ANNUAL REPORT 2015

Abeona THERAPEUTICS

Working together to find a cure.

To Our Shareholders,

Abeona Therapeutics Inc. is a biopharmaceutical company focused on developing and delivering gene therapies and plasma-based protein drugs for severe and life-threatening rare diseases.

The past year has led to significant advancements in our goal of building a leadership position in the field of gene therapy and plasma protein therapies towards transforming the lives of patients with rare diseases. In 2015, we expanded our pipeline with two clinical stage AAV gene therapies for Sanfilippo syndrome types A and B, added a third AAV gene therapy product in Juvenile Neuronal Ceroid Lipofuscinosis (JNCL) (also known as juvenile Batten disease), signed a license to an innovative CRISPR-Cas9 gene editing platform in rare blood disorders, with an initial focus in Fanconi anemia, strengthened our team, and added substantial financial resources to our balance sheet. In 2016, our priorities include driving our AAV gene therapies and alpha-1 protease inhibitor program into the clinic, and advancing our gene editing programs including defining of regulatory pathways to bring our CRISPR product candidates to patients.

This coming year 2016 will be an exciting, transformative year for us as we position ourselves to enter multiple human clinical trials with our pipeline of innovative product candidates. As recently announced, the FDA allowance of the IND for the Phase 1/2 clinical study of ABO-102 for patients with Sanfilippo syndrome type A (MPS IIIA) moves our programs into the clinic here in the US, and we look forward to working with our collaborators to expand this program into Europe and Australia later this year. We believe that our gene therapy programs in Sanfilippo syndrome type B (ABO-101) and Juvenile Neuronal Ceroid Lipofuscinosis (ABO-201) will follow shortly.

Gene therapy and plasma protein programs

Sanfilippo syndrome gene therapy programs: On February 29, 2016, Abeona announced the FDA allowance of an Investigational New Drug (IND) for systemic AAV Phase 1/2 clinical study with ABO-102 gene therapy for patients with Sanfilippo syndrome type A (MPS IIIA). On January 11, 2016, we announced that initial regulatory approvals from European bodies — the Genetically Modified Organism (GMO) Voluntary Release regulatory filings, and the ethical committee regulatory filings — for both the ABO-101 and ABO-102 programs in Spain. Abeona plans to commence both programs for the upcoming human clinical trials to be conducted in Spain and Australia. Both the ABO-101 and ABO-102 programs have received Orphan Drug and Pediatric Rare Disease designations from the FDA.

SDF-Alpha plasma protein program: Abeona has completed optimization of the downstream chromatography steps for our SDF-Alpha™ (alpha-1 protease inhibitor) for inherited COPD. Additional provisional patent applications have been filed to provide us with expanded intellectual property protection. We have expanded our CMO relationships to ensure we have the ability to manufacture clinical material for future trials. We confirm that our proprietary SDF platform provides significantly enhanced yields of alpha-1 protease inhibitor, at levels up to 10 times of that achievable with the industry standard Cohn processes, and with purity levels consistent with that achieved by other commercial processes.

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Advanced pipeline programs: Together with our academic collaborators, we continued to progress our pre-clinical programs in juvenile Batten disease and our CRISPR-Cas9 program in Fanconi anemia (FA) and other rare blood disorders. Juvenile Batten disease is the most common form of a group of disorders known as neuronal ceriod lipofuscinosis (NCL), a lysosomal storage disease that affects the nervous system in children and for which there are no approved treatment options. Fanconi anemia is a rare pediatric blood disease characterized by multiple physical abnormalities, bone marrow failure and a higher than normal risk of cancer.

Financial and business

Acquisition of Abeona Therapeutics LLC ("Abeona LLC"): On May 15, 2015 we acquired Abeona LLC. In connection with the acquisition we issued Abeona LLC members a total of 3,979,761 common shares and may issue up to an additional $5 million in performance milestones, in common stock or cash, at the our option. On June 19, 2015 we changed our name to Abeona Therapeutics Inc. from PlasmaTech Biopharmaceuticals, Inc.

Financings: The Company executed a number of private and direct equity placements in 2015, strengthening the Company's financial position and enabling us to execute on our business plan. These financings include:

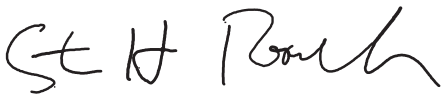
- $7.0 million private placement of common stock consisting of 2,333,333 shares of our common stock at a price of $3.00 per share on April 23, 2015
- $10.0 million private placement of common stock consisting of 1,250,000 shares of our common stock at a price of $8.00 per share and warrants to purchase 625,000 shares of stock on May 11, 2015
- $15.5 million direct placement of registered common stock consisting of 2.83 million shares of stock at a price of $5.50 per share on July 31, 2015
- During the second quarter of 2015 the Company received additional financing of $4.6 million through warrant exercises of our $5.00 warrants
- The 2015 financings are in addition to the closing of a public offering on December 31, 2014 of 3,500,000 shares of our common stock and 3,500,000 warrants

Acknowledgements

I would like to thank our investors, partners, researchers, collaborators, dedicated patient foundations, employees, scientific advisors and board members for their continued support as we execute our strategic plan.

I look forward to achieving the objectives that we have set for Abeona Therapeutics during the upcoming twelve months.

Respectfully,



Steven H. Rouhandeh
Executive Chairman

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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	83-0221517
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3333 Lee Parkway, Suite 600, Dallas, TX	75219
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $0.01 par value

Title of each Class

NASDAQ Capital Markets

Name of each exchange on which registered

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 definitions of ''large accelerated filer,'' ''accelerated filer'' and ''smaller reporting company'' in Rule 12b-2 of the Act. (Check one):

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the average bid and asked price of such common equity, as of June 30, 2015, was approximately $74,700,000.

The number of shares outstanding of the registrant's common stock as of March 30, 2016 was 32,743,013 shares.

DOCUMENTS INCORPORATED BY REFERENCE.

Portions of the registrant's definitive Proxy Statement relating to our 2016 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

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FORWARD-LOOKING STATEMENTS

This Form 10-K (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 Form 10-K, 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, including those set forth below in Item 1A. Risk Factors and elsewhere in this Form 10-K. The factors set forth under "Risk Factors" and other cautionary statements made in this Form 10-K should be read and understood as being applicable to all related forward-looking statements wherever they appear in this Form 10-K. The forward-looking statements contained in this Form 10-K represent our judgment only as of the date of this Annual Report on Form 10-K. 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.

PART I

ITEM 1. BUSINESS

Business

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

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 AAV to deliver the correct lysosomal gene that is defective in juvenile neuronal ceroid lipofuscinosis. Delivered via a single injection, these drugs are only given once.

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 AB0-101 or AB0-102 are well tolerated with minimal side effects.

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

ABO-201 (AAV CLN3) is an AAV-based gene therapy which has shown promising preclinical efficacy in delivery of a normal copy of the defective CLN3 gene to cells of the central nervous system with the aim of reversing the effects of the genetic errors that cause JNCL. JNCL is a rare, fatal, autosomal recessive (inherited) disorder of the nervous system that typically begins in children between 4 and 8 years of age. Often the first noticeable sign of JNCL is vision impairment, which tends to progress rapidly and eventually result in blindness. As the disease progresses, children experience 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 JNCL disease.

JNCL 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 JNCL 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 JNCL 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. Reparing 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 aveolii.

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

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

Polymer Hydrogel Technology (PHT™)

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

MuGard® is our marketed product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no other established treatment. MuGard, a proprietary nanopolymer formulation, 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.

Intellectual Property

We believe that the value of technology both to us and to our potential corporate partners is established and enhanced by our broad intellectual property positions. Consequently, we have already been issued and seek to obtain additional U.S. and foreign patent protection for our products, including those under development and for new discoveries. Patent applications are filed with the U.S. Patent and Trademark Office and, when appropriate, with the Paris Convention's Patent Cooperation Treaty (PCT) Countries (most major countries in Western Europe and the Far East) for our inventions and prospective products.

We have a strategy of maintaining an ongoing line of patent continuation applications for each major category of patentable carrier and delivery technology. By this approach, we are extending the intellectual property protection of our basic targeting technology and initial agents to cover additional specific carriers and agents, some of which are anticipated to carry the priority dates of the original applications.

Gene licensed patents

We have secured an exclusive license through Nationwide Children's Hospital to the ABO-101 and ABO-102 patent portfolios for developing treatments for patients with Sanfilippo Syndrome Type A and Type B. This portfolio comprises one patent family: ''Products and methods for delivery of polynuleotides by adeno-associated virus for lysosomal storage disorders''. Additionally, we have secured FDA Orphan drug designation for both Sanfilippo A and B, which will provide 7 years of post-launch market exclusivity for both ABO-101 and ABO-102 in the U.S. ABO-101 and ABO-102 are also eligible for 12 years of Biologics exclusivity upon approval in the US and 10 years of exclusivity in the EU upon marketing authorization. We will be seeking Orphan Drug Status within the EMA, which will grant 10 years of post-market exclusivity in the European Union.

We licensed the rights to two patents (62/092,501 and 62/146,793) with an exclusive, worldwide, licensing agreement with the UNeMed Corporation. The patents are ''Compositions and Methods for the Treatment of Juvenile Neuronal Ceroid Lipofuscinosis'' and ''Gene Therapy for Juvenile Batten Disease'' for an AAV gene therapy for the treatment of juvenile Batten disease.

We licensed one patent (62/000,590), ''Method for Editing a Genetic Sequence'' with an exclusive, worldwide, licensing agreement with the University of Minnesota for an AAV gene therapy for the treatment of patients with Fanconi anemia (FA) disorder and other rare blood diseases.

We licensed two patents (13/594,773 and EPO 12756603.2) with a nonexclusive license agreement with Stanford University for an AAV delivery vector for the treatment of FA and rare blood disease platform.

Plasma based patents

We licensed our SDF patents from Licensor issued U.S. Patents #7,879,331, #7,879,332, and #8,293,242, the last of which expires in September 2025. We have also licensed issued patents in Europe, China and Australia and pending applications in Canada and India. SDF patents from Licensor the last of which expires in September 2025.

MuGard patents

For our mucoadhesive liquid technology, used in MuGard, two U.S. patents have been issued and two European patents have been granted. One European patent has been issued in 19 European countries the other patent is in nationalization process. Patents have also been granted, or are under review, in several other major

territories worldwide. Our mucoadhesive liquid technology patents and applications cover a range of products for a variety of diseases and conditions affecting the oral cavity, including the management of the various phases of mucositis. MuGard mucoadhesive technology patents expire in 2022

In addition to issued patents, we have a number of pending patent applications. If issued, the patents underlying these applications could extend the patent life of our technologies beyond the dates listed above.

Government Regulation

We are subject to extensive regulation by the federal government, principally by the FDA, and, to a lesser extent, by other federal and state agencies as well as comparable agencies in foreign countries where registration of products will be pursued. Although a number of our formulations incorporate extensively tested drug substances, because the resulting formulations make claims of enhanced efficacy and/or improved side effect profiles, they are expected to be classified as new drugs by the FDA.

The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern the testing, manufacturing, safety, labeling, storage, shipping and record keeping of our products. The FDA has the authority to approve or not approve new drug applications and inspect research, clinical and manufacturing records and facilities.

Among the requirements for drug approval and testing is that the prospective manufacturer's facilities and methods conform to the FDA's Code of Good Manufacturing Practices regulations, which establishes the minimum requirements for methods to be used in, and the facilities or controls to be used during, the production process. Such facilities are subject to ongoing FDA inspection to insure compliance.

The steps required before a pharmaceutical product may be produced and marketed in the U.S. include preclinical tests, the filing of an Investigational New Drug (''IND'') application with the FDA, which must become effective pursuant to FDA regulations before human clinical trials may commence, numerous phases of clinical testing and the FDA approval of a New Drug Application (NDA) prior to commercial sale.

Preclinical tests are conducted in the laboratory, usually involving animals, to evaluate the safety and efficacy of the potential product. The results of preclinical tests are submitted as part of the IND application and are fully reviewed by the FDA prior to granting the sponsor permission to commence clinical trials in humans. All trials are conducted under International Conference on Harmonization, good clinical practice guidelines. All investigator sites and sponsor facilities are subject to FDA inspection to insure compliance. Clinical trials typically involve a three-phase process. Phase 1 the initial clinical evaluations, consists of administering the drug and testing for safety and tolerated dosages and in some indications such as cancer and HIV, as preliminary evidence of efficacy in humans. Phase 2 involves a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosage and dose interval and to identify possible adverse side effects and risks in a larger patient group. When a product is found safe, and initial efficacy is established in Phase 2, it is then evaluated in Phase 3 clinical trials. Phase 3 trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit-to-risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of an NDA for approval to commence commercial sales.

The process of forming the requisite testing, data collection, analysis and compilation of an IND and an NDA is labor intensive and costly and may take a protracted time period. In some cases, tests may have to be redone or new tests instituted to comply with FDA requests. Review by the FDA may also take considerable time and there is no guarantee that an NDA will be approved. Therefore, we cannot estimate with any certainty the length of the approval cycle.

We are also governed by other federal, state and local laws of general applicability, such as laws regulating working conditions, employment practices, as well as environmental protection.

License Agreements

Gene therapy license agreements

On May 15, 2015, we acquired Abeona Therapeutics LLC which had a an exclusive license through Nationwide Children's Hospital to the AB-101 and AB-102 patent portfolios for developing treatments for patients with Sanfilippo Syndrome Type A and Type B. This portfolio comprises 1 patent family: ''Products

and methods for delivery of polynuleotides by adeno-associated virus for lysosomal storage disorders''. Additionally, Abeona has secured FDA Orphan drug designation for both Sanfilippo A and B, which will provide 7 years of post-launch market exclusivity for both ABX-A and ABX-B in the U.S. Abeona will be seeking Orphan Drug Status within the EMA, which will grant 10 years of post-market exclusivity in the European Union.

On June 5, 2015, we entered into an exclusive, worldwide, licensing agreement with the UNeMed Corporation, the technology transfer and commercialization office for the University of Nebraska Medical Center (UNMC) in Omaha, Nebraska, for an AAV gene therapy for the treatment of juvenile Batten disease. We licensed the rights to two patents (62/092,501 and 62/146,793). Under the terms of the licensing agreement, we paid a license fee of $75,000 and will pay milestone payments on certain milestone events. Commencing with the first commercial sale of licensed products a royalty will be paid. Terms of the agreement require we execute a sponsored research agreement with UNMC focused on additional efficacy studies within 12 months.

On October 14, 2015 we entered into a sponsored research agreement with UNMC to support ongoing AAV/CLN3 projects in the amount of $215,000.

On June 5, 2015, we entered into an exclusive, worldwide, licensing agreement with the University of Minnesota for an AAV gene therapy for the treatment of patients with Fanconi anemia (FA) disorder and other rare blood diseases. We licensed one patent (62/000,590), Method for Editing a Genetic Sequence. Under terms of the licensing agreement, we paid a license fee of $80,000, will pay an additional license fee of $50,000, will pay annual maintenance fees and a royalty fee with the first commercial sale of licensed products.

