ZOGENIX, INC.
Form 8-K
January 11, 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): January 11, 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

12400 High Bluff Drive, Suite 650, San Diego, CA 92130

(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 2.02 Results of Operations and Financial Condition.

On January 11, 2016, Zogenix, Inc. (the Company or Zogenix) announced that its preliminary unaudited cash and cash equivalents as of December 31, 2015 were approximately $155.9 million. In addition, $10.0 million is being held in escrow from the proceeds of the sale of Zohydro ER to Pernix Therapeutics Holdings, Inc.

The preliminary unaudited cash position discussed above is subject to the completion of financial closing procedures and other developments that may arise between now and the time the financial results for the fourth quarter are finalized, as well as the completion of the audit of the 2015 financial statements. Therefore, actual results may differ materially from these estimates. In addition, the above estimates do not present all information necessary for an understanding of Zogenix s financial condition as of December 31, 2015.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the Securities Act), or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

Beginning on January 11, 2016, representatives of Zogenix will be attending meetings with investors, analysts and other parties in connection with the J.P. Morgan 33rd Annual Healthcare Conference in San Francisco, California. During these meetings, Zogenix will present the slides attached as Exhibit 99.1 to this Current Report on Form 8-K, which is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1, is being furnished pursuant to Item 7.01 and shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

Item 8.01 Other Events.

On January 11, 2016, Zogenix announced the initiation of the first Phase 3 clinical trial for its lead product candidate, ZX008, as an adjunctive treatment of seizures in children with Dravet syndrome.

The Phase 3 program for ZX008 includes two randomized, double-blind placebo-controlled studies that will include 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. Zogenix intends to enroll 105 subjects in each of the two studies, with 35 patients in each treatment arm. In addition to the U.S. Phase 3 study, a second multi-national study, which will be conducted primarily in Europe, is expected to initiate in the first quarter of 2016. 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 and convulsive seizure-free interval.

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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, 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 Zogenix s cash position as of December 31, 2015 and the timing of the commencement of the second Phase 3 clinical study for ZX008. 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 report due to the risks and uncertainties inherent in Zogenix s business, including, without limitation: risks related to changes in estimated financial amounts based on the completion of financial closing procedures and the audit of the financial statements; 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; 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Slide Presentation

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 11, 2016

By: /s/ Ann D. Rhoads

Name: Ann D. Rhoads
Title: Executive Vice President,

Chief Financial Officer,

Treasurer and Secretary

EXHIBIT INDEX

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