ZOGENIX, INC.
Form 8-K
May 05, 2016

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 5, 2016

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))

Item 8.01 Other Events.

On May 5, 2016, Zogenix, Inc. (the Company) announced new data which continues to demonstrate the sustained effectiveness and cardiovascular safety of ZX008 (low-dose fenfluramine) as an adjunctive therapy for seizures associated with Dravet syndrome. In addition, for the first time, data were presented on patient and caregiver sleep quality and quality of life. The podium presentation was given at the 14th International Child Neurology Congress (ICNC), taking place this week in Amsterdam, The Netherlands. ZX008 is designated as an orphan drug in both the United States and Europe, and recently received Fast Track designation in the United States, for the treatment of Dravet syndrome.

The data presented highlighted the updated results from the new patient cohort, which now includes nine Dravet syndrome patients. All of these patients began add-on treatment with low-dose fenfluramine (5 mg to 20 mg per day) at various starting points between 2010 and the end of January 2016. Median treatment duration was 1.5 years (range 0.3 to 5.1 years). During the 90-day run-in period prior to initiating low-dose fenfluramine treatment, the median frequency of major motor seizures (defined as tonic, clonic, tonic-clonic, atonic, and myoclonic seizures lasting >30 seconds) was 15.0 per month (range 0.4 to 39.7). Over the entire observation period, the median frequency of major motor seizures was reduced to 1.5 per month, and the median decrease was 75% (range 28-100%). Six of the nine patients had at least a 70% reduction in major motor seizures.

In addition, parents/caregivers were asked to rate both their child s and their own sleep quality and quality of life using 0-10 scales where 0 = extremely bad and 10 = very good. At the most recent visit, mean sleep quality reported for patients and parents was 8.1/10 and 7.9/10, respectively, while mean Quality of Life scores were 7.4/10 for both groups.

In this new cohort of patients, treatment with low-dose fenfluramine continued to be generally well-tolerated, and did not result in any echocardiographic or clinical signs of cardiac valve abnormalities, pulmonary hypertension or any other cardiovascular abnormalities. The most common treatment-emergent adverse events were mild-to-moderate somnolence (n=6), diminished appetite (n=4), mood changes (n=2), and non-convulsive status epilepticus (n=2). 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 further extends the findings initially reported for the original twelve subjects in 2012 and the initial report from this new cohort in December of 2015.

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 5, 2016

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