

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

POST-EFFECTIVE AMENDMENT NO. 2 TO  
FORM S-1  
On FORM S-3

REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933

**ABEONA THERAPEUTICS INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**3841**  
(Primary Standard Industrial  
Classification Code Number)

**83-0221517**  
(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 the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: ☐

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 of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, 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, please 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 statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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 ☒

**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.**

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**EXPLANATORY NOTE**

This Post-Effective Amendment No. 2 (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 pursuant to Section 10(a)(3) of the Securities Act to update certain disclosures in the Registration Statement to, among other things, (i) include the information contained in the Company’s Annual Report on Form 10-K (the “Annual Report”) for the fiscal year ended December 31, 2016 that was filed with the SEC on March 30, 2017, (ii) make certain other updates contained herein so that such information is current as of the date of filing, and (iii) convert the Registration Statement on Form S-1 into a Form S-3.

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 filing fees payable in connection with the registration of the shares registered by the Registration Statement were paid at the time of the original filing of the Registration Statement.

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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 APRIL 25, 2017

**PROSPECTUS**

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



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 to purchase one share of Abeona common stock and expires December 24, 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 April 24, 2017, the last reported sale price of our common stock was \$5.25 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.

**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.**

THE DATE OF THIS PROSPECTUS IS APRIL 25, 2017.

## 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 23.*

ABOUT ABEONA

**Company Overview**

Abeona Therapeutics Inc. (together with our subsidiaries, “we”, “our”, “Abeona” or the “Company”) is a Delaware corporation. We are a clinical stage biopharmaceutical company developing gene therapies for life-threatening rare genetic diseases. Our lead programs are ABO-102 (AAV-SGSH) and ABO-101 (AAV-NAGLU), adeno-associated virus (AAV) based gene therapies for Sanfilippo syndrome (MPS IIIA and IIIB, respectively). We are also developing EB-101 (gene-corrected skin grafts) for recessive dystrophic epidermolysis bullosa (RDEB), EB-201 for epidermolysis bullosa (EB), ABO-201 (AAV-CLN3) gene therapy for juvenile Batten disease (JNCL), ABO-202 (AAV-CLN1) gene therapy for treatment of infantile Batten disease (INCL), and ABO-301 (AAV-FANCC) for Fanconi anemia (FA) disorder and ABO-302 using a novel CRISPR/Cas9-based gene editing approach to gene therapy for rare blood diseases. In addition, we have a plasma-based protein therapy platform, using our proprietary SDF<sup>TM</sup> (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](http://www.abeonatherapeutics.com).

**Recent Developments**

On March 29, 2017, Harrison G. Wehner resigned as our Chief Financial Officer and became our Executive Vice President, Plasma.

On March 8, 2017, we announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products granted Orphan Drug Designation for our EB-101 gene therapy program for patients with recessive dystrophic epidermolysis bullosa (RDEB).

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

- ABO-102 gene therapy well tolerated in 4 subjects (N=3 low dose, N=1 high dose) through 650 days follow up with no Serious Adverse Events.
- 63% +/- 0.5% central nervous system reduction of heparan sulfate GAG 6 months post-injection (N=2).
- Continued evidence of biopotency including reduced liver and spleen volumes and decreased urinary GAGs.

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- Two subjects assessed at the 6-month time point showed evidence for stabilization or improvement (average 60% over 2 subjects) in several Mullen subdomains.
- Adaptive behavior ratings on the Vineland stabilized.
- Subjects showed improved ability to complete individual items on the Leiter-R non-verbal IQ assessment resulting in improved raw scores.

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

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

On January 9, 2017, Mark J. Ahn, Ph.D., resigned from his position as Vice Chairman and director of the Company.

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

### **Other Key Developments**

On November 1, 2016, we closed an underwritten public offering of 6,000,000 shares of common stock, at a public offering price of \$7.00 per share. On November 23, 2016, we closed a follow-on offering of 293,889 shares as permitted by the underwriting agreement at the same offering price of \$7.00 per share. The gross proceeds to the Company were approximately \$44,000,000, before deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company.

On October 25, 2016, we announced that the FDA granted Fast Track designation for ABO-102, a single intravenous injection of AAV gene therapy for subjects with MPS IIIA (Sanfilippo syndrome type A).

