole discretion of the Compensation Committee which shall make its evaluation prior to the end of each calendar year during the Term of this Agreement. The Annual Bonus will be calculated and be paid in accordance with the terms of the Company's cash bonus plan, within 30 days after the end of the applicable calendar year. Such cash and equity bonus awards shall be made by the Compensation Committee based upon, among other factors, the achievement of reasonable performance goals; provided that the Company may from time to time change the Program or institute a successor to the Program, so long as the Executive continues to be eligible to receive bonus awards of the percentage of annual Base Salary in amounts at least equal to those specified as in effect on the date hereof.

(ii) Stock Option Plan - Executive shall be entitled to participate in the Company's stock option plan, as in effect from time to time. In accordance with this plan the Compensation Committee may from time to time, but without any obligation to do so, grant stock options, restricted stock awards or other equity compensation awards to the Executive upon such terms and conditions as the Compensation Committee shall determine in its sole discretion. As soon as practicable following the Effective Date, and subject to the approval of the Compensation Committee and the adoption and approval of the Company's 2015 Equity Incentive Plan (the "Equity Incentive Plan") by Company stockholder approval, the Company shall grant, pursuant to a Company standard stock option agreement (the "Option Agreement") to be entered into between the Company and the Executive, a stock option (the "Option") to purchase 400,000 shares of the Company's Common Stock (the "Option Shares") at an exercise price per share equal to the closing price of shares of Common Stock on the NASDAQ on the date of grant. The Option Shares will vest over a forty-eight (48) month period, with one quarter (25%) of vesting on the one-year anniversary of the Effective Date and the remaining seventy-five percent (75%) of the Option Shares vesting in equal monthly installments thereafter over the remaining thirty-six (36) months, commencing with the first such month following the first anniversary of the Effective Date, subject to the Executive's continued employment with the Company and/or its Affiliates through to the applicable vesting dates, and subject to the terms and conditions of the Company's Equity Incentive Plan.

3.4 If the Executive is prevented by disability, for a period of six consecutive months, from continuing fully to perform the essential functions of his duties as CEO, with or without reasonable accommodations, the Employee shall perform his obligations hereunder to the extent he is able and after the following six months (in other words, twelve months after the disability was identified by the Company as affecting his work performance) the Company may reduce his annual Base Salary to reflect the extent of the disability; provided that in no event may such rate, when added to payments received by him under any disability or qualified retirement or pension plan to which the Company or an Affiliate contributes or has contributed, be less than \$200,000. The Company acknowledges that it has an obligation to provide reasonable accommodation to Executive for a disability in accordance with the Americans with Disability Act and similar state laws and will not reduce Executive's salary if he can perform the essential functions of his duties as CEO with or without reasonable accommodation. If there should be a dispute about the existence of Executive's disability, or his ability to perform essential functions of his duties as CEO, disability shall be determined by a majority vote of the Board (with the Executive abstaining from any such vote) based upon a report from a physician, reasonably acceptable to the Executive and the Company, who shall have examined the Executive. If the Executive claims disability, the Executive agrees to submit to a physical examination at any reasonable time or times by a qualified physician designated by the Board and reasonably acceptable to the Executive.

4. Executive Benefits

4.1. During the Term, the Executive shall be entitled to participate in the employee benefit plans and programs maintained by the Company that are made generally available to other executive officers of the Company, including (without limitation) retirement plans, deferred compensation plans, health and welfare plans and fringe benefit programs, subject in each case to the eligibility and other terms and conditions of the plan or program in question, as in effect from time to time.

4.2. During the Term, the Company shall maintain directors' and officers' liability insurance applicable to the Executive in amounts established by the Board of Directors and comparable to the amounts provided for like positions.

4.3. The Company shall pay, or reimburse the Executive for, all reasonable relocation expenses incurred by the Executive to be approved by the Board, relating to any relocation if said relocation is in the best interests for the Company to conduct business. If the Executive terminates his employment pursuant to a General Resignation (as defined below) or is terminated by the Company pursuant to a Discharge for Cause (as defined below) during the 6 month period following the Effective Date, the Executive shall be required to repay the Company the gross amount of any relocation expenses paid.

