#### 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): July 26, 2018

# ABEONA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware

001-15771

83-0221517

(State or other jurisdiction of incorporation)

(Commission File Number)

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

### 1330 Avenue of the Americas, 33<sup>rd</sup> Floor New York, NY 10019

(Address of principal executive offices) (Zip Code)

(646) 813-4705

(Registrant's telephone number, including area code)

<u>N/A</u>

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

# Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) On July 26, 2018, the Company issued a press release announcing that Jeffrey B. Davis will be stepping down from his role as Chief Operating Officer at the end of the quarter, effective September 30, 2018.

# Item 7.01. Other Events

On July 26, 2018, the Company issued a press release announcing that Jeffrey B. Davis will be stepping down from his role as Chief Operating Officer at the end of the quarter, effective September 30, 2018. The full text of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in this Item is being furnished and shall not be deemed "filed" for any other purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act regardless of any general incorporation language in any such filing.

# Item 9.01 Financial Statements and Exhibits

# (d) Exhibits.

# Exhibit No. Description

99.1 Press Release entitled "Abeona Therapeutics Announces Leadership Appointments with Max Colao as Chief Commercial Officer"

# 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

Dated: July 30, 2018



# Abeona Therapeutics Announces Leadership Appointments with Max Colao as Chief Commercial Officer

**NEW YORK and CLEVELAND** – July 26, 2018: Abeona Therapeutics Inc. (NASDAQ: ABEO), a leading clinical- stage biopharmaceutical company focused on developing novel cell and gene therapies for life-threatening rare genetic diseases, today announced the appointment of Max Colao as Chief Commercial Officer. Mr. Colao has more than 20 years of global pharmaceutical and biotechnology experience, having most recently served as the Senior Vice President of US Commercial Operations at Alexion Pharmaceuticals, Inc. The Company also announced Jeffrey B. Davis will be stepping down from his role as Chief Operating Officer at the end of the quarter to ensure a smooth transition. In an ongoing commitment to enhance the capabilities of its senior team, Abeona recently appointed Kristina Maximenko as Global Head of Human Resources.

"With our pipeline maturing toward commercial stages, we're focused on building a strong team to deliver on our ambitious goals," stated Carsten Thiel, Ph.D., Abeona's Chief Executive Officer. "I am excited to welcome Max to our organization given his broad commercial experience and deep understanding of the healthcare industry. We are pleased to have Kristina on board, who will help us continue building a vibrant culture and engaged workforce. Finally, I would like to thank Jeff for his work over many years with our company."

In his most recent role at Alexion, Mr. Colao led a team of several hundred people and was responsible for \$2 billion in sales across three franchises. Mr. Colao has an extensive track record of successful innovative and competitive biotechnology launches in oncology, nephrology, rheumatology, and ultra-rare diseases. He earlier served as Vice President of the US Metabolic Disorders Business Unit where he established Alexion's second business unit and launched two novel enzyme replacement therapies including the successful launch of Strensiq®. Prior to Alexion, Mr. Colao spent 18 years at Amgen, where he held roles of increasing responsibility in global sales and marketing, departing in 2013 as Vice President of Inflammation Sales. Mr. Colao earned his MBA from the University of Southern California in Los Angeles and his undergraduate degree from the University of California, Los Angeles, with a Bachelor of Science in Applied Mathematics and Economics.

"I am very pleased to join Abeona at this exciting time and look forward to building a fully-integrated commercial organization focused on bringing important new therapies to patients suffering from devastating rare genetic disorders with vast unmet medical needs, " said Mr. Colao.

Ms. Maximenko has more than 15 years of human resources experience, having most recently served as the Global HR Director for Advanced Accelerator Applications (AAAP), a Novartis company. Prior to Novartis' acquisition of AAAP, she served as a strategic human resources partner and global HR lead responsible for more than 700 employees operating in a matrix environment within 11 International locations and in more than 20 US states. Ms. Maximenko is trained in employment law, receiving her Master of Laws degree in International Law from Far Eastern National University with additional certifications in Human Resources.

"We look forward to working closely with Max and Kristina whose experience will greatly enhance our senior leadership team during this exciting time," stated Steven H. Rouhandeh, Executive Chairman at Abeona. "As one of the original employees at Abeona, Jeff has made a significant impact on the organization's progress since inception. On behalf of the Board of Directors, we would like to collectively extend our gratitude to Jeff for his many contributions to Abeona over the past several years."

**About Abeona:** Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing cell and gene therapies for lifethreatening rare genetic diseases. Abeona's lead programs include EB-101 (gene-corrected skin grafts) for recessive dystrophic epidermolysis bullosa (RDEB), ABO-102 (AAV-SGSH), an adeno-associated virus (AAV) based gene therapy for Sanfilippo syndrome type A (MPS IIIA) and ABO-101 (AAV-NAGLU), an adeno-associated virus (AAV) based gene therapy for Sanfilippo syndrome type B (MPS IIIB). Abeona is also developing ABO-201 (AAV-CLN3) gene therapy for CLN3 disease, ABO-202 (AAV-CLN1) for treatment of CLN1 disease, EB-201 for epidermolysis bullosa (EB), 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, Abeona is developing a proprietary vector platform, AIM<sup>TM</sup>, for next generation product candidates. For more information, visit www.abeonatherapeutics.com.

# **Investor Contact:**

Christine Silverstein SVP, Finance & Investor Relations Abeona Therapeutics Inc. +1 (646) 813-4707 csilverstein@abeonatherapeutics.com

#### Media Contact:

Lynn Granito Berry & Company Public Relations +1 (212) 253-8881 lgranito@berrypr.com

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 statements regarding our pipeline maturing toward commercial stages; our expectation that the broad experience, deep understanding of the healthcare industry, development of high performing teams, effective resource allocation and proven ability to achieve ambitious outcomes by Max Colao and Kristina Maximenko will serve our growing commercial focus well; and our expectation that we will build a commercial organization focused on bringing new therapies to patients suffering from devastating rare genetic disorders. We have attempted to identify forward looking statements by such terminology as "may," will," "anticipate," "believe," "estimate," "expect," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances), which constitute and are intended to identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, 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 and licenses; 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.