As filed with the Securities and Exchange Commission on September 9, 2016
Registration Number 333-197220

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

ABEONA THERAPEUTICS INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**3841**	**83-0221517**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

3333 Lee Parkway, Suite 600
Dallas, Texas 75219
(214) 665-9495
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Stephen B. Thompson
Vice President Finance
Abeona Therapeutics Inc.
3333 Lee Parkway, Suite 600
Dallas, Texas 75207
(214) 665-9495
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

with a copy to:
John J. Concannon III, Esq.
Morgan, Lewis & Bockius LLP
One Federal Street
Boston, MA 02110
(617) 951-8000

Approximate date of commencement of proposed sale to public:
As soon as practicable after the effective date hereof.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. ☑

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. ☐

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

Larger accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☒

EXPLANATORY NOTE

This Post-Effective Amendment No. 1 (this "Post-Effective Amendment") to the Registration Statement on Form S-1 (333-197220) ("the "Registration Statement"), as declared effective by the Securities Exchange Commission (the "SEC") on December 18, 2014 is being filed to update certain disclosures in the Registration Statement and the prospectus contained therein to, among other things, include the information contained in the Company's Annual Report on Form 10-K (the "Annual Report") for the fiscal year ended December 31, 2015 that was filed with the SEC on March 30, 2016, and to make certain other updates contained herein. No additional securities are being registered under this Post-Effective Amendment. Accordingly, this Post-Effective Amendment concerns only the exercise of the Warrants (defined below) registered under the Registration Statement. All applicable registration fees were paid at the time of the original filing of the Registration Statement.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SECTION 8(A), MAY DETERMINE.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities or the solicitation of an offer to buy these securities in any state in which such offer, solicitation, or sale is not permitted.

SUBJECT TO COMPLETION DATED SEPTEMBER 9, 2016

PROSPECTUS

Up to 2,572,881 Shares of Common Stock Upon Exercise of Outstanding Warrants

Abeona Therapeutics Inc.

This Prospectus relates to 2,572,881 shares of common stock, $0.01 par value per share of Abeona Therapeutics Inc. ("Abeona" or the "Company"), which as of the date of this Prospectus, are issuable upon exercise of outstanding warrants originally issued on December 22, 2014 (the "Warrants").

As of the date of this Prospectus, each Warrant has an exercise price of $5.00 and entitles its holder to purchase one share of Abeona common stock and expires December 22, 2019.

The Warrants were issued as part of a registered public offering that closed on December 24, 2014.

If the Warrants are exercised, Abeona will receive the proceeds from such exercise. All costs associated with this registration will be borne by Abeona.

On September 7, 2016, the last reported sale price of our common stock was $4.79 per share. Our common stock is listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "ABEO". These prices will fluctuate based on the demand for the shares of common stock. The Warrants are also listed on Nasdaq under the symbol "ABEOW". These prices will fluctuate based on the demand for the shares of common stock.

Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under the applicable state law or that an exemption from registration is available.

No underwriter or person has been engaged to facilitate the sale of shares of common stock in this offering. None of the proceeds from the sale of stock by the selling stockholders will be placed in escrow, trust or any similar account.

INVESTING IN THE OFFERED SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 6 OF THIS PROSPECTUS FOR A DISCUSSION OF INFORMATION THAT YOU SHOULD CONSIDER BEFORE INVESTING IN OUR SECURITIES.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

These securities have not been approved or disapproved by the Securities and Exchange Commission or any state securities commission nor has the Securities and Exchange Commission or any state securities commission passed upon the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offense.

THE DATE OF THIS PROSPECTUS IS SEPTEMBER 9, 2016.

FORWARD-LOOKING STATEMENTS

This prospectus 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 prospectus, 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 under “Risk Factors” and elsewhere in this prospectus. The factors set forth under “Risk Factors” and other cautionary statements made in this prospectus should be read and understood as being applicable to all related forward-looking statements wherever they appear in this prospectus. The forward-looking statements contained in this prospectus represent our judgment only as of the date of this prospectus. 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.

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You should rely only on the information provided in this prospectus or amendment thereto. We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give to you. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock and warrants.

PROSPECTUS SUMMARY

2,572,881 Shares of Common Stock Upon Exercise of Outstanding Warrants

This summary highlights certain information appearing elsewhere in this prospectus. For a more complete understanding of this offering, you should read the entire prospectus carefully, including the risk factors and the financial statements. References in this prospectus to "we," "us," "our," "Company" and "Abeona" refer to Abeona Therapeutics Inc. You should read both this prospectus and any prospectus supplement together with additional information described below under the heading "Where You Can Find More Information" on page 58.

ABOUT ABEONA

Company Overview

We are a clinical-stage biopharmaceutical company focused on delivering gene and plasma- based therapeutics for life-threatening rare diseases. We were incorporated in 1974 in Delaware. 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; 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; and EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)), and the AAV-based gene therapy EB-201 (AAV DJ COL7A1) technology, gene therapy treatments for epidermolysis bullosa ("EB"). In addition, we are also developing rare plasma protein therapies including PTB-101 SDF Alpha™ (alpha-1 protease inhibitor) for inherited COPD using our proprietary SDF™ (Salt Diafiltration) ethanol-free process. Our principal executive office is located at 3333 Lee Parkway, Suite 600, Dallas, Texas 75219. Our website address is *www.abeonatherapeutics.com*.

Recent Developments

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

On August 3, 2016, we announced that we entered into an agreement ("Agreement") with EB Research Partnership ("EBRP") and Epidermolysis Bullosa Medical Research Foundation ("EBMRF") to collaborate on gene therapy treatments for EB. The Agreement became effective, August 3, 2016, on the execution of two licensing agreements with The Board of Trustees of Leland Stanford Junior University ("Stanford") described below.

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

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

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

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

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

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.

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).

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.

SUMMARY OF THE OFFERING

Securities offered by us	Up to 2,572,881 shares of our common stock issuable from time to time upon exercise of the Warrants.
Description of Warrants	Each Warrant has an exercise price of $5.00 and entitles the holder to purchase one share of common stock. The Warrants expire on December 22, 2019.
Common stock to be outstanding immediately after this offering	36,118,584 shares of our common stock if the Warrants are exercised in full.
Use of proceeds	The net proceeds if all the Warrant holders, as of the date of this Prospectus, exercise their Warrants will be approximately $12.9 million, however, we are unable to predict the timing or amount of potential Warrant exercises. As such, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds will be used for general corporate purposes. It is possible that some, or all, of the Warrants may expire and never be exercised.
Risk Factors	You should read the "Risk Factors" section starting on page 6 for a discussion of factors to consider carefully before deciding to invest in our securities.
NASDAQ Capital Market Trading Symbol	Our shares of common stock and warrants are listed on Nasdaq under the symbol "ABEO" and "ABEOW," respectively.

The total number of shares of our common stock outstanding is 33,545,703 as of September 9, 2016 and excludes the following:

- 2,572,881 shares issuable upon the exercise of Warrants;
- 3,118,323 shares of common stock reserved for future issuance under our equity incentive plans. As of September 9, 2016, there were options to purchase 3,763,060 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of $5.84 per share;
- 1,226,143 shares of common stock issuable upon exercise of outstanding warrants as of September 9, 2016 with exercise prices ranging from $5.00 per share to $100.00 per share;
- 1,000,000 shares of common stock issued to Plasma Technologies LLC for licensed technology; and
- 557,103 shares of common stock to be issued to previous members of Abeona Therapeutics LLC if Milestone 3 is met prior to November 15, 2016.

RISK FACTORS

Any investment in our securities involves a high degree of risk. You should carefully consider the risks described below, which we believe represent certain of the material risks to our business, together with the information contained elsewhere in this Prospectus, before you make a decision to invest in our securities. If any of the following events occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our securities could decline and you could lose all or part of your investment.

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 40.8%, 5.1%, 5.1% and 5.0%, respectively, of our common stock as of September 9, 2016. 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.