5. Termination Date; Consequences for Compensation and Benefits

5.1. Definition of Termination Date. The first to occur of the following events shall be the "Termination Date":

5.1.1. The date on which the Executive's employment is terminated by the Company by reason of his disability;

5.1.2. The Executive's death;

5.1.3. Voluntary resignation after one of the following events shall have occurred, which event shall be specified to the Company by the Executive at the time of resignation: (i) a material diminution in the Executive's authority, duties, or responsibilities or (ii) any other action or inaction that constitutes a material breach by the Company of this Agreement (including, without limitation, any material failure by the Company to grant the Option for the Executive to purchase the Option Shares pursuant to the terms of Section 3.3(ii) of this Agreement), provided that the Executive has provided written notice to the Company of the existence of any event described in (i) or (ii) above within 60 days of the initial existence of the event and the event continues for 60 days following such notice (the "Cure Period") without being remedied by the Company, and provided further that such voluntary resignation occurs within 30 days after the end of the applicable Cure Period ("Resignation with Reason");

5.1.4. Voluntary resignation (other than a Resignation with Reason) not accompanied by a notice of reason described in Section 5.1.3 ("General Resignation");

5.1.5 Discharge of the Executive by the Company after one of the following events shall have occurred, which event shall be specified in writing to the Executive by the Company at the time of discharge:

(i) a felonious act committed by Executive during his employment hereunder or commission of any act of fraud or any other act of dishonesty of a material nature with respect to the Company (including, but not limited to, theft or embezzlement of Company funds or assets), (ii) any act or omission on the part of Executive not requested or approved by the Company constituting willful malfeasance or gross negligence in the performance of his duties hereunder, (iii) conviction of the Executive or the entry of a plea of guilty or nolo contendere by the Executive to any crime involving moral turpitude, (iv) any material breach of any material term of this Agreement by the Executive which is not cured within 60 days after written notice from the Board to the Executive setting forth the nature of the breach ("Discharge for Cause");

For purposes of this subparagraph (5.1.5), no act or failure to act on the Executive's part shall be considered "willful" unless done or omitted to be done by Executive not in good faith and without reasonable belief by Executive that Executive's action or omission was in the best interest of the Company. Notwithstanding the foregoing, Executive shall not be deemed to have been discharged for a Discharge for Cause unless and until there shall have been delivered to Executive a copy of a Notice of Termination (as defined below) from the Board stating that in their good faith opinion Executive was guilty of conduct set forth in clauses (i), (ii), (iii) or (iv) above of this subparagraph (5.1.5) and specifying the particulars thereof in detail.

5.1.6 Discharge of the Executive by the Company other than a Discharge for Cause or by reason of the Executive's disability ("General Discharge").

For purposes of this Agreement "Notice of Termination" shall mean a notice which indicates the specific termination provision in this Agreement relied upon and sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated. Except for Discharge for Cause, each Notice of Termination shall be delivered at least ten (10) days prior to the effective date of termination.

5.2 Consequences for Compensation and Benefits

(a) If the Termination Date occurs by reason of disability, death, General Resignation or Discharge for Cause, the Company shall pay or provide, as the case may be, (i) any Base Salary earned but unpaid to the Executive through the Termination Date, (ii) all benefits accrued and owing to the Executive through the Termination Date, payable in accordance with the respective terms of the plans, practices and arrangements under which the benefits were accrued, and (iii) any unpaid reimbursements for reasonable expenses incurred but not paid prior to the Termination Date so long as documentation thereof is submitted to the Company within thirty (30) days following the Termination Date.

