ZOGENIX, INC.
Form 8-K
October 02, 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): October 1, 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 October 1, 2013, Zogenix, Inc. (Zogenix) announced that it had been informed by the U.S. Food and Drug Administration (FDA) that an action letter on the New Drug Application (NDA) for Zohydro™ ER (*hydrocodone* bitartrate) extended-release capsules could follow after a further delay of short duration. The FDA had previously informed Zogenix that it expected to issue an action letter over the summer. The original goal date for FDA action on the NDA under the Prescription Drug User Fee Act (PDUFA) was March 1, 2013.

In September 2013, the FDA announced safety labeling changes and post-marketing requirements for extended-release (ER) and long-acting (LA) opioid analgesics. Previously, the FDA had indicated a decision on the Zohydro ER NDA could follow after a significant class-wide action on ER/LA opioid analgesics. Following the announcement, Zogenix and the FDA have completed the final labeling and reached agreement on the post-marketing requirements for Zohydro ER. The FDA has also reconfirmed there are no deficiencies in the NDA. While the FDA indicated its intent to take prompt action on the Zohydro ER NDA, the timing for a decision may be impacted by the current federal government shutdown. The FDA indicated to Zogenix that agency activities funded by PDUFA user-fees remain operational.

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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 Zogenix s current beliefs and expectations. These forward-looking statements include statements regarding: the potential for, and timing of, approval of the NDA for Zohydro ER. 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: the potential for the FDA to further delay the PDUFA target action date due to the federal government shutdown, the FDA s internal resource constraints or other reasons; the uncertainty of the FDA approval process and other regulatory requirements, including the potential for changes to final labeling and post-marketing requirements; the potential for additional safety and abuse deterrence studies and Risk Evaluation and Mitigation Strategy requirements; 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: October 2, 2013

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

Treasurer and Secretary