Risks relating to this offering

Future sales by our stockholders may adversely affect our stock price and our ability to raise funds in new stock offerings.

Sales of our common stock in the public market following this offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable or at all. We have issued 33,545,703 shares of common stock as of September 9, 2016. Of these shares, (i) 17,606,724 shares are unrestricted and held by non-affiliates, and are freely tradable without restriction under the Securities Act, (ii) 15,136,289 shares are restricted and held by affiliates and are subject to the restrictions of Rule 144, and (iii) 802,690 shares are restricted and held by non-affiliates and are subject to the restrictions of Rule 144. The sale of 1,226,143 shares issuable upon exercise of outstanding warrants (in addition to the Warrants) could also lower the market price of our common stock.

USE OF PROCEEDS

The net proceeds if all the Warrant holders, as of the date of this Prospectus, exercise their Warrants will be approximately $12.9 million, however, we are unable to predict the timing or amount of potential Warrant exercises. As such, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds will be used for general corporate purposes. It is possible that some, or all, of the Warrants may expire and never be exercised.

DILUTION

Our net tangible book value as of June 30, 2016 was approximately $27.3 million, or approximately $0.83 per share. Net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of common stock outstanding as of June 30, 2016.

After giving effect to the exercise of 2,572,881 Warrants sold in the offering that remain outstanding at June 30, 2016 at an exercise price of $5.00 per Warrant share, our as adjusted net tangible book value as of June 30, 2016 would have been approximately $40.1 million, or approximately $1.13 per share. This represents an immediate increase in net tangible book value of $0.30 per share to existing stockholders of our Company and an immediate decrease in the net tangible book value of $3.87 per share to holders of warrants exercised from this offering, as illustrated in the following table:

Exercise price per warrant		$ 5.00
Net tangible book value per share as of June 30, 2016	$ 0.83	
Increase in net tangible book value per share attributable to holders of Warrants	$ 0.30	
As adjusted net tangible book value per share as of September 9, 2016, after giving effect to the exercise of 2,572,881 Warrants		$ 1.13
Decrease in net tangible book value per share to holders of Warrants exercised from this offering		$ 3.87

PRICE RANGE OF OUR COMMON STOCK

Market Information

Our common stock has traded on The NASDAQ Capital Market ("Nasdaq") under the symbol ABEO since June 22, 2015.

Our common 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, ("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. We also changed our corporate name to Abeona Therapeutics Inc. on June 19, 2015.

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 2016 year-to-date and fiscal years 2015 and 2014, as appilicable. 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 2016 Year-to-date		
First quarter	$ 3.50	$ 2.10
Second quarter	3.26	2.27
Third quarter (through September 7, 2016)	4.79	2.32
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

Holders

The number of record holders of our common stock at September 8, 2016 was approximately 7,000. On September 7, 2016, the closing price for the common stock as quoted on the Nasdaq was $4.79. There were 33,545,703 shares of common stock outstanding at September 8, 2016.

Options and Warrants

There are 3,799,024 outstanding warrants and 3,763,060 outstanding options to purchase our common equity as of September 8, 2016.

Shares Eligible for Future Sales

Abeona has issued 33,545,703 shares of common stock as of September 9, 2016. Of these shares, (i) 17,606,724 shares are unrestricted and held by non-affiliates, and are freely tradable without restriction under the Securities Act, (ii) 15,136,289 shares are restricted and held by affiliates and are subject to the restrictions of Rule 144 as described below, and (iii) 802,690 shares are restricted and held by non-affiliates and are subject to the restrictions of Rule 144 as described below.

Rule 144

In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the ninety (90) days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six (6) months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person is entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates, are entitled to sell within any three (3)-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately 361,185 shares if the Warrants are exercised in full, or

- the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 must be made through unsolicited brokers' transactions. They are also subject to manner of sale provisions, notice requirements and the availability of current public information about us.

DIVIDEND POLICY

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.

CAPITALIZATION

The following table presents a summary of our cash and cash equivalents and capitalization as of June 30, 2016:

- on an actual basis: and
- on a pro forma as adjusted basis to:

  (i) give effect to the net proceeds if all the Warrant holders, as of the date of this Prospectus, exercise their Warrants will be approximately $12.9 million, however, we are unable to predict the timing or amount of potential Warrant exercises. As such, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds will be used for general corporate purposes. It is possible that some, or all, of the Warrants may expire and never be exercised;

  (ii) Give effect to up to 2,572,881 shares of our common stock issuable from time to time upon exercise of the Warrants.

You should read the following table in conjunction with "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and historical financial statements and the related notes thereto included in this Prospectus.

	As of June 30, 2016 (in thousands except share data)	
	Actual	Pro forma as adjusted
Stockholders' equity:		
Common stock – $.01 par value; authorized 200,000,000 shares; 32,795,703 shares issued and outstanding, actual; 36,118,584 shares issued and outstanding, pro forma as adjusted	$ 328	$ 361
Additional paid-in capital	383,999	396,830
Accumulated deficit	(322,847)	(322,847)
Total stockholders' equity	61,480	74,344
Total capitalization	$ 61,480	$ 74,344

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 Prospectus.

OVERVIEW

We are a clinical-stage biopharmaceutical company focused on delivering gene and plasma- based therapeutics for life-threatening rare diseases. We were incorporated in 1974 in Delaware. 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; 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; and EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)), and the AAV-based gene therapy EB-201 (AAV DJ COL7A1) technology, gene therapy treatments for epidermolysis bullosa ("EB"). 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*.

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 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.

On August 3, 2016, we announced that we entered into an agreement ("Agreement") with EB Research Partnership ("EBRP") and Epidermolysis Bullosa Medical Research Foundation ("EBMRF") to collaborate on gene therapy treatments for EB. The Agreement became effective, August 3, 2016, on the execution of two licensing agreements with The Board of Trustees of Leland Stanford Junior University ("Stanford") described below.

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

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

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

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 at December 31, 2015. The second milestone of dosing of first-patient-in second Phase I clinical study by May 15, 2016 was not met. The Company recognized $591,000 in Miscellaneous Income for change in fair value of our contingent consideration liability at March 31, 2016.

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.

Results of Operations

Comparison of Second Quarter 2016 and Second Quarter 2015

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

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

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

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

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

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

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

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

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

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

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

Comparison of Six Months Ended June 30, 2016 and Six Months Ended June 30, 2015

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

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

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

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

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

- increased stock based compensation expense for granted stock options ($1,338,000) and granted stock ($1,642,000);
- increased salary and related costs and annual bonus payments ($314,000);
- increased net other general and administrative expense ($73,000).
- offset by decreased investor relations fees ($397,000); and
- offset by decreased legal fees ($230,000).

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

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

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

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

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

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

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

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

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.

If we raise additional funds by selling additional equity securities, the relative equity ownership of our existing investors will be diluted and the new investors could obtain terms more favorable than previous investors.

We have incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of June 30, 2016 of $322,847,000. We cannot provide assurance that we will ever be able to generate sufficient product sales or royalty revenue to achieve profitability on a sustained basis, or at all.

Since our inception, we have devoted our resources primarily to fund our research and development programs. We have been unprofitable since inception and to date have received limited revenues from the sale of products. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials and regulatory compliance.

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.

Off-Balance Sheet Transactions

None.

BUSINESS

We are a clinical-stage biopharmaceutical company focused on delivering gene and plasma- based therapeutics for life-threatening rare diseases. We were incorporated in 1974 in Delaware. 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; 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; and EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)), and the AAV-based gene therapy EB-201 (AAV DJ COL7A1) technology, gene therapy treatments for epidermolysis bullosa ("EB"). 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 a severe and life-threatening disease. While rare diseases can affect any age group, about 50% of people affected are children (15 million), and rare diseases account for 35% of deaths in the first year of life. These rare diseases are often poorly diagnosed, very complex, and have no treatment or not very effective treatment—over 95% of rare diseases do not have a single FDA or EMA approved drug treatment. However, most rare diseases are often caused by changes in genes—80% are genetic in origin and can present at any stage of life. We believe emerging insights in genetics and advances in biotechnology, as well as new approaches and collaboration between researchers, industry, regulators and patient groups, provide significant opportunities to develop breakthrough treatments for rare diseases.