On October 20, 2016, we announced an update on clinical results through 30 days post-injection for the completed low-dose cohort (n=3) in the ongoing Phase 1/2 trial for ABO-102 (AAV-SGSH). The ongoing Phase 1/2 study is designed to evaluate safety and preliminary indications of efficacy of ABO-102 in subjects suffering from Mucopolysaccharidosis Type A (MPS IIIA or Sanfilippo syndrome type A). Observations 30 days post-injection for the low dose cohort demonstrated:

- ABO-102 was well-tolerated in subjects injected with the low dose of 5E12 vg/kg ABO-102 with no treatment related adverse events or serious adverse events (SAEs). Following favorable review of the safety data by the independent Data Safety Monitoring Board (DSMB), enrollment in the high dose cohort has commenced.
- In the natural history study evaluating MPS III subjects, urine and cerebral spinal fluid GAG (heparan sulfate or "HS") were significantly elevated in the subject population as a symptom of disease pathology.
- All subjects in the low-dose cohort experienced reductions from baseline in both urinary HS and CSF. At 30 days post-injection, urinary HS reduction was 57.6% +/- 8.2%. Reduction in CSF HS was 25.6% +/- 0.8%, suggesting that ABO-102 crossed the blood brain barrier after intravenous administration.
- The natural history study in 25 subjects with MPS III (*Truxal et. al., 2016, Mol. Genet. Metab.*) demonstrated that study subjects had increased liver and spleen volumes averaging 116% and 88%, respectively, at baseline that did not change over a year of follow up.
- All three subjects demonstrated significant reductions in liver volume (17.7% +/- 1.9%), and spleen volume (17.6% +/- 7.1%) from baseline, as measured by MRI at 30 days post-injection.

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The Data Safety Monitoring Board approved dose escalation of the high-dose cohort in the fourth quarter of 2016.

On October 18, 2016, we announced that the EMA Committee for Orphan Medicinal Products granted Orphan Drug Designation for our lead gene therapy program ABO-102 for the treatment of patients with Sanfilippo syndrome type A (MPS IIIA).

On October 7, 2016, we announced that preclinical data supporting clinical trials for ABO-201 (AAV-CLN3), the AAV-based single intravenous gene therapy program for juvenile Batten disease, (juvenile neuronal ceroid lipofuscinosis, JNCL), were published in the September 2016 issue of the Journal of Neuroscience. Researchers concluded that a single intravenous injection “led to widespread virus biodistribution in the brain, spinal cord, and eye” that was capable of “improving motor function, attenuating microglial and astrocyte activation, and reducing lysosomal pathology, all hallmarks of JNCL” at an age when significant lysosomal pathology had already manifested.

On September 26, 2016, we announced that the first patient was enrolled in the Phase 2 portion of the clinical trial for EB-101 (gene-corrected skin grafts).

On September 21, 2016, we announced the exclusive worldwide license of a next-generation gene therapy AAV capsid portfolio from University of North Carolina at Chapel Hill. The AIM<sup>TM</sup> vector system is a next generation platform of AAV capsids capable of widespread central nervous system gene transfer and can be used to confer high transduction efficiency for various therapeutic indications. Studies indicate that AIM vectors can efficiently and broadly target CNS tissue, and may provide a treatment for patients that have inhibitory antibodies to natural AAV serotypes. Importantly, the AIM vector system may provide second-generation treatment approaches for patients that have received a previous AAV injection.

On September 8, 2016, we announced that we enrolled the fifth patient in the Phase 1/2 clinical trial for EB-101 (gene-corrected skin grafts). The Phase 1/2 clinical trial with gene-corrected skin grafts has shown promising wound healing and safety in patients with RDEB. Investigators at Stanford are now expanding enrollment to adolescent patients for the Phase 1/2 trial to determine the safety and efficacy of COL7A1 gene-corrected grafts on wound healing efficacy. Clinical data on the initial four patients in the Phase 1/2 trial were recently presented at the opening Plenary Session of the Society for Investigative Dermatology.

