ZOGENIX, INC.
Form 8-K
July 16, 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): July 13, 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 July 16, 2012, Zogenix, Inc. (the Company or Zogenix) announced that the U.S. Food and Drug Administration (the FDA) has accepted for review the New Drug Application (NDA) for Zohydro (hydrocodone bitartrate extended-release capsules), the Company s lead investigational product candidate for the treatment of moderate to severe chronic pain. Under the Prescription Drug User Fee Act (PDUFA), the goal for a standard review of an NDA is 10 months from NDA submission, and the FDA has assigned a target action date of March 1, 2013 for the Zohydro NDA. Based on a recent discussion with the FDA, the Company anticipates the agency will convene an advisory committee for Zohydro during the PDUFA review period. The advisory committee provides the FDA with independent expert advice and recommendations; however, the final decision regarding approval 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 NDA. The inclusion of forward-looking statements should not be regarded as 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 delay the PDUFA target action date of March 1, 2013 due to the FDA s internal resource constraints or other reasons; the uncertainty of the FDA approval process and other regulatory requirements; the top-line data Zogenix has reported for Zohydro 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 trial, 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; the potential for delays associated with any additional data required to be submitted by Zogenix in support of the NDA; the potential for Zohydro to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to Zohydro to delay or prevent regulatory approval or commercialization; and other risks described in the 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: July 16, 2012

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