Developing Next Generation Gene Therapy

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ABO-301 for Fanconi Anemia (FA)

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

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

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

EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)) and EB-201 (AAV DJ COL7A1) technology for gene therapy treatments for EB

On August 3, 2016, we announced that we entered into an agreement ("Agreement") with EB Research Partnership ("EBRP") and Epidermolysis Bullosa Medical Research Foundation ("EBMRF") to collaborate on gene therapy treatments for EB. The Agreement became effective, August 3, 2016, on the execution of two licensing agreements with The Board of Trustees of Leland Stanford Junior University ("Stanford") described below.

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

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

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

Plasma-based Therapeutics using the SDF™ technology platform

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

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

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

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

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

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

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

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

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

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

Polymer Hydrogel Technology (PHT™)

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

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

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.

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

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.

On August 3, 2016, we announced that we entered into an agreement ("Agreement") with EB Research Partnership ("EBRP") and Epidermolysis Bullosa Medical Research Foundation ("EBMRF") to collaborate on gene therapy treatments for EB. The Agreement became effective, August 3, 2016, on the execution of two licensing agreements with The Board of Trustees of Leland Stanford Junior University ("Stanford") described below.

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

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

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

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.

Recent Developments

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

On August 3, 2016, we announced that we entered into an agreement ("Agreement") with EB Research Partnership ("EBRP") and Epidermolysis Bullosa Medical Research Foundation ("EBMRF") to collaborate on gene therapy treatments for EB. The Agreement became effective, August 3, 2016, on the execution of two licensing agreements with The Board of Trustees of Leland Stanford Junior University ("Stanford") described below.

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

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

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

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

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

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.

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).

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.

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, 27 th Floor, New York, NY 10019. We also have offices and laboratory in Ohio at 6555 Carnegie Ave., 4th Floor, Cleveland, OH 44103.

We were incorporated in 1974. 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 September 9, 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.

PROPERTY

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.

LEGAL PROCEEDINGS

The Company is not currently subject to any material pending legal proceedings.

MANAGEMENT

The following table sets forth the Directors, Executive Officers, and Key Employees of Abeona along with their respective ages and positions as of September 9, 2016:

Name	Age	Title
Steven H. Rouhandeh	59	Chairman of the Board and Executive Chairman*
Mark J. Ahn, Ph.D.	54	Vice Chairman of the Board
Timothy J. Miller	44	President and Chief Executive Officer and Director
Jeffrey B. Davis	53	Chief Operating Officer and Director*
Mark J. Alvino	49	Director
Stephen B. Howell, M.D.	72	Director
Todd Wider, M.D.	52	Director
Stephen B. Thompson	63	Vice President Finance Chief Accounting Officer, Treasurer, Secretary
Harrison G. Wehner	52	Chief Financial Officer

* Appointed to the board of directors by SCO Capital Partners LLC ("SCO") pursuant to a Director Designation Agreement between SCO and Abeona.

None of our directors, officers, affiliates or promoters has, within the past five years, filed any bankruptcy petition, been convicted in or been the subject of any pending criminal proceedings, or is any such person the subject or any order, judgment or decree involving the violation of any state or federal securities laws.

The following is a brief account of the business experience during the past five years of each of our directors and executive officers, including principal occupations and employment during that period and the name and principal business of any corporation or other organization in which such occupation and employment were carried on.

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 a B.A. Political Science, from Southern Illinois University. Mr. Rouhandeh's qualifications to serve our Board include his institutional knowledge of our Company and his extensive domestic and international financial experience in the healthcare industry.

Mark J. Ahn, Ph.D., Vice Chairman became a director in September 2006 and is Vice Chairman of the Board of Directors as of January 1, 2015. Dr. Ahn is chairman of the Compensation Committee of the Board and also a member of the Nominating & Corporate Governance Committee. Dr. Ahn is a Principal at Pukana Partners LLC which provides strategic consulting to life science companies; and Associate Professor (adjunct) at Portland State University. He previously served as Professor and Chair, Science & Technology Management, Victoria University. Dr. Ahn has held senior positions at public and private biotech and healthcare companies including Galena Biopharma, Hana Biosciences, Genentech, Amgen, and Bristol Myers Squibb Company, and currently serves on the board of Immusoft. Dr. Ahn received a B.A. and M.B.A. from Chaminade University, and M.A. from Victoria University, and Ph.D. from the University of South Australia. Dr. Ahn is a Henry Crown Fellow at the Aspen Institute. D r. Ahn's qualifications to serve our Board include his leadership skills and his experience in the areas of financial management and business strategy in the biopharmaceutical field.

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). Dr. Miller's qualifications to serve our Board include his leadership skills and his experience in the areas of scientific research, product development, regulatory and clinical operations in the biopharmaceutical field.

Mr. Jeffrey B. Davis became a director in March 2006. Since January 19, 2015, Mr. Davis is our Chief Operating Officer. 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 holds a B.S. in biomedical engineering from Boston University and an M.B.A. degree from the Wharton School, University of Pennsylvania. Mr. Davis' qualifications to serve on our Board include his past experience as our CEO leading the day to day operations of our Company and his prior experience serving our Board since 2006, as well as his extensive domestic and international financial experience in the healthcare industry.

Mr. Mark J. Alvino became a director in March 2006 initially as a designee of SCO Capital Partners LLC and is chairman of the Audit Committee. He is no longer a designee of SCO Capital Partners LLC. Mr. Alvino is also a member of the Compensation Committee and Nominating and Corporate Governance Committees. Mr. Alvino is currently with Hudson Square Capital LLC since October 2014. From 2013 to October 2014 Mr. Alvino was leading the LifeSciences efforts of Bradley Woods, & Co. Ltd. Mr. Alvino was Managing Director for Griffin Securities from 2007 to 2013. Mr. Alvino was Managing Director for SCO Financial Group LLC from 2002 to 2007. Mr. Alvino was a member of the board of directors of MacroChem Corporation from 2007 until February 2009. He previously worked at Feinstein Kean Healthcare, an Ogilvy Public Relations Worldwide Company. There he was Senior Vice President, responsible for managing both investor and corporate communications programs for many private and public companies and acted as senior counsel throughout the agency's network of offices. Prior to working at FKH, Mr. Alvino served as Vice President of Investor Relations and managed the New York Office of Allen & Caron, Inc., an investor relations agency. His base of clients included medical devices, biotechnology, and e-healthcare companies. Mr. Alvino also spent several years working with Wall Street brokerages including Ladenburg, Thallman & Co. and Martin Simpson & Co. Mr. Alvino's qualifications to serve our Board include his leadership skills and his experience in the areas of financial management and business strategy in the biopharmaceutical field.

Stephen B. Howell, M.D. has served as our director since 1996. Dr. Howell is a member of the Compensation Committee and Nominating and Corporate Governance Committee of the Board. Dr. Howell has been Professor of Medicine at the University of California, San Diego since 1977, and director of the Cancer Pharmacology Program of the UCSD Cancer Center since 2006. Dr. Howell is a recipient of the Milken Foundation prize for his contributions to the field of cancer chemotherapy. He has served on the National Research Council of the American Cancer Society and is on the editorial boards of multiple medical journals. Dr. Howell founded DepoTech, Inc. and served as a member of its board of directors from 1989 to 1999. Dr. Howell served on the board of directors of Matrix Pharmaceuticals from 2000 to 2002. Dr. Howell received his A.B. at the University of Chicago and his M.D. from Harvard Medical School. Dr. Howell's qualifications to serve our Board include his technical expertise and strong commitment to promoting and advancing innovation in the healthcare industry as well as his qualifications include experience as a medical doctor in oncology, his experience as director of several biotech companies and his executive skills and experience as a founder of a biotech company.

