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): **December 20, 2019**

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, 33rd Floor,
New York, NY 10019
(Address of principal executive offices) (Zip Code)

(646) 813-4712
(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))

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

Title of Each Class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	**ABEO**	**Nasdaq Capital Market**

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 ☐

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 8.01. Other Events.

On December 20, 2019, Abeona Therapeutics Inc. (the "Company") issued a press release entitled "Abeona Therapeutics Receives European Medicines Agency PRIME Designation for ABO-102 Gene Therapy in MPS IIIA." On December 24, 2019, the Company issued a press release entitled "Abeona Announces Closing of $103.5 Million Underwritten Public Offering and Full Exercise of Underwriters' Option to Purchase Additional Shares." The full text of each press release is filed as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated December 20, 2019, entitled "Abeona Therapeutics Receives European Medicines Agency PRIME Designation for ABO-102 Gene Therapy in MPS IIIA"
99.2	Press release dated December 24, 2019, entitled "Abeona Announces Closing of $103.5 Million Underwritten Public Offering and Full Exercise of Underwriters' Option to Purchase Additional Shares"

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/ Edward A. Sturchio
Name: Edward A. Sturchio
Title: Senior Vice President and General Counsel

Date: December 26, 2019

Exhibit 99.1

Abeona Therapeutics Receives European Medicines Agency PRIME Designation for ABO-102 Gene Therapy in MPS IIIA

PRIME is sixth regulatory designation for the ABO-102 clinical program

NEW YORK and CLEVELAND, Dec. 20, 2019 – Abeona Therapeutics Inc. (Nasdaq: ABEO), a fully-integrated leader in gene and cell therapy, today announced that the European Medicines Agency (EMA) has granted Priority Medicines (PRIME) designation to the Company's ABO-102 program studying its adeno-associated virus 9 (AAV9) gene therapy for Sanfilippo syndrome type A (MPS IIIA). The PRIME designation is based on nonclinical data and clinical data from the Transpher A Study, a global Phase 1/2 clinical trial evaluating a single-dose of ABO-102 for the treatment of children with MPS IIIA.

"EMA's PRIME designation for the ABO-102 program recognizes the urgent need for a treatment option for children suffering from MPS IIIA, and underscores the potential of ABO-102 to modify the course of this devastating lysosomal storage disease," said João Siffert, M.D., Chief Executive Officer.

The Transpher A Study is enrolling patients at sites in the U.S., Spain, and Australia. Additional information about the trial is available at AbeonaTrials.com and ClinicalTrials.gov (NCT02716246).

The PRIME initiative provides access to enhanced support for the development of medicines targeting an unmet medical need. The designation affords sponsors with enhanced interaction and early dialogue regarding promising medicines, as well as the possibility of accelerated assessment of medicines applications. PRIME is intended to optimize development plans and speed up evaluation so these medicines can help patients to benefit as early as possible from therapies that may significantly improve their quality of life.

About ABO-102
ABO-102 is a novel gene therapy in Phase 1/2 development for Sanfilippo syndrome type A (MPS IIIA), a rare lysosomal storage disease with no approved treatment that primarily affects the central nervous system (CNS). ABO-102 is dosed in a one-time intravenous infusion using an AAV9 vector to deliver a functional copy of the SGSH gene to cells of the CNS and peripheral organs. The therapy is designed to address the underlying SGSH enzyme deficiency responsible for abnormal accumulation of glycosaminoglycans in the brain and throughout the body that results in progressive cell damage and neurodevelopmental and physical decline. In the U.S., Abeona holds Regenerative Medicine Advanced Therapy, Fast Track, Rare Pediatric Disease, and Orphan Drug designations for the ABO-102 clinical program. In the EU, the Company holds PRIME and Orphan medicinal product designations.

About The Transpher A Study
The Transpher A Study (NCT02716246) is an ongoing, two-year, open-label, dose-escalation, Phase 1/2 global clinical trial assessing ABO-102 for the treatment of patients with Sanfilippo syndrome type A (MPS IIIA). The study, also known as ABT-001, is intended for patients 6 months to 2 years of age and patients older than 2 years with a cognitive Developmental Quotient of 60% or above. The study has enrolled 14 patients to date across three dose cohorts (N=3, N=3, N=8) and remains open for enrollment. The ABO-102 gene therapy is delivered using AAV9 technology via a single-dose intravenous infusion. The study's primary endpoints are neurodevelopment and safety, with secondary endpoints including behavior evaluations, quality of life, enzyme activity in cerebrospinal fluid (CSF) and plasma, heparan sulfate levels in CSF, plasma and urine, and brain and liver volume.

