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): February 6, 2018

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

Delaware	**001-34962**	**20-5300780**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5858 Horton Street, #455, Emeryville, CA	**94608**
(Address of Principal Executive Offices)	**(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))

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 February 6, 2018, Zogenix, Inc. (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has granted Breakthrough Therapy Designation for the Company's investigational product, ZX008 (low-dose fenfluramine), for the treatment of seizures associated with Dravet syndrome.

FDA Breakthrough Therapy Designation is intended to expedite the development and review of medicines aimed at treating a serious or life-threatening disease where there is preliminary clinical evidence that the investigational therapy may offer substantial improvement over existing therapies on at least one clinically significant endpoint. FDA Breakthrough Therapy Designation for ZX008 is based on the results from Study 1, the Company's first global Phase 3 trial of ZX008, which met the primary efficacy endpoint, as well as all prespecified key secondary efficacy endpoints.

ZX008 is designated as an orphan drug in both the U.S. and Europe for Dravet syndrome and Lennox-Gastaut syndrome, and has received Fast Track designation in the U.S. for the treatment of Dravet syndrome.

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The Company cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements regarding: ZX008's potential as a treatment for seizures associated with Dravet syndrome, the potential for expedited development based on the FDA's decision to designate ZX008 as a Breakthrough Therapy, and the timing of completing the Phase 3 clinical program in Dravet syndrome. These statements are based on the Company's current beliefs and expectations. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of its plans will be achieved. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in the Company's business, including, without limitation: Breakthrough Therapy Designation does not guarantee that the FDA will approve ZX008 or expedite its review of ZX008; the FDA may not agree with the Company's interpretation of the results of the Study 1 and other data; the uncertainties associated with the clinical development and regulatory approval of product candidates such as ZX008; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 that could limit approval and/or commercialization, or that could result in recalls or product liability claims; the potential that earlier clinical trials and studies may not be predictive of future results; the Company's reliance on third parties to conduct its clinical trials, enroll patients, manufacture its preclinical and clinical drug supplies; and other risks described in the Company's prior press releases as well as in public periodic filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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: February 6, 2018

By: /s/ Michael P. Smith
Name: Michael P. Smith
Title: Executive Vice President, Chief Financial Officer, Treasurer and Secretary