On August 9, 2016, we announced, together with the EB Research Partnership and EB Medical Research Foundation, a collaboration for the development of treatments for recessive dystrophic epidermolysis bullosa (RDEB). Clinical results for the lead EB program (EB-101) were presented at the opening Plenary Session of the Society for Investigative Dermatology in May 2016, and investigators at Stanford are recruiting patients for a Phase 2 clinical trial of EB-101 in adolescents age 13 and older to determine the effect of type VII collagen gene corrective grafts on wound healing efficacy.

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 we anticipate conducting the Phase 1/2 clinical study in Spain this year.

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

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



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In connection with the EB Agreement Abeona issued 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 EB Agreement agreed that they 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 EB Agreement. The shares are subject to restrictions on selling, transferring or otherwise disposing of such shares. These restrictions 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 EB 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 to license the invention "Gene Therapy for Recessive Dystrophic EB using Genetically Corrected Autologous Keratinocytes". Under the terms of the licensing agreements, we paid upfront licensing fees in cash, and will pay annual license maintenance fees and, subject to the achievement of certain milestones, regulatory approval milestone payments, as well as royalty payments on annual net sales of the licensed product.

On May 24, 2016, we announced that the FDA 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, had 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 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 Comité Ético De Investigación Clínica de Euskadi (CEIC-E) approved the ethical committee regulatory filings for both ABO-101 and ABO-102.

### **Corporate Information**

Our principal executive office is located at 3333 Lee Parkway, Suite 600, Dallas, Texas 75219. Our telephone number in Dallas is (214) 665-9495. We also have offices in New York at 1325 Avenue of the Americas, 27<sup>th</sup> Floor, New York, NY 10019. Our telephone number in New York is (212) 786-6201. We also have offices and laboratory in Ohio at 6555 Carnegie Ave., 4<sup>th</sup> Floor, Cleveland, OH 44103. Our phone number in Cleveland is (216) 282-8145.

We were incorporated in Wyoming in 1974 as Chemex Corporation, and in 1983 we changed our name to Chemex Pharmaceuticals, Inc. We changed our state of incorporation from Wyoming to Delaware on June 30, 1989. In 1996 we merged with Access Pharmaceuticals, Inc., a private Texas corporation, and changed our name to Access Pharmaceuticals, Inc. On October 24, 2014 we changed our name to PlasmaTech Biopharmaceuticals, Inc. On May 15, 2015 we acquired Abeona Therapeutics LLC and on June 19, 2015 we changed our name to Abeona Therapeutics Inc.

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**SUMMARY OF THE OFFERING**

|   |   |
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| 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 24, 2019.   |
| Common stock to be outstanding immediately after this offering  | 42,827,963 shares of our common stock if the Warrants are exercised in full.  |
| Use of proceeds   | The net proceeds to us 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 actual 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 40,255,082 as of April 24, 2017 and excludes the following:   |   |
| <ul style="list-style-type: none"><li>• 2,572,881 shares issuable upon the exercise of Warrants;</li><li>• 1,858,323 shares of common stock reserved for future issuance under our equity incentive plans. As of April 24, 2017, there were options to purchase 4,770,935 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$5.61 per share;</li><li>• 1,163,736 shares of common stock issuable upon exercise of outstanding warrants as of April 24, 2017 with exercise prices ranging from \$5.00 per share to \$25.00 per share; and</li><li>• 1,000,000 shares of common stock issued to Plasma Technologies LLC for licensed technology.</li></ul> |   |

## 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 \$332.5 million through December 31, 2016 and \$310.6 million through December 31, 2015. Net loss allocable to common stockholders for the year ended December 31, 2016 was \$21.9 million and the net loss for the year ended December 31, 2015 was \$14.5 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 as well as public offerings of our common stock. 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

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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

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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 rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business, financial condition and results of operations could be substantially harmed.**

We have relied upon and plan to continue to rely upon third-parties, including contract research organizations, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our licensed ongoing preclinical and clinical programs. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our vendors are required to comply with current requirements on good manufacturing practices, or cGMP, good clinical practices, or GCP, and good laboratory practice, or GLP, which are a collection of laws and regulations enforced by the FDA, EMA or comparable foreign authorities for all of our drug candidates in clinical development.

Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

If any of our relationships with these third parties, medical institutions, clinical investigators or contract laboratories terminate, we may not be able to enter into arrangements with alternative contract research organizations on commercially reasonable terms, or at all. In addition, our contract research organizations are not our employees, and except for remedies available to us under our agreements with such contract research organizations, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates.

Contract research organizations may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our drug candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional contract research organizations, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization commences work replacing a previous contract research organization. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our contract

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research organizations, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition or results of operations.

### **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.

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### **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

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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



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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; 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.

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### **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

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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 suits 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

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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.

We are aware of an issued U.S. patent owned by a third party directed to the AAV9 viral vector and methods for its use. This patent was issued in 2002. We understand that the owner of this patent grants licenses under the patent from time to time, and we expect that, prior to commercializing our ABO-101 or ABO-102 product candidates (which utilize the AAV9 vector), we would seek to license this patent. Other licensed technologies may also require the licensing of additional patents for commercialization.

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**We are substantially dependent on technologies we license from Nationwide Children's Hospital for ABO-101 and ABO-102, and if we lose the license to such technologies or the applicable license is terminated for any reason, our ability to develop ABO-101 and ABO-102 would be harmed, and our business, financial condition and results of operations would be materially and adversely affected.**

Our business is substantially dependent upon technology licensed from Nationwide Children's Hospital. Pursuant to the Nationwide Children's Hospital License Agreement, we have been granted exclusive rights for the intellectual property for ABO-101 and ABO-102. All of the intellectual property related to our ABO-101 and ABO-102 is currently owned by Nationwide Children's Hospital, and we have the rights to use such intellectual property pursuant to the Nationwide Children's Hospital License Agreement. Therefore, our ability to develop and commercialize our drug candidates depends entirely on the effectiveness and continuation of the Nationwide Children's Hospital agreement. If we lose the right to license any of these key compounds, our ability to develop existing and new drug candidates would be harmed.

Nationwide Children's Hospital has the right to terminate the Nationwide Children's Hospital License Agreement under certain circumstances, including, but not limited to: (1) in the event of our insolvency or bankruptcy, (2) written notice with at least six months' notice, or (3) if we default on certain of our material obligations and fail to cure the default within a specified period of time.

### **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.

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### **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, 2016 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 SEC or other regulatory authorities.

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### **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, 2016, we had net operating loss carryforwards aggregating approximately \$217 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 beneficially owned approximately 34.5% of our common stock as of April 24, 2017. 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 40,255,082 shares of common stock as of April 24, 2017. Of these shares, (i) 16,378,621 shares are unrestricted and held by non-affiliates, and are freely tradable without restriction under the Securities Act, (ii) 15,520,611 shares are restricted and held by affiliates and are subject to the restrictions of Rule 144, and (iii) 8,355,850 shares are restricted and held by non-affiliates and are subject to the restrictions of Rule 144. The sale of 1,182,501 shares issuable upon exercise of outstanding warrants (in addition to the Warrants) could also lower the market price of our common stock.

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**USE OF PROCEEDS**

The net proceeds to us 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 December 31, 2016 was approximately \$62.5 million, or approximately \$1.55 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 December 31, 2016.

After giving effect to the exercise of 2,572,881 Warrants that remain outstanding at December 31, 2016 at an exercise price of \$5.00 per Warrant share, our as adjusted net tangible book value as of December 31, 2016 would have been approximately \$75.4 million, or approximately \$1.76 per share. This represents an immediate increase in net tangible book value of \$0.21 per share to existing stockholders of our Company and an immediate decrease in the net tangible book value of \$3.24 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 December 31, 2016  | \$ 1.55 |
| Increase in net tangible book value per share attributable to holders of Warrants  | \$ 0.21 |
| As adjusted net tangible book value per share as of December 31, 2016, after giving effect to the exercise of 2,572,881 Warrants | \$ 1.76 |
| Decrease in net tangible book value per share to holders of Warrants exercised from this offering                                | \$ 3.24 |



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**CAPITALIZATION**

The following table presents a summary of our cash and cash equivalents and capitalization as of December 31, 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; and
  - (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,” beginning on page 19 along with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and historical financial statements and the related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2016 which is incorporated herein by reference.