About Sanfilippo Syndrome Type A (MPS IIIA)
Sanfilippo syndrome type A (MPS IIIA) is a rare, fatal lysosomal storage disease with no approved treatment that primarily affects the CNS and is characterized by rapid neurodevelopmental and physical decline. Children with MPS IIIA present with progressive language and cognitive decline and behavioral abnormalities. Other symptoms include sleep problems and frequent ear infections. Additionally, distinctive facial features with thick eyebrows or a unibrow, full lips and excessive body hair for one's age, and liver/spleen enlargement are also present in early childhood. MPS IIIA is caused by genetic mutations that lead to a deficiency in the SGSH enzyme responsible for breaking down glycosaminoglycans, which accumulate in cells throughout the body resulting in rapid health decline associated with the disorder.

About Abeona Therapeutics
Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing gene and cell therapies for serious diseases. The Company's clinical programs include EB-101, its autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa, as well as ABO-102 and ABO-101, novel AAV9-based gene therapies for Sanfilippo syndrome types A and B (MPS IIIA and MPS IIIB), respectively. The Company's portfolio of AAV9-based gene therapies also features ABO-202 and ABO-201 for CLN1 disease and CLN3 disease, respectively. Its preclinical assets include ABO-401, which uses a novel vector from Abeona's AIM™ AAV capsid platform to address all mutations of cystic fibrosis. Abeona has received numerous regulatory designations from the FDA and EMA for its pipeline candidates, including Regenerative Medicine Advanced Therapy designation for two candidates (EB-101 and ABO-102).

Forward Looking Statement
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 Section 21E of the Securities Exchange Act of 1934, as amended, and that involve risks and uncertainties. These statements include statements regarding the potential of ABO-102 to modify the course of lysosomal storage disease; our pipeline including the therapeutic potential for ABO-202 in the treatment of CLN1; the ability to obtain regulatory marketing approvals; and the Company's goals and objectives. We have attempted to identify forward looking statements by such terminology as "may," will," "anticipate," "believe," "estimate," "expect," "intend," and similar expressions.

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 initiate and enroll patients in clinical trials, the impact of competition, the ability to secure licenses for any technology that may be necessary to commercialize our products, the ability to achieve or obtain necessary regulatory approvals, the impact of changes in the financial markets and global economic conditions, risks associated with data analysis and reporting, and other risks as may be detailed from time to time in the Company's annual reports on Form 10-K and quarterly reports on Form 10-Q and other reports filed by the Company with the Securities and Exchange Commission. The Company undertakes no obligation to revise the forward-looking statements or update them to reflect events or circumstances occurring after the date of this presentation, whether as a result of new information, future developments or otherwise, except as required by the federal securities laws.

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Exhibit 99.2

Abeona Announces Closing of $103.5 Million Underwritten Public Offering and Full Exercise of Underwriters' Option to Purchase Additional Shares

NEW YORK and CLEVELAND, Dec. 24, 2019 – Abeona Therapeutics Inc. (Nasdaq: ABEO), a fully-integrated leader in gene and cell therapy, today announced the closing of its underwritten public offering, with a gross offering size of approximately $103.5 million, which includes the full exercise of the underwriters' option to purchase 5,400,000 additional shares of common stock, at a public offering price of $2.50 per share. In addition, as part of the offering, Abeona sold to Great Point Partners ("GPP"), an existing investor, pre-funded warrants to purchase up to an aggregate of 9,017,055 shares of common stock at a purchase price of $2.4999 per pre-funded warrant, which equals the public offering price per share of the common stock less the $0.0001 per share exercise price of each pre-funded warrant.

The Company has granted to affiliates of GPP the right to nominate two Board members to Abeona's Board of Directors, including a new Executive Chairman, due to GPP's considerable investment in the transaction. As a result, Steven H. Rouhandeh will step down as Executive Chairman and will retain a seat on the Board, while Mark J. Alvino and Richard Van Duyne will exit the Board. These changes will be effective upon the Board's qualification and election of GPP's nominees. Such replacement members will be independent of GPP.

