ZOGENIX, INC.
Form 8-K
October 28, 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 25, 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 25, 2013, the U.S. Food and Drug Administration (FDA) approved Zogenix, Inc. s New Drug Application (NDA) for Zohydro™ ER (hydrocodone bitartrate) extended-release capsules, an opioid agonist, extended-release oral formulation of hydrocodone without acetaminophen, for the management of pain severe enough to require daily, around-the-clock, long-term treatment and for which alternative treatment options are inadequate. Zohydro ER is the first extended-release formulation hydrocodone therapy without acetaminophen.

Zogenix currently expects to launch Zohydro ER in approximately four months. Zohydro ER capsules will be available in six dosage strengths ranging from 10 mg to 50 mg with dosing every 12 hours.

Zogenix will implement the Risk Evaluation and Mitigation Strategy for extended release (ER) and long acting (LA) opioids required by the FDA for all the products in the class. In addition, Zogenix will participate in the design and implementation of post-marketing studies, as recently outlined by the FDA. NDA sponsors of ER/LA opioids are now required to conduct studies to assess the serious risks associated with long-term use.

Zohydro ER is classified as a Drug Enforcement Agency (DEA) Schedule II drug under the Controlled Substances Act, making it subject to stricter prescribing and dispensing rules compared to immediate-release hydrocodone-acetaminophen combination products, which are currently classified as Schedule III drugs. On October 24, 2013, the FDA announced its intention to submit a formal recommendation to the Department of Health and Human Services by early December to reclassify hydrocodone combination products from DEA Schedule III to Schedule II.

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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 timing of the launch of Zohydro ER, the planned dosage strengths and regimen for Zohydro ER, and the FDA s proposal to change the schedule for hydrocodone combination products from Schedule III to Schedule II under the Controlled Substances Act. 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 timing and success of any subsequent commercial launch of Zohydro ER; Zogenix s ability to successfully launch and drive market demand for Zohydro ER; competition from other pharmaceutical or biotechnology companies; Zogenix s ability to obtain additional financing as needed to support its operations; the scope and validity of patent protection for Zohydro ER and Zogenix s ability to commercialize Zohydro ER without infringing the patent rights of others; the potential for Paragraph IV challenges and related litigation for Zohydro ER; unexpected adverse side effects or inadequate therapeutic efficacy of Zohydro ER that could limit commercialization, or that could result in recalls or product liability claims; other difficulties or delays relating to the development, testing, manufacturing and marketing of and maintaining regulatory approval for Zogenix s products; 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 28, 2013

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

Treasurer and Secretary