ZOGENIX, INC.
Form 8-K
May 27, 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): May 27, 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 May 27, 2015, Zogenix, Inc. (the Company or Zogenix) announced new data demonstrating sustained efficacy and tolerability for patients treated with low-dose fenfluramine as an adjunctive therapy for Dravet syndrome. The data was authored by Berten Ceulemans, M.D., Ph.D. and Lieven Lagae, M.D., Ph.D., from the Universities of Antwerp and Leuven in Belgium, and was presented as an online poster presentation at the European Paediatric Neurology Society meeting taking place this week in Vienna, Austria. Zogenix intends to initiate Phase 3 clinical studies for ZX008, the Company s investigational proprietary pediatric formulation of low-dose fenfluramine during the second half of 2015

The results presented are from the latest five-year follow-up period (2010-2014) in a group of Dravet syndrome patients being treated with low-dose fenfluramine (10 mg to 20 mg per day). This analysis, which includes ten patients from the original study group (as published in 2012) and two patients who began treatment in 2011, demonstrated that during any given year of the follow-up period, at least 80% of patients achieved a greater than or equal to 75% reduction in the frequency of seizures. In addition, three patients (25%) were seizure-free for all five years and five patients (42%) were seizure-free for two to four years.

The use of low-dose fenfluramine in this group of patients was shown to be generally well tolerated, with the most common adverse events being transient loss of appetite and fatigue/somnolence. No patient discontinued treatment due to adverse events. No clinically meaningful cardiac adverse events were noted.

In addition to the ongoing clinical study, a recently published translational research study to elucidate fenfluramine s mechanuism of action in Dravet syndrome has demonstrated the ability of fenfluramine to significantly reduce locomotion and eliminate epileptiform EEG activity in a gene knockdown zebrafish model of Dravet syndrome. These data support the clinical results obtained in the Belgium cohort of patients.

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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 the Company s current beliefs and expectations. These forward-looking statements include statements regarding: the timing of the commencement of Phase 3 clinical studies for ZX008 and the potential to replicate earlier results in such studies. 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 inherent risks of clinical development of ZX008, and Zogenix s dependence on third parties in such development; the potential that earlier clinical studies may not be predictive of future results; 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; other difficulties or delays relating to the development, testing, manufacturing and marketing of and obtaining regulatory approval for ZX008; 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: May 27, 2015

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