Todd Wider, M.D. became a director in May 2015. Dr. Wider is a surgeon and has served as consultant to numerous entities in the biotechnology space. Dr. Wider holds an M.D. from Columbia College of Physicians and a B.A. from Princeton University. Dr. Wider's qualifications to serve our Board include his biotechnology expertise as well as his experience as a surgeon.

Mr. Stephen B. Thompson, the Company's 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.

Mr. Harrison G. Wehner, III became President and 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 CanaccordGenuity 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.

Committees of the Board of Directors

The Board established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of the committees of the Board acts pursuant to a separate written charter adopted by the Board.

The Audit Committee is currently comprised of Mr. Mark J. Alvino (Chairman) and Todd Wider, M.D. The Board has determined that Mr. Alvino is an "audit committee financial expert," under applicable SEC rules and regulations. The Audit Committee's responsibilities and duties are, among other things, to engage the independent auditors, review the audit fees, supervise matters relating to audit functions and review and set internal policies and procedure regarding audits, accounting and other financial controls. The Board has determined that Mr. Alvino and Dr. Wider are independent under applicable SEC and NASDAQ rules and regulations. The Audit Committee acts pursuant to a written charter which is available on our website at www.abeonatherapeutics.com under "Investors."

The Compensation Committee is currently comprised of Mark J. Ahn, Ph.D. (Chairman), Stephen B. Howell, M.D. and Mark J. Alvino. Dr. Ahn, Dr. Howell and Mr. Alvino are non-employee directors under applicable SEC rules, and are "outside" directors under Internal Revenue Code Section 162(m). Dr. Ahn, Dr. Howell and Mr. Alvino are independent under applicable NASDAQ rules and regulations. The Compensation Committee acts pursuant to a written charter which is available on our website at www.abeonatherapeutics.com under "Investors."

The Nominating and Corporate Governance Committee is currently comprised of Mark Ahn, Ph.D., Mr. Mark J. Alvino and Stephen B. Howell, M.D. All committee members are independent under applicable SEC and NASDAQ rules and regulations. The Nominating and Corporate Governance Committee is responsible for, among other things, considering potential Board members, making recommendations to the full Board as to nominees for election to the Board, assessing the effectiveness of the Board and implementing our corporate governance guidelines. The Nominating and Corporate Governance Committee acts pursuant to a written charter which is available on our website at www.abeonatherapeutics.com under "Investors."

Director Independence

We are listed on NASDAQ Capital Market ("NASDAQ") and follow NASDAQ rules and regulations governing director independence. The Board has determined that each of Dr. Ahn, Mr. Alvino, Dr. Howell and Mr. Wider are independent under applicable NASDAQ rules.

Board Leadership Structure

The Board has no set policy with respect to the separation of the offices of Chairman and the Chief Executive Officer. Currently, Steven H. Rouhandeh serves as our Chairman of the Board and as Executive Chairman. There are currently no lead independent directors serving on the Board.

Our Board leadership structure is commonly utilized by other public companies in the United States, and we believe that it is effective for us. This leadership structure is appropriate for us given the size and scope of our business, the experience and active involvement of our independent directors, and our corporate governance practices, which include regular communication with and interaction between and among the Executive Chairman and the Chief Accounting Officer and the independent directors. Of the seven members of our Board, four are independent from management. At this time, we believe that having one person as Chairman and Executive Chairman and independent chairs for each of our Board committees provides the best form of leadership for us.

Board of Director's Role in Risk Oversight

The Board is responsible for overseeing our management and operations, including overseeing our risk assessment and risk management functions. We believe that our directors provide effective oversight of risk management functions. On a regular basis we perform a risk review wherein the management team evaluates the risks we expect to face in the upcoming year and over a longer term horizon. From this risk assessment plans are developed to deal with the risks identified. The results of this risk assessment are provided to the Board for their consideration and review. In addition members of our management periodically present to the Board the strategies, issues and plans for the areas of our business for which they are responsible. While the Board oversees risk management, our management is responsible for day-to-day risk management processes. Additionally, the Board requires that management raise exceptional issues to the Board. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that the Board leadership structure supports this approach.

Code of Business Conduct and Ethics

We have adopted a written Code of Business Conduct and Ethics that applies to all of our directors, officers and employees. A copy of our Code of Business Conduct and Ethics is available on our website at www.abeonatherapeutics.com and print copies are available to any stockholder that requests a copy. Any amendment to the Code of Business Conduct and Ethics or any waiver of the Code of Business Conduct and Ethics will be disclosed on our website at www.abeonatherapeutics.com promptly following the date of such amendment or waiver.

EXECUTIVE COMPENSATION

The following table sets forth the aggregate compensation paid to our CEO and our next two most highly paid executives whose aggregate salary and bonus exceeded $100,000 for services rendered in all capacities for the fiscal years ended December 31, 2015 and 2014.

Summary Compensation Table

Name and Principal Position	Year	Salary ($) (1)	Stock Awards ($) (2)	Option Awards ($) (3)	All Other Compensation (4)	Total ($)
Steven H. Rouhandeh[5]	2015	$ 360,000	$ 2,753,000	$ 398,000	$ -	$ 3,511,000
Executive Chairman	2014	-	-	523,000	-	523,000
Timothy J. Miller, PhD[6]	2015	$ 214,000	$ -	$ 351,000	$ -	$ 565,000
President and Chief Executive Officer						
Scott W. Schorer[7]	2015	$ 123,000	-	$ -	$ 100,000	$ 3,022,000
Former Chief Executive Officer	2014	97,000	-	-	-	97,000
Jeffrey B. Davis [8]	2015	$ 325,000	$ 2,202,000	$ 495,000	$ -	$ 3,022,000
Chief Operating Officer	2014	290,000	-	262,000	-	552,000
Former Chief Executive Officer						
Harrison G. Wehner [9]	2015	$ 350,000	$ -	$ 351,000	$ -	$ 701,000
Chief Financial Officer	2014	97,000	-	-	-	97,000

(1) Includes amounts deferred under our 401(k) Plan, if applicable.

(2) Represents expense recognized in 2015 and 2014 for the fair value of Common Stock vested. The fair value used is the stock price on the date the Common Stock is vested. No Common Stock was vested in 2014.

(3) The value listed in the above table represents the fair value of the options granted in prior years that was recognized in 2015 and 2014 under ASC 718. Fair value is calculated as of the grant date using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards made on the date of grant is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. Our assumptions in determining fair value are described in note 10 to our audited financial statements for the year ended December 31, 2015, included in our annual report on Form 10-K.

(4) Mr. Schorer was paid a severance payment of $100,000 in 2015.

(5) Mr. Rouhandeh, our Chairman of the Board, became Executive Chairman on January 1, 2015, the principal executive officer of the Company. Mr. Rouhandeh was granted 375,000 shares of our Common Stock on May 11, 2015 at a price of $7.34 per share on the grant date. The shares will vest on May 11, 2019.

(6) Dr. Miller became President and Chief Executive Officer on May 15, 2015.

(7) Mr. Schorer was Chief Executive Officer from September 19, 2014 until May 6, 2015.

(8) Mr. Davis was Chief Executive Officer from December 2007 until September 19, 2014. Since January 9, 2015 Mr. Davis is our Chief Operating Officer. Mr. Davis was granted 300,000 shares of our Common Stock on May 11, 2015 at a price of $7.34 per share on the grant date. The shares will vest on May 11, 2016.

(9) Mr. Wehner was President and Chief Financial Officer from September 19, 2014 until May 6, 2015. Since May 6, 2015 he is our Chief Financial Officer.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the aggregate number of option awards held by our named executive officers at December 31, 2015.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)(1)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Steven H. Rouhandeh[2]	-	125,000	$ 7.34	05/11/25	375,000	$ 1,260,000
	80,000	-	18.50	03/07/24		
Timothy J, Miller, PhD[3]	-	400,000	$ 7.34	05/15/25	-	-
Scott W. Schorer[4]	-	-	-	-	-	-
Jeffrey B. Davis [5]	-	100,000	$ 7.34	05/11/25	300,000	$ 1,008,000
	40,000	-	18.50	03/07/24		
	500	-	31.25	08/14/16		
Harrison G. Wehner [6]	-	400,000	$ 7.34	05/11/25	-	-

(1) On December 31, 2015, the closing price of our Common Stock as quoted on NASDAQ was $3.36 per share.

