ZOGENIX, INC.
Form 8-K
December 03, 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): December 3, 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 December 3, 2018, Zogenix, Inc. (the Company) reported that late-breaking data will be presented on the use of its investigational drug, FINTEPLA (ZX008; low-dose fenfluramine), in children and young adults with Dravet syndrome. These three presentations will include data from the second pivotal Phase 3 trial (Study 1504), and long-term efficacy and safety data from a formal interim analysis of the ongoing open-label extension (OLE) trial (Study 1503). A post-hoc exploration of the clinical meaningfulness of seizure control from the first pivotal Phase 3 trial (Study 1) will also be presented. The data will be presented at the 72nd American Epilepsy Society Annual Meeting in New Orleans.

Study 1504: Positive Results from a Second Phase 3 Clinical Trial

Results from Study 1504 will be presented as a follow-up to topline results that were released in July 2018. Patients (n=87) were taking a background anti-epileptic drug (AED) medication regimen that included stiripentol and were randomized to placebo (n=44) or FINTEPLA 0.5 mg/kg/day (n=43). Consistent with Study 1, Study 1504 met the primary endpoint and all key secondary endpoints. Results demonstrated the statistically significant efficacy of FINTEPLA when added to a stiripentol regimen in children and young adults with Dravet syndrome.

Children and young adults treated with FINTEPLA achieved a 54.0% greater reduction in mean monthly convulsive seizures compared to placebo ($p<0.001$). The median reduction in monthly convulsive seizure frequency was 63.1% in the FINTEPLA group compared to 1.1% in placebo patients.

The Study 1504 results showed the odds of achieving a clinically meaningful (³50%) or substantial (³75%) reduction in convulsive seizure frequency were 26 and 24 times higher, respectively, among patients treated with FINTEPLA 0.5 mg/kg/day than in patients treated with placebo. The study also demonstrated statistically significant differences in seizure-free intervals, with a median longest seizure-free interval of 22 days in patients treated with FINTEPLA 0.5 mg/kg/day vs. 13 days for patients in the placebo group ($p=0.004$).

The incidence of serious adverse events was similar in both the treatment and placebo groups. The most common adverse events in the FINTEPLA group were decreased appetite (44%), pyrexia (26%), fatigue (26%), diarrhea (23%), and nasopharyngitis (16%).

There was no evidence of valvular heart disease (valvulopathy) or pulmonary hypertension in any patient at any time during the trial. These safety results are consistent with the findings of Study 1, as well as the now released interim analysis of long-term safety data from the OLE trial. Across all trials, no safety signal of any valvular heart disease has been identified to date.

Study 1503: Interim Analysis of Ongoing Open-Label Extension Trial

Data from Study 1503 will be presented in two posters, one which focuses on effectiveness and overall tolerability of FINTEPLA and a second on the long-term cardiovascular assessments and observations.

A total of 232 patients in Study 1503 were included in the interim analysis of the ongoing OLE trial. The median duration of treatment with FINTEPLA was 256 days and the range 58-634 days (equivalent to 161 patient-years of exposure to FINTEPLA). A total of 22 (9.5%) patients discontinued treatment: lack of efficacy (16), subject withdrawal (2), adverse event (1), Sudden Unexpected Death in Epilepsy (SUDEP) (1), physician decision (1), and withdrawal by caregiver (1). More than 90% of patients remained in the study.

The median percent reduction in monthly convulsive seizure frequency over the entire OLE treatment period was 66.8% (compared with baseline frequency established in the core Phase 3 studies). Over the same period, 64.4% of children and young adults demonstrated a ≥50% reduction in convulsive seizure frequency and 41.2% demonstrated a

≥75% reduction.

Clinically meaningful reduction in convulsive seizure frequency was noted at the first time point measured, one month, and continued over the entire treatment period analyzed. Based on the most current assessment during the OLE treatment period, 66.1% of caregivers and 65.9% of investigators rated patients as much improved or very much improved.

The occurrence of adverse events was consistent with the Phase 3 placebo-controlled studies. The most common adverse events occurring in more than 10% of children and young adults were pyrexia (22%), nasopharyngitis (20%), decreased appetite (16%), influenza (12%), diarrhea (11%), and upper respiratory tract infection (10%). A total of 13.4% of children lost >7% body weight at some point during the trial; in 42% of those children weight loss abated during the period covered by the interim analysis. Over the course of open-label treatment, one patient died from SUDEP that was considered unrelated to FINTEPLA.

A total of 703 color doppler echocardiograms were performed to assess cardiovascular health at baseline, week 4 or 6, and then every 3 months during the OLE trial. No patient developed valvular heart disease (valvulopathy) or pulmonary arterial hypertension at any time after daily treatment with FINTEPLA.

Investor Update Lunch at American Epilepsy Society

Zogenix will host an Investor Update Lunch on FINTEPLA today, December 3, 2018, from 12:00 PM to 2:00 PM CST. If you are an institutional investor, sell-side analyst, investment banker, or business development professional, please RSVP in advance if you plan to attend by using this link: https://events.r20.constantcontact.com/register/eventReg?oeidk=a07efrzxoygbf16cf13&oseq=&c=&ch. A live webcast and replay of the presentations will be accessible at https://zogenixinc.gcs-web.com.

About Zogenix

Zogenix is committed to developing and commercializing transformative therapies to improve the lives of patients and their families living with rare diseases.

Forward Looking Statements

The Company cautions you that statements included in this report or in the poster presentations 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 ide forward-looking statements. These statements include the Company s belief that Study 1504 are consistent with the results from Study 1; the results observed to date supporting the potential long-term safety and efficacy of FINTEPLA; the timing of submission of the NDA for FINTEPLA; and the Company s belief that FINTEPLA may positively impact the lives of patients, if approved by the FDA. 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 Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this release or in any poster presentation due to the risks and uncertainties inherent in the Company s business, including, without limitation: the uncertainties associated with the clinical development and regulatory approval of product candidates such as FINTEPLA; the additional data presented is based on Zogenix s analysis of the efficacy and safety data received to date, and such data may be supplemented as Zogenix receives additional data from the OLE study and such data may not accurately reflect the complete results of the study, and the FDA may not agree with Zogenix s interpretation of such results; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit approval and/or commercialization, or that could result in recalls or product liability claims; the potential that the FDA will disagree the Company s analysis of Study 1503, Study 1504 or Study 1, including the safety profile of FINTEPLA; the potential that the results from the ongoing OLE study and earlier studies may not be predictive of future results; the potential for the FDA s earlier marketing approval of drugs other than FINTEPLA to cause the FDA

to revoke Breakthrough Therapy designation; 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 Zogenix undertakes no obligation to revise or update this press release 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 3, 2018

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

Treasurer and Secretary