(b) If the Termination Date occurs by reason of General Discharge or Resignation with Reason, (i) all unvested Option Shares held by the Executive pursuant to the Option shall immediately vest and become immediately exercisable for the period set forth in the Option Agreement and the Equity Incentive Plan, (ii) if the Executive elects coverage under Section 4980B of the Internal Revenue Code of 1986, as amended (the “Code”), or under similar applicable health care continuation coverage laws of a State (“COBRA”), the Company shall reimburse the Executive for that portion of the cost of the continuation coverage that the Company pays for similarly situated active employees of the Company, for Executive and Executive’s covered dependents (but not for any spouse or dependent who separately elects COBRA coverage as a “qualified beneficiary,” as defined in Code Section 4980B(g)(1)), for a period ending upon the earlier of twelve (12) months after the Termination Date or the date the Executive’s COBRA coverage ceases (the “Health Severance”), *provided, however*, that the Health Severance shall be payable only to the extent that it would not result in a tax or penalty to the Company under the Patient Protection and Affordable Care Act of 2010, as amended, and regulations thereunder (“ACA”), and *further provided* that the Company may elect, in its sole discretion, to report the Health Severance as taxable income to the Executive in order to satisfy the requirements of Section 105(h) of the Code or Section 2716 (Prohibition on Discrimination in Favor of Highly Compensated Individuals) of the Public Health Service Act, as incorporated by Section 9815(a)(1) of the Code, (iii) the Executive shall be entitled to receive the amount set forth in Section 5.2.1, which shall be paid on or before the 60th day following the Termination Date, provided that the Executive signs a valid and effective Release (defined in Section 5.2.3) in the time set forth in such Release (which shall in no case cause the payment under this Section 5.2(b)(iii) to be made after the 60 day period after the Termination Date), and provided that, if such 60-day period straddles two taxable years, the payment shall be made in the second taxable year, and (iv) the Company shall reimburse Executive for any unpaid reimbursements for reasonable expenses incurred but not paid prior to the Termination Date so long as documentation thereof is submitted to the Company within ten (10) days following the Termination Date.

5.2.1. A lump sum payment equal to one times (1x) the Executive’s Base Salary for the year in which the Termination Date occurs.

5.2.2 . If the Executive's employment is terminated by the Executive pursuant to a General Resignation, the Executive shall be entitled to receive any earned but unpaid Annual Bonus with respect to any completed calendar year immediately preceding the Termination Date, which shall be paid on the otherwise applicable payment date except to the extent payment is otherwise deferred pursuant to any applicable deferred compensation arrangement.

5.2.3. The severance payments and benefits described in this Section 5 are expressly contingent on the Executive’s execution of a severance and release agreement (a “Release”) in substantially the form attached hereto as Exhibit A within the time set forth in the Release, and such Release becoming effective by its terms on or before the 60th day following the Termination Date.

5.3 Change in Control. In the event of the occurrence of a Change in Control (as defined below), this Agreement may be terminated by Executive upon the occurrence thereafter of one or more of the following events:

1) A material diminution in Executive’s authority, duties, or responsibilities within the six month period subsequent to a Change in Control;

2) A material diminution in Executive’s compensation within the six month period subsequent to a Change in Control, which shall include the occurrence of any of the following without the prior written consent of Executive: (i) a material reduction in the aggregate of Executive’s then-current Base Salary or a material reduction in the benefits under, or becoming ineligible to participate in, the Company incentive compensation programs outlined in Section 3.3 of this Agreement, or (ii) a material reduction in the scope or value of the Executive’s overall compensation and benefits;

3) A breach of Section 11.5 of this Agreement by either the Company or any successor or successors to which all or a significant portion of its business and/or assets have been transferred (directly or by operation of law), which the parties hereby agree and acknowledge constitutes a material breach of this Agreement;

4) A General Discharge of Executive within the six month period subsequent to a Change in Control; or

5) A breach of the requirement under Section 1 of this Agreement that Executive shall be nominated to serve as a voting member on the Board for the duration of the Term, which the parties hereby agree and acknowledge constitutes a material breach of this Agreement;

provided that the Executive has provided written notice to the Company (or any successor, as the case may be) of the existence of any event described in 1) through 5) above with 30 days of the initial existence of the event and the event continues for 30 days following such notice (the "Change in Control Cure Period") without being remedied by the Company (or any successor, as the case may be), and provided further that such termination of this Agreement occurs within 60 days after the end of the applicable Change in Control Cure Period.

5.3.1 A "Change in Control" of the Company as used in this Agreement shall be deemed to have occurred upon the first to occur of the date when (a) a person or group "beneficially owns" (as defined in Rule 13d-3 promulgated under the Securities Exchange Act of 1934) in the aggregate 50% or more of the outstanding shares of capital stock entitled to vote generally in the election of the Directors of the Company or (b) there occurs a sale of all or substantially all of the business and/or assets of the Company, all other than to an affiliate of the Company or through a reorganization or similar restructuring of the Company; provided, that a Change in Control shall not be deemed to occur if any current shareholder of the Company becomes a beneficial owner of 50% or more of the outstanding shares of the Company.

