ZOGENIX, INC.
Form 8-K
October 19, 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): October 19, 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 October 19, 2015, Zogenix, Inc. (Zogenix) announced the recent receipt of a request from the U.S. Food and Drug Administration (FDA) for additional information related to Zogenix s proposed Phase 3 program for ZX008 prior to the FDA declaring Zogenix s Investigational New Drug Application effective. ZX008 previously received orphan drug designation from the FDA and is expected to enter Phase 3 clinical studies for the treatment of Dravet syndrome, a rare and debilitating form of epilepsy that begins in infancy.

The FDA s specific information requests are related to normative ranges for echocardiograms being conducted during the course of the pediatric Phase 3 program and an amended Phase 3 study protocol to reflect a required follow-up echocardiogram three to six months after patients discontinue treatment with ZX008. Zogenix responded with the requested information required to initiate the clinical program, and the expected ZX008 clinical development timeline remains unchanged, including the expectation that the Phase 3 program will begin in the fourth quarter of 2015.

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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 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 commencement of clinical trials and the receipt of regulatory approvals; the potential that earlier clinical trials may not be predictive of future results; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 that could limit approval and/or commercialization; Zogenix s ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its product development activities; 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: October 19, 2015

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