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 31, 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 January 31, 2018, Zogenix, Inc. (the "Company") announced that the last patient had been randomized into the treatment period of Study 1504, its second Phase 3 clinical trial evaluating ZX008 (low-dose fenfluramine) as an adjunctive treatment for seizures in children and young adults with Dravet syndrome. Previously, in the third quarter of 2017, the Company announced positive top-line data from its first global Phase 3 trial of ZX008, Study 1, that met the primary efficacy endpoint, as well as all prespecified key secondary efficacy endpoints.

Study 1504 is a double-blind, randomized, two arm Phase 3 trial with approximately 40 subjects per treatment group being conducted in the U.S., France, Spain, the Netherlands, U.K., Canada, and Germany, in which all subjects are taking stiripentol as part of their baseline standard of care. Randomized subjects are titrated to an active dose of 0.5 mg/kg/day ZX008 (maximum of 20 mg/day) or placebo, over three weeks and then held at that fixed dose for 12 weeks of maintenance treatment. The study dose of ZX008 accounts for the established drug-drug interaction between stiripentol and ZX008 and provides the same systemic exposure of ZX008 as the dose of 0.8 mg/kg/day (maximum 30 mg/day) previously evaluated in Study 1, where concomitant use of stiripentol was excluded. As in Study 1, the primary efficacy measure in Study 1504 is a comparison of the change in monthly convulsive seizure frequency between ZX008 and placebo during the treatment period compared with the baseline observation period.

Study 1 results were announced in fall 2017. The trial met its primary objective of demonstrating that ZX008, at a dose of 0.8 mg/kg/day, is superior to placebo as adjunctive therapy in the treatment of Dravet syndrome in children and young adults based on change in the frequency of convulsive seizures between the 6-week baseline observation period and the 14-week treatment period ($p<0.001$). ZX008 0.8 mg/kg/day also achieved statistically significant improvements versus placebo in all key secondary measures, including the proportion of patients with clinically meaningful reductions in seizure frequency and longest seizure-free interval. The same analyses comparing a 0.2 mg/kg/day ZX008 dose versus placebo also demonstrated significant improvement compared with placebo. Both doses of ZX008 were safe and well-tolerated during the study, and most adverse events were mild or moderate in severity, and consistent with the known profile of the compound.

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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, and the timing of top-line results from Study 1504. 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: 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 2, 2018

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