(2) Mr. Rouhandeh's options to purchase 125,000 shares of Common Stock will be fully vested in May 2016.

(3) Dr. Miller's options to purchase 400,000 shares of Common Stock will be fully vested in May 2019.

(4) No amounts to report.

(5) Mr. Davis' options to purchase 100,000 shares of Common Stock will be fully vested in May 2016. Mr. Davis is no longer CEO as of September 19, 2014. Mr. Davis is currently Chief Operating Officer of the Company.

(6) Mr. Wehner's options to purchase 400,000 shares of Common Stock will be fully vested in April 2019.

Compensation Pursuant to Agreements and Plans

Employment Agreements

Executive Chairman

Steven H. Rouhandeh, our Chairman of the Board, was named by the Board as Executive Chairman effective January 1, 2015. Mr. Rouhandeh currently does not have an employment agreement with the Company but is entitled to be paid an annual base salary of $360,000 and receive similar employee benefits as our other executive officers. He was paid $360,000 in 2015.

On March 7, 2014, Mr. Rouhandeh was granted stock options to purchase 80,000 shares of our Common Stock which vested in 2015. On May 11, 2015, Mr. Rouhandeh was granted stock options to purchase 125,000 shares of our Common Stock which will vest in May 2016. Also on May 11, 2015, Mr. Rouhandeh was granted 375,000 shares of our Common Stock which will vest in May 2019.

President and Chief Executive Officer

We are a party to an employment agreement with Timothy J. Miller, PhD, who was named by the Board as our President and Chief Executive Officer and Director, effective as of May 15, 2015. Dr. Miller's employment agreement, dated May 15, 2015 is renewed automatically every year. Pursuant to the terms of his employment agreement, Dr. Miller is entitled to receive an annual base salary of $350,000. He was paid $214,000 in 2015. On May 15, 2015, Dr. Miller was granted stock options to purchase 400,000 shares of our Common Stock which will vest in April 2019. Dr. Miller is entitled to similar employee benefits as our other executive officers.

Former Chief Executive Officer

We were a party to an employment letter agreement with Scott W. Schorer, effective September 19, 2014, who was named by the Board as our Chief Executive Officer from September 19, 2014 until May 6, 2015. Pursuant to the terms of his employment agreement, Mr. Schorer was entitled to be paid an annual base salary of $350,000 subject to annual increases each year, at the discretion of the Board. He was entitled to a merit bonus up to 30% of his annual base salary at the discretion of the Compensation Committee of the Board. Mr. Schorer was entitled to similar employee benefits as our other executive officers. Mr. Schorer was paid a severance payment of $100,000 in 2015.

Chief Operating Officer / Former President and Chief Executive Officer

We were party to an employment agreement, with Jeffrey B. Davis, a Director, who was named by the Board as our Chief Executive Officer, effective from December 26, 2007 until September 19, 2014. Mr. Davis' employment agreement, dated January 4, 2008, was amended April 9, 2008 and was renewed automatically every year. Pursuant to the terms of his employment agreement, as amended, Mr. Davis was entitled to be paid an annual salary of $290,000 in 2014. Under this agreement, Mr. Davis was entitled to receive an annual base salary of $325,000. Mr. Davis was previously awarded stock options to purchase 500 shares of our Common Stock prior to becoming CEO and on March 7, 2014 was awarded stock options to purchase 40,000 shares of our Common Stock.

Mr. Davis became Chief Operating Officer on January 19, 2015 and is entitled to receive an annual base salary of $325,000 and receive similar employee benefits as our other executive officers. On May 11, 2015, Mr. Davis was granted stock options to purchase 100,000 shares of our Common Stock which will vest in May 2016. Also on May 11, 2015, Mr. Davis was granted 300,000 shares of our Common Stock which will vest in May 2016.

Chief Financial Officer

We are a party to an employment letter agreement with Harrison G. Wehner, III, effective September 19, 2014, who was named by the Board as our President and Chief Financial Officer from September 19, 2014 until May 6, 2015. Pursuant to the terms of his employment agreement, Mr. Wehner is entitled to be paid an annual base salary of $350,000 subject to annual increases each year, at the discretion of the Board. He is entitled to a merit bonus up to 30% of his annual base salary at the discretion of the Compensation Committee of the Board. On May 5, 2015, Mr. Wehner became our Chief Financial Officer. Mr. Wehner is entitled to similar employee benefits as our other executive officers. Mr. Wehner was paid $350,000 in 2015. On May 11, 2015, Mr. Wehner was granted stock options to purchase 400,000 shares of our Common Stock which will vest in April 2019.

Compensation of Directors

Each director who is not also an Abeona employee receives a quarterly fee of $10,000. Each director will have $2,000 deducted from his fee if the director misses more than one Board meeting, and $1,000 deducted per committee meeting not attended. In addition, we reimbursed each director, whether an employee or not, the expense of attending Board and committee meetings.

During 2015, each of our outside directors received $10,000 cash compensation for each quarter of 2015 he was a director. During 2015, Dr. Ahn, as Vice Chairman, from May 1, 2015, received a monthly director fee of $23,750. Also during 2015, Dr. Ahn, as Vice Chairman, received an aggregate of 300,000 shares of Common Stock for his service as Vice Chairman; Mr. Alvino and Dr. Howell, as directors, each received an aggregate of 75,000 shares of Common Stock; and, Dr. Wider received 50,000 shares of Common Stock when he was first appointed as a director.

Director Compensation Table – 2015

The table below represents the compensation paid to our outside directors during the year ended December 31, 2015:

Name	Fees earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Mark J. Ahn, Ph.D.	250,000	$ 2,202,000	$ 387,000	-	2,839,000(2)
Mark J. Alvino	40,000	551,000	299,000	-	890,000(3)
Stephen B. Howell, MD	40,000	551,000	299,000	-	890,000(4)
Todd Wider, MD	30,000	176,000	176,000	-	574,000(5)

(1) The value listed represents the fair value of the options recognized as expense under ASC 718 during 2015. Fair value is calculated as of the grant date using a Black-Scholes ("Black-Scholes") option-pricing model. The determination of the fair value of share-based payment awards made on the date of grant is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. Our assumptions in determining fair value are described in note 10 to our audited financial statements for the year ended December 31, 2015, included in our Annual Report on Form 10-K.

(2) Represents expense recognized in 2015 in respect of the fair value of options to purchase 100,000 shares of our Common Stock based on a grant date, May 11, 2015 and options to purchase 10,000 shares of our Common Stock based on a grant date, March 7, 2014. Dr. Ahn had options to purchase 115,320 shares of our Common Stock at December 31, 2015. Dr. Ahn was granted 300,000 shares of our Common Stock on May 11, 2015 at a price of $7.34 per share on the grant date. The shares vest on May 11, 2016.

(3) Represents expense recognized in 2015 in respect of the fair value of options to purchase 75,000 shares of our Common Stock based on a grant date, May 11, 2015 and options to purchase 10,000 shares of our Common Stock based on a grant date, March 7, 2014. Mr. Alvino had options to purchase 87,120 shares of our Common Stock at December 31, 2015. Mr. Alvino was granted 75,000 shares of our Common Stock on May 11, 2015 at a price of $7.34 per share on the grant date. The shares vest on May 11, 2016.

(4) Represents expense recognized in 2015 in respect of the fair value of options to purchase 75,000 shares of our Common Stock based on a grant date, May 11, 2015 and options to purchase 10,000 shares of our Common Stock based on a grant date, March 7, 2014. Dr. Howell had options to purchase 90,344 shares of our Common Stock at December 31, 2015. Dr. Howell was granted 75,000 shares of our Common Stock on May 11, 2015 at a price of $7.34 per share on the grant date. The shares vest on May 11, 2016.

