ZOGENIX, INC.
Form 8-K
December 10, 2013

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): December 10, 2013

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 December 10, 2013, Zogenix, Inc. (Zogenix) announced that the U.S. Food and Drug Administration approved Zogenix s supplemental New Drug Application for a 4 mg dose of Sumavel DosePro (sumatriptan injection) Needle-free Delivery System. Sumavel DosePro is also approved in a 6 mg dose for the treatment of acute migraine and cluster headache.

Zogenix currently expects to launch the 4 mg dose of Sumavel DosePro in approximately June 2014.

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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 expects 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 a statement regarding the timing of the launch of 4 mg dose of Sumavel DosePro. 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 risk and uncertainties inherent in Zogenix s business, including, without limitation: the market potential for migraine treatments, and Zogenix s ability to compete within that market, including with the 4 mg dose of Sumavel DosePro; Zogenix s ability to successfully execute its sales and marketing strategy for the commercialization of Sumavel DosePro; unexpected adverse side effects relating to Sumavel DosePro that could result in recalls or product liability claims; Zogenix s reliance on Mallinckrodt to co-promote Sumavel DosePro; and other risks 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: December 10, 2013

By: /s/ Ann D. Rhoads
Name: Ann D. Rhoads
Title: Executive Vice President,

Chief Financial Officer,

Treasurer and Secretary