

ZOGENIX, INC.
Form 8-K
January 19, 2016

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): January 19, 2016

ZOGENIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

001-34962
(Commission

File Number)

20-5300780
(IRS Employer

Identification No.)

5858 Horton Street, #455, Emeryville, CA
(Address of Principal Executive Offices)

94608
(Zip Code)

Registrant's telephone number, including area code: (510) 550-8300

(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.

January 19, 2016, Zogenix, Inc. (the Company) announced receipt of Fast Track designation from the U.S. Food and Drug Administration (the FDA) for the development program of its investigational product, ZX008, as a treatment of seizures associated with Dravet syndrome, a rare and catastrophic form of childhood epilepsy.

The FDA's Fast Track program was established to facilitate the development and expedite the review of drugs with the potential to treat serious conditions and address unmet medical needs. Companies that receive Fast Track designation are provided the opportunity for more frequent interactions with the FDA during clinical development and are eligible for accelerated approval and/or priority review, if relevant criteria are met. Additionally, companies that receive Fast Track designation are allowed to submit completed sections of their New Drug Application for the drug on a rolling basis, resulting in the potential for an expedited FDA review process.

SIGNATURES

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.

ZOGENIX, INC.

Date: January 19, 2016

By: /s/ Ann D. Rhoads

Name: Ann D. Rhoads

Title: Executive Vice President,

Chief Financial Officer,

Treasurer and Secretary