On September 17, 2015, we entered into a nonexclusive license agreement with Stanford University for an AAV delivery vector for the treatment of FA and rare blood disease platform. This license augments the University of Minnesota agreement. We licensed two patents (13/594,773 and EPO 12756603.2). Under terms of the licensing agreement, we paid a license fee of $25,000, will pay annual maintenance fees and a royalty fee with the first commercial sale of licensed products.

Plasma-based therapeutics license agreements

On September 22, 2014, we entered into an exclusive, worldwide, licensing agreement with Licensor to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma. Under the terms of the licensing agreement, as amended on January 23, 2015, we paid a license fee of $1 million in cash, will pay $4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process.

We believe that Licensor's proprietary fractionation process is expected to significantly enhance yields of key value blood proteins, including A1PI, expanding market opportunities, while greatly enhancing margins. The Company obtained rights to utilize and sub-license to other pharmaceutical firms the recently patented improved methods for the extraction of therapeutic biologics from human plasma. We believe that Licensor's lead product, A1PI, offers a low-risk, high revenue, short time to market respiratory product for treatment of inherited COPD (pulmonary emphysema), among other genetic A1PI deficiencies. Additionally, the ability to extract several additional therapeutically useful and important proteins, due to the process being less destructive than historical fractionation processes, may enable us to seek new therapeutic applications and address high-value-added orphan indications.

MuGard license agreements

On June 6, 2013 we entered into an exclusive license agreement with AMAG related to the commercialization of MuGard in the U.S. and its territories. Under the terms of the licensing agreement, we received an upfront licensing fee of $3.3 million and will receive a tiered, double-digit royalty on net sales of MuGard in the licensed territories. AMAG also purchased our existing MuGard inventory. The $3.3 million license fee is accounted for as deferred revenue and is recognized over ten years, which is the life of the license agreement.

The license term expires June 6, 2023. The license can also terminate in the event of breach by either us or AMAG or by AMAG at anytime with 180 days prior notice of termination.

On March 11, 2014, we announced we had entered into an exclusive license agreement with Hanmi related to MuGard commercialization in South Korea. Under the terms of the agreement, we received an upfront licensing fee and double digit royalties on sales of MuGard in the licensed territory. The license term expires February 26, 2024. The license can also terminate in the event of breach or by Hanmi at anytime with 180 days prior notice of termination.

On August 7, 2014, we entered into an exclusive license agreement with Norgine, a leading independent European specialty pharmaceutical company, for the commercialization of MuGard in Europe. Under the terms of the license agreement, we could receive up to $10 million in milestone payments and an escalating double digit royalty on the net sales of the oral mucositis product, MuGard, in the licensed territories. Norgine will develop, manufacture, and commercialize MuGard in the European Union, Switzerland, Norway, Iceland and Lichtenstein. Norgine anticipates launching MuGard in 2016.

Competition

The pharmaceutical and biotechnology industry is characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and other product areas where we may develop and market products in the future. Most of our potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater financial, marketing, sales and technical resources than are available to us. Additionally, many of our potential competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with our product lines. Our potential products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be addressed by our developments, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our potential competitors. Our business, financial condition and results of operation could be materially adversely affected by any one or more of such developments. We cannot assure you that we will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or with the assistance of major health care companies in areas where we are developing product candidates. We are aware of certain development projects for products to treat or prevent certain diseases targeted by us, and the existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed by us.

Gene therapy competition

The gene therapy industry is highly competitive and driven by several large competitors including Bluebird, Voyager, Regenx, Spark, Dimension, Avalanche, Uniqure, and Lysogene. We face competition from both US based and international based producers of plasma products who may have greater access to capital, production facilities and resources for both research and development as well as commercialization.

Plasma-based therapeutics competition

The plasma therapeutics industry is highly competitive and driven by several large competitors including Baxter International, Inc. (‘‘Baxter’’), CSL Behring (‘‘CSL’’) and Grifols SA (‘‘Grifols’’). Each of these groups produce A1PI under the name of the following, Baxter (Aralast, license of Glassia from Kamada), CSL (Zemairia) and Grifols (Prolastin) Other regional competitors include, but are not limited to, BPL, Kedrion, LFB Group SA, and Octapharma AG. We face competition from both US based and international based producers of plasma products who may have greater access to capital, production facilities and resources for both research and development as well as supplies of plasma.

Furthermore, plasma derived products also face competition from products that are not derived from plasma, and other courses of treatment.

MuGard competition

ActoGeniX N.V., Alder Biopharmaceuticals, Inc., Applied Protein Sciences, LLC, Avaxia Biologics, Inc., BioAlliance Pharma S.A., BMG Pharma s.r.l., Camurus AB, DARA BioSciences, Inc. EUSA Pharma, Galera Therapeutics, Inc. Maya Biotech Ltd., NephRx, Piramal Healthcare Ltd., Soligenix, Inc. and Synedgen are developing products to treat mucositis that may compete with our mucoadhesive liquid technology. Products which are marketed to treat mucositis include Caphosol by EUSA Pharma, Gelclair by DARA BioSciences, Inc., Episil by Camurus AB, and Kepivance by Biovitrum.

Many of these competitors have greater financial and other resources, including larger research and development, marketing and manufacturing organizations. As a result, our competitors may successfully develop technologies and drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

In addition, some of our competitors have greater experience than we do in conducting preclinical and clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than we do. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage. Drugs resulting from our research and development efforts or from our joint efforts with collaborative partners therefore may not be commercially competitive with our competitors' existing products or products under development.

In the area of advanced drug delivery, which is the focus of our early stage research and development activities, a number of companies are developing or evaluating enhanced drug delivery systems. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as various alternative delivery system technologies achieve similar if not identical advantages.

Even if our products are fully developed and receive required regulatory approval, of which there can be no assurance, we believe that our products can only compete successfully if marketed by a company having expertise and a strong presence in the therapeutic area. Consequently, we do not currently plan to establish an internal marketing organization. By forming strategic alliances with major and regional pharmaceutical companies, management believes that our development risks should be minimized and that the technology potentially could be more rapidly developed and successfully introduced into the marketplace.

Other Key Developments

2015 Financings

On April 23, 2015 we closed a $7 million private placement of common stock consisting of 2,333,333 shares of our common stock, at a price of $3.00 per share.

On May 11, 2015, we closed a $10 million private placement of common stock consisting of 1,250,000 shares of our common stock, at a price of $8.00 per share and warrants to purchase 625,000 shares of common stock. The warrants have an exercise price of $8.00 per share and are exercisable for 30 months from the closing date. A total net of $9.2 million was received.

Also in connection with the financing, the placement agent received warrants to purchase 50,000 shares of common stock at $11.00 per share and which are exercisable for five years from the closing date.

During the second quarter we received additional financing of $4.6 million through warrant exercises of our $5.00 warrants.

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.

$14 Million Financing

On December 24, 2014, we announced the closing of an underwritten public offering of 3,500,000 shares of our common stock, and warrants to purchase up to an aggregate 3,500,000 shares of common stock, at an offering price of $4.00 per share and $.01 per warrant. The warrants have a per share exercise price of $5.00,

are exercisable immediately, and expire 5 years from the date of issuance. The gross proceeds to the Company from this offering were $14,035,000, before deducting underwriting discounts and commissions and other estimated offering expenses. All of the shares and warrants in the offering were sold by the Company. The shares and warrants began trading on The NASDAQ Capital Market on December 19, 2014 under the symbols ''PTBI'' and ''PTBIW,'' respectively. In connection with the closing of the public offering, on December 24, 2014, all of our outstanding Series A and Series B preferred stock was converted into common stock.

Acquisition of Abeona Therapeutics LLC

On May 5, 2015, the Company, Plasmatech Merger Sub Inc. (''Merger Sub''), a wholly owned subsidiary of the Company and a Delaware corporation, Abeona Therapeutics LLC, an Ohio limited liability company (''Abeona Ohio'') and Paul A. Hawkins, an individual, solely in his capacity as Member Representative (''Member Representative'') entered into an Agreement and Plan of Merger (the ''Merger Agreement''). Pursuant to the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub merged with and into Abeona Ohio, with Abeona Ohio continuing as the surviving corporation and became a wholly owned subsidiary of the Company (the ''Merger''). Our Board of Directors and the Managers of Abeona Ohio have unanimously approved the transaction. The merger closed on May 15, 2015.

In connection with the Merger, the Company issued to Abeona Ohio members a total of 3,979,761 common shares upon closing of the transaction, and may issue up to an additional $9 million in performance milestones, in common stock or cash, at the Company's option.

Plasma Technologies LLC License ("Licensor")

On September 22, 2014, we entered into an exclusive, worldwide licensing agreement with Licensor to obtain rights to utilize and to sub-license its patented methods for the extraction of therapeutic biologics from human plasma. Plasma biologics are bio-pharmaceutical 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. Because plasma biologics are biosimilar, they are less likely than recombinant or transgenic proteins to cause toxic or other adverse reactions, or cause adverse immunological responses such as the stimulation of inhibitors in recipients.

Under the terms of the licensing agreement, as amended on January 23, 2015, we paid a license fee of $1 million in cash, will pay $4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process.

Miscellaneous

On March 5, 2015 we announced that enrollment has begun in a clinical trial at UCLA's Jonsson Comprehensive Cancer Center that is evaluating MuGard in the prevention and treatment of stomatitis in breast cancer patients using Everolimus (marketed by Novartis Oncology under the tradename Afinitor®). The title of the trial is ''Phase II Randomized Trial of MuGard Compared With Best Supportive Care for Prevention and Treatment of Stomatitis in Women With Hormone Receptor Positive Breast Cancer Initiating Treatment With Everolimus-based Endocrine Therapy'' and details on the trial design and enrollment can be found on its website, clinicaltrials.gov, under the identifier NCT02015559.

On March 31, 2015 we announced that Hanmi has received marketing approval in Korea from the country's Ministry of Food and Drug Safety (''MFDS'') and the Korea Testing & Research Institute (KTR) for MuGard. Under the terms of the previously announced marketing agreement, Hanmi will import MuGard from the United States and marketing will commence. Hanmi intends to market MuGard in Korea under the trade name Mucogard.

On April 7, 2015 we announced we had appointed Charlie Strange, M.D. to our Scientific Advisory Board (SAB). Dr. Strange is a highly regarded thought leader in the Alpha-1 community, and has extensive clinical experience in designing and managing Alpha-1 clinical studies. We believe his advice and counsel will help accelerate development and approval of our proprietary SDF Alpha™ biologic drug.

On May 12, 2015 we announced that Todd Wider, MD joined our board of directors. Dr. Wider has a strong medical background and significant experience in small and mid-cap biotechnology companies.

On May 15, 2015 Timothy J. Miller, PhD became our President and CEO and joined our board of directors. Dr. Miller was President & CEO of Abeona Therapeutics LLC from 2013 to 2015. He has 16 years of scientific research, product development, regulatory and clinical operations expertise, with a focus on transitioning novel biotherapeutics through pre-clinical phases and into Phase 1 and 2 human clinical trials. Dr. Miller earned his PhD in Pharmacology with a focus on Gene therapy/Cystic Fibrosis from Case Western University. He also holds a B.S. in Biology and M.S. in Molecular Biology from John Carroll University (Cleveland, OH).

On June 8, 2015 we licensed exclusive worldwide rights to an AAV gene therapy and intellectual property for the treatment of JNCL also known as juvenile Batten disease from UNeMed Corporation, the technology transfer and commercialization office for the University of Nebraska Medical Center in Omaha, Nebraska for undisclosed terms.

On June 15, 2015 we licensed exclusive worldwide rights to an AAV gene therapy and intellectual property from the University of Minnesota to treat patients with Fanconi anemia (FA) disorder and other rare blood diseases using the CRISPR/cas9 technology platform for undisclosed terms.

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

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 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 January 11, 2016 we announced initial regulatory approval for Phase 1/2 gene therapy clinical studies for patients with Sanfilippo syndrome types A and B. The Interministerial Council of Genetically Modified Organisms has approved the Genetically Modified Organism (GMO) Voluntary Release regulatory filings for both Phase 1/2 Gene Therapy Clinical Studies to treat patients with ABO-101 (AAV NAGLU) and ABO-102 (AAV SGSH) for patients with Sanfilippo syndrome type A (MPS IIIA) or type B (MPS IIIB). Additionally, the Comite Etico De Investigacion Clinica de Euskadi (CEIC-E) has approved the ethical committee regulatory filings for both ABO-101 and ABO-102. Abeona plans to file CTAs for both programs shortly for the upcoming clinical studies to be conducted at Cruces University Hospital (Bilbao, Spain).

On February 29, 2016 we announced the FDA cleared our Investigational New Drug Application for ABO-102 (AAV-SGSH), a single treatment strategy for Mucopolysaccharidosis Type IIIA (MPS IIIA). The ABO-102 IND application is now active and enables Nationwide Children's Hospital (Columbus, OH) to initiate a Phase 1/2 clinical study designed to assess the safety, tolerability and potential efficacy of ABO-102 in children with MPS III A.

Corporate Information

Our principal executive office is located at 3333 Lee Parkway, Suite 600, Dallas, Texas 75219. Our telephone number is (214) 665-9495. We also have offices in New York at 1325 Avenue of the Americas, 27th Floor, New York, NY 10019. Our telephone number is (212) 786-6208. We also have offices and laboratory in Ohio at 6555 Carnegie Ave., 4th Floor, Cleveland, OH 44103.

We were incorporated in Wyoming in 1974 as Chemex Corporation, and in 1983 we changed our name to Chemex Pharmaceuticals, Inc. We changed our state of incorporation from Wyoming to Delaware on June 30, 1989. In 1996 we merged with Access Pharmaceuticals, Inc., a private Texas corporation, and changed our name to Access Pharmaceuticals, Inc. On October 24, 2014 we changed our name to PlasmaTech Biopharmaceuticals, Inc. On June 19, 2015 we changed our name to Abeona Therapeutics Inc.

Suppliers

Some materials used by us are specialized. We obtain materials from several suppliers based in different countries around the world. If materials are unavailable from one supplier we generally have alternate suppliers available.

Employees

As of March 30, 2016, we had 15 full-time employees, six of whom have advanced scientific degrees. We have never experienced employment-related work stoppages and consider that we maintain good relations with our personnel. In addition, to complement our internal expertise, we have contracts with scientific consultants, contract research organizations and university research laboratories that specialize in various aspects of drug development including clinical development, regulatory affairs, toxicology, process scale-up and preclinical testing.

Web Availability

We make available free of charge through our website, *www.abeonatherapeutics.com*, our annual reports on Form 10-K and other reports that we file with the Securities and Exchange Commission as well as certain of our corporate governance policies, including the charters for the audit, compensation and nominating and corporate governance committees of the Board of Directors (the ''Board'') and our code of ethics, corporate governance guidelines and whistleblower policy. We will also provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to us at: Abeona Therapeutics Inc. c/o Investor Relations, 3333 Lee Parkway, Suite 600, Dallas, TX 75219.

ITEM 1A. RISK FACTORS

Risks Relating to our Business and Industry

We have experienced a history of losses, we expect to incur future losses and we may be unable to obtain necessary additional capital to fund operations in the future.