(5) Represents expense recognized in 2015 in respect of the fair value of options to purchase 100,000 shares of our Common Stock based on a grant date, May 11, 2015. Dr. Wider had options to purchase 100,000 shares of our Common Stock at December 31, 2015. Dr. Wider was granted 50,000 shares of our Common Stock on May 11, 2015 at a price of $7.34 per share on the grant date. 50% of the shares vest on May 11, 2016 and 50% vest on May 11, 2017.

PRINCIPAL STOCKHOLDERS

Based solely upon information made available to us, the following table sets forth certain information with respect to the beneficial ownership of our Common Stock as of September 9, 2016 by (i) each person who is known by us to beneficially own more than five percent of any class of our capital stock; (ii) each of our directors; (iii) each of our named executive officers; and (iv) all our executive officers and directors as a group. Beneficial ownership as reported in the following table has been determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended. The address of each holder listed below, except as otherwise indicated, is c/o Abeona Therapeutics Inc., 3333 Lee Parkway, Suite 600, Dallas, Texas 75219.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership Common Stock [1]	Percent of Common Stock[2]
Steven H. Rouhandeh [3]	580,000	1.7%
Timothy J. Miller, Ph.D. [4]	518,810	1.5%
Mark J. Ahn, Ph. D. [5]	634,002	1.9%
Mark J. Alvino [6]	212,120	*
Jeffrey B. Davis [7]	440,647	1.3%
Stephen B. Howell, M.D. [8]	215,315	*
Todd Wider, M.D. [9]	170,000	*
Harrison G. Wehner, III [10]	150,000	*
Stephen B. Thompson [11]	173,496	*
SCO Capital Partners LLC, SCO Capital Partner LP, and Beach Capital LLC [12]	13,844,660	40.8%
Perceptive Advisors LLC [13]	1,762,881	5.1%
Quantum Partners [14]	1,712,122	5.1%
Europa International Inc. [15]	1,666,667	5.0%
All Directors and Executive Officers as a group (consisting of 9 persons) [16]	4,806,012	13.7%

*- Less than 1%

(1) Includes our outstanding shares of Common Stock held plus all shares of Common Stock issuable upon exercise of options, warrants and other rights exercisable within 60 days of September 9, 2016.

(2) Based upon 33,545,703 shares of Common Stock issued and outstanding as of September 9, 2016

(3) Mr. Rouhandeh, our Chairman and Executive Chairman, is known to beneficially own an aggregate of 375,000 shares of our Common Stock, presently exercisable options for the purchase of 125,000 shares of our Common Stock pursuant to the 2015 Equity Incentive Plan and 80,000 shares of our Common Stock pursuant to the 2005 Equity Incentive Plan. He is also Chairman of SCO Financial Group LLC. His address is c/o SCO Capital Partners LLC, 1325 Avenue of the Americas, 27th Floor, New York, NY 10019. SCO Financial Group LLC and affiliates (SCO Capital Partner LP and Beach Capital LLC) are known to beneficially own an aggregate of 13,444,659 shares of our Common Stock and warrants to purchase an aggregate of 400,001 shares of our Common Stock. Mr. Rouhandeh disclaims beneficial ownership of all such shares except to the extent of his pecuniary interest therein.

(4) Dr. Miller, our President and CEO and director, is known to beneficially own an aggregate of 368,810 shares of our Common Stock and presently exercisable options for the purchase of 150,000 shares of our Common Stock pursuant to the 2015 Equity Incentive Plan.

(5) Dr. Ahn, our Vice Chairman and director, is known to beneficially own an aggregate of 343,682 shares of our Common Stock, warrants to purchase an aggregate of 25,000 shares of our Common Stock, presently exercisable options for the purchase of 250,000 shares of our Common Stock pursuant to the 2015 Equity Incentive Plan and 15,320 shares of our Common Stock pursuant to the 2005 Equity Incentive Plan.

(6) Mr. Alvino, our director, is known to beneficially own an aggregate of 75,000 shares of our Common Stock, presently exercisable options for the purchase of 125,000 shares of our Common Stock pursuant to the 2015 Equity Incentive Plan and 12,120 shares of our Common Stock pursuant to the 2005 Equity Incentive Plan.

(7) Mr. Davis, our Chief Operating Officer and director, beneficially owns an aggregate of 300,147 shares of our Common Stock, presently exercisable options for the purchase of 100,000 shares of our Common Stock pursuant to the 2015 Equity Incentive Plan and 40,500 shares of our Common Stock pursuant to the 2005 Equity Incentive Plan. Lake End Capital LLC's address is 36 Lake End Road, Newfoundland, NJ 07435. Lake End Capital LLC is known to beneficially own an aggregate of 963,511 shares of our Common Stock and warrants to purchase an aggregate of 62,500 shares of our Common Stock. Mr. Davis disclaims beneficial ownership of all such shares except to the extent of his pecuniary interest therein.

(8) Dr. Howell, our director, is known to beneficially own an aggregate of 75,495 shares of our Common Stock, presently exercisable options for the purchase of 125,000 shares of our Common Stock pursuant to the 2015 Equity Incentive Plan and 14,820 shares of our Common Stock pursuant to the 2005 Equity Incentive Plan.

(9) Dr. Wider, our director, is known to beneficially own an aggregate of 70,000 shares of our Common Stock and presently exercisable options for the purchase of 100,000 shares of our Common Stock pursuant to the 2015 Equity Incentive Plan

(10) Mr. Wehner, our Chief Financial Officer, is known to beneficially own presently exercisable options for the purchase of 150,000 shares of our Common Stock pursuant to the 2015 Equity Incentive Plan

(11) Mr. Thompson, our Vice President Finance and Chief Accounting Officer, is known to beneficially own an aggregate of 83,496 shares of our Common Stock, presently exercisable options for the purchase of 75,000 shares of our Common Stock pursuant to the 2015 Equity Incentive Plan and 15,000 shares of our Common Stock pursuant to the 2005 Equity Incentive Plan.

(12) SCO Capital Partners LLC, SCO Capital Partner LP, Beach Capital LLC and SCO Financial Group's address is 1325 Avenue of the Americas, 27th Floor, New York, NY 10019. SCO Financial Group LLC and affiliates (SCO Capital Partners LP and Beach Capital LLC) are known to beneficially own an aggregate of 13,444,659 shares of our Common Stock and warrants to purchase an aggregate of 400,001 shares of our Common Stock. Mr. Rouhandeh, director of Abeona, and Mr. Rouhandeh is an executive of SCO Capital Partners LLC and disclaims his beneficial ownership of such shares except to the extent of his pecuniary interest therein.

(13) Perceptive Advisors LLC's address is 499 Park Avenue, 25 th Floor, New York, NY 10022 is known to beneficially own an aggregate of 1,762,881 shares of our Common Stock.

(14) Quantum Partners, Soros Fund Management LLC, George Soros and Robert Soros whose address is 250 West 55 th Street, 38th Floor, New York, NY 10019 are known to beneficially own an aggregate of 1,462,122 shares of our Common Stock and warrants to purchase an aggregate of 250,000 shares of our Common Stock.

(15) Europa International Inc.'s address is c/o Knoll Capital Management 5 East 44 th Street, Suite 12, New York, NY 10017. Europa International is known to beneficially own an aggregate of 1,666,667 shares of our Common Stock.

(16) Does not include shares held by SCO Financial Group LLC and affiliates.

CERTAIN TRANSACTIONS

On occasion we may engage in certain related party transactions.

On September 10, 2014, we entered into an Unsecured Grid Note, for up to $250,000 with 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 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.

DESCRIPTION OF SECURITIES

Our certificate of incorporation authorizes the issuance of 100,000,000 shares of its common stock, $.01 par value per share, and 2,000,000 shares of preferred stock, $.01 par value per share, which may be issued in one or more series. As of September 9, 2016 there were 33,545,703 shares of Abeona's common stock outstanding and held of record by approximately 7,000 stockholders, and there were no shares of preferred stock outstanding.

