
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **August 3, 2016**

ABEONA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

0-9314

(Commission File Number)

83-0221517

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

3333 Lee Parkway, Suite 600

Dallas, TX 75219

(Address of principal executive offices) (Zip Code)

(214) 214-665-9495

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01. Entry into a Material Definitive Agreement

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

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

In connection with the Agreement Abeona will issue to EBRP and EBMRF an aggregate of 750,000 unregistered shares of Abeona Common Stock, \$0.01 par value per share.

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

Item 3.02. Unregistered Sales of Equity Securities.

As described in Item 1.01 of this Current Report on Form 8-K, as part of the Agreement Abeona will issue an aggregate of 750,000 unregistered shares of Abeona Common Stock, \$0.01 par value, 375,000 each to EBRP and EBMRF. The offer, sale, and issuance of the shares of Abeona common stock are exempt from registration pursuant to Rule 506 of Regulation D and Section 4(2) of the Securities Act of 1933, as amended. The recipients of securities under the Agreement agreed that day are acquiring the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends are to be affixed to the securities to be issued in conjunction with the Agreement. The shares will be subject to restrictions on selling, transferring or otherwise disposing of such shares. These restrictions shall lapse with respect to an aggregate 250,000 shares on the first anniversary of the issue date; and with respect to an additional aggregate 500,000 shares on the second anniversary of the issue date. We have an option to acquire an additional license in the future for an additional amount shares as set forth in the Agreement.

Item 8.01. Other Events

On August 9, 2016, we issued a press release announcing the definitive agreement entitled "Abeona Therapeutics, EB Research Partnership and EB Medical Research Foundation to Collaborate on Epidermolysis Bullosa (EB) Treatments". The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

No. Description

99.1	Press release dated August 9, 2016, entitled “Abeona Therapeutics, EB Research Partnership and EB Medical Research Foundation to Collaborate on Epidermolysis Bullosa (EB) Treatments”
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SIGNATURE

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

Abeona Therapeutics Inc.
(Registrant)

By: /s/ Stephen B. Thompson
Stephen B. Thompson
Vice President Finance
Chief Accounting Officer

Date: August 9, 2016

EXHIBIT INDEX

Exhibit Number

99.1 Press release dated August 9, 2016, entitled “Abeona Therapeutics, EB Research Partnership and EB Medical Research Foundation to Collaborate on Epidermolysis Bullosa (EB) Treatments”



Abeona Therapeutics, EB Research Partnership and EB Medical Research Foundation to Collaborate on Epidermolysis Bullosa (EB) Treatments

New York, NY and Cleveland, OH – August 9, 2016 – Abeona Therapeutics Inc. (Nasdaq: ABEO)

- *Collaboration will focus on gene therapy treatments for epidermolysis bullosa (EB)*
- *EB-101, an ex vivo gene therapy for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), demonstrated promising Phase 1 results*
- *Phase 2 clinical trials expected to begin in 3Q2016 for EB-101*
- *EB-201 is a pre-clinical candidate targeting a novel, AAV-mediated gene editing and delivery approach to correct gene mutations in skin cells (keratinocytes)*

Abeona Therapeutics Inc. (Nasdaq: ABEO), a clinical-stage biopharmaceutical company focused on delivering gene and plasma-based therapy for life-threatening rare diseases, EB Research Partnership (EBRP) and EB Research Medical Foundation (EBMRF) announced today a collaboration focusing on gene therapy treatments for epidermolysis bullosa (EB), a group of devastating rare genetic skin disorders impacting children; characterized by skin blisters and erosions all over the body.

“The addition of the EB gene therapy programs to our clinical pipeline advances our mission of serving those impacted by rare disease. The strong Phase 1 clinical data demonstrate safety and initial efficacy one year post treatment, and support a follow-on Phase 2 trial for children suffering from EB,” said Timothy Miller, PhD., President and CEO of Abeona Therapeutics.

“This collaboration builds on our strengths in developing gene therapies for devastating rare diseases in partnership with patient groups and academic research centers,” said Steven H. Rouhandeh, Executive Chairman of Abeona Therapeutics. “We are proud to work with the EB Research Partnership, EB Medical Research Foundation and Stanford University to accelerate these promising product candidates towards commercialization.”

Phase 1 clinical trial results for the lead EB program, EB-101 for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), were recently presented at the opening Plenary Session of the Society for Investigative Dermatology in May 2016. Investigators at Stanford are recruiting patients for a Phase 2 trial to begin soon. These novel gene therapy products were developed at the Stanford University School of Medicine and are exclusively licensed to Abeona.