We have recorded minimal revenue to date and have incurred an accumulated deficit of approximately $310.6 million through December 31, 2015 and $296.1 million through December 31, 2014. Net loss allocable to common stockholders for the year ended December 31, 2015 was $14.5 million and the net loss for the year ended December 31, 2014 was $29.7 million. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop clinical drug candidates, from losses due to derivatives and from the associated administrative costs. We expect to incur additional operating losses over the next several years. We also expect cumulative losses to increase if we expand research and development efforts and preclinical and clinical trials.

We require substantial capital for our development programs and operating expenses, to pursue regulatory clearances and to prosecute and defend our intellectual property rights. We will need to raise substantial additional capital to support our ongoing and planned operations.

If we raise additional funds by issuing equity securities, further dilution to existing stockholders will result and future investors may be granted rights superior to those of existing stockholders. If adequate funds are not available to us through additional equity offerings, we may be required to delay, reduce the scope of or eliminate one or more of our research and development programs or to obtain funds by entering into arrangements with collaborative partners or others that require us to issue additional equity securities or to relinquish rights to certain technologies or drug candidates that we would not otherwise issue or relinquish in order to continue independent operations.

We do not have significant operating revenue and may never attain profitability.

To date, we have funded our operations primarily through private sales of common stock, preferred stock and convertible notes. Contract research payments and licensing fees from corporate alliances and mergers have also provided funding for our operations. Our ability to achieve significant revenue or profitability depends upon our licensees ability to successfully market MuGard in North America, Europe, Australia, New Zealand, Korea and China or to complete the development of our drug candidates, to develop and obtain patent protection and regulatory approvals for our drug candidates and to manufacture and commercialize the resulting drugs. We are not expecting any significant revenues in the short-term from our products or product candidates. Furthermore, we may not be able to ever successfully identify, develop, commercialize, patent, manufacture, obtain required regulatory approvals and market any additional products. Moreover, even if we do identify, develop, commercialize, patent, manufacture, and obtain required regulatory approvals to market additional products, we may not generate revenues or royalties from commercial sales of these products for a significant number of years, if at all. Therefore, our proposed operations are subject to all the risks inherent in the establishment of a new business enterprise. In the next few years, our revenues may be limited to minimal product sales and royalties, and any amounts that we receive under strategic partnerships and research or drug development collaborations that we may establish and, as a result, we may be unable to achieve or maintain profitability in the future or to achieve significant revenues in order to fund our operations.

We may not successfully commercialize our drug candidates.

Our drug candidates are subject to the risks of failure inherent in the development of pharmaceutical products based on new technologies, and our failure to develop safe commercially viable drugs would severely limit our ability to become profitable or to achieve significant revenues. We may be unable to successfully commercialize our drug candidates because:

- some or all of our drug candidates may be found to be unsafe or ineffective or otherwise fail to meet applicable regulatory standards or receive necessary regulatory clearances;
- our drug candidates, if safe and effective, may be too difficult to develop into commercially viable drugs;

- it may be difficult to manufacture or market our drug candidates on a large scale;
- proprietary rights of third parties may preclude us from marketing our drug candidates; and
- third parties may market superior or equivalent drugs.

The success of our research and development activities, upon which we primarily focus, is uncertain.

Our primary focus is on our research and development activities and the commercialization of compounds covered by proprietary biopharmaceutical patents and patent applications. Research and development activities, by their nature, preclude definitive statements as to the time required and costs involved in reaching certain objectives. Actual research and development costs, therefore, could significantly exceed budgeted amounts and estimated time frames may require significant extension. Cost overruns, unanticipated regulatory delays or demands, unexpected adverse side effects or insufficient therapeutic efficacy will prevent or substantially slow our research and development effort and our business could ultimately suffer. We anticipate that we will remain principally engaged in research and development activities for an indeterminate, but substantial, period of time.

We may be unable to successfully develop, market, or commercialize our products or our product candidates without establishing new relationships and maintaining current relationships and our ability to successfully commercialize, and market our product candidates could be limited if a number of these existing relationships are terminated.

Our strategy for the research, development and commercialization of our potential pharmaceutical products may require us to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others, in addition to our existing relationships with other parties. Specifically, we may seek to joint venture, sublicense or enter other marketing arrangements with parties that have an established marketing capability or we may choose to pursue the commercialization of such products on our own. We may, however, be unable to establish such additional collaborative arrangements, license agreements, or marketing agreements as we may deem necessary to develop, commercialize and market our potential pharmaceutical products on acceptable terms. Furthermore, if we maintain and establish arrangements or relationships with third parties, our business may depend upon the successful performance by these third parties of their responsibilities under those arrangements and relationships.

We may be unable to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes without the assistance of contract manufacturers, which may be difficult for us to obtain and maintain.

We have limited experience in the manufacture of pharmaceutical products in clinical quantities or for commercial purposes and we may not be able to manufacture any new pharmaceutical products that we may develop. As a result, we have established, and in the future intend to establish arrangements with contract manufacturers to supply sufficient quantities of products to conduct clinical trials and for the manufacture, packaging, labeling and distribution of finished pharmaceutical products if any of our potential products are approved for commercialization. If we are unable to contract for a sufficient supply of our potential pharmaceutical or biopharmaceutical products on acceptable terms, our preclinical and human clinical testing schedule may be delayed, resulting in the delay of our clinical programs and submission of product candidates for regulatory approval. This may cause our business to suffer if there are delays or difficulties in establishing relationships with manufacturers to produce, package, label and distribute our finished pharmaceutical or biopharmaceutical or other medical products, if any. Moreover, US contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by the FDA. In this regard, the FDA will not issue a pre-market approval or product and establishment licenses, where applicable, to a manufacturing facility for the products until the manufacturing facility passes a pre-approval plant inspection. If we are unable to obtain or retain third party manufacturing on commercially acceptable terms, we may not be able to commercialize our products as planned. Our potential dependence upon third parties for the manufacture of our products may adversely affect our ability to generate profits or acceptable profit margins and our ability to develop and deliver such products on a timely and competitive basis.

We are subject to extensive governmental regulation which increases our cost of doing business and may affect our ability to commercialize any new products that we may develop.

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of pharmaceutical products through lengthy and detailed laboratory, preclinical and clinical testing procedures and other costly and time-consuming procedures to establish safety and efficacy. All of our drugs and drug candidates require receipt and maintenance of governmental approvals for commercialization. Preclinical and clinical trials and manufacturing of our drug candidates will be subject to the rigorous testing and approval processes of the FDA and corresponding foreign regulatory authorities. Satisfaction of these requirements typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product.

Due to the time-consuming and uncertain nature of the drug candidate development process and the governmental approval process described above, we cannot assure you when we, independently or with our collaborative partners, might submit a New Drug Application, or NDA, for FDA or other regulatory review. Further, our ability to commence and/or complete development projects will be subject to our ability to raise enough funds to pay for the development costs of these projects. Government regulation also affects the manufacturing and marketing of pharmaceutical products. Government regulations may delay marketing of our potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon our activities and furnish a competitive advantage to larger companies or companies more experienced in regulatory affairs. Delays in obtaining governmental regulatory approval could adversely affect our marketing as well as our ability to generate significant revenues from commercial sales.

Our drug candidates may not receive FDA or other regulatory approvals on a timely basis or at all. Moreover, if regulatory approval of a drug candidate is granted, such approval may impose limitations on the indicated use for which such drug may be marketed. Even if we obtain initial regulatory approvals for our drug candidates, our drugs and our manufacturing facilities would be subject to continual review and periodic inspection, and later discovery of previously unknown problems with a drug, manufacturer or facility may result in restrictions on the marketing or manufacture of such drug, including withdrawal of the drug from the market. The FDA and other regulatory authorities stringently apply regulatory standards and failure to comply with regulatory standards can, among other things, result in fines, denial or withdrawal of regulatory approvals, product recalls or seizures, operating restrictions and criminal prosecution.

The uncertainty associated with preclinical and clinical testing may affect our ability to successfully commercialize new products.

Before we can obtain regulatory approvals for the commercial sale of any of our potential drugs, the drug candidates will be subject to extensive preclinical and clinical trials to demonstrate their safety and efficacy in humans. Preclinical or clinical trials of future drug candidates may not demonstrate the safety and efficacy to the extent necessary to obtain regulatory approvals and our drug candidates could result in injury or death to patients in our clinical trials. In this regard, for example, adverse side effects can occur during the clinical testing of a new drug on humans which may delay ultimate FDA approval or even lead it to terminate our efforts to develop the drug for commercial use. Companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after demonstrating promising results in earlier trials, including injury or death. The failure to adequately demonstrate the safety and efficacy of a drug candidate under development could delay or prevent regulatory approval of the drug candidate. A delay or failure to receive regulatory approval for any of our drug candidates could prevent us from successfully commercializing such candidates and we could incur substantial additional expenses in our attempt to further develop such candidates and obtain future regulatory approval.

We may incur substantial product liability expenses due to the use or misuse of our products for which we may be unable to obtain insurance coverage.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. These risks will expand with respect to our drug candidates, if any, that receive regulatory approval for commercial sale and we may face substantial liability for damages in the event of adverse side effects, including injury or death, or product defects identified with any of our products that

are used in clinical tests or marketed to the public. Product liability insurance for the biotechnology industry is generally expensive, if available at all, and as a result, we may be unable to obtain insurance coverage at acceptable costs or in a sufficient amount in the future, if at all. We may be unable to satisfy any claims for which we may be held liable as a result of the use or misuse of products which we developed, manufactured or sold and any such product liability claim could adversely affect our business, operating results or financial condition.

Intense competition may limit our ability to successfully develop and market commercial products.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our competitors in the U.S. and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of our competitors have and employ greater financial and other resources, including larger research and development, marketing and manufacturing organizations. As a result, our competitors may successfully develop technologies and drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

In addition, some of our competitors have greater experience than we do in conducting preclinical and clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than we can. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage. Drugs resulting from our research and development efforts or from our joint efforts with collaborative partners therefore may not be commercially competitive with our competitors' existing products or products under development.

Our ability to successfully develop and commercialize our drug candidates will substantially depend upon the availability of reimbursement funds for the costs of the resulting drugs and related treatments.

Market acceptance and sales of our product candidates may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third-party payers, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payors pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that coverage or reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates reimbursed by government or third party payors. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to commercialize our products. In recent years, officials have made numerous proposals to change the health care system in the U.S. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the U.S., third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs.

The market may not accept any pharmaceutical products that we develop.

The drugs that we are attempting to develop may compete with a number of well-established drugs manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any drugs developed by us will depend on a number of factors, including the establishment and demonstration of the clinical efficacy and safety of our drug candidates, the potential advantage of our drug candidates over existing therapies and the reimbursement policies of government and third-party payers. Physicians, patients or the medical community in general may not accept or use any drugs that we may develop independently or with our collaborative partners and if they do not, our business could suffer.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, in March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA. This law will substantially change the way healthcare is financed by both government health plans and private insurers, and significantly impact the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of our products. In addition, as part of the PPACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the ''donut hole''), we will be required to provide a discount on branded prescription drugs equal to 50% of the government-negotiated price, for drugs provided to certain beneficiaries who fall within the donut hole. Similarly, PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by Medicaid managed care organizations. The PPACA also includes significant changes to the 340B drug discount program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive our products. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and sub regulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no assurances that future legislation or regulations will not decrease the coverage and price that we may receive for our proposed products. Other third-party payors are

increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our proposed products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunities. Our results of operations could be materially adversely affected by proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future. In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

Our business could suffer if we lose the services of, or fail to attract, key personnel.

We are highly dependent upon the efforts of our senior management, including our Executive Chairman, Principal Executive Officer, and board member, Steven H. Rouhandeh; our President and Chief Executive Officer, and board member, Timothy J. Miller; our Chief Operating Officer and board member, Jeffrey B. Davis; our Chief Financial Officer, Harrison G. Wehner, III; and our Chief Accounting Officer, Stephen B. Thompson. The loss of the services of these individuals could delay or prevent the achievement of our research, development, marketing, or product commercialization objectives. We do not have employment contracts with our other key personnel. We do not maintain any 'key-man' insurance policies on any of our key employees and we do not intend to obtain such insurance. In addition, due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific and technical personnel and consultants. In view of the stage of our development and our research and development programs, we have restricted our hiring to research scientists, consultants and a small administrative staff and we have made only limited investments in manufacturing, production, sales or regulatory compliance resources. There is intense competition among major pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions for qualified personnel in the areas of our activities, however, and we may be unsuccessful in attracting and retaining these personnel.

Trends toward managed health care and downward price pressures on medical products and services may limit our ability to profitably sell any drugs that we may develop.

Lower prices for pharmaceutical products may result from:

- third-party-payers' increasing challenges to the prices charged for medical products and services;
- the trend toward managed health care in the U.S. and the concurrent growth of HMOs and similar organizations that can control or significantly influence the purchase of healthcare services and products; and
- legislative proposals to reform healthcare or reduce government insurance programs.

The cost containment measures that healthcare providers are instituting, including practice protocols and guidelines and clinical pathways, and the effect of any healthcare reform, could limit our ability to profitably sell any drugs that we may successfully develop. Moreover, any future legislation or regulation, if any, relating to the healthcare industry or third-party coverage and reimbursement, may cause our business to suffer.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our business partners and third party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our business partners or third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Risks Related to our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure protection of such rights.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. We will only be able to protect our product candidates from unauthorized making, using, selling and offering to sell or importation by third parties to the extent that we have rights under valid and enforceable patents or trade secrets that cover these activities. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S. The biotechnology patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our issued patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to produce compounds or molecules that are competitive with our product candidates but that are not covered by the claims of our patents;
- we may not have been the first to make the inventions covered by our pending patent applications;
- we may not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents and it is possible that our issued patents could be narrowed in scope, invalidated, held to be unenforceable, or circumvented;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business; or others may be able to misappropriate our trade secrets.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the

outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Our competitors have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO, to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Future litigation, including product liability claims, private securities litigation, stockholder derivative suits and contract litigation, may adversely affect our financial condition and results of operations or liquidity.

The development, manufacture and marketing of pharmaceutical products of the types that we produce entail an inherent risk of product liability claims. A number of factors could result in an unsafe condition or injury to a patient with respect to these or other products that we manufacture or sell, including inadequate disclosure of product-related risks or product-related information. In addition, we may be the subject of litigation involving contract disputes, stockholder derivative suites or private securities litigation. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, including not only actual damages, but

also punitive damages. The magnitude of the potential losses relating to these lawsuits may remain unknown for substantial periods of time. In addition, the cost to defend against any future litigation may be significant. Product liability claims, securities and commercial litigation and other litigation in the future, regardless of the outcome, could have a material adverse effect on our financial condition, results of operations or liquidity.

We may not be successful in protecting our intellectual property and proprietary rights.

Our success depends, in part, on our ability to obtain U.S. and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate our business without infringing the proprietary rights of third parties. Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under such patents are still developing and there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. The patent position of a biotechnology firm is highly uncertain and involves complex legal and factual questions. We cannot assure you that any existing or future patents issued to, or licensed by, us will not subsequently be challenged, infringed upon, invalidated or circumvented by others. We cannot assure you that any patents will be issued from any of the patent applications owned by, or licensed to, us. Furthermore, any rights that we may have under issued patents may not provide us with significant protection against competitive products or otherwise be commercially viable.

