ZOGENIX, INC.
Form 8-K
February 27, 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): February 26, 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 February 26, 2013, Zogenix, Inc. (Zogenix or the Company) announced that it has been informed by the U.S. Food and Drug Administration (FDA) that the Company is unlikely to receive an action letter for its New Drug Application (NDA) for Zohydro ER (hydrocodone bitartrate extended-release capsules) by the Prescription Drug User Fee Act (PDUFA) goal date of March 1, 2013. Under the performance goals set by the FDA under PDUFA, the agency can miss the prescribed goal date for approximately 10% of the NDAs that are submitted each year and still meet the performance goals for review of priority and standard applications.

The FDA has not provided the Company with information as to the reason for the possible delay, but has indicated that the delay would likely be brief and may last only several weeks. The Company has not been informed of any deficiencies in the application during the review process to date.

If approved, Zohydro ER will be classified as a Drug Enforcement Agency Schedule II drug, making it subject to stricter prescribing and dispensing rules, compared to the hydrocodone-acetaminophen combination products, which are classified as Schedule III drugs. The Schedule II designation recognizes the potential for abuse and dependence, and is an important measure in the effort to promote appropriate use and minimize the potential of abuse or diversion of hydrocodone products. Zohydro ER will also have a Risk Evaluation and Mitigation Strategy (REMS) consistent with the recently introduced FDA-approved REMS for Extended Release and Long Acting Opioids.

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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, potential, suggests, assuming, designed and similar ex 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 timing for the FDA to complete its review of the Zohydro ER NDA. 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 risk and uncertainties inherent in Zogenix s business, including, without limitation: the potential for the FDA to further delay the PDUFA target action date due to the FDA s internal resource constraints or other reasons; the FDA following its advisory committee s recommendation to not approve the Zohydro ER NDA; the uncertainty of the FDA approval process and other regulatory requirements; the potential for additional safety and abuse deterrence studies and REMS requirements and the related delay in approval of the Zohydro ER NDA and/or commercialization of this product candidate; the potential for delays associated with any additional data required to be submitted by Zogenix in support of the NDA; the potential for Zohydro ER to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to Zohydro ER to delay or prevent regulatory approval or commercialization; the impact of any inability to raise sufficient capital to fund ongoing operations; 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: February 26, 2013

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

Treasurer and Secretary