ZOGENIX, INC.
Form 8-K
December 07, 2015

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 7, 2015

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.)**

12400 High Bluff Drive, Suite 650, San Diego, CA 92130
(Address of Principal Executive Offices) (Zip Code)
Registrant s telephone number, including area code: (858) 259-1165

(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))

Item 8.01. Other Events.

On December 7, 2015, Zogenix, Inc. (Zogenix) announced new data demonstrating sustained effectiveness and cardiovascular-related safety for patients treated with ZX008 (low-dose fenfluramine) as an adjunctive therapy for seizures associated with Dravet syndrome. The data were presented at the 69th Annual American Epilepsy Society Meeting, taking place this week in Philadelphia, Pennsylvania. Zogenix expects to initiate a Phase 3 program for ZX008 in 2015.

The data presented highlight the initial results from a new cohort of seven Dravet syndrome patients who began add-on treatment with low-dose fenfluramine (5 mg to 15 mg per day) at various starting points between 2010 and 2014. Median treatment duration was 0.9 years (range 0.2 to 3.9 years). During the 90-day run-in period prior to initiating low-dose fenfluramine treatment, the median frequency of tonic-clonic seizures was 3.0 per month (range 0.4 to 39.7). At the six-month evaluation after starting low-dose fenfluramine treatment, the median frequency of tonic-clonic seizures was 1.2 per month, and the median decrease was 73% (range 48-100%). Over the entire observation period, the median frequency of tonic-clonic seizures was 0.9 per month, and the median decrease was 84% (range 55% to 100%).

During this observation period from 2010 to 2015, treatment with low-dose fenfluramine was generally well-tolerated, and in this new cohort of patients, treatment for periods of 0.9 to 3.9 years did not result in any echocardiographic or clinical signs of cardiac valve abnormalities, pulmonary hypertension or any other cardiovascular abnormalities. The most common treatment-related adverse events were mild-to-moderate somnolence (n=6) and anorexia (n=4). There were no fenfluramine discontinuations due to adverse events or lack of effect.

The observed effectiveness, tolerability and cardiovascular-related safety with add-on, low-dose fenfluramine in this new cohort of Dravet syndrome patients extends the findings previously reported in the original cohort in 2012.

In addition, a separate, recently published study evaluated the mechanism of action for fenfluramine as a treatment for Dravet syndrome using a gene knockout zebrafish model. As a result of this study, certain $5\text{-HT}_{subtype}$ receptors that appear to be involved in the mechanism-of-action of fenfluramine were identified. Specifically, the elevation of serotonin levels and interaction with three 5-HT receptor subtypes, 5-HT1D, 5-HT2A and 5-HT2C, were found to be responsible for reducing both abnormal motor behavior and brain activity in this model of Dravet syndrome.

***

Zogenix cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. Words such as believes, indicates, will, plans, designed and similar expressions are intended to identify forward-looking statements. These statements are based on Zogenix s current beliefs and expectations. These forward-looking statements include statements regarding the timing of the commencement of Phase 3 clinical studies for ZX008. Actual results may differ from those set forth in this report due to the risk and uncertainties inherent in Zogenix s business, including, without limitation: the uncertainties associated with the clinical development and regulatory approval of product candidates such as ZX008, including potential delays in the commencement, enrollment and completion of clinical trials; the potential that earlier clinical trials and studies may not be predictive of future results; Zogenix s reliance on third parties to conduct its clinical trials, enroll patients, manufacture its preclinical and clinical drug supplies and manufacture commercial supplies of its drug products, if approved; 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; and other risks described in Zogenix s 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 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 7, 2015

By: /s/ Ann D. Rhoads
Name: Ann D. Rhoads
Title: Executive Vice President, Chief Financial Officer, Treasurer and Secretary