|  | <b>As of December 31, 2016</b>          |                              |
|--|---|------------------------------|
|  | <b>(in thousands except share data)</b> |                              |
|  | <b>Actual</b>                           | <b>Pro forma as adjusted</b> |
| Stockholders’ equity:  |   |                              |
| Common stock – \$.01 par value; authorized 200,000,000 shares; 40,254,457 shares issued and outstanding, actual; 42,827,963 shares issued and outstanding, pro forma as adjusted | \$ 403                                  | \$ 429                       |
| Additional paid-in capital   | 431,168                                 | 444,008                      |
| Accumulated deficit  | (332,473)                               | (332,473)                    |
| Total stockholders’ equity   | 99,098                                  | 111,964                      |
| Total capitalization   | <u>\$ 99,098</u>                        | <u>\$ 111,964</u>            |

#### **PLAN OF DISTRIBUTION**

We will deliver shares of our common stock offered hereby upon exercise of the Warrants. 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.

#### **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 April 24, 2017 there were 40,255,082 shares of Abeona's common stock outstanding and held of record by approximately 8,600 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 April 24, 2017, 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 24, 2019.

In addition, as of April 24, 2017, warrants to purchase 1,163,736 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of \$13.76 per warrant, all of which are exercisable through various dates expiring between October 24, 2018 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.

##### **The NASDAQ Capital Market**

Our common stock is listed on The NASDAQ Capital Market ("Nasdaq") under the symbol "ABEO". The Warrants are also listed on Nasdaq under the symbol "ABEOW".

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### **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 individuals 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.

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**EXPERTS**

The consolidated financial statements of Abeona for the years ended December 31, 2016 and 2015, incorporated by reference from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, were audited by Whitley Penn LLP, an independent registered public accounting firm, as stated in their report, which is incorporated by reference into this Prospectus. Such financial statements have been so incorporated 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 this 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 SEC, Washington, D.C. 20549, under the Securities Act of 1933, a registration statement on Form S-3 relating securities 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 SEC 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 SEC. The SEC also maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The SEC's website is <http://www.sec.gov>.

We file periodic reports, proxy statements and other information with the SEC 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 SEC referred to above. In addition, you may request a copy of any of our periodic reports filed with the SEC 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.

#### INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference in this Prospectus the information in documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information in this Prospectus updates (and, to the extent of any conflict, supersedes) information incorporated by reference that we have filed with the SEC prior to the date of this Prospectus. **You should read the information incorporated by reference because it is an important part of this Prospectus.**

We incorporate by reference the documents listed below (SEC File No. 001-36833):

- Our Annual Report on Form 10-K for the fiscal year ended December 30, 2016, filed with the SEC on March 30, 2017;
- Our Current Reports on Form 8-K filed with the SEC on January 9, 2017, January 27, 2017, February 3, 2017 and February 17, 2017 and February 23, 2017; and
- The description of our common stock and warrants to purchase common stock in our Registration Statement on Form 8-A, filed with the SEC on November 4, 2014, including any amendment or reports filed for the purpose of updating such description.

We also incorporate by reference any future filings we will make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act (other than filings or portions of filings that are furnished under applicable SEC rules rather than filed), including those made after the date of filing of the Registration Statement and prior to its effectiveness, until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We hereby undertake to provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, a copy of any or all documents that are incorporated by reference into this prospectus, but not delivered with the prospectus, other than exhibits to such documents unless such exhibits are specifically incorporated by reference into the documents that this prospectus incorporates. To request such materials, please contact Investor Relations, Abeona Therapeutics Inc., 3333 Lee Parkway, Suite 600, Dallas, Texas 75219, (214) 665-9495. These documents are also available free of charge through the Investors section on our website at <http://www.abeonatherapeutics.com> as soon as practicable after such materials have been electronically filed with, or furnished to, the SEC.

#### Item 3. 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 or persons controlling the Company pursuant to the foregoing provisions, the Company has been informed that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

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



PROSPECTUS

APRIL 25, 2017

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 14. Other Expenses of Issuance and Distribution**

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

|                                  |    |        |
|----------------------------------|----|--------|
| SEC registration fee             | \$ | 0*     |
| Legal Fees and Expenses          | \$ | 10,000 |
| Accountants' Fees and Expenses   | \$ | 5,000  |
| Printing and Miscellaneous Costs | \$ | 0      |
| Total                            | \$ | 15,000 |

\* The Registrant previously paid \$5,490.45 to the SEC in connection with the registration of the Warrants.

