ZOGENIX, INC.
Form 8-K
January 30, 2017

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): January 30, 2017

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 January 30, 2017, Zogenix, Inc. (the Company) announced the recent issuance of U.S. Patent No. 9,549,909 from the U.S. Patent & Trademark Office. The patent, entitled Method for the Treatment of Dravet Syndrome , covers claims related to a method for the adjunctive treatment of seizures associated with Dravet syndrome with ZX008. This patent is expected to provide protection of the associated claims through 2033.

Zogenix s Phase 3 program for ZX008 in Dravet syndrome continues to enroll patients in the U.S. and internationally. ZX008 is designated as an orphan drug in both the U.S. and Europe, and also received Fast Track designation in the U.S., for the treatment of Dravet syndrome.

The assignees of this U.S. patent are University of Leuven and University Hospital Antwerp, in Belgium. Zogenix secured exclusive world-wide rights to the recently issued U.S. patent and additional intellectual property through its 2014 acquisition of Brabant Pharma Limited, pursuant to a sale and purchase agreement with Brabant.

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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 the expiration of the newly issued patent covering the treatment of seizures associated with Dravet syndrome using fenfluramine as an adjunctive therapy; ZX008 s potential as a treatment for seizures associated with Dravet syndrome; and the enrollment of patients in the two on-going Phase 3 clinical trials of ZX008 for patients with Dravet syndrome. 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 due to the risks 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; Zogenix s ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities; Fast Track designation may not result in an expedited regulatory review process; and other risks described in the Company s prior 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: January 30, 2017

By: /s/ Matthew P. Smith
Name: Matthew P. Smith
Title: Executive Vice President, Chief Financial Officer, Treasurer and Secretary