Patents may have been granted to third parties or may be granted covering products or processes that are necessary or useful to the development of our drug candidates. If our drug candidates or processes are found to infringe upon the patents or otherwise impermissibly utilize the intellectual property of others, our development, manufacture and sale of such drug candidates could be severely restricted or prohibited. In such event, we may be required to obtain licenses from third parties to utilize the patents or proprietary rights of others. We cannot assure you that we will be able to obtain such licenses on acceptable terms, if at all. If we become involved in litigation regarding our intellectual property rights or the intellectual property rights of others, the potential cost of such litigation, regardless of the strength of our legal position, and the potential damages that we could be required to pay could be substantial.

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.

Risks Related to our Common Stock

The market price of our common stock may be volatile and adversely affected by several factors.

The market price of our common stock could fluctuate significantly in response to various factors and events, including:

- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- announcements concerning product development results, including clinical trial results, or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- loss of any strategic relationship;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies; economic and other external factors;
- period-to-period fluctuations in our financial results; and
- whether an active trading market in our common stock develops and is maintained.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

We have not paid cash dividends in the past and do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the common stock price appreciates.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially.

Provisions of our charter documents could discourage an acquisition of our company that would benefit our stockholders and may have the effect of entrenching, and making it difficult to remove, management.

Provisions of our Certificate of Incorporation and By-laws may make it more difficult for a third party to acquire control of us, even if a change in control would benefit our stockholders. In particular, shares of our preferred stock may be issued in the future without further stockholder approval and upon such terms and conditions, and having such rights, privileges and preferences, as our Board of Directors may determine, including, for example, rights to convert into our common stock. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any of our preferred stock that may be issued in the future. The issuance of our preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire control of us. This could limit the price that certain investors might be willing to pay in the future for shares of our common stock and discourage these investors from acquiring a majority of our common stock. Further, the existence of these corporate governance provisions could have the effect of entrenching management and making it more difficult to change our management.

Failure to achieve and maintain effective internal controls could have a material adverse effect on our business.

Effective internal controls are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our operating results could be harmed. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Based on our evaluation, our management concluded that there is no material weakness in our internal control over financial reporting for the year ended December 31, 2015 based on the criteria established in Internal Control — Integrated Framework, 2013, issued by the Committee of Sponsoring Organizations of the Treadway Commission (''COSO'').

While we continue to evaluate and improve our internal controls, we cannot be certain that these measures will ensure adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Failure to achieve and maintain an effective internal control environment could cause investors to lose confidence in our reported financial information, which could have a material adverse effect on our stock price. Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the Securities and Exchange Commission (''SEC'') or other regulatory authorities.

There can be no assurance that we will be able to comply with continued listing standards of the NASDAQ Capital Market.

We cannot assure you that we will be able to continue to comply with the minimum bid price and the other standards that we are required to meet in order to maintain a listing of our common stock on the NASDAQ Capital Market. Our failure to continue to meet these requirements may result in our common stock being delisted from the NASDAQ Capital Market.

Our ability to use our net operating loss carry forwards may be subject to limitation.

Generally, a change of more than 50% in the ownership of a company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit our ability to use our net operating loss carryforwards attributable to the period prior to the change. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for us. At December 31, 2015, we had net operating loss carryforwards aggregating approximately $209.7 million.

Ownership of our shares is concentrated in the hands of a few investors which could limit the ability of our other stockholders to influence the direction of the company.

As calculated by SEC rules of beneficial ownership, SCO Capital Partners LLC and affiliates; Perceptive Advisors LLC (and affiliates Joseph Edelman); Quantum Partners (and affiliates Soros Fund Management LLC); and Europa International Inc. (and affiliates Knoll Capital Management) each beneficially owned approximately 42.2%, 5.2%, 5.2% and 5.1%, respectively, of our common stock as of December 31, 2015. Accordingly, they collectively have the ability to significantly influence or determine the election of all of our directors or the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of our other stockholders.

ITEM 2. PROPERTIES

We maintain approximately 2,000 square feet of business office suites for administrative offices in New York, New York. We have a lease agreement for the facility, which terminates in December 2016. We also have administrative offices in Dallas, Texas. We have a lease agreement for the facility, which terminates in August 2016. We also have a laboratory and administrative offices of approximately 11,600 square feet in Cleveland, Ohio with an additional 4,377 square feet available this year. We have a lease agreement for the facility, which terminates in December 2025.

We believe that our existing properties are suitable for the conduct of our business and adequate to meet our present needs.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

EXECUTIVE OFFICERS OF THE REGISTRANT

Mr. Steven H. Rouhandeh, became our Executive Chairman, Principal Executive Officer, on January 1, 2015. Mr. Rouhandeh has been a director and Chairman of the Board since March 4, 2008. He has been Chief Investment Officer of SCO Capital Partners, a group of New York based life sciences funds since 1997. Mr. Rouhandeh possesses a diverse background in financial services that includes experience in asset management, corporate finance, investment banking and law. He has been active throughout recent years as an executive in venture capital and as a founder of several companies in the biotech field. His experience also includes positions as Managing Director of a private equity group at Metzler Bank, a private European investment firm and Vice President, Investment Banking at Deutsche Bank. Mr. Rouhandeh was also a corporate attorney at New York City-based Cravath, Swaine & Moore. Mr. Rouhandeh holds a J.D., from Harvard Law School, Harvard University and B.A. Political Science, from Southern Illinois University.

Timothy J. Miller, Ph.D., became our President and Chief Executive Officer and Director on May 15, 2015. Dr. Miller was President & CEO of Abeona Therapeutics LLC from 2013 to 2015. He has 16 years of scientific research, product development, regulatory and clinical operations expertise, with a focus on transitioning novel biotherapeutics through pre-clinical phases and into Phase 1 and 2 human clinical trials. Dr. Miller was President & CEO of Red5 Pharmaceuticals from 2013 until 2015 and was Vice President, Business Development of BioEnterprise Inc. in 2015. He was Senior Director of Product Development at SironRX Therapeutics from 2010 to 2013. Between 1996 and 2010 Dr. Miller held various positions at several companies focusing on gene therapy and regenerative medicine. Dr. Miller earned his PhD in Pharmacology with a focus on Gene therapy/Cystic Fibrosis from Case Western University. He also holds a B.S. in Biology and M.S. in Molecular Biology from John Carroll University (Cleveland, OH).

Mr. Jeffrey B. Davis became our Chief Operating Officer on January 19, 2015. Mr. Davis is also a director since March 2006. Mr. Davis was our Chief Executive Officer from December 26, 2007 until September 19, 2014. Mr. Davis became Acting Chief Financial Officer, Treasurer and Secretary on November 1, 2013 through September 19, 2014. Previously, Mr. Davis served in a variety of senior investment banking and management positions, and in senior management at a publicly traded healthcare technology company. Prior to that, Mr. Davis was an investment banker with various Deutsche Bank banking organizations, both in the U.S. and Europe. Mr. Davis also served in senior marketing and product management positions at AT&T Bell Laboratories, where he was also a member of the technical staff, and at Philips Medical Systems North America. Mr. Davis is currently on the board of Uluru, Inc., a public biotechnology company. Mr. Davis holds a B.S. in biomedical engineering from Boston University and an M.B.A. degree from the Wharton School, University of Pennsylvania.

Mr. Harrison G. Wehner became our Chief Financial Officer on September 19, 2014. Mr. Wehner previously was a Managing Director with Plasma Technologies LLC since June 1, 2014. He has over 20 years' experience in investment banking advising on equity and debt finance and mergers and acquisitions advisory assignments. Previously, Mr. Wehner held various senior banking roles at Canaccord Genuity from 2012 to

2013, with CitiGroup from 2005 to 2011, and UBS from 1994 to 2005 where he worked on a variety of banking transactions in the healthcare sector, including advisory and transactional experience in the blood fractionation industry. Mr. Wehner holds a BA from The College of William and Mary, and an MBA from the Ross School of Business at the University of Michigan.

Stephen B. Thompson, Vice President Finance, became the Chief Accounting Officer, Secretary and Treasurer on January 1, 2015. Mr. Thompson consulted with the Company from December 1, 2013 through December 31, 2014. Prior to December 1, 2013 Mr. Thompson was our Vice President from 2000 and our Chief Financial Officer from 1996. From 1990 to 1996, he was Controller and Administration Manager of Access Pharmaceuticals, Inc., a private Texas corporation. Previously, from 1989 to 1990, Mr. Thompson was Controller of Robert E. Woolley, Inc., a hotel real estate company where he was responsible for accounting, finances and investor relations. From 1985 to 1989, he was Controller of OKC Limited Partnership, an oil and gas company, where he was responsible for accounting, finances and SEC reporting. Between 1975 and 1985 he held various accounting and finance positions with Santa Fe International Corporation.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Price Range of Common Stock and Dividend Policy

Our common stock has traded on The NASDAQ Capital Market (''NASDAQ'') under the symbol ABEO since June 22, 2015. We also changed our corporate name to Abeona Therapeutics Inc. on June 19, 2015.

Our stock traded under the following symbols and markets during these time periods

- PTBI — NASDAQ — from December 19, 2014 until June 19, 2015
- PTBI — OTC Bulletin Board, or OTCQB — from November 21, 2014 until December 17, 2014
- ACCPD — OTCQB — from October 24, 2014 until November 21, 2014
- ACCP — OTCQB — from June 5, 2006 until October 24, 2014

On October 24, 2014 we changed our corporate name to PlasmaTech Biopharmaceuticals, Inc. from Access Pharmaceuticals, Inc. and effected a 1 for 50 reverse stock split.

The following table sets forth, for the periods indicated, the high and low closing prices as reported by NASDAQ and OTCQB for our common stock for fiscal years 2014 and 2013. The OTCQB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

All per share information reflect a 1-for-50 reverse stock split effected on October 24, 2014.

	Common Stock	
	High	Low
Fiscal Year Ended December 31, 2015		
First quarter	$ 3.55	$ 2.91
Second quarter	9.80	2.77
Third quarter	6.89	3.98
Fourth quarter	4.80	3.36
Fiscal Year Ended December 31, 2014		
First quarter	$29.50	$12.50
Second quarter	27.00	14.00
Third quarter	17.50	11.50
Fourth quarter	13.50	3.44

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. The payment of dividends, if any, in the future is within the discretion of our Board of Directors and will depend on our earnings, capital requirements and financial condition and other relevant facts. We currently intend to retain all future earnings, if any, to finance the development and growth of our business.

However, during 2014 we were required to pay dividends on our Series A preferred stock at the rate of 6% per year. We were also required to pay dividends on our Series B preferred stock at the rate of 12% per year. Both Series A and Series B preferred stock were converted into common stock on December 24, 2014. We currently have no outstanding shares of preferred stock.

The number of record holders of our common stock at March 29, 2016 was approximately 7,300. On March 29, 2016, the closing price for the common stock as quoted on NASDAQ was $2.86. There were 32,743,013 shares of common stock outstanding at March 30, 2016.

Equity Compensation Plan Information

The following table sets forth, as of December 31, 2015, information about shares of common stock outstanding and available for issuance under our existing equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options warrants and rights	Weighted-average exercise price of outstanding options warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders:			
2015 Equity Incentive Plan	1,994,000	$ 6.90	1,601,323
2015 Equity Incentive Plan	330,084	13.49	—
Equity compensation plans not approved by security holders	—	—	—
Total	2,324,084	$ 8.00	1,601,323

Issuer Purchases of Equity Securities

None

Recent Sales of Unregistered Securities

None

ITEM 6. SELECTED FINANCIAL DATA

Not applicable

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and related notes included in this Form 10-K.

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

Results of Operations

Comparison of Years Ended December 31, 2015 and December 31, 2014

Our licensing revenue for the year ended December 31, 2015 was $602,000 as compared to $598,000 for the same period of 2014, an increase of $4,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We recorded royalty revenue for MuGard of $438,000 for year ended December 31, 2015 as compared to $327,000 for the same period of 2014, an increase of $111,000. We licensed MuGard to AMAG and currently receive quarterly royalties from AMAG under our agreement.

Total research and development spending for the year ended December 31, 2015 was $4,715,000, as compared to $333,000 for the same period of 2014, an increase of $4,382,000. The increase in research and development expenses was primarily due to:

- increased development work on our products ($2,092,000);
- increased salary and related costs ($868,000) from increased scientific staff;
- increased stock based compensation expense for granted restricted stock ($345,000) and granted stock options ($617,000);
- scientific consulting ($157,000); and
- other net increases in research spending ($303,000).

Total general and administrative expenses were $14,320,000 for the year ended December 31, 2015, as compared to $3,712,000 for the same period of 2014, an increase of $10,608,000. The increase in expenses was due primarily to the following:

- increased stock based compensation expense for granted restricted stock ($4,504,000) and granted options ($1,841,000);
- increased investor relations expenses ($1,243,000);
- increased legal and audit fees ($1,238,000);
- increased salary and related costs ($992,000) from hiring additional general and administrative staff;
- increased director fees ($482,000); and
- net increase other general and administrative expenses ($308,000).

Depreciation and amortization was $551,000 for the year ended December 31, 2015 as compared to $11,000 for the same period in 2014, an increase of $540,000. The increase is due to amortization of licensed technology $529,000 and depreciation $11,000. We acquired new licenses and fixed assets in 2015.

Total operating expenses for the year ended December 31, 2015 were $19,586,000 as compared to total operating expenses of $4,056,000 for the same period of 2014, an increase of $15,530,000 for the reasons listed above.

Interest and miscellaneous income was $4,026,000 for the year ended December 31, 2015 as compared to $45,000 for the same period of 2014, an increase of $3,981,000. Miscellaneous income is higher in 2015 than for the same period in 2014 due to change in fair value of our contingent consideration liability ($3,898,000) related to the acquisition of Abeona Ohio and write-offs of certain accounts payables ($38,000) and interest income ($45,000).

Interest and other expense was $6,000 for the year ended December 31, 2015 as compared to $582,000 in the same period of 2014, a decrease of $576,000. 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 $23,110,000 for the year ended December 31, 2014. The preferred stock related to the dividends was converted into common stock in December 2014.

Preferred stock dividends of $2,875,000 were accrued for the year ended December 31, 2014. The preferred stock related to the dividends was converted into common stock in December 2014.

Net loss allocable to common stockholders for the year ended December 31, 2015 was $14,526,000, or a $0.53 basic and diluted loss per common share as compared to a net loss of $29,653,000, or a $15.26 basic and diluted loss per common share, for the same period in 2014, a decreased loss of $15,127,000.

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 December 31, 2015. As of December 31, 2015, our cash and cash equivalents were $40,138,000.

As of December 31, 2015, our working capital was $39,091,000. Our working capital at December 31, 2015 represented an increase of $30,434,000 as compared to our working capital as of December 31, 2014 of $8,657,000. The net increase in the working capital at December 31, 2015 reflects financings, warrant exercises and the acquisition of Abeona Therapeutics LLC (Abeona Ohio) less twelve 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.

On May 11, 2015, we closed a $10 million private placement of common stock consisting of 1,250,000 shares of our common stock, at a price of $8.00 per share and warrants to purchase 625,000 shares of common stock. The warrants have an exercise price of $8.00 per share and are exercisable for 30 months from the closing date. A total net of $9.2 million was received.

