

REGENXBIO Inc.
Form 8-K
October 01, 2015

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): October 1, 2015

REGENXBIO INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction

of incorporation)

001-37553
(Commission

File Number)

47-1851754
(I.R.S. Employer

Identification No.)

9712 Medical Center Drive, Suite 100

Rockville, Maryland
(Address of principal executive offices)

(240) 552-8181

20850
(Zip Code)

(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 October 1, 2015, REGENXBIO Inc. (the Company) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to the Company's investigational gene therapy product candidate, RGX-111, for the treatment of mucopolysaccharidosis Type I (MPS I). MPS I is a rare neurodegenerative disease caused by deficiency of the α -l-iduronidase gene.

A copy of the Company'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 October 1, 2015 |

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: October 1, 2015

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 October 1, 2015 |