Common Stock

Holders of Abeona's common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and have the right to vote cumulatively for the election of directors. This means that in the voting at Abeona's annual meeting, each stockholder or his proxy, may multiply the number of his shares by the number of directors to be elected then cast the resulting total number of votes for a single nominee, or distribute such votes on the ballot among the nominees as desired. Holders of Abeona's common stock are entitled to receive ratably such dividends, if any, as may be declared by Abeona's Board of Directors out of funds legally available therefor, subject to any preferential dividend rights for Abeona's outstanding preferred stock. Upon Abeona's liquidation, dissolution or winding up, the holders of Abeona's common stock are entitled to receive ratably Abeona's net assets available after the payment of all debts and other liabilities and subject to the prior rights of any of Abeona's outstanding preferred stock. Holders of Abeona's common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of Abeona's common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of Abeona's preferred stock which Abeona may designate and issue in the future.

Preferred Stock

Abeona's Board of Directors is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 2,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control.

Warrants

As of September 9, 2016, warrants to purchase 2,572,881 shares of our common stock, included in this Prospectus were outstanding, all exercisable at an exercise price of $5.00 per warrant and expire on December 22, 2019.

In addition, as of September 9, 2016, warrants to purchase 1,226,143 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of $16.69 per warrant, all of which are exercisable through various dates expiring between November 10, 2016 and July 31, 2020.

The descriptions of the warrants are only a summary and are qualified in their entirety by the provisions of the forms of the warrant.

Transfer Agent and Registrar

The transfer agent and registrar of our common stock is American Stock Transfer & Trust Company, New York, New York.

Delaware Law and Certain Charter and By-Law Provisions

Certain anti-takeover provisions.

We are subject to the provisions of Section 203 of the General Corporation Law of Delaware. Section 203 prohibits certain publicly held Delaware corporations from engaging in a "business combination" with an "interested stockholder," for a period of three years after the date of the transaction in which the person became an "interested stockholder", unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an "interested stockholder" is a person or entity who, together with affiliates and associates, owns (or within the preceding three years, did own) 15% or more of the corporation's voting stock. The statute contains provisions enabling a corporation to avoid the statute's restrictions if the stockholders holding a majority of the corporation's voting stock approve our Certificate of Incorporation provides that our directors shall be divided into three classes, with the terms of each class to expire on different years.

In addition, our Certificate of Incorporation, in order to combat "greenmail," provides in general that any direct or indirect purchase by us of any of our voting stock or rights to acquire voting stock known to be beneficially owned by any person or group which holds more than five percent of a class of our voting stock and which has owned the securities being purchased for less than two years must be approved by the affirmative vote of at least two-thirds of the votes entitled to be cast by the holders of voting stock, subject to certain exceptions. The prohibition of "greenmail" may tend to discourage or foreclose certain acquisitions of our securities which might temporarily increase the price of our securities. Discouraging the acquisition of a large block of our securities by an outside party may also have a potential negative effect on takeovers. Parties seeking control of us through large acquisitions of its securities will not be able to resort to "greenmail" should their bid fail, thus making such a bid less attractive to persons seeking to initiate a takeover effort.

Elimination of Monetary Liability for Officers and Directors

Our Certificate of Incorporation incorporates certain provisions permitted under the General Corporation Law of Delaware relating to the liability of directors. The provisions eliminate a director's liability for monetary damages for a breach of fiduciary duty, including gross negligence, except in circumstances involving certain wrongful acts, such as the breach of director's duty of loyalty or acts or omissions, which involve intentional misconduct or a knowing violation of law. These provisions do not eliminate a director's duty of care. Moreover, these provisions do not apply to claims against a Director for certain violations of law, including knowing violations of federal securities law. Our Certificate of Incorporation also contains provisions to indemnify the directors, officers, employees or other agents to the fullest extent permitted by the General Corporation Law of Delaware. We believe that these provisions will assist us in attracting and retaining qualified individual to serve as directors.

Indemnification of Officers and Directors

Our Certificate of Incorporation also contains provisions to indemnify the directors, officers, employees or other agents to the fullest extent permitted by the General Corporation Law of Delaware. These provisions may have the practical effect in certain cases of eliminating the ability of shareholders to collect monetary damages from directors. We believe that these provisions will assist us in attracting or retaining qualified individuals to serve as our directors.

Disclosure of Commission Position on Indemnification For Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, the Registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

PLAN OF DISTRIBUTION

We will deliver shares of our common stock offered hereby upon exercise of the Warrants we issued on December 22, 2014. As of the date of this Prospectus, the Warrants were exercisable for a total of up to 2,572,881 shares of our common stock, which can be adjusted pursuant to the terms of the Warrants, and no more of the Warrants will be issued. We will not issue fractional shares upon exercise of the Warrants. Each of the Warrants contains instructions for exercise. In order to exercise any of the Warrants, the holder must deliver to us or our transfer agent the information required in the Warrants, along with payment for the exercise price of the shares to be purchased. We will then deliver shares of our common stock in the manner described in the form of warrant, which is filed as an exhibit to the Registration Statement of which this Prospectus is a part.

EXPERTS

The consolidated financial statements of Abeona for the years ended December 31, 2015 and 2014 included in this prospectus, and included in the Registration Statement, were audited by Whitley Penn LLP, an independent registered public accounting firm, as stated in their report appearing with the consolidated financial statements herein and incorporated in this Registration Statement, and are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The independent registered public accounting firm named above has no interest in the prospectus.

LEGAL MATTERS

Morgan, Lewis & Bockius LLP has previously passed upon the validity of the securities offered hereby.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission, Washington, D.C. 20549, under the Securities Act of 1933, a registration statement on Form S-1 relating to the shares of common stock offered hereby. This Prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to our company and the shares we are offering by this Prospectus you should refer to the registration statement, including the exhibits and schedules thereto. You may inspect a copy of the registration statement without charge at the Public Reference Section of the Securities and Exchange Commission at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission. The Securities and Exchange Commission also maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Securities and Exchange Commission. The Securities and Exchange Commission's World Wide Web address is http://www.sec.gov.

We file periodic reports, proxy statements and other information with the Securities and Exchange Commission in accordance with requirements of the Exchange Act. These periodic reports, proxy statements and other information are available for inspection and copying at the regional offices, public reference facilities and Internet site of the Securities and Exchange Commission referred to above. In addition, you may request a copy of any of our periodic reports filed with the Securities and Exchange Commission at no cost, by writing or telephoning us at the following address:

Investor Relations
Abeona Therapeutics Inc.
3333 Lee Parkway, Suite 600
Dallas, Texas 75219
(214) 665-9495

Information contained on our website is not a prospectus and does not constitute a part of this Prospectus.

You should rely only on the information contained in or incorporated by reference or provided in this Prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume the information in this Prospectus is accurate as of any date other than the date on the front of this Prospectus.

INDEX TO THE FINANCIAL STATEMENTS OF
ABEONA THERAPEUTICS INC.

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	Treasury	Accumulated	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount	capital	stock	(deficit)	(deficit)
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.

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.

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.

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:

(in thousands, except share and per share amounts)

	For the year ended December 31, 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

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 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 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.

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.

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

	Number of	Weighted average		Number of	Weighted-average	
Range of exercise prices	options outstanding	Remaining life in years	Exercise price	options exercisable	Remaining life in years	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.

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

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

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Operations
(unaudited)

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

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity
(unaudited)

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

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

Abeona Therapeutics Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows
(unaudited)

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

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

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

(1) Interim Financial Statements

The condensed consolidated balance sheet as of June 30, 2016, the condensed consolidated statements of operations for the three and six months ended June 30, 2016 and 2015, the condensed consolidated statements of stockholders' equity for the three and six months ended June 30, 2016, and the condensed consolidated statements of cash flows for the six months ended June 30, 2016 and 2015, were prepared by management without audit. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. It is suggested that these interim financial statements be read in conjunction with the consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2015. The results of operations for the period ended June 30, 2016 are not necessarily indicative of the operating results which may be expected for a full year. The condensed consolidated balance sheet as of December 31, 2015 contains financial information taken from the audited Abeona financial statements as of that date.