**Item 15. 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 16. Exhibits**

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

|     | Exhibit<br>Number |
|-----|-------------------|
| 3.1 |                   |
| 3.2 |                   |
| 3.3 |                   |
| 3.4 |                   |
| 3.5 |                   |
| 3.6 |                   |

3.7

3.8

3.9



|      | Exhibit<br>Number |
|------|-------------------|
| 3.10 |                   |
| 3.11 |                   |
| 3.12 |                   |
| 3.13 |                   |
| 3.14 |                   |
| 3.15 |                   |

3.16

3.17

3.18

4.1\*

4.2\*

5.1

10.1

23.1\*\*

23.2

24

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

\*\* Filed herewith.

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

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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) 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.
  - (3) 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.
  - (4) 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 and each post-effective amendment that contains a form of prospectus 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.
  - (5) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.
  - (6) 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

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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.

(7) That, for the purpose of determining liability under the Securities Act of 1933 to any purchase if the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *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 effective date, 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 effective date.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Post-Effective Amendment No. 2 to Form S-1 on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Dallas, state of Texas, on April 25, 2017.

|                     |  |
|---------------------|--|
| Date April 25, 2017 | ABEONA THERAPEUTICS INC.<br>By: <u>/s/ Steven H. Rouhandeh</u><br>Steven H. Rouhandeh<br>Executive Chairman<br>Principal Executive Officer             |
| Date April 25, 2017 | By: <u>/s/ Stephen B. Thompson</u><br>Stephen B. Thompson<br>Vice President Finance<br>Principal Financial Officer and<br>Principal Accounting Officer |

Pursuant to the requirements of the Securities Act of 1933, this Post-Effective Amendment No. 2 to Form S-1 on Form S-3 has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

|                     |  |
|---------------------|--|
| Date April 25, 2017 | By: <u>/s/ Steven H. Rouhandeh</u><br>Steven H. Rouhandeh<br>Executive Chairman<br>Principal Executive Officer<br>Chairman of the Board                |
| Date April 25, 2017 | By: <u>/s/ Stephen B. Thompson</u><br>Stephen B. Thompson<br>Vice President Finance<br>Principal Financial Officer and<br>Principal Accounting Officer |
| Date April 25, 2017 | By: <u>*</u><br>Mark J. Alvino, Director   |
| Date April 25, 2017 | By: <u>/s/ Jeffrey B. Davis</u><br>Jeffrey B. Davis, Chief Operating Officer and<br>Director   |
| Date April 25, 2017 | By: <u>*</u><br>Stephen B. Howell, Director  |
| Date April 25, 2017 | By: <u>/s/ Timothy J. Miller</u><br>Timothy J. Miller, President & CEO and Director  |
| Date April 25, 2017 | By: <u>/s/ Todd Wider</u><br>Todd Wider, Director  |

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\* Executed April 25, 2017 by Jeffrey B. Davis as attorney-in-fact under power of attorney granted in Registration Statement Previously Filed July 2, 2014.

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|     | Exhibit<br>Number |
|-----|-------------------|
| 3.1 |                   |
| 3.2 |                   |
| 3.3 |                   |
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| Exhibit<br>Number | Description of Document   |
|-------------------|---|
| 4.2*              | 2015 Equity Incentive Plan amendment (Incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed on April 4, 2016)   |
| 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              | 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)   |
| 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)                                   |

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

\*\* Filed herewith.

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

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We have issued our report dated March 30, 2017, accompanying the consolidated financial statements included in the Annual Report of Abeona Therapeutics Inc. and Subsidiaries on Form 10-K for the years ended December 31, 2016 and 2015. We hereby consent to the incorporation by reference of said report in Abeona Therapeutics, Inc.'s Registration Statement on Post-Effective Amendment No. 2 to Form S-1 on Form S-3 (File No 333-197220). We also consent to the reference to our firm under the heading "Experts" in such Registration Statement.

/s/ Whitley Penn LLP

Dallas, Texas

April 25, 2017

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