“This collaboration exemplifies the mission of EBRP to advance commercially sustainable research aimed at treating and ultimately curing epidermolysis bullosa,” stated Alexander Silver, co-founder and Chairman, EBRP. “We believe that Abeona can fully realize our mission of progressing research insights from academia into life-changing treatment solutions for EB patients and their families. This partnership also validates EBRP’s venture philanthropy model, which is important in getting treatments to patients as soon as possible. We are thankful to the team at Stanford for all their hard work and assistance in forming this partnership.”

Recessive dystrophic epidermolysis bullosa (RDEB) is a severe inherited blistering skin disease caused by absence of a protein known as type VII collagen. Patients with RDEB develop large, severely painful blisters and chronic wounds from minor trauma to their skin and there are currently no FDA approved treatments. The Phase 1 clinical trial with gene-corrected skin grafts has shown promising wound healing and safety in adult patients with RDEB. Investigators at Stanford are now recruiting patients for a Phase 2 trial with EB-101 in adolescents age 13 and older to determine the effect of type VII collagen gene-corrected grafts on wound healing efficacy.

About Epidermolysis Bullosa (EB): EB is a group of devastating, life-threatening genetic skin disorders impacting children that is characterized by skin blisters and erosions all over the body. One of the most severe forms is recessive dystrophic epidermolysis bullosa (RDEB) characterized by chronic skin blistering, open and painful wounds, joint contractures, esophageal strictures, pseudosyndactyly, corneal abrasions, and a shortened life span. Patients with RDEB lack functional type VII collagen owing to mutations in the gene COL7A1 that encodes for C7. C7 is the main component of anchoring fibrils that attach the dermis to the epidermis. EB patients suffer through intense pain throughout their lives, with few or no effective treatments available to reduce the severity of their symptoms. Along with the life-threatening infectious complications associated with this disorder, many individuals will develop an aggressive form of squamous cell carcinoma (SCC). Abeona’s lead EB product, EB-101 (gene-corrected skin grafts), is a gene therapy currently in clinical trials for the treatment of RDEB patients.

About Abeona: Abeona Therapeutics Inc. is a clinical stage company developing gene therapy and plasma-based therapies for severe and life-threatening rare genetic diseases. Abeona's 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 ABO-201 (AAV-CLN3) gene therapy for juvenile Batten disease (JBD); and ABO-301 (AAV-FANCC) for Fanconi anemia (FA) disorder using a novel CRISPR/Cas9-based gene editing approach to gene therapy program for rare blood diseases. In addition, Abeona is developing plasma protein therapies, including SDF Alpha™ (alpha-1 protease inhibitor) for inherited COPD, using our proprietary SDF™ (Salt Diafiltration) ethanol-free process. For more information, visit www.abeonatherapeutics.com.

About EB Research Partnership (EBRP): EBRP is the largest 501(c)(3) nonprofit dedicated to funding research aimed at treating and ultimately curing Epidermolysis Bullosa, a group of devastating and life-threatening skin disorders that affect children from birth. EBRP uses a sustainable philanthropic model via venture philanthropy for all of its research commitments. To learn more, please visit ebresearch.org.

About EB Medical Research Foundation (EBMRF): The Epidermolysis Bullosa Medical Research Foundation was founded in 1991 with the mission of funding a cure for EB and is currently headed by The Joseph Family in Los Angeles. The Foundation is dedicated to raising funds and awareness for critical EB research, as well as providing outreach through the media and various fundraising programs. To learn more, please visit www.ebkids.org

This press release contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended, and that involve risks and uncertainties. These statements include, without limitation, our plans for continued development and internationalization of our clinical programs, management plans for the Company, our expectation to accelerate our product candidates towards commercialization, and general business outlook. These statements are subject to numerous risks and uncertainties, including but not limited to continued interest in our rare disease portfolio, our ability to enroll patients in clinical trials, the impact of competition; the ability to develop our products and technologies; the ability to achieve or obtain necessary regulatory approvals; the impact of changes in the financial markets and global economic conditions; and other risks as may be detailed from time to time in the Company's Annual Reports on Form 10-K and other reports filed by the Company with the Securities and Exchange Commission. The Company undertakes no obligations to make any revisions to the forward-looking statements contained in this release or to update them to reflect events or circumstances occurring after the date of this release, whether as a result of new information, future developments or otherwise.

Company and Media Contact:

Andre'a Lucca
Vice President, Communications & Operations
Abeona Therapeutics Inc
+1 (212)-786-6208
alucca@abeonatherapeutics.com

Christine Berni-Silverstein
Vice President, Investor Relations
Abeona Therapeutics Inc
+1 (212)-786-6212
csilverstein@abeonatherapeutics.com

EBRP Company and Media Contact:

Jessica Scheer
Executive Director
EB Research Partnership
+1 (212) 554-1413
jessica@ebresearch.org
