ZOGENIX, INC.
Form 8-K
February 02, 2015

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): **January 30, 2015**

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 January 30, 2015, the U.S. Food and Drug Administration (FDA) approved a new formulation of Zohydro™ ER (hydrocodone bitartrate) Extended-Release Capsules, CII, with BeadTek . BeadTek is a formulation technology designed to provide abuse-deterrent properties without changing the release properties of hydrocodone when Zohydro ER is used as intended.

Concurrently, Zogenix, Inc. has ongoing Human Abuse Liability studies, which will further characterize the abuse-deterrent properties of the new formulation. Zogenix intends to submit these data in the second half of 2015 to the FDA to support an amended product label, including abuse-deterrent claims consistent with the FDA s current draft Guidance for Industry, Abuse-Deterrent Opioids Evaluation and Labeling. Transition to Zohydro ER with BeadTek is expected to occur in the second quarter of 2015 for all prescribed strengths ranging from 10 mg to 50 mg, without disruption to patients currently on therapy.

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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, designed 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 ability of BeadTek to reduce the abuse potential of Zohydro ER; the expected timing of the transition to the Zohydro ER formulation with BeadTek and the submission of data to support an amended label for Zohydro ER with BeadTek and the transition to the Zohydro ER with BeadTek formulation; and the safety and effectiveness of Zohydro ER with BeadTek. 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: Zogenix s dependence on the successful commercialization of Zohydro ER; public concern regarding the safety of drug products such as Zohydro ER and the impact of negative publicity and political influences relating to the regulation of the pain management market in general and opioids and Zohydro ER in particular; unexpected adverse side effects or inadequate therapeutic efficacy of the modified Zohydro ER formulation that could limit commercialization, or that could result in recalls or product liability claims; Zogenix s ability to achieve broad market acceptance and generate revenues from sales of Zohydro ER; competition from other pharmaceutical or biotechnology companies; Zogenix s dependence on its contract manufacturers and its ability to ensure an adequate and continued supply of Zohydro ER with BeadTek to meet market demand for the transition to the modified Zohydro ER formulation; other difficulties or delays relating to the development, testing, manufacturing and marketing of an abuse deterrent formulation of Zohydro ER; 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 2, 2015

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