5.3.2 If a Change in Control of the Company shall have occurred within six (6) months prior to the Termination Date (other than a Termination Date due to a General Resignation, a termination due to the Executive's disability, or a Discharge for Cause) or the Executive terminates this Agreement under Section 5.3, then, following such Termination Date, (i) the Executive will be entitled to receive a lump sum payment equal to two (2) times the sum of the Executive's Base Salary for the year in which the Termination Date occurs, which shall be paid on the 60th day following the Termination Date, provided that the Executive signs a valid and effective Release in the time set forth in such Release (which shall in no case cause the payment under this Section 5.3.2(i) to be made after the 60 day period after the Termination Date), (ii) all unvested Option Shares held by the Executive shall immediately vest and become immediately exercisable and shall remain exercisable in accordance with the terms thereof and the Company's Equity Incentive Plan, and (iii) the Executive shall be entitled to Health Severance, upon the terms set forth in Section 5.2(b(ii)), for a period ending upon the earlier of six (6) months after the Termination Date or the date the Executive's COBRA coverage ceases.

6. Indemnification

In the event that the Executive is made a party or threatened to be made a party to any action, suit, or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), other than any Proceeding initiated by the Executive or the Company related to any contest or dispute between the Executive and the Company or any of its affiliates with respect to this Agreement or the Executive's employment hereunder, by reason of the fact that the Executive is or was a director or officer of the Company, or any affiliate of the Company, or is or was serving at the request of the Company as a director, officer, member, employee or agent of another corporation or a partnership, joint venture, trust or other enterprise, the Executive shall be indemnified and held harmless by the Company to the maximum extent permitted under applicable law from and against any liabilities, costs, claims and expenses, including all costs and expenses incurred in defense of any Proceeding (including attorneys' fees). Costs and expenses incurred by the Executive in defense of such Proceeding (including attorneys' fees) shall be paid by the Company in advance of the final disposition of such litigation upon receipt by the Company of: (i) a written request for payment; (ii) appropriate documentation evidencing the incurrence, amount and nature of the costs and expenses for which payment is being sought; and (iii) an undertaking adequate under applicable law made by or on behalf of the Executive to repay the amounts so paid if it shall ultimately be determined that the Executive is not entitled to be indemnified by the Company under this Agreement.

7. Fulfillment of Duties

During the Term, The Executive shall devote substantially all of his business time and attention, skills and best efforts to the performance of his duties herein for the Company, its Subsidiaries and Affiliates and shall not, during the Term, engage in any other business, profession or occupation for compensation or otherwise which would conflict with, compete with or otherwise interfere with the performance of such services with directly or indirectly without the prior written consent of the Board. Notwithstanding the foregoing, nothing contained herein shall preclude the Executive from (a) serving on the boards of directors of other companies or organizations with the approval of the Board (not to be unreasonably withheld) or serving on the boards of directors of not-for-profit companies or organizations without the approval of the Board, (b) investing in and managing passive investments, or (c) pursuing his personal, financial and legal affairs provided that such activity does not materially interfere with the performance of the Executive's obligations hereunder. The Executive's activities and roles within Red5 Pharmaceuticals shall not be a violation of this Agreement.

8. Agreement Not to Compete, Not to Solicit

The Executive agrees that the following obligations are reasonable and are necessary to protect the Company's goodwill and business interests, these obligations do not restrict the Executive's ability to be gainfully employed, and the Executive acknowledges that any geographic boundary, scope of prohibited activities, and time duration in these obligations are reasonable in nature and no broader than are necessary to protect the Company's legitimate goodwill and business interests.

For one year following any Termination Date, regardless of the reason, the Executive agrees not to, singly, jointly or as a partner, member, employee, agent, officer, consultant, independent contractor, officer, director, stockholder (except as a holder, for investment purposes of not more than three percent (3%) of the outstanding stock of any company listed on a national securities exchange, or actively traded in a national over-the-counter market), equity holder, lender, or joint venturer of any other person, or in any other capacity, directly or beneficially, own, manage, operate, join, control, participate in the ownership, management, operation or control of, or permit the use of his name by, or work for, or provide consulting, financial or other assistance to any person engaged in, or otherwise engage in (other than on behalf of the Company) the business of developing pharmaceutical products or platform technologies that are similar or substantially similar to those of the Company (the "Business") as of the Termination Date in any state in which the Company conducts the Business as of the Termination Date.

