ZOGENIX, INC.
Form 8-K
June 07, 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): June 7, 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 June 7, 2016, Zogenix, Inc. (the Company) announced the initiation of its second Phase 3 clinical trial, a multi-national study (Study 1502), for the Company s lead product candidate, ZX008, as an adjunctive treatment of seizures in children with Dravet syndrome. ZX008 is designated as an orphan drug in both the United States and Europe, and received Fast Track designation in the United States, for the treatment of Dravet syndrome.

The Phase 3 program for ZX008 includes two randomized, double-blind placebo-controlled studies investigating two dose levels of ZX008 (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg), as well as placebo. The Company intends to enroll 105 subjects in each of the two studies, with 35 patients in each treatment arm. The primary endpoint of both studies is the change in frequency of convulsive seizures as compared to placebo. The key secondary endpoints include 40% and 50% responder analyses, which are important for European regulatory submissions, and the convulsive seizure free interval, which is of significant interest to parents and to patients. The first Phase 3 clinical trial, Study 1501, is currently enrolling patients at sites throughout North America. Enrollment in Study 1502 will take place at sites in Western Europe and Australia.

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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 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 subject enrollment in the Phase 3 clinical studies for ZX008 and ZX008 s potential as a treatment option for seizures associated with Dravet syndrome. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of its plans will be achieved. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in the Company 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 enrollment and completion of clinical trials; the potential that earlier clinical trials may not be predictive of future results; the Company 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; the Company s ability to fully comply with numerous federal, state and local laws and regulatory requirements 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 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: June 7, 2016

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