"Today's event strengthens our financial position, providing cash runway into 2021 and resources that will allow us to fund continued clinical development of pipeline products, including the initiation and enrollment of the EB-101 pivotal Phase 3 VIITAL^{TM} study, and achieve critical near-term milestones," said João Siffert, M.D., Chief Executive Officer of Abeona. "On behalf of the Board and all Abeona employees, I am grateful to our outgoing members for their service and dedication to the company, and particularly to Steven, who has served as Chairman of our Board of Directors for a number of years. Finally, I would like to thank our shareholders and new investors for their ongoing support and confidence in our pipeline and the Abeona team."

"We are excited to lead this recapitalization of Abeona," said David Kroin, Managing Director of Great Point Partners. "The Company is one of the world leaders in gene therapy technology, developing products using retrovirus, adeno-associated viruses and next generation capsids with potentially improved tropism profiles for a variety of devastating diseases. This funding greatly enhances Abeona's financial position, and we believe it can now reach its full potential, as other gene therapy companies in which Great Point Partners has invested have been able to do. We intend to recruit the highest caliber people to guide the Company at the Board level in order to unlock the potential of a fully functioning manufacturing facility in Cleveland, Ohio, a late stage pivotal program in Recessive Dystrophic Epidermolysis Bullosa that has BreakThrough and RMAT Designations from the FDA, a pipeline of exciting neurology programs, and a wonderful team of professionals."

Concurrently, the Company announced that its review of strategic options announced on September 3, 2019 has been completed. The Board of Directors concluded that it is in the best interest of the Company and its shareholders to develop its pipeline products independently, and with the additional funding and planned leadership nominations announced today. While the Board determined that this pathway was the best course of action to advance the Company's mission and maximize stakeholder value, it was not due to a lack of interested partners, and Abeona continues to entertain strategic alternatives consistent with standard industry practices.

Jefferies LLC and SVB Leerink LLC acted as joint book-running managers and underwriters for the offering.

The securities described above were offered pursuant to a shelf registration statement on Form S-3 (File No. 333-224867) that was filed with the Securities and Exchange Commission (the "SEC") on May 11, 2018 and amended on June 1, 2018, and that was declared effective by the SEC on June 7, 2018. The offering was made only by means of the written prospectus and prospectus supplement that form a part of the registration statement. The preliminary prospectus supplement and the accompanying prospectus that form a part of the registration statement has been filed with the SEC and is available on the SEC's website at www.sec.gov. Copies of the preliminary prospectus supplement and the accompanying prospectus may also be obtained by contacting Jefferies LLC, Attention: Equity Syndicate Prospectus Department, 520 Madison Avenue, 2nd Floor, New York, NY 10022, via telephone at (877) 821-7388, or email at: Prospectus_Department@Jefferies.com; or SVB Leerink LLC, Attention: Syndicate Department, One Federal Street, 37th Floor, Boston, MA 02110, by telephone at (800) 808-7525, ext. 6132, or by e-mail at syndicate@svbleerink.com.

The securities described above have not been qualified under any state blue sky laws. This press release does not constitute an offer to sell or the solicitation of offers to buy any securities of Abeona being offered, and shall not constitute an offer, solicitation or sale of any security in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Abeona Therapeutics

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Forward-Looking Statements

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 Section 21E of the Securities Exchange Act of 1934, as amended, and that involve risks and uncertainties. These statements include statements about the Company's future liquidity and capital resources; the initiation and enrollment of the EB-101 pivotal Phase 3 VIITAL™ study; the Company's clinical trials and its products and product candidates, future regulatory interactions with regulatory authorities, as well as the Company's goals and objectives. We have attempted to identify forward looking statements by such terminology as "may," "will," "believe," "estimate," "expect," 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 outcome of any future meetings with the U.S. Food and Drug Administration or other regulatory agencies, the impact of competition, the ability to secure licenses for any technology that may be necessary to commercialize our products, the ability to achieve or obtain necessary regulatory approvals, the impact of changes in the financial markets and global economic conditions, risks associated with data analysis and reporting, and other risks as may be detailed from time to time in the Company's Annual Reports on Form 10-K and quarterly reports on Form 10-Q and other periodic reports filed by the Company with the Securities and Exchange Commission. The Company undertakes no obligation to revise the forward-looking statements or to update them to reflect events or circumstances occurring after the date of this presentation, whether as a result of new information, future developments or otherwise, except as required by the federal securities laws.

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