For one year following any Termination Date, regardless of the reason, the Executive shall not solicit any employee of the Company or an Affiliate to leave such employment and to provide services to the Executive or any business entity by which the Executive is employed or in which the Executive has a material financial interest. Soliciting a former employee of the Company and its Affiliates to provide such services shall not be a violation of this Agreement.

9. Confidential Information

The Executive acknowledges that during his employment with the Company, he will have access to trade secrets and other non-public confidential and/or proprietary information relating to the Company's business ("Confidential Information"), which will be the exclusive property of the Company. The following does not constitute "Confidential Information": information (i) which is, at the time Executive receives such information, available to the general public; (ii) which becomes at a later date available to the general public through no fault of the Executive and then only after said later date; or (iii) which the Executive can demonstrate by written record was in his possession prior to the Term. Unless the Executive shall first secure the written consent of the Company or unless required pursuant to a legal proceeding, the Executive shall not disclose or use, either during or after the Term for a period of five (5) years, any Confidential Information of the Company or any Affiliate, whether or not developed by the Executive, except as required by his duties to the Company or the Affiliate or under applicable law.

Concurrently with the execution of this Agreement, the Executive will sign a standard Confidential Disclosure and Limited Use Agreement, which shall control over this Agreement if any conflict exists between it and this Agreement.

10. Arbitration

Any dispute or differences concerning any provision of this Agreement which cannot be settled by mutual accord between the parties shall be settled by arbitration in New York, New York, in accordance with the rules then in effect of the American Arbitration Association, except as otherwise provided herein. The dispute or differences shall be referred to a single arbitrator, if the parties agree upon one, or otherwise to three arbitrators, one to be appointed by each party and a third arbitrator to be appointed by the first named arbitrators; and if either party shall refuse or neglect to appoint an arbitrator within 30 days after the other party shall have appointed an arbitrator and shall have served a written notice upon the first mentioned party requiring such party to make such appointment, then the arbitrator first appointed shall, at the request of the party appointing him, proceed to hear and determine the matters in difference as if he were a single arbitrator appointed by both parties for the purpose, and the award or determination which shall be made by the arbitrator shall be final and binding upon the parties hereto.

The arbitrator or arbitrators shall each have not less than five-(5) years' experience in dealing with the subject matter of the dispute or differences to be arbitrated. Any award may be enforced in any court of competent jurisdiction. The expenses of any such arbitration shall be paid by the non-prevailing party, as determined by the final order of the arbitrators.

The non-prevailing party in any dispute agrees to pay all reasonable legal fees and expenses of the prevailing party in connection with any dispute under this Agreement.

11. Miscellaneous

11.1 Notices

All notices in connection with this Agreement shall be in writing and sent by postage prepaid first class mail, courier, or telefax, and if relating to default or termination, by certified mail, return receipt requested, addressed to each party at the address indicated below:

If to the Company:
PlasmaTech Biopharmaceuticals, Inc.
4848 Lemmon Avenue
Suite 517
Dallas, TX 75219
Attn: Chief Financial Officer

Copy To:
John J. Concannon III, Esq.
Morgan Lewis & Bockius LLP
One Federal Street
Boston, MA 02110

If to the Executive:
Timothy J. Miller
2240 Delaware Drive
Cleveland, OH 44106

Or to such other address as the addressee shall last have designated by notice to the communicating party. The date of giving of any notice shall be the date of actual receipt.

11.2 Governing Law

This Agreement shall be governed by the internal and substantive laws of the State of Delaware.

11.3 Severability

Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision or in the interpretation in any other jurisdiction; however, such provision shall be deemed amended to conform to applicable laws and to accomplish the intentions of the parties.

11.4 Entire Agreement; Amendment

This Agreement constitutes the entire agreement of the parties and may be altered or amended or any provision hereof waived only by an agreement in writing signed by the party against whom enforcement of any alteration, amendment, or waiver is sought. No waiver by a party of any breach of this Agreement shall be considered as a waiver of any subsequent breach.

