ZOGENIX, INC.
Form 8-K
December 10, 2012

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 7, 2012

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 7, 2012, Zogenix, Inc. (the Company) announced that the U.S. Food and Drug Administration s (FDA) Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) voted 2-11 [with 1 abstention] against the approval of Zohydro ER (hydrocodone bitartrate extended-release capsules), an extended-release formulation of hydrocodone without acetaminophen, for the management of moderate-to-severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

The Prescription Drug User Fee Act (PDUFA) date for completion of FDA review of Zohydro ER New Drug Application (NDA) for approval is March 1, 2013. The AADPAC provides FDA with independent expert advice and recommendations, but the final decision regarding approval of a medication is made by the FDA.

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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 target action date 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 press release due to the risks and uncertainties inherent in Zogenix s business, including, without limitation: the potential for the FDA to delay the PDUFA target action date of March 1, 2013 due to the FDA s internal resource constraints or other reasons; the FDA following AADPAC s recommendation to not approve the Zohydro ER NDA; the uncertainty of the FDA approval process and other regulatory requirements; the top-line data Zogenix has reported for Zohydro ER is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trials, and may also change in connection with the continued review of such data as part of the FDA s review of the NDA for Zohydro ER; 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 press release 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 7, 2012

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