(2) Intangible Assets

Intangible assets consist of the following (in thousands):

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

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

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

(3) Fair Value Measurements

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

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

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

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

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

Financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2016 and December 31, 2015 are summarized below:

(in thousands)

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

(in thousands)

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

(4) Stock Based Compensation and Restricted Stock Compensation

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

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

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

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

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

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

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

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

(5) Litigation

We are not currently subject to any material legal proceedings.

(6) Subsequent Events

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

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

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

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

Up to 2,572,881 Shares of Common Stock
Issuable Upon Exercise of Outstanding Warrants

PROSPECTUS

SEPTEMBER 9, 2016

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

Expenses of the Registrant in connection with the issuance and distribution of the securities being registered, are estimated as follows:

Printing and Engraving Expenses	$	0
Legal Fees and Expenses	$	10,000
Accountants' Fees and Expenses	$	5,000
Miscellaneous Costs	$	0
Total	$	25,000

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation law empowers a Delaware corporation to indemnify its officers and directors and certain other persons to the extent and under the circumstances set forth therein.

The our Certificate of Incorporation, as amended, and By-laws, as amended, provide for indemnification of our officers and directors and certain other persons against liabilities and expenses incurred by any of them in certain stated proceedings and under certain stated conditions.

The above discussion of the Registrant's Certificate of Incorporation, as amended, By-laws, as amended, and Section 145 of the Delaware General Corporation Law is not intended to be exhaustive and is qualified in its entirety by such Certificate of Incorporation, By-Laws and statute.

Item 15: Recent Sales of Unregistered Securities

On August 3, 2016, we issued 750,000 shares of restricted common stock, at a price of $3.27 per share per our agreements to two foundations. The issuance of the shares of our common stock was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

On April 21, 2016, we issued 52,690 shares of restricted common stock, at a price of $2.85 per share to a foundation per a previous agreement. The issuance of the shares of our common stock was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

On April 23, 2015 we closed a $7 million private placement of common stock consisting of 2,333,333 shares of common stock, at a price of $3.00 per share. The issuance of shares of our common stock was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

On May 11, 2015, we closed a $10 million private placement of common stock consisting of 1,250,000 shares of 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 $10.00 per share and are exercisable for 30 months following the closing date. In connection with the private placement, 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. The issuance of shares of our common stock and warrants to purchase shares of our common stock was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

On May 15, 2015, we closed our acquisition of Abeona Ohio. In connection with the closing, we issued a total of 3,979,761 shares of common stock to Abeona Ohio members.

All of the above-described issuances were exempt from registration pursuant to Section 4(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder, as transactions not involving a public offering.

Item 16. Exhibits

The following is a list of exhibits filed as a part of this Registration Statement:

Exhibit Number	Description of Document
1.1	Form of Underwriting Agreement (Incorporated by reference to Exhibit 1.1 of our Registration Statement on Form S-1, filed on November 6, 2014, Commission File No. 333-197220)
1.2	At Market Issuance Sales Agreement, dated August 26, 2016, by and among the Company, FBR Capital Markets & Co., JonesTrading Institutional Services LLC, and Maxim Group LLC (Incorporated by reference to Exhibit 1.1 of our Form 8-K filed August 26, 2016)
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)
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)
5.1	Opinion of Morgan, Lewis & Bockius LLP (incorporated by reference to Exhibit 5.1 of our Registration Statement on Form S-1 filed on December 3, 2014, Commission File No. 333-197220)
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)
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 10.16 to our Form 10-Q for the quarter ended June 30, 2013 filed on August 14, 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 filed on March 31, 2015)
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 filed on August 14, 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 on 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 on 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 filed on August 14, 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 filed on August 14, 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 filed on November 16, 2015)
10.22	Form of Indemnification Agreement, between us and directors and officers of the Company (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the quarter ended June 30, 2016 filed on August 15, 2016)
21	Subsidiaries of the Registrant (Incorporated by reference to Exhibit 21 to our Form 10-K for the year ended December 31, 2015 filed on March 31, 2016)
23.1	Consent of Whitley Penn LLP
23.2	Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1)
24	Power of Attorney (included in signature page to our Registration Statement on Form S-1, filed on November 6, 2014, Commission File No. 333-197220)

* 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 Securities 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.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (ii), and (iii) of this section do not apply if the registration statement is on Form S-1 (§ 239.11 of this chapter), Form S-3 (§ 239.13 of this chapter), Form SF-3 (§ 239.45 of this chapter) or Form F-3 (§ 239.33 of this chapter) and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)) that are incorporated by reference in the registration statement, or, as to a registration statement on Form S-3, Form SF-3 or Form F-3, is contained in a form of prospectus filed pursuant to § 230.424(b) of this chapter that is part of the registration statement.

(2) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(3) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(4) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this Post-Effective Amendment No. 1 on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized in the city of Dallas, state of Texas, on September 9, 2016.

ABEONA THERAPEUTICS INC.

Date September 9, 2016 By: /s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
Principal Executive Officer

Date September 9, 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 Act of 1933, this Post-Effective Amendment No.1 on Form S-1 has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date September 9, 2016 By: /s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
Principal Executive Officer
Chairman of the Board

Date September 9, 2016 By: /s/ Stephen B. Thompson
Stephen B. Thompson
Vice President Finance
Principal Financial Officer and
Principal Accounting Officer

Date September 9, 2016 By: *
Mark J. Ahn, Director

Date September 9, 2016 By: *
Mark J. Alvino, Director

Date September 9, 2016 By: /s/ Jeffrey B. Davis
Jeffrey B. Davis, Chief Operating Officer and Director

Date September 9, 2016 By: *
Stephen B. Howell, Director

Date September 9, 2016 By: /s/ Timothy J. Miller
Timothy J. Miller, President & CEO and Director

Date September 9, 2016 By: /s/ Todd Wider
Todd Wider, Director

* Executed September 9, 2016 by Jeffrey B. Davis as attorney-in-fact under power of attorney granted in Registration Statement Previously Filed July 2, 2014.

Exhibit Number	Description of Document

Exhibit Number

1.1	Form of Underwriting Agreement (Incorporated by reference to Exhibit 1.1 of our Registration Statement on Form S-1, filed on November 6, 2014, Commission File No. 333-197220)
1.2	At Market Issuance Sales Agreement, dated August 26, 2016, by and among the Company, FBR Capital Markets & Co., JonesTrading Institutional Services LLC, and Maxim Group LLC (Incorporated by reference to Exhibit 1.1 of our Form 8-K filed August 26, 2016)
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)
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)
5.1	Opinion of Morgan, Lewis & Bockius LLP (incorporated by reference to Exhibit 5.1 of our Registration Statement on Form S-1 filed on December 3, 2014, Commission File No. 333-197220)
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)
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 10.16 to our Form 10-Q for the quarter ended June 30, 2013 filed on August 14, 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 filed on March 31, 2015)
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 filed on August 14, 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 on 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 on 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 filed on August 14, 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 filed on August 14, 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 filed on November 16, 2015)
10.22	Form of Indemnification Agreement, between us and directors and officers of the Company (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the quarter ended June 30, 2016 filed on August 15, 2016)
21	Subsidiaries of the Registrant (Incorporated by reference to Exhibit 21 to our Form 10-K for the year ended December 31, 2015 filed on March 31, 2016)
23.1	Consent of Whitley Penn LLP
23.2	Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1)
24	Power of Attorney (included in signature page to our Registration Statement on Form S-1, filed on November 6, 2014, Commission File No. 333-197220)

* 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 Securities 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.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement on Post-Effective Amendment No. 1 to Form S-1 of Abeona Therapeutics Inc. of our report dated March 30, 2016 relating to our audits of the consolidated financial statements of Abeona Therapeutics Inc. as of and for the years ended December 31, 2015 and 2014. We also consent to the reference to our firm under the heading "Experts" in such Registration Statement.

/s/ Whitley Penn, LLP
Dallas, Texas
September 9, 2016