Also in connection with the financing, the placement agent received warrants to purchase 50,000 shares of common stock at $11.00 per share and which are exercisable for five years from the closing date.

On April 23, 2015 we closed a $7 million private placement of common stock consisting of 2,333,333 shares of our common stock, at a price of $3.00 per share.

During the second quarter we received additional financing of $4.6 million through warrant exercises of our $5.00 warrants.

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.

On September 10, 2014, we entered into an Unsecured Grid Note, for up to $250,000 with SCO (''Grid Note I''). As of December 31, 2014 we had drawn a total of $250,000. The interest rate is 8% per annum and the maturity date is August 31, 2015 unless a financing of at least $5,000,000 occurs. The financing occurred December 24, 2014 and the Grid Note I was paid in full on January 5, 2015.

On December 1, 2014, we entered into a second Unsecured Grid Note (''Grid Note II''), for up to $250,000 with SCO. As of December 31, 2014 we had drawn a total of $150,000. The interest rate is 8% per annum and the maturity date is November 30, 2015 unless a financing of at least $5,000,000 occurs. The financing occurred December 24, 2014 and the Grid Note II was paid in full on January 5, 2015.

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 December 31, 2015 of $310,600,000. 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.

We plan to expend substantial funds to conduct research and development programs, preclinical studies and clinical trials of potential products, including research and development with respect to our acquired and developed technology. Our future capital requirements and adequacy of available funds will depend on many factors, including:

- the successful development and commercialization of our other product candidates;
- the successful development and commercialization of products derived from our recent license of Licensor technologies;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- successful regulatory filings.

We have devoted substantially all of our efforts and resources to research and development conducted on our own behalf. The following table summarizes research and development spending by project category, which spending includes, but is not limited to, payroll and personnel expense, lab supplies, preclinical expense, development cost, clinical trial expense, outside manufacturing expense and consulting expense:

(in thousands)	Twelve Months ended December 31,		Inception To Date[1]
Project	2015	2014	
Gene therapy	$2,332	$ —	$ 2,332
Plasma therapy	2,332	—	2,332
MuGard	51	301	5,367
Others[2]	—	32	40,020
Total	$4,715	$333	$50,051

(1) Cumulative spending from inception of the Company or project through December 31, 2015.

(2) Includes other projects which the Company is no longer focused.

Due to uncertainties and certain of the risk factors described above, including those relating to our ability to successfully commercialize our drug candidates, our ability to obtain necessary additional capital to fund operations in the future, our ability to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes, government regulation to which we are subject, the uncertainty associated with preclinical and clinical testing, intense competition that we face, market acceptance of our products and protection of our intellectual property, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed in the risk factors above, including without limitation those relating to the uncertainty of the success of our research and development activities and our ability to obtain necessary additional capital to fund operations in the future. As discussed in such risk factors, delays in our research and development efforts and any inability to raise additional funds could cause us to eliminate one or more of our research and development programs.

We plan to continue our policy of investing any available funds in certificates of deposit, money market funds, government securities and investment-grade interest-bearing securities. We do not invest in derivative financial instruments.

We do not believe inflation or changing prices have had a material impact on our revenue or operating costs in the past three years.

Climate Change

We do not believe there is anything unique to our business which would result in climate change regulations having a disproportional effect on us as compared to U.S. industry overall.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reported period. In applying our accounting principles, we must often make individual estimates and assumptions regarding expected outcomes or uncertainties. As you might expect, the actual results or outcomes are often different than the estimated or assumed amounts. These differences are usually minor and are included in our consolidated financial statements as soon as they are known. Our estimates, judgments and assumptions are continually evaluated based on available information and experience. Because of the use of estimates inherent in the financial reporting process, actual results could differ from those estimates.

Receivables

Receivables are reported in the balance sheets at the outstanding amount net of an allowance for doubtful accounts. We continually evaluate the creditworthiness of our customers and their financial condition and generally do not require collateral. The allowance for doubtful accounts is based upon reviews of specific customer balances, historic losses, and general economic conditions. As of December 31, 2015 and 2014, no allowance was recorded as all accounts were considered collectible.

Licensed Technology

We maintain licensed technology on our consolidated balance sheet until either the licensed technology agreement underlying it is completed or the asset becomes impaired. When we determine that an asset has become impaired or we abandon a project, we write down the carrying value of the related intangible asset to its fair value and take an impairment charge in the period in which the impairment occurs.

Generally licensed technology is amortized over the life of the patent or the agreement.

We test our intangible assets for impairment on an annual basis, or more frequently if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding our drug candidate or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate or new information regarding potential sales for the drug. In connection with each annual impairment assessment and any interim impairment assessment, we compare the fair value of the asset as of the date of the assessment with the carrying value of the asset on our consolidated balance sheet.

In 2015, we did not impair any licensed technology.

Gene therapy license agreements

On May 15, 2015, we acquired Abeona Therapeutics LLC which had a an exclusive license through Nationwide Children's Hospital to the AB-101 and AB-102 patent portfolios for developing treatments for patients with Sanfilippo Syndrome Type A and Type B. This portfolio comprises 1 patent family: ''Products and methods for delivery of polynuleotides by adeno-associated virus for lysosomal storage disorders''. Additionally, Abeona has secured FDA Orphan drug designation for both Sanfilippo A and B, which will provide 7 years of post-launch market exclusivity for both ABX-A and ABX-B in the U.S. Abeona will be seeking Orphan Drug Status within the EMA, which will grant 10 years of post-market exclusivity in the European Union. The license is amortized over the life of the license of 20 years.

On June 5, 2015, we entered into an exclusive, worldwide, licensing agreement with the UNeMed Corporation, the technology transfer and commercialization office for the University of Nebraska Medical Center (UNMC) in Omaha, Nebraska, for an AAV gene therapy for the treatment of juvenile Batten disease. We licensed the rights to two patents (62/092,501 and 62/146,793). Under the terms of the licensing agreement, we paid a license fee of $75,000 and will pay milestone payments on certain milestone events. Commencing with the first commercial sale of licensed products a royalty will be paid. Terms of the agreement require we execute a sponsored research agreement with UNMC focused on additional efficacy studies within 12 months.

On October 14, 2015 we entered into a sponsored research agreement with UNMC to support ongoing AAV9/CLN3 projects in the amount of $215,000.

On June 5, 2015, we entered into an exclusive, worldwide, licensing agreement with the University of Minnesota for an AAV gene therapy for the treatment of patients with Fanconi anemia (FA) disorder and other rare blood diseases. We licensed one patent (62/000,590), Method for Editing a Genetic Sequence. Under terms of the licensing agreement, we paid a license fee of $80,000, will pay an additional license fee of $50,000, will pay annual maintenance fees and a royalty fee with the first commercial sale of licensed products.

On September 17, 2015, we entered into a nonexclusive license agreement with Stanford University for an AAV delivery vector for the treatment of FA and rare blood disease platform. This license augments the University of Minnesota agreement. We licensed two patents (13/594,773 and EPO 12756603.2). Under terms

of the licensing agreement, we paid a license fee of $25,000, will pay annual maintenance fees and a royalty fee with the first commercial sale of licensed products.

Plasma-based therapeutics license agreements

On September 22, 2014, we entered into an exclusive, worldwide licensing agreement with Licensor to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma. Under the terms of the licensing agreement, as amended on January 23, 2015, we paid a license fee of $1 million in cash, will pay $4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process. The license is amortized over the life of the patent of 11 years.

Goodwill

As of December 31, 2015, goodwill of $32.5 million was recorded on the Company's balance sheet. The implied fair value of goodwill represented the excess of the Abeona Ohio's value over and above the fair value of its tangible assets and identifiable intangible assets. In accordance with Accounting Standards Codification (''ASC'') No. 350 — *Intangibles — Goodwill and Other,* goodwill is not amortized, but is rather tested annually for impairment and whenever changes in circumstances occur that would indicate impairment.

Contingent consideration liability

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 was estimated at $6,489,000.

The first milestone of receiving IND allowance from the FDA to initiate a Phase 1 clinical study from MPS IIIA or MPSIIIB by November 15, 2015 was not met. The Company recognized $3,898,000 in Miscellaneous Income for change in fair value of our contingent consideration liability.

License Revenues and Royalties

Our revenues are generated from licensing, research and development agreements, royalties and product sales. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104), Revenue Recognition. License revenue is recognized over the remaining life of the underlying patent or period of performance obligation. Research and development revenues are recognized as services are performed. Royalties and product revenues are recognized in the period of sales.

Stock Based Compensation Expense

We account for stock based compensation expense in accordance with FASB ASC 718, Stock Based Compensation. We have two stock-based compensation plans under which incentive and qualified stock options and restricted shares may be granted to employees, directors and consultants. We measure the cost of the employee/director/consultant services received in exchange for an award of equity instruments based on the grant date fair value for employees and directors and vesting date fair value of the award for consultants. We use the Black-Scholes option pricing model to value our options which includes expected volatility, risk-free interest rate, dividend yield and estimated expected term.

Stock-based compensation expense recognized for the years ended December 31, 2015 and 2014 was approximately $4,368,000 and $1,305,000, respectively.

Off-Balance Sheet Transactions

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements required by this Item are incorporated in this Annual Report Form 10-K on pages F-1 through F-19 hereto. Reference is made to Item 15 of this Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 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.

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of the design and operation of our ''disclosure controls and procedures'' (''Disclosure Controls'') as of the end of the period covered by this Form 10-K. The Disclosure Controls evaluation was conducted under the supervision and with the participation of management and consultants, including our Executive Chairman and Chief Accounting Officer. Disclosure Controls are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure Controls are also designed to provide reasonable assurance that such information is accumulated and communicated to our management, including our Executive Chairman and Chief Accounting Officer, as appropriate to allow timely decisions regarding required disclosure.

The evaluation of our Disclosure Controls included a review of the controls' objectives and design, our implementation of the controls and the effect of the controls on the information generated for use in this Form 10-K. During the course of our evaluation of our internal control over financial reporting, we advised the Audit Committee of our Board of Directors that we identified no material weakness as defined under standards established by the Public Company Accounting Oversight Board (United States). A material weakness is a deficiency, or combination of 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.

This Annual Report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the SEC that permit smaller reporting companies like us to provide only management's report in this Annual Report on Form 10-K.

This report shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Reports of Beneficial Ownership. The information required by this Item is incorporated herein by reference from the information to be contained in our 2016 Proxy Statement to be filed with the U.S. Securities and Exchange Commission in connection with the solicitation of proxies for our 2016 Annual Meeting of Stockholders (the Proxy Statement). The information under the heading ''Executive Officers of the Registrant'' in Part I of this Form 10-K is also incorporated by reference.

Code of Ethics. We have adopted a Code of Business Conduct and Ethics (the Code) that applies to all of our employees (including executive officers) and directors. The Code is available on our website at *www.abeonatherapeutics.com* under the heading ''Investor Information.'' We intend to satisfy the disclosure requirement regarding any waiver of a provision of the Code applicable to any executive officer or director, by posting such information on such website. We shall provide to any person without charge, upon request, a copy of the Code. Any such request must be made in writing to Abeona Therapeutics Inc., c/o Investor Relations, 3333 Lee Parkway, Suite 600, Dallas, TX 75219.

Our corporate governance guidelines and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee of the Board of Directors are available on our website at *www.abeonatherapeutics.com* under the heading ''Investor Information''. We shall provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to Abeona Therapeutics Inc., c/o Investor Relations, 3333 Lee Parkway, Suite 600, Dallas, TX 75219.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is contained in the Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is contained in the Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is contained in the Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is contained in the Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

b. Exhibits

Exhibit Number	Description of Document
2.1	Amended and Restated Agreement of Merger and Plan of Reorganization between the Registrant and Chemex Pharmaceuticals, Inc., dated as of October 31, 1995 (Incorporated by reference to Exhibit A of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
2.2	Agreement and Plan of Merger, by and among the Registrant, Somanta Acquisition Corporation, Somanta Pharmaceuticals, Inc., Somanta Incorporated and Somanta Limited, dated April 19, 2007 (Incorporated by reference to Exhibit 2.1 to our Form 8-K dated April 18, 2007)
2.3	Agreement and Plan of Merger, by and among the Registrant, MACM Acquisition Corporation and MacroChem Corporation, dated July 9, 2008 (Incorporated by reference to Exhibit 2.3 of our Form 10-Q for the quarter ended June 30, 2008)
3.1	Certificate of Incorporation (Incorporated by reference to Exhibit 3(a) of our Form 8-K dated July 12, 1989, Commission File Number 9-9134)
3.2	Certificate of Amendment of Certificate of Incorporation filed August 13, 1992 (Incorporated by reference to Exhibit 3.3 of our Form 10-K for year ended December 31, 1995)
3.3	Certificate of Merger filed January 25, 1996 (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
3.4	Certificate of Amendment of Certificate of Incorporation filed January 25, 1996 (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
3.5	Certificate of Amendment of Certificate of Incorporation filed July 18, 1996 (Incorporated by reference to Exhibit 3.7 of our Form 10-K for the year ended December 31, 1996)
3.6	Certificate of Amendment of Certificate of Incorporation filed June 18, 1998. (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended June 30, 1998)
3.7	Certificate of Amendment of Certificate of Incorporation filed July 31, 2000 (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended March 31, 2001)
3.8	Certificate of Designations of Series A Junior Participating Preferred Stock filed November 7, 2001 (Incorporated by reference to Exhibit 4.1.H of our Registration Statement on Form S-8 dated December 14, 2001, Commission File No. 333-75136)
3.9	Amended and Restated Bylaws (Incorporated by reference to Exhibit 2.1 of our Form 10-Q for the quarter ended June 30, 1996)

