ZOGENIX, INC.
Form 8-K
July 12, 2018

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): July 12, 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 July 12, 2018, Zogenix, Inc. (the Company) reported positive top-line results from its second confirmatory Phase 3 study (Study 1504) for its investigational drug, ZX008 (low-dose fenfluramine hydrochloride), for the treatment of children and young adults with Dravet syndrome. The study results, which are consistent with those reported in Study 1, the Company s first pivotal Phase 3 study, successfully met the primary endpoint and all key secondary endpoints, demonstrating that ZX008, at a dose of 0.5 mg/kg/day (maximum 20 mg/day), is superior to placebo when added to a stiripentol regimen.

Key findings included:

Patients taking ZX008 achieved a 54.7% greater reduction in mean monthly convulsive seizures compared to placebo (p<0.001). The median reduction in monthly convulsive seizure frequency was 62.7% in the ZX008 group compared to 1.2% in placebo patients.

ZX008 also demonstrated statistically significant improvement versus placebo in both key secondary measures, including patients with clinically meaningful reductions (>50%) in seizure frequency and longest seizure-free interval.

ZX008 was generally well-tolerated in this study with the adverse events consistent with those observed in Study 1 and the known safety profile of fenfluramine. No patient exhibited cardiac valvulopathy or pulmonary hypertension at any time in the study.

Secondary endpoints assessed ZX008 compared to placebo in terms of the proportions of patients who achieved ³50% reductions and ³75% reductions in monthly convulsive seizures, as well as the median of the longest convulsive seizure-free interval. These results are shown in the following table.

	ZX008 0.5 mg/kg/day (N=43)	**Placebo (N=44)**
Patients with ³50% reduction in monthly convulsive seizures*	53.5% (p<0.001)	6.8%
Patients with ³75% reduction in monthly convulsive seizures	32.6% (p=0.004)	2.3%
Longest seizure-free interval (median)*	22 days (p<0.005)	13 days

* Key secondary endpoints

ZX008 was generally well-tolerated in this study, with the adverse events consistent with those observed in Study 1 and the known safety profile of fenfluramine. The incidence of treatment emergent adverse events was similar in both the treatment and placebo groups, with 97.7% (n=42) of patients receiving ZX008 experiencing at least one treatment

emergent adverse event compared to 95.5% (n=42) of patients in the placebo group. The most common adverse events in the ZX008 group were decreased appetite, diarrhea, pyrexia, fatigue, and nasopharyngitis.

The incidence of serious adverse events was similar in both the treatment and placebo groups, with 14% (n=6) of patients in the ZX008 group experiencing at least one treatment emergent serious adverse event compared to 15.9% (n=7) of patients in the placebo group. Two patients in the ZX008 group had an adverse event leading to study discontinuation compared to one in the placebo group.

Prospective cardiac safety monitoring throughout the study did not identify clinical or echocardiographic evidence of cardiac valvulopathy or pulmonary hypertension in any patient. This confirms the observations from Study 1 which also reported no valvulopathy or pulmonary hypertension in any patient. Furthermore, approximately 300 patients are currently enrolled in the ongoing open-label safety extension study (Study 1503), some of whom have been treated with ZX008 on a daily basis for over 2 years. In all studies, no safety signal of any cardiovascular abnormality has been identified to date.

The double blind, placebo controlled, Phase 3 study (Study 1504) randomized 87 patients, with a median age of 9 years (range, 2-19 years), across sites in Europe, the United States, and Canada. Following a six-week baseline observation period, patients were assigned to one of two treatment groups in which ZX008 (n=43) or placebo (n=44) was added to their stable background regimen of stiripentol plus other antiepileptic drugs. The ZX008 dose of 0.5 mg/kg/day (20 mg maximum daily dose) in this study accounted for a drug-drug interaction between stiripentol and ZX008 and was designed to approximate the 0.8 mg/kg/day dose evaluated in Study 1 where stiripentol use was not permitted. The mean baseline convulsive seizure frequency across all treatment groups in Study 1504 was approximately 25 seizures per month. Patients were titrated to their target dose over three weeks and then remained at that fixed dose for 12 weeks.

ZX008 is designated as an orphan drug in both the U.S. and Europe, and has received Breakthrough Therapy designation in the U.S. for the treatment of Dravet syndrome. Earlier this year, the Company conducted a positive meeting with the U.S. Food and Drug Administration (FDA) regarding the ZX008 clinical development program and planned New Drug Application (NDA) submission in Dravet syndrome in which FDA affirmed Study 1 and Study 1504 were suitable as the clinical basis for the NDA submission.

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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 to be a transformative treatment for Dravet syndrome; and the projected timing of the Company s applications for regulatory approvals of ZX008 in the U.S. and Europe. 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 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; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 may limit regulatory approval and/or commercialization, or may result in recalls or product liability claims; and other risks described in the Company s 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: July 12, 2018

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

Treasurer and Secretary