ZOGENIX, INC.
Form 8-K
September 29, 2017

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): September 29, 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 7.01. Regulation FD Disclosure.

The slides attached as Exhibit 99.1 to this Current Report contain certain additional information related to the clinical results discussed in Item 8.01 below. Zogenix, Inc. (the Company) intends to present the slides during a conference call and webcast with the investment community on September 29, 2017, at 8:30 a.m. ET.

The information set forth in this Item 7.01 is being furnished pursuant to Item 7.01 and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act) or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly provided by specific reference in such a filing.

Item 8.01. Other Events.

On September 29, 2017, the Company announced positive top-line results from its first Phase 3 trial (Study 1) for its investigational drug, ZX008 (low-dose fenfluramine hydrochloride), for the treatment of Dravet syndrome. 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 demonstrated 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 statistically significant improvement compared with placebo.

Study 1 is a prospective merged analysis of two identical randomized, double-blind, placebo-controlled Phase 3 studies, ZX008-1501 (US/Canada) and ZX008-1502 (Europe/Australia). The study enrolled 119 patients across sites in the United States, Canada, Europe, and Australia. The median age of patients was 8 years (range, 2-18 years). Following a six-week baseline observation period, patients were randomized to one of three treatment groups: ZX008 0.8 mg/kg/day (30 mg maximum daily dose; n=40), ZX008 0.2 mg/kg/day (n=39) and placebo (n=40) in which ZX008 or placebo was added to current regimens of antiepileptic drugs. Patients were titrated to their target dose over two weeks and then remained at that fixed dose for 12 weeks. The mean baseline convulsive seizure frequency across the study groups was approximately 40 seizures per month.

The primary efficacy measure was a comparison of the change in mean monthly convulsive seizure frequency between ZX008 0.8 mg/kg/day and placebo during the 14-week treatment period compared with the 6-week baseline observation period. Patients taking ZX008 0.8 mg/kg/day achieved a 63.9% reduction in mean monthly convulsive seizures compared to placebo ($p<0.001$). The median percent reduction in monthly convulsive seizure frequency was 72.4% among ZX008 0.8 mg/kg/day patients compared to 17.4% in placebo patients.

A key secondary endpoint was the same analysis for a comparison of ZX008 0.2 mg/kg/day and placebo. Patients taking ZX008 0.2 mg/kg/day achieved a reduction in mean monthly convulsive seizures of 33.7% compared to placebo ($p=0.019$). Collectively, these top-line data suggest a dose-response relationship for ZX008 in the adjunctive treatment of convulsive seizures in Dravet syndrome.

Additional key secondary objectives of the study were to compare 0.8 mg/kg/day and 0.2 mg/kg/day ZX008 (independently) with placebo in terms of (1) the proportion of patients who achieved ³50% reductions in monthly convulsive seizures and (2) the median of the longest convulsive seizure-free interval. These results are shown in the following table. The proportion of patients who achieved ³75% seizure reductions, a secondary efficacy measure, is also presented.

	ZX008 0.8 mg/kg/day (N=40)	ZX008 0.2 mg/kg/day (N=39)	Placebo (N=40)
Patients with ³50% reduction in monthly convulsive seizures	70.0% (p<0.001)	41.0% (p=0.001)	7.5%
Patients with ³75% reduction in monthly convulsive seizures	45.0% (p=0.001)	20.5% (p=0.033)	2.5%
Longest seizure-free interval (median)	20.5 days (p<0.001)	14 days (p=0.011)	9 days

ZX008 was generally well-tolerated in this study with the adverse events consistent with the known safety profile of fenfluramine. The incidence of treatment emergent adverse events was higher in the treatment groups as compared to the placebo group, with 95% (n=38) of patients in the 0.8mg/kg/day group and 94.9% (n=37) of patients in the 0.2 mg/kg/day group experiencing at least one treatment emergent adverse event compared to 65.0% (n=26) of patients in the placebo group. The incidence of serious adverse events was similar in all three groups with 12.5% (n=5) of patients in the 0.8mg/kg/day group and 10.3% (n=4) of patients in the 0.2 mg/kg/day group experiencing at least one treatment emergent serious adverse event compared to 10.0% (n=4) of patients in the placebo group . Five patients in the 0.8 mg/kg/day group had an adverse event leading to study discontinuation compared to none in the other treatment groups. Prospective cardiac safety monitoring throughout the study demonstrated no clinical or echocardiographic evidence of cardiac valvulopathy or pulmonary hypertension.

The Company is conducting a second double-blind, randomized, two-arm pivotal Phase 3 trial, Study 1504, in which all patients will be taking stiripentol, valproate and clobazam as part of their baseline standard care. In February 2017, the Company announced the initiation of the safety and efficacy portion of Study 1504, which compares a single dose of ZX008 versus placebo across the titration and 12-week maintenance periods. Study 1504 will enroll 40 patients per treatment group. The Company expects to report top-line results from Study 1504 in the first half of 2018. The Company believes it remains on track to submit applications for regulatory approvals in the U.S. and Europe in the second half of 2018.

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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, 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; the timing of topline results from Study 1504; and regulatory submission timelines for ZX008. 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 release due to the risks and uncertainties inherent in the Company s business, including, without limitation: the top-line data the Company has reported is based on preliminary analysis of

key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such top-line data may not accurately reflect

the complete results of the trial, and the FDA may not agree with the Company s interpretation of such results; the uncertainties associated with the clinical development and regulatory approval of product candidates such as ZX008, including potential delays in the enrollment and completion of clinical trials; 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; 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 Company s ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities; 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Slide Presentation

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: September 29, 2017

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