UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 2, 2016

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

Delaware	**001-37553**	**47-1851754**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

9712 Medical Center Drive, Suite 100 **Rockville, Maryland** **(Address of principal executive offices)**	**20850** **(Zip Code)**

(240) 552-8181
(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))

Item 8.01. Other Events.

On August 2, 2016, REGENXBIO Inc. (“REGENXBIO”) issued a press release announcing that the U.S. Food and Drug Administration has granted Rare Pediatric Disease Designation to REGENXBIO’s investigational gene therapy product candidate, RGX-121, for the treatment of Mucopolysaccharidosis Type II (“MPS II”). MPS II is a rare neurodegenerative disease caused by a deficiency in the lysosomal enzyme iduronate-2-sulfatase (IDS).

A copy of REGENXBIO’s press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	REGENXBIO Inc. Press Release dated August 2, 2016

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.

REGENXBIO INC.

Date: August 2, 2016

By: /s/ Kenneth T. Mills
Kenneth T. Mills
President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	REGENXBIO Inc. Press Release dated August 2, 2016

FDA Grants Rare Pediatric Disease Designation to REGENXBIO's RGX-121 Gene Therapy for the Treatment of Mucopolysaccharidosis Type II (MPS II)

ROCKVILLE, Md., August 2, 2016 — REGENXBIO Inc. (Nasdaq:RGNX), a leading biotechnology company focused on the development, commercialization and licensing of recombinant adeno-associated virus (AAV) gene therapy based on its proprietary NAV® Technology Platform, today announced that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation to RGX-121, REGENXBIO's investigational gene therapy product candidate for the treatment of Mucopolysaccharidosis Type II (MPS II).

"Along with RGX-111 for the treatment of MPS I, this is our second MPS program to achieve a Rare Pediatric Disease Designation and builds upon the Orphan Drug Designation granted to RGX-121 at the end of 2015 by the FDA, underscoring the therapy's potential to provide meaningful benefit to children struggling with this severely debilitating disease," said Kenneth T. Mills, President and Chief Executive Officer of REGENXBIO. "Both of these programs use our NAV AAV9 vector and we plan to file Investigational New Drug applications for RGX-111 and RGX-121 in the first half of 2017. We look forward to working with the FDA to advance this platform of gene therapies for MPS to patients in need."

The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the U.S., primarily aged from birth to 18 years. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application or biologics license application for a rare pediatric disease may be eligible for a voucher, which can be redeemed to obtain priority review for any subsequent marketing application and may be sold or transferred.

MPS II, also known as Hunter syndrome, is a rare, X-linked recessive disease caused by a deficiency in the lysosomal enzyme iduronate-2-sulfatase (IDS). Approximately 500 to 1,000 individuals with MPS II are estimated to be born each year worldwide. In severe forms of the disease, early developmental milestones may be met, but developmental delay is readily apparent by 18 to 24 months. Developmental progression begins to plateau between three and five years of age, with regression reported to begin around six and a half years. RGX-121 uses an AAV9 vector to deliver the IDS gene to the central nervous system.

About REGENXBIO

REGENXBIO is a leading biotechnology company focused on the development, commercialization and licensing of recombinant adeno-associated virus (AAV) gene therapy. REGENXBIO's NAV® Technology Platform, a proprietary AAV gene delivery platform, consists of exclusive rights to more than 100 novel AAV vectors, including AAV7, AAV8, AAV9 and AAVrh10. REGENXBIO's mission is to transform the lives of patients suffering from severe diseases with significant unmet medical need by developing and commercializing *in vivo* gene therapy products based on REGENXBIO's NAV Technology Platform. REGENXBIO seeks to accomplish this mission through a combination of internal development efforts and third-party NAV Technology Platform licensees. As of March 31, 2016, REGENXBIO's NAV Technology Platform was being applied in the development of 28 product candidates for a variety of diseases, including five internally developed candidates and 23 partnered candidates developed by REGENXBIO's licensees.

Forward Looking Statements

This press release contains "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995, regarding, among other things, REGENXBIO's research, development and regulatory plans for RGX-111, RGX-121 and other gene therapies. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could cause actual results to differ materially from those projected by such forward-looking statements. All of REGENXBIO's development timelines could be subject to adjustment depending on recruitment rate, regulatory agency review and other factors that could delay the initiation

and completion of clinical trials. Meaningful factors which could cause actual results to differ include, but are not limited to, the timing of enrollment, commencement and completion of REGENXBIO's clinical trials; the timing and success of preclinical studies and clinical trials conducted by REGENXBIO, its development partners and its NAV Technology Licensees; the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize REGENXBIO's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing REGENXBIO's product candidates; REGENXBIO's ability to obtain and maintain intellectual property protection for our product candidates and technology; trends and challenges in REGENXBIO's business and the markets in which REGENXBIO operates; REGENXBIO's ability to attract or retain key personnel; the size and growth of the potential markets for REGENXBIO's product candidates and the ability to serve those markets; the rate and degree of market acceptance of any of REGENXBIO's product candidates; REGENXBIO's ability to establish and maintain development partnerships, including those with NAV Technology Licensees; REGENXBIO's expenses and revenue, the sufficiency of REGENXBIO's cash resources and needs for additional financing, regulatory developments in the United States and foreign countries, as well as other factors discussed in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of REGENXBIO's Annual Report on Form 10-K for the year ended December 31, 2015 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of REGENXBIO's Form 10-Q for the quarter ended June 30, 2016, to be filed with the SEC in the third quarter of 2016. In addition to the risks described above and in REGENXBIO's filings with the SEC, other unknown or unpredictable factors also could affect REGENXBIO's results. There can be no assurance that the actual results or developments anticipated by REGENXBIO will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, REGENXBIO. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All forward-looking statements contained in this press release are expressly qualified by the cautionary statements contained or referred to herein. REGENXBIO cautions investors not to rely too heavily on the forward-looking statements REGENXBIO makes or that are made on its behalf. These forward-looking statements speak only as of the date of this press release (unless another date is indicated). REGENXBIO undertakes no obligation, and specifically declines any obligation, to publicly update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

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