11.5 Successors and Assigns

11.5.1 Any successor of the Company (whether direct or indirect, by purchase, merger, consolidation or otherwise) shall expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. As used in this Section 11.5.1, "Company" shall mean the Company as hereinbefore defined and any successor to its business and/or assets as aforesaid which executes and delivers the Agreement provided for in this Section 11.5.1 or which otherwise becomes bound by all the terms and provisions of this Agreement by operation of law.

11.5.2 This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors and assigns, except that Executive may not assign any of his rights or delegate any of his duties without the prior written consent of the Company.

11.6 Assignability

Neither this Agreement nor any benefits payable to the Executive hereunder shall be assigned, pledged, anticipated, or otherwise alienated by the Executive, or subject to attachment or other legal process by any creditor of the Executive, and notwithstanding any attempted assignment, pledge, anticipation, alienation, attachment, or other legal process, any benefit payable to the Executive hereunder shall be paid only to the Executive or his estate.

11.7 Code Section 409A

11.7.1 To the extent applicable, it is intended that this Agreement (including all amendments hereto) either meet the requirements for exclusion from coverage under Code Section 409A, or alternatively comply with the requirements of Code Section 409A, so that the income inclusion provisions of Code Section 409A(a)(1) do not apply to Executive. This Agreement shall be interpreted and administered in a manner consistent with this intent. However, the Company does not warrant to Executive that all amounts paid or delivered to him hereunder will be exempt from, or paid in compliance with, Code Section 409A. Executive understands and agrees that he bears the entire risk of any adverse federal, state or local tax consequences and penalty taxes which may result from payment on a basis contrary to the provisions of Code Section 409A or comparable provisions of any applicable state or local income tax laws. Executive acknowledges that he has been advised to seek the advice of a tax advisor with respect to the tax consequences of all payments pursuant to this Agreement, including any adverse tax consequence under Code Section 409A and applicable state tax law.

11.7.2 To the extent that payment of amounts under this Agreement that are subject to Code Section 409A are payable upon Executive's termination of employment, such amounts shall only be payable if such termination also constitutes a "separation from service," within the meaning of Code Section 409A, from the Company. If the Executive is deemed on the date of his separation from service to be a "specified employee" within the meaning of Code Section 409A(a)(2)(B), of the Company, then, notwithstanding any other provision herein, with regard to any payment that is nonqualified deferred compensation subject to Code Section 409A and that is payable on account of Executive's "separation from service," such payment shall not be made prior to the earlier of (i) the expiration of six months following the date of Executive's separation from service, and (ii) the date of the Executive's death, following which all payments so delayed shall be paid to the Executive in a lump sum without interest.

11.7.3 Any taxable reimbursement of business or other expenses provided for under this Agreement that is subject to Code Section 409A shall be subject to the following conditions: (i) the expenses eligible for reimbursement in one taxable year shall not affect the expenses eligible for reimbursement in any other taxable year; (ii) the reimbursement of an eligible expense shall be made no later than the end of the year after the year in which such expense was incurred; and (iii) the right to reimbursement shall not be subject to liquidation or exchange for another benefit.

11.7.4 In applying Code Section 409A to amounts paid pursuant to this Agreement, any right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments. Whenever a payment under this Agreement specifies a payment period within a specified number of days, the actual date of payment within the specified period shall be within the sole discretion of the Company.

[Remainder of Page Intentionally Left Blank]

IN WITNESSES WHEREOF, the Company and its officers hereunto duly authorized, and the Employee have signed and sealed this Agreement as of the date first written above.

PLASMATECH BIOPHARMACEUTICALS, INC.

By: /s/ Steven H. Rouhandeh
Name: Steven H. Rouhandeh
Title: Chairman

EXECUTIVE:

/s/ Timothy J. Miller
Timothy J. Miller

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 fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(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: November 16, 2015

/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 fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(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: November 16, 2015

/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 September 30, 2015 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 16th day of November, 2015.

/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 September 30, 2015 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 16th day of November, 2015.

/s/ Stephen B. Thompson

Stephen B. Thompson

Vice President Finance

Principal Financial and Accounting Officer