Exhibit Number	Description of Document
3.10	Certificate of Designation, Rights and Preferences of Series A Cumulative Convertible Preferred Stock filed November 9, 2007 (Incorporated by reference to Exhibit 3.10 to our Form SB-2 filed on December 10, 2007.
3.11	Certificate of Amendment to Certificate of Designations, Rights and Preferences of Series A Cumulative Convertible Preferred Stock filed June 11, 2008 (Incorporated by reference to Exhibit 3.11 of our Form 10-Q for the quarter ended June 30, 2008)
3.12	Certificate of Designations, Rights and Preferences of Series B Cumulative Convertible Preferred Stock filed October 26, 2012 (Incorporated by reference to Exhibit 10.3 of our Form 8-K filed October 26, 2012)
3.13	Certificate of Amendment of Certificate of Incorporation filed July 1, 2013 increasing the aggregate number of shares of Common Stock which we have authority to issue to Two Hundred Million (200,000,000) shares with a par value of one cent ($0.01) per share.
3.14	Certificate of Amendment of Certificate of Incorporation filed October 23, 2014 (Incorporated by reference to Exhibit 3.14 of our Form 8-K filed October 23, 2014)
3.15	Certificate of Amendment to Certificate of Designations, Rights and Preferences of Series A Cumulative Convertible Preferred Stock (Incorporated by reference to Exhibit 3.15 of our Form 8-K filed on October 23, 2014)
3.16	Amendment to Bylaws (Incorporated by reference to Exhibit 3.1 of our Form 8-K filed January 5, 2015)
3.17	Amendment to Bylaws (Incorporated by reference to Exhibit 3.1 of our Form 8-K filed March 5, 2015)
3.18	Certificate of Amendment of Certificate of Incorporation filed June 19, 2015 (Incorporated by reference to Exhibit 3.1 of our June 22, 2015)
4.1*	2015 Equity Incentive Plan (Incorporated by reference to Exhibit 4.1 to our Form S-8 filed May 11, 2015)
10.1*	1995 Stock Option Plan (Incorporated by reference to Exhibit F of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
10.2*	Amendment to 1995 Stock Option Plan (Incorporated by reference to Exhibit 10.25 of our Form 10-K for the year ended December 31, 2001)
10.3*	401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10-K for the year ended December 31, 1999)
10.4*	2005 Equity Incentive Plan (Incorporated by reference to Exhibit 1 of our Proxy Statement filed on April 18, 2005)
10.5	Asset Sale Agreement dated as of October 12, 2005, between the Registrant and Uluru, Inc. (Incorporated by reference to Exhibit 10.25 of our 10-K for the year ended December 31, 2005)
10.6	Amendment to Asset Sale Agreement dated as of December 8, 2006, between the Registrant and Uluru, Inc. (Incorporated by reference to Exhibit 10.16 of our Form 10-KSB filed on April 2, 2007)
10.7	License Agreement dated as of October 12, 2005, between the Registrant and Uluru, Inc. (Incorporated by reference to Exhibit 10.26 of our 10-K for the year ended December 31, 2005)
10.8	Board Designation Agreement dated November 15, 2007, between the Registrant and SCO Capital Partners LLC (Incorporated by reference to Exhibit 10.26 of our Form S-1 filed on March 11, 2008)
10.9	Form of Securities Purchase Agreement dated as of November 1, 2011 by and among us and the Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed on November 10, 2011)

Exhibit Number	Description of Document
10.10	Form of Common Stock Warrant (Five Year Warrant) issued by us (Incorporated by reference to Exhibit 10.3 of our Form 8-K filed on November 10, 2011)
10.11	Form of Common Stock Warrant issued by us (Incorporated by reference to Exhibit 10.3 of our Form 8-K filed on October 26, 2012)
10.12+	License Agreement, dated June 6, 2013, by and between us and AMAG Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.6 to our Form 10-Q for the quarter ended June 30, 2013)
10.13+	License Agreement, dated September 19, 2014, by and between us and Plasma Technologies, LLC. (Incorporated by reference to Exhibit 10.30 of our Form 8-K filed September 24, 2014)
10.14*	Employment Letter Agreement dated September 19, 2014, by and between us and Harrison Wehner. (Incorporated by reference to Exhibit 10.32 of our Form 8-K filed September 24, 2014)
10.15	Amendment No. 1 to License Agreement, dated September 19, 2014, by and between us and Plasma Technologies, LLC, dated January 23, 2015 (Incorporated by reference to Exhibit 10.29 to our Form 10-K for the year ended December 31, 2014)
10.16	Agreement and Plan of Merger, dated May 5, 2015, by and among the Company, Plasmatech Merger Sub Inc., Abeona Therapeutics LLC and Paul A. Hawkins, in his capacity as Member Representative (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the quarter ended June 30, 2015)
10.17	Letter Agreement, dated July 31, 2015, by and among the Company, Sabby Healthcare Master Fund Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (Incorporated by reference to Exhibit 10.1 to our Form 8-K filed July 31, 2015)
10.18	Form of Purchase Agreement, dated July 27, 2015 (Incorporated by reference to Exhibit 10.1 to our Form 8-K filed August 3, 2015)
10.19	Form of Common Stock Purchase Agreement, dated April 1, 2015 (Incorporated by reference to Exhibit 10.4 to our Form 10-Q for the quarter ended June 30, 2015)
10.20	Form of Securities Purchase Agreement dated May 6, 2015 (Incorporated by reference to Exhibit 10.5 to our Form 10-Q for the quarter ended June 30, 2015)
10.21*	Employment Agreement dated May 6, 2015 between Registrant and Timothy J. Miller (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the quarter ended September 30, 2015)
21	Subsidiaries of the Registrant
23.1	Consent of Whitley Penn LLP
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**	Principal Executive Officer Certification and Principal Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2015 and for the fiscal year ended December 31, 2014, formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' Deficit, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

* Management contract or compensatory plan required to be filed as an Exhibit to this Form pursuant to Item 15c of the report.

** 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 the Section, nor shall it be deemed incorporated by reference in any filings under the Security Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.

+ Portions of this exhibit were omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to a request for confidential treatment.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 March 30, 2016 By: /s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
Principal Executive Officer

Date March 30, 2016 By: /s/ Stephen B. Thompson
Stephen B. Thompson
Vice President Finance
Principal Financial Officer and
Principal Accounting Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date March 30, 2016 By: /s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
Principal Executive Officer
Chairman of the Board

Date March 30, 2016 By: /s/ Stephen B. Thompson
Stephen B. Thompson
Vice President Finance
Principal Financial Officer and
Principal Accounting Officer

Date March 30, 2016 By: /s/ Mark J. Ahn
Mark J. Ahn, Director

Date March 30, 2016 By: /s/ Mark J. Alvino
Mark J. Alvino, Director

Date March 30, 2016 By: /s/ Jeffrey B. Davis
Jeffrey B. Davis,
Chief Operating Officer and Director

Date March 30, 2016 By: /s/ Stephen B. Howell
Stephen B. Howell,
Director

Date March 30, 2016 By: /s/ Timothy J. Miller
Timothy J. Miller,
President & CEO and Director

Date March 30, 2016 By: /s/ Todd Wider
Todd Wider,
Director

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Abeona Therapeutics Inc.

We have audited the accompanying consolidated balance sheets of Abeona Therapeutics Inc. and subsidiaries (the ''Company''), as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Abeona Therapeutics Inc. and subsidiaries as of December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ WHITLEY PENN LLP

Dallas, Texas
March 30, 2016

Abeona Therapeutics Inc. and Subsidiaries

CONSOLIDATED BALANCE SHEETS

	December 31, 2015	December 31, 2014
ASSETS		
Current assets		
Cash and cash equivalents	$ 40,138,000	$ 11,520,000
Receivables	115,000	35,000
Prepaid expenses and other current assets	315,000	—
Total current assets	40,568,000	11,555,000
Property and equipment, net	350,000	4,000
Licensed technology, net	6,609,000	4,991,000
Goodwill	32,466,000	—
Other assets	62,000	32,000
Total assets	$ 80,055,000	$ 16,582,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 875,000	$ 1,896,000
Short-term notes payable	—	400,000
Current portion of deferred revenue	602,000	602,000
Total current liabilities	1,477,000	2,898,000
Contingent consideration liability	2,591,000	—
Payable due Licensor	4,000,000	4,000,000
Long-term deferred revenue	4,266,000	4,868,000
Total liabilities	12,334,000	11,766,000
Commitments and contingencies		
Stockholders' equity		
Common stock – $.01 par value; authorized 200,000,000 shares; issued 32,743,013 at December 31, 2015; issued 19,960,801 at December 31, 2014	328,000	200,000
Additional paid-in capital	377,993,000	300,690,000
Accumulated deficit	(310,600,000)	(296,074,000)
Total stockholders' equity	67,721,000	4,816,000
Total liabilities and stockholders' equity	$ 80,055,000	$ 16,582,000

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

Abeona Therapeutics Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the year ended December 31,	
	2015	**2014**
Revenues		
License revenues	$ 602,000	$ 598,000
Royalties	438,000	327,000
Total revenues	1,040,000	925,000
Expenses		
Research and development	4,715,000	333,000
General and administrative	14,320,000	3,712,000
Depreciation and amortization	551,000	11,000
Total expenses	19,586,000	4,056,000
Loss from operations	(18,546,000)	(3,131,000)
Interest and miscellaneous income	4,026,000	45,000
Interest and other expense	(6,000)	(582,000)
Loss on change in fair value of derivative- preferred stock	—	(23,110,000)
	4,020,000	(23,647,000)
Net loss	(14,526,000)	(26,778,000)
Less preferred stock dividends	—	(2,875,000)
Net loss allocable to common stockholders	$(14,526,000)	$(29,653,000)
Basic and diluted loss per common share	$ (0.53)	$ (15.26)
Weighted average number of common shares outstanding	27,597,434	1,942,905

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

Abeona Therapeutics Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Preferred Stock – A		Preferred Stock – B		Additional paid-in capital	Treasury stock	Accumulated (deficit)	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2013	514,589	$ 6,000	2,903.3617	$—	1,000	$—	$251,640,000	$(4,000)	$(266,421,000)	$(14,779,000)
Common stock issued for services	22,000	—	—	—	—	—	349,000	—	—	349,000
Preferred stock converted into common stock	4,000	—	(10.0000)	—	—	—	—	—	—	—
Additional adjustments for reverse stock split	6,609	—	—	—	—	—	—	—	—	—
Cancel treasury stock	(3)	—	—	—	—	—	(4,000)	4,000	—	—
Common stock issued for $4.00 share net of costs	3,500,000	35,000	—	—	—	—	12,272,000	—	—	12,307,000
Common stock issued for Series A preferred stock	7,233,404	72,000	(2,893.3617)	—	—	—	(72,000)	—	—	—
Common stock issued for Series A preferred stock unpaid dividends and interest	1,728,365	17,000					7,066,000	—	—	7,083,000
Elimination of derivative liability – preferred stock	—	—	—	—	—	—	24,300,000	—	—	24,300,000
Series B preferred stock issued for unpaid Series B dividends and interest	—	—	—	—	304	—	3,047,000	—	—	3,047,000
Series B preferred stock issued for unpaid liquidated damages	—	—	—	—	86	—	857,000	—	—	857,000
Common stock issued for Series B preferred stock, unpaid dividends and interest and liquidated damages	6,951,837	70,000			(1,390)	—	(70,000)	—	—	—
Stock option compensation expense	—	—	—	—	—	—	1,305,000	—	—	1,305,000
Preferred dividends	—	—	—	—	—	—	—	—	(2,875,000)	(2,875,000)
Net loss	—	—	—	—	—	—	—	—	(26,778,000)	(26,778,000)
Balance, December 31, 2014	19,960,801	200,000	—	—	—	—	300,690,000	—	(296,074,000)	4,816,000
Common stock issued for services	105,177	1,000	—	—	—	—	400,000	—	—	401,000
Common stock issued to employees	10,000	—	—	—	—	—	32,000	—	—	32,000
Restricted common stock issued to employees	1,350,000	13,000	—	—	—	—	4,807,000	—	—	4,820,000
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 for $5.50 share net of costs	2,829,091	28,000	—	—	—	—	15,383,000	—	—	15,411,000
Common stock issued to Abeona Ohio holders	3,979,761	40,000	—	—	—	—	31,718,000	—	—	31,758,000
Transfer agent correction 2014 reverse stock split	(2,270)	—	—	—	—	—	—	—	—	—
Stock option compensation expense	—	—	—	—	—	—	4,368,000	—	—	4,368,000
Net loss	—	—	—	—	—	—	—	—	(14,526,000)	(14,526,000)
Balance, December 31, 2015	32,743,013	$328,000	—	$—	$ —	—	$377,993,000	$ —	$(310,600,000)	$ 67,721,000

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

Abeona Therapeutics Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	$(14,526,000)	$(26,778,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Loss on change in fair value of derivative-preferred stock	—	23,110,000
Depreciation and amortization	551,000	11,000
Stock option compensation expense	4,368,000	1,305,000
Stock issued to directors, employees and consultants	4,852,000	—
Stock issued for services	401,000	349,000
Change in operating assets and liabilities:		
Receivables	(79,000)	39,000
Prepaid expenses and other current assets	(287,000)	77,000
Other assets	(29,000)	—
Accounts payable and accrued expenses	(1,174,000)	33,000
Interest on dividends payable	—	592,000
Contingent consideration milestone	(3,898,000)	—
Deferred revenue	(602,000)	(349,000)
Net cash used in operating activities	(10,423,000)	(1,611,000)
Cash flows from investing activities:		
Capital expenditures	(308,000)	—
Cash from Abeona Ohio acquisition	3,697,000	—
Net cash provided by investing activities	3,389,000	—
Cash flows from financing activities:		
Proceeds from $3.00 common stock issuances net of costs	7,001,000	—
Proceeds from $8.00 common stock issuances net of costs	9,005,000	—
Proceeds from $5.50 common stock issuances net of costs	15,411,000	—
Proceeds from exercise of $5.00 warrants	4,635,000	—
Proceeds from $4.00 common stock net of costs	—	12,307,000
Proceeds/payment of short-term debt	(400,000)	400,000
Net cash provided by financing activities	35,652,000	12,707,000
Net increase in cash and cash equivalents	28,618,000	11,096,000
Cash and cash equivalents at beginning of year	11,520,000	424,000
Cash and cash equivalents at end of year	$ 40,138,000	$ 11,520,000
Supplemental cash flow information:		
Cash paid for interest	*$ 7,000*	*$ 7,000*
Supplemental disclosure of noncash transactions		
Shares issued to holders of Abeona Ohio for acquisition	*31,758,000*	—
Contingent milestones to Abeona Ohio members	*2,591,000*	—
Licensed technology from Abeona Ohio	*2,156,000*	—
Conversion of Series A preferred stock unpaid dividends and interest into shares of common stock	—	*7,081,000*
Conversion of Series B preferred stock unpaid dividends and interest and liquidated damages into shares of common stock	—	*3,094,000*
Cancel treasury stock	—	*4,000*
Payable in cash or future issuance of common shares for licensed technology	—	*5,000,000*
Preferred stock dividends in dividends payable	—	*2,875,000*

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

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

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

Certain amounts have been reclassified to conform with current period classification.

A summary of the significant accounting policies applied in the preparation of the accompanying consolidated financial statements follows:

Principles of Consolidation

The consolidated financial statements include the financial statements of Abeona Therapeutics Inc. and our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reported period. Actual results could differ from these estimates and assumptions.

Segments

The Company operates in a single segment.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2015 and 2014, we had no such investments. We maintain deposits primarily in two financial institutions, which may at times exceed amounts covered by insurance provided by the U.S. Federal Deposit Insurance Corporation (FDIC). We have not experienced any losses related to amounts in excess of FDIC limits.

Receivables

Receivables are reported in the balance sheets at the outstanding amount net of an allowance for doubtful accounts. We continually evaluate the creditworthiness of our customers and their financial condition and generally do not require collateral. The allowance for doubtful accounts is based upon reviews of specific customer balances, historic losses, and general economic conditions. As of December 31, 2015 and 2014, no allowance was recorded as all accounts are considered collectible.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over estimated useful lives ranging from three to five years. Expenditures for major renewals and betterments that extend the useful lives are capitalized. Expenditures for normal maintenance and repairs are expensed as incurred. The cost of assets sold or abandoned and the related accumulated depreciation are eliminated from the accounts and any gains or losses are recognized in the accompanying consolidated statements of operations of the respective period.

