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): December 4, 2017

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 December 4, 2017, Zogenix, Inc. (the "Company") announced new data from its first Phase 3 trial (Study 1) of its investigational drug, ZX008 (low-dose fenfluramine hydrochloride), for the treatment of Dravet syndrome. The updated Study 1 results, as well as additional data supporting the further investigation of ZX008 in refractory epilepsies, were presented at the 71st American Epilepsy Society (AES) Annual Meeting, taking place this week in Washington, D.C.

The new Study 1 results presented at AES showed the odds of achieving a clinically meaningful (≥50%) or substantial (≥75%) reduction in convulsive seizure frequency were 29 and 50 times higher, respectively, among patients treated with ZX008 0.8 mg/kg/day than in patients treated with placebo. The study also measured improvement on the Clinical Global Impression ("CGI-C") rating. Fifty-five percent of patients treated with ZX008 0.8 mg/kg/day were rated by parents/caregivers as very much improved or much improved in overall condition on the CGI-C compared to 10% of the placebo group (p=0.001) and 62.5% of patients treated with ZX008 0.8 mg/kg/day were rated by investigators as very much improved or much improved in overall condition on the CGI-C compared to 10% of the placebo group (p=0.001).

The most common treatment emergent adverse events (>10% in any treatment group) in Study 1 include diarrhea, vomiting, fatigue, pyrexia, nasopharyngitis, upper respiratory tract infection, fall, weight decreased, decreased appetite, lethargy, seizure and somnolence. Prospective cardiac safety monitoring throughout the study demonstrated trace regurgitation on mitral or aortic valves were recorded on at least one echocardiogram in >10% of subjects among all three treatment groups, placebo included. There was no clinical or echocardiographic evidence of cardiac valvulopathy or pulmonary hypertension. No patient discontinued participation or required a change in monitoring in the study due to cardiac factors.

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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 statements are based on the Company's current beliefs and expectations. These forward-looking statements include statements regarding ZX008's potential as a treatment for seizures associated with Dravet syndrome, refractory epilepsies, and LGS; 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: December 4, 2017

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