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

Licensed Technology

We maintain licensed technology on our consolidated balance sheet until either the licensed technology agreement underlying it is completed or the asset becomes impaired. When we determine that an asset has become impaired or we abandon a project, we write down the carrying value of the related intangible asset to its fair value and take an impairment charge in the period in which the impairment occurs.

Generally licensed technology is amortized over the life of the patent or the agreement.

We test our intangible assets for impairment on an annual basis, or more frequently if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding our drug candidate or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate or new information regarding potential sales for the drug. In connection with each annual impairment assessment and any interim impairment assessment, we compare the fair value of the asset as of the date of the assessment with the carrying value of the asset on our consolidated balance sheet.

In 2015, we did not impair any licensed technology.

Gene therapy license agreements

On May 15, 2015, we acquired Abeona Therapeutics LLC which had a an exclusive license through Nationwide Children's Hospital to the AB-101 and AB-102 patent portfolios for developing treatments for patients with Sanfilippo Syndrome Type A and Type B. This portfolio comprises 1 patent family: ''Products and methods for delivery of polynuleotides by adeno-associated virus for lysosomal storage disorders''. Additionally, Abeona has secured FDA Orphan drug designation for both Sanfilippo A and B, which will provide 7 years of post-launch market exclusivity for both ABX-A and ABX-B in the U.S. Abeona will be seeking Orphan Drug Status within the EMA, which will grant 10 years of post-market exclusivity in the European Union.

The license is amortized over the life of the license of 20 years.

Plasma-based therapeutics license agreements

On September 22, 2014, we entered into an exclusive, worldwide licensing agreement with Plasma Technologies LLC (''Licensor'') to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma. Under the terms of the licensing agreement, as amended on January 23, 2015, we paid a license fee of $1 million in cash, will pay $4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process.

The license is amortized over the life of the patent of 11 years.

License Revenues and Royalties

Our revenues are generated from licensing, research and development agreements, royalties and product sales. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104), *Revenue Recognition*. License revenue is recognized over the remaining life of the underlying patent. Research and development revenues are recognized as services are performed. Royalties and product sales are recognized in the period of sales.

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

Goodwill

As of December 31, 2015, goodwill of $32.5 million was recorded on the Company's consolidated balance sheet. The implied fair value of goodwill represented the excess of the Abeona Ohio's value over and above the fair value of its tangible assets and identifiable intangible assets. In accordance with Accounting Standards Codification (''ASC'') No. 350 — *Intangibles — Goodwill and Other,* goodwill is not amortized, but is rather tested annually for impairment and whenever changes in circumstances occur that would indicate impairment.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses include, but are not limited to, payroll and personnel expense, lab supplies, preclinical, development cost, clinical trial expense, outside manufacturing and consulting. The cost of materials and equipment or facilities that are acquired for research and development activities and that have alternative future uses are capitalized when acquired.

General and administrative expense

General and administrative expenses primarily consist of personnel, contract personnel, personnel expenses to support our administrative and operating activities, facility costs and professional expenses (i.e., legal expenses), and investor relations fees.

Other Income

In 2015 and 2014, we recognized miscellaneous income of $4,026,000 and $45,000, respectively, due to the termination of the milestone recorded on the contingent consideration liability in 2015 and sales of platinum and monomers in 2014 and write-offs and settlements of other accounts payable for both years.

In some of our license agreements we are responsible as agent for arranging the manufacture of MuGard (mucoadhesive oral wound rinse) and have entered into supply agreements with our license partners. Terms vary with each agreement but generally we arrange for the manufacture of MuGard with a third-party and receive a fee to cover our administration, handling and overhead costs. The income is recorded in other income.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided for deferred tax assets to the extent their realization is in doubt.

We account for uncertain income tax positions in accordance with FASB ASC 740, *Income Taxes*. Interest costs and penalties related to income taxes are classified as interest expense and general and administrative costs, respectively, in our consolidated financial statements. For the years ended December 31, 2015 and 2014, we did not recognize any uncertain tax positions or interest or penalty expense related to income taxes. It is determined not to be reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next 12 months. We are currently subject to a three year statute of limitations by major tax jurisdictions for the years ended 2012, 2013 and 2014. We and our subsidiaries file income tax returns in the U.S. federal jurisdiction.

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

Income (Loss) Per Share

We have presented basic income (loss) per share, computed on the basis of the weighted average number of common shares outstanding during the year, and diluted income (loss) per share, computed on the basis of the weighted average number of common shares and all dilutive potential common shares outstanding during the year. Potential common shares result from stock options, preferred stock and warrants. Common equivalent shares have not been included in the net loss per share calculations for years ended December 31, 2015 and 2014 because the effect of including them would have been anti-dilutive.

Basic and diluted net loss per share were determined as follows:

	For the year ended December 31,	
(in thousands, except share and per share amounts)	2015	2014
Net loss allocable to common stockholders	$ (14,526)	$ (29,653)
Weighted average shares outstanding	27,597,434	1,942,905
Basic and diluted net loss per common share	$ (0.53)	$ (15.26)
Net loss allocable to common stockholders	$ (14,526)	$ (29,653)

We did not include the following securities in the table below in the computation of diluted net loss per common share because the securities were anti-dilutive during the periods presented:

	For the year ended December 31,	
	2015	2014
Warrants	3,799,024	4,164,756
Stock options	2,324,084	210,134
Total	6,123,108	4,374,890

Stock-Based Compensation

We account for stock based compensation expense in accordance with FASB ASC 718, *Stock Based Compensation*. We have two stock-based compensation plans under which incentive and qualified stock options and restricted shares could be granted to employees, directors and consultants. Our 2015 Equity Incentive Plan was approved by shareholders in May 7, 2015. As of January 20, 2015, no further grants can be made under our old plan, the 2005 Equity Incentive Plan. We measure the cost of the employee/director/consultant services received in exchange for an award of equity instruments based on the grant date fair value for the employees and directors and vesting date fair value for consultants of the award. We use the Black-Scholes option pricing model to value our options.

The following table summarizes stock-based compensation for the years ended December 31, 2015 and 2014 which was allocated as follows (in thousands):

	Year ended December 31, 2015	Year ended December 31, 2014
Research and development	$ 773	$ 104
General and administrative	3,595	1,201
Stock-based compensation expense included in operating expense	4,368	1,305
Total stock-based compensation expense	4,368	1,305
Tax benefit	—	—
Stock-based compensation expense, net of tax	$4,368	$1,305

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

Recent Accounting Pronouncements

In May 2014, as part of its ongoing efforts to assist in the convergence of U.S. GAAP and International Financial Reporting Standards (''IFRS''), the FASB issued ASU 2014-09 related to revenue recognition. The new guidance sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed in U.S. GAAP. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in the prior accounting guidance. The ASU provides alternative methods of initial adoption and is effective for annual periods beginning after December 15, 2016 and interim periods within those annual periods. In August 2015, the FASB issued ASU 2015-14 which defers the effective date of ASU 2014-09 one year making it effective for annual reporting periods beginning on or after December 15, 2017 while also providing for early adoption as of the original effective date. We are currently continuing to evaluate the impact that this standard will have on our consolidated financial statements as well as the appropriate method of adoption.

NOTE 2 — RELATED PARTY TRANSACTIONS

On September 10, 2014, we entered into an Unsecured Grid Note, for up to $250,000 with SCO Capital Partners LLC (SCO). As of December 31, 2014 we had drawn a total of $250,000. The interest rate was 8% per annum and the maturity date was August 31, 2015 unless a financing of at least $5,000,000 occurred. The financing occurred December 24, 2014 and the Grid Note was paid in full on January 5, 2015.

On September 10, 2014 we entered into a Share Exchange Agreement for Series B Preferred Stock between us and SCO and Beach Capital LLC whereby we agreed in connection with the consummation of the an offering for the Series B Preferred Stock to be converted into Common Stock. All Series B Preferred Stock dividends payable, interest on Series B Preferred Stock dividends payable and liquidated damages will be converted into Series B Preferred Stock just prior to an offering of at least $10 million. The Series B Preferred Stock, including the shares of Series B Preferred Stock issued upon conversion of all accrued dividends payable, interest on dividends payable and liquidated damages thereon, subject to a liquidation preference, will be exchanged for shares of Common Stock upon consummation of an offering at the offering price pursuant to a Share Exchange Agreement dated September 10, 2014. The conversion into Common Stock occurred on December 24, 2014.

On December 1, 2014, we entered into a second Unsecured Grid Note, for up to $250,000 with SCO. As of December 31, 2014 we had drawn a total of $150,000. The interest rate was 8% per annum and the maturity date was November 30, 2015 unless a financing of at least $5,000,000 occurred. The financing occurred December 24, 2014 and the Grid Note was paid in full on January 5, 2015.

NOTE 3 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	December 31,	
	2015	2014
Equipment laboratory	$139,000	$ —
Furniture and office equipment	209,000	14,000
Leasehold improvement	33,000	—
	381,000	14,000
Less accumulated depreciation and amortization	31,000	10,000
Property and equipment, net	$350,000	$ 4,000

Depreciation and amortization on property and equipment was $13,000 and $2,000 for the years ended December 31, 2015 and 2014, respectively.

NOTE 4 — LICENSED TECHNOLOGY

On September 22, 2014, we entered into an exclusive, worldwide, licensing agreement with Licensor to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma.

On May 15, 2015, we acquired Abeona Therapeutics LLC which had a an exclusive license through Nationwide Children's Hospital to the AB-101 and AB-102 patent portfolios for developing treatments for patients with Sanfilippo Syndrome Type A and Type B.

Licensed technology consists of the following:

	December 31,	
	2015	2014
Licensed technology	$7,156,000	$5,000,000
Less accumulated amortization	547,000	9,000
Licensed technology, net	$6,609,000	$4,991,000

Amortization on licensed technology was $538,000 and $9,000 for the years ended December 31, 2015 and 2014, respectively. The aggregate estimated amortization expense for intangible assets remaining as of December 31, 2015 is as follows:

2016	$ 582
2017	582
2018	582
2019	582
2020	582
Thereafter	3,699
Total	$6,609

NOTE 5 — 401(k) PLAN

We have a tax-qualified employee savings and retirement plan (the 401(k) Plan) covering all our employees. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit ($18,000 in 2015 and $17,500 in 2014) and to have the amount of such reduction contributed to the 401(k) Plan. The 401(k) Plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by employees or by us to the 401(k) Plan, and income earned on 401(k) Plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that contributions by us, if any, will be deductible by us when made. At the direction of each participant, we invest the assets of the 401(k) Plan in any of 60 investment options. Company contributions under the 401(k) Plan were $0 in 2015 and 2014.

NOTE 6 — COMMITMENTS AND CONTINGENCIES

Operating Leases

At December 31, 2015, we had a commitment under a non-cancelable operating lease for our New York office until December 31, 2016 totaling $187,000. We also had a non-cancelable operating lease for our Dallas office and lab until August 31, 2016 totaling $7,000. We had an operating lease for our Cleveland office and lab until December 31, 2025 totaling $2,520,000. We have the option to extend the lease for an additional five years. We can also terminate the lease early at December 31, 2020, at the end of year five, and pay for unamortized tenant improvements. Our total lease costs and unamortized tenant improvements would total $1,744,000 with the termination provision.

The five year lease payment schedule is (in thousands):

2016	$ 365
2017	241
2018	246
2019	250
2020	256
Thereafter	1,356
Total	$2,714

Rent expense for the years ended December 31, 2015 and 2014 was $219,000 and $178,000, respectively.

Legal

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

NOTE 7 — FAIR VALUE MEASUREMENTS

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

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

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for

NOTE 7 — FAIR VALUE MEASUREMENTS – (continued)

similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

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

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

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

Financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2015 and December 31, 2014 are summarized below:

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

(in thousands) Description	As of December 31, 2014	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability – preferred stock	$—	$—	$—	$—	$(23,110)

In order to calculate the Level 3 Derivative liability — preferred stock, we used the Monte Carlo simulation to estimate future stock prices. The use of valuation techniques requires the Company to make various key assumptions for inputs into the model, including assumptions about the expected future volatility of the price of the Company's stock. The preferred stock liability was converted into common stock on December 24, 2014.

NOTE 8 — PREFERRED STOCK

Series A Cumulative Convertible Preferred Stock

All Series A Preferred Stock, Series A dividends payable and interest on Series A Preferred Stock dividends payable were converted into 8,961,769 shares of common stock just prior to the closing of the financing on December 24, 2014.

Derivative Liability

Effective January 1, 2009, we adopted the provisions of FASB ASC 815, *"Derivatives and Hedging"* (FASB ASC 815) (previously EITF 07-5, *"Determining Whether an Instrument (or an Embeded Feature) is Indexed to an Entity's Own Stock"*). As a result of adopting FASB ASC 815, warrants to purchase 77,091 of our common stock previously treated as equity pursuant to the derivative treatment exemption were no longer afforded equity treatment. These warrants had an exercise price of $175.00 and expired on November 10, 2013 and February 4, 2014.

We determined that the anti-dilution provision built into the Series A Preferred Stock and warrants issued should be considered for derivative accounting. FASB ASC 815 requires freestanding contracts that are settled in a company's own stock to be designated as an equity instrument, assets or liability. Under the provisions of

NOTE 8 — PREFERRED STOCK – (continued)

FASB ASC 815, a contract designated as an asset or liability must be initially recorded and carried at fair value until the contract meets the requirements for classification as equity, until the contract is exercised or until the contract expires. We determined that the anti-dilution provision associated with the November 2007 and February 2008 preferred shares and warrants no longer met the criteria for equity accounting through the revised criteria in FASB ASC 815.

Accordingly, at January 1, 2009, we determined that the warrants and the Series A Preferred Stock conversion feature should be accounted for as derivative liabilities. The preferred stock conversion feature was determined to have no fair market value at both issuance dates as well as each reporting period until the third quarter of 2010 since management asserted that the likelihood of issuing any new equity at a price that would trigger the anti-dilution effect to be nil. During the third quarter of 2010 we were actively raising capital. With our stock price below $150.00 a share it was possible that we would sell shares below $150.00 per share. Since this would require an adjustment to our convertible preferred stock we recorded a derivative liability and expense at September 30, 2010. The derivative liability and expense was revalued at December 31, 2013 was $1,190,000; and at December 24, 2014 was $24,300,000. The change in the fair value of the derivative was a loss of $23,110,000 in 2014. The Series A Preferred Stock was converted into common stock at December 24, 2014 and the amount of the derivative liability was reclassified to stockholders equity.

The warrants were valued at issuance and each reporting period since using the Black-Scholes model. On January 1, 2009 we reclassified the fair value of the warrants from equity to liability as if these warrants were treated as a derivative liability since their issue date. We recorded derivative gain of $271,000 for the year ended December 31, 2013. Warrants to purchase 72,998 shares of our common stock expired November 10, 2013. The remaining 9,992 warrants expired February 4, 2014.

Series B Cumulative Convertible Preferred Stock

All Series B Preferred Stock, Series B dividends payable, interest on Series B Preferred Stock dividends payable and liquidated damages were converted into 6,951,837 shares of common stock just prior to the closing of the financing on December 24, 2014.

Liquidated Damages

Pursuant to the terms of an Investor Rights Agreement with the Purchasers of Series A Preferred Stock, we were required to maintain an effective registration statement. The Securities and Exchange Commission declared the registration statement effective November 13, 2008 relating to a portion of such securities, and as a result, we accrued $857,000 in potential liquidated damages as of December 31, 2013 and December 31, 2012. Potential liquidated damages were capped at 10% of each holder's investment. The accrued liquidated damages of $857,000 were converted into common stock at December 24, 2014.

Preferred Stock Dividends — Series A

Unpaid preferred stock dividends and interest of $6,913,416 accrued at December 24, 2014 was converted into common stock at December 24, 2014.

Preferred Stock Dividends — Series B

Unpaid preferred stock dividends and interest of $3,046,553 accrued at December 31, 2014 was converted into common stock at December 24, 2014.

NOTE 9 — STOCKHOLDERS' EQUITY

2015 Financing

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.

During the second quarter we received additional financing of $4.6 million through Warrant exercises of our $5.00 warrants.

On May 11, 2015 we closed a $10 million private placement of common stock consisting of 1,250,000 shares of our common stock, at a price of $8.00 per share, and warrants to purchase 625,000 shares of our common stock with an exercise price of $10 per share.

Also in connection with the financing, the placement agent received warrants to purchase 50,000 shares of common stock at $11.00 per share and which are exercisable for five years from the closing date.

On April 23, 2015 we closed an upsized $7 million private placement of common stock consisting of 2,333,333 shares of our common stock, at a price of $3.00 per share.

On December 24, 2014, we closed an underwritten public offering of 3,500,000 shares of common stock, and warrants to purchase up to an aggregate 3,500,000 shares of common stock, at an offering price of $4.00 per share and $.01 per warrant. The warrants have a per share exercise price of $5.00, are exercisable immediately, and expire 5 years from the date of issuance. The gross proceeds to the Company from this offering were $14,035,000, before deducting underwriting discounts and commissions and other estimated offering expenses. All of the shares and warrants in the offering were sold by the Company. In addition the underwriter received warrants to purchase 87,500 shares of common stock at $5.00 per share. The warrants are exercisable on December 18, 2015 and expire on December 18, 2019.

Just before the financing closed on December 24, 2014, the Series A and Series B preferred stock and unpaid dividends and interest and liquidated damages were converted into common stock.

Warrants

There were warrants to purchase a total of 3,799,024 shares of common stock outstanding at December 31, 2015. All warrants were exercisable at December 31, 2015. The warrants had various exercise prices and terms as follows:

Summary of Warrants	Warrants Outstanding	Exercise Price	Expiration Date
2015 Financing 7/31/15[(a)]	20,000	$ 6.05	07/31/20
2015 Financing 5/11/15[(b)]	625,000	10.00	11/11/17
2015 Financing 5/11/15 agent warrants[(b)]	50,000	11.00	5/11/20
2014 Financing 12/24/14[(c)]	2,572,881	5.00	12/24/19
2014 Financing 12/24/14 agent warrants[(c)]	87,500	5.00	12/18/19
2012 Series B private placement[(d)]	400,001	25.00	10/24/18
2011 November private placement[(e)]	42,898	100.00	11/10 & 30/16
2011 November placement agent warrants[(e)]	744	83.50 & 100.00	11/10 & 30/16
Total	3,799,024		

(a) In connection with the offering on July 31, 2015, the placement agent received warrants to purchase 20,000 share of common stock at $6.05 per share. The warrants are exercisable and expire on July 31. 2020.

NOTE 9 — STOCKHOLDERS' EQUITY – (continued)

(b) In connection with the offering on May 11, 2015, warrants to purchase 625,000 shares of common stock at $10.00 per share were issued. All of the warrants exercisable and expire November 11, 2017.

Also in connection with the offering on May 11, 2015, the placement agent received warrants to purchase 50,000 share of common stock at $11.00 per share. The warrants are exercisable and expire on May 11. 2020.

(c) In connection with an offering on December 24, 2014, warrants to purchase 3,500,000 shares of common stock at $5.00 per share were purchased and issued for $0.01 per warrant. All of the warrants are exercisable immediately and expire on December 24, 2019. At December 31, 2015, 2,572,881 warrants are outstanding.

Also in connection with the offering on December 24, 2014, the underwriter received warrants to purchase 87,500 shares of common stock at $5.00 per share. The warrants were exercisable on December 18, 2015 and expire on December 18, 2019.

(d) In connection with a private placement offering on October 25, 2012, warrants to purchase 400,001 shares of common stock at $25.00 per share were issued. All of the warrants are exercisable immediately and expire on October 24, 2018.

(e) In connection with a private placement offering on November 10 and 30, 2011, warrants to purchase 42,898 shares of common stock at $100.00 per share were issued. All of the warrants are exercisable immediately and 37,148 warrants expire November 10, 2016 and 5,750 warrants expire November 30, 2016.

Also in connection with a private placement offering on November 10 and 30, 2011, placement agent warrants to purchase 372 shares of common stock at $83.50 per share were issued. Also in connection with a private placement offering on November 10 and 30, 2011, placement agent warrants to purchase 372 shares of common stock at $100.00 per share were issued. All the placement agent warrants are exercisable immediately and 372 warrants expire November 10, 2016 and 372 warrants expire November 30, 2016.

NOTE 10 — STOCK OPTION PLANS

Our stock-based employee compensation plans described below:

2015 Equity Incentive Plan

We have a stock awards plan, (the 2015 Equity Incentive Plan), under which 5,000,000 shares of our authorized but unissued common stock were reserved for issuance to employees, consultants, or to non-employee members of the Board or to any board of directors (or similar governing authority) of any affiliate of the Company. The 2015 Equity Incentive Plan, approved by our shareholders on May 7, 2015, replaced the previously approved stock option plan (the 2005 Equity Incentive Plan).

For the 2015 Equity Incentive Plan, the fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in fiscal 2015: dividend yield of 0%; volatility of 102%; risk-free interest rate of 0.86%; and expected lives of 5.0 years. The weighted average fair value of options granted was $6.90 per share during 2015.

Summarized information for the 2015 Equity Incentive Plan is as follows:

	Options	Weighted-average exercise price
Outstanding options at January 1, 2015	—	$ —
Granted, fair value of $5.18 per share	1,994,000	6.90
Outstanding options at December 31, 2015	1,994,000	6.90
Exercisable at December 31, 2015	35,000	7.34

There was no intrinsic value related to the outstanding or exercisable options under this plan at December 31, 2015.

NOTE 10 — STOCK OPTION PLANS – (continued)

Further information regarding options outstanding under the 2015 Equity Incentive Plan at December 31, 2015 is summarized below:

Range of exercise prices	Number of options outstanding	Weighted-average Remaining life in years	Weighted-average Exercise price	Number of options exercisable	Weighted-average Remaining life in years	Weighted-average Exercise price
$4.38 – 7.34	1,994,000	9.0	$6.90	35,000	9.0	$7.34

2005 Equity Incentive Plan

Under the 2005 Equity Incentive Plan, as amended, shares of our authorized but unissued common stock were reserved for issuance to employees, consultants, or to non-employee members of the Board or to any board of directors (or similar governing authority) of any affiliate of the Company. As of January 20, 2015 no additional shares were available for grant under the 2005 Equity Incentive Plan. A total of 330,084 options were outstanding and exercisable under this plan at December 31, 2015.

For the 2005 Equity Incentive Plan, the fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in fiscal 2015: dividend yield of 0%; volatility of 102%; risk-free interest rate of 1.41%; and expected lives of 4.6 years. The weighted average fair value of the options grants was $4.52 per share in 2015.

The assumptions for fiscal 2014 are: dividend yield of 0%; volatility of 102%; risk-free interest rate of 0.79%; and expected lives of 5.5 years. The weighted average fair value of the options granted was $14.50 per share in 2014.

Summarized information for the 2005 Equity Incentive Plan is as follows:

	Options	Weighted-average exercise price
Outstanding options at January 1, 2014	28,784	$59.00
Granted, fair value of $14.50 per share	212,500	18.50
Expired/forfeited	(31,200)	37.61
Outstanding options at December 31, 2014	210,084	20.19
Granted, fair value of $4.52	120,000	3.25
Outstanding options at December 31, 2015	330,084	13.49
Exercisable at December 31, 2015	319,884	15.02

The intrinsic value related to the outstanding or exercisable options under this plan at December 31, 2015 was $13,000 and $12,000, respectively. At December 31, 2014, the intrinsic value related to the outstanding or exercisable options was none.

Further information regarding options outstanding under the 2005 Equity Incentive Plan at December 31, 2015 is summarized below:

Range of exercise prices	Number of options outstanding	Weighted-average Remaining life in years	Weighted-average Exercise price	Number of options exercisable	Weighted-average Remaining life in years	Weighted-average Exercise price
$3.25	120,000	4.0	$ 3.25	110,000	4.0	$ 3.25
$11.50 – 18.50	200,000	7.7	$ 18.33	199,800	7.7	$ 18.32
$30.50 – 42.50	4,000	4.1	$ 32.19	4,000	4.1	$ 32.19
$69.00	1,400	4.0	$ 69.00	1,400	4.0	$ 69.00
$113.50 – 157.50	4,684	5.0	$ 119.99	4,684	5.0	$119.99
	330,084		319,884			

NOTE 11 — 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 (AA NAGLU) and ABO-102 (AAV SGSH), adeno-associated virus (AAV)-based gene therapies for Sanfilippo syndrome (MPS IIIA and IIIB, respectively) in collaboration with patient advocate groups, researchers and clinicians, anticipated to commence clinical trials in 2016.

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 was estimated at $6,489,000.

The following purchase price allocation is as follows:

Total purchase price	
Initial consideration	$31,758,000
Contingent consideration	6,489,000
Total purchase price	$38,247,000
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	3,625,000
Licensing agreement	2,156,000
Goodwill	32,466,000
Total net asset value	$38,247,000

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

The first milestone of receiving IND allowance from the FDA to initiate a Phase 1 clinical study from MPS IIIA or MPSIIIB by November 15, 2015 was not met after the measurement period ended. The Company recognized $3,898,000 in Miscellaneous Income for change in fair value of our contingent consideration liability.

Goodwill is not expected to be deductible for tax purposes.

NOTE 12 — INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

	2015	2014
Income taxes at U.S. statutory rate	$(4,939,000)	$(9,105,000)
Current year reserve	6,257,000	1,254,000
Other	(1,318,000)	7,851,000
Total tax expense	$ —	$ —

Deferred taxes are provided for the temporary differences between the financial reporting bases and the tax bases of our assets and liabilities. The temporary differences that give rise to deferred tax assets were as follows:

	December 31,	
	2015	2014
Deferred tax assets		
Net operating loss carryforwards	$ 68,636,000	$ 68,263,000
General business credit carryforwards	2,497,000	2,486,000
State credits	2,055,000	2,061,000
Property, equipment and goodwill	(25,000)	—
Stock options	3,678,000	542,000
Derivatives	(92,000)	(92,000)
Deferred revenue	1,669,000	92,000
Intangible assets	595,000	464,000
Accrued interest	253,000	253,000
Other	231,000	231,000
Gross deferred tax assets	79,497,000	74,300,000
Valuation allowance	(79,497,000)	(74,300,000)
Net deferred taxes	$ —	$ —

At December 31, 2015, we had approximately $209,666,000 of net operating loss carryforwards and approximately $2,497,000 of general business credit carryforwards. These carryforwards expire as follows:

	Net operating loss carryforwards	General business credit carryforwards
2016	$ —	$ —
2017	—	—
2018	3,324,000	112,000
Thereafter	206,342,000	2,385,000
	$209,666,000	$2,497,000

As a result of a merger on January 25, 1996, a change in control occurred for federal income tax purposes, which limits the utilization of pre-merger net operating loss carryforwards of approximately $3,100,000 to approximately $530,000 per year.

Additionally, we acquired MacroChem Corporation on February 25, 2009 and Somanta Pharmaceuticals, Inc. on January 4, 2008. Both corporations were loss companies at the time of the acquisition. Therefore, the net operating losses related to those acquisitions may be subject to annual limitations as provided by IRC Sec. 382.

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Corporate Information

Directors

Steven H. Rouhandeh
Chairman of the Board
Executive Chairman
Chief Investment Officer
SCO Capital Partners

Mark J. Ahn
Vice Chairman
Principal Pukana Partners

Mark J. Alvino
Hudson Square Capital LLC

Jeffrey B. Davis
Chief Operating Officer

Stephen B. Howell, MD
Professor of Medicine at the University of California San Diego
Director of the Cancer Pharmacology Program – UCSD Cancer Center

Timothy J. Miller, PhD
President and CEO

Todd Wider, MD
Investor

Officers & Senior Management

Steven H. Rouhandeh
Executive Chairman
Principal Executive Officer

Timothy J. Miller, PhD
President and CEO

Jeffrey B. Davis
Chief Operating Officer

Harrison G. Wehner
Chief Financial Officer

Stephen B. Thompson
Vice President Finance
Principal Accounting Officer

Corporate Headquarters

Abeona Therapeutics Inc.
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214-905-5101 (fax)
alucca@abeonatherapeutics.com (e-mail)

Internet Web Site - Corporate

http://www.abeonatherapeutics.com

Corporate Counsel

Morgan, Lewis & Bockius LLP
Boston, Massachusetts

Patent Counsel

Foley & Lardner LLP
Palo Alto, California

Independent Auditors

Whitley Penn LLP
Dallas, Texas

Transfer Agent

American Stock Transfer & Trust Company
Shareholder Services
6201 15th Avenue, 3rd Floor
Brooklyn, New York 11219
718-921-8200
800-937-5449

Investor Relations

SEC Form 10K
A copy of our annual report to the Securities and Exchange Commission on Form 10-K is available without charge upon written request to:

Abeona Therapeutics Inc.
Attn: Investor Relations
1325 Avenue of the Americas,
27th Floor
New York, NY 10019

Price Range of Common Stock

2015	High	Low
1st quarter	$3.55	$2.91
2nd quarter	$9.80	$2.77
3rd quarter	$6.89	$3.98
4th quarter	$4.80	$3.36

2014	High	Low
1st quarter	$29.40	$12.50
2nd quarter	$27.00	$14.00
3rd quarter	$17.50	$11.50
4th quarter	$13.50	$ 3.44

As of June 19, 2015 our Common Stock trades on NASDAQ under the symbol ABEO. On June 19, 2015 we changed our name to Abeona Therapeutics Inc.

From December 19, 2014 until June 18, 2015 our Common Stock traded on NASDAQ under the symbol PTBI. From November 21, 2014 until December 18, 2014 our Common Stock was traded under the symbol PTBI on the OTC Bulletin Board, or QTCQB. From October 24, 2014 until November 20, 2014 our Common Stock was traded under the symbol ACCPD on the OTCQB. On October 24, 2014 we changed our corporate name from Access Pharmaceuticals, Inc. to PlasmaTech Biopharmaceuticals, Inc. and effected a 1 for 50 reverse stock split. Prior to October 24, 2014, our Common Stock was traded under the symbol ACCP on the QTCQB.

No cash dividends have been paid on our Common Stock and we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. As of April 5, 2016 there were approximately 7,300 holders of record of our Common Stock and the closing price on that date was $3.03 per share.

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