ZOGENIX, INC.
Form 8-K
October 01, 2014

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): September 30, 2014

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 September 30, 2014, Zogenix, Inc. (the Company) submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration for a modified formulation of Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules, CII, which has been designed to have abuse deterrent properties. The Company anticipates a target action date on the sNDA during the first quarter of 2015, and if approved, a transition from the currently marketed product to this new formulation of Zohydro ER in the second quarter of 2015.

* * *

Zogenix cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. Words such as designed, anticipates, expects, and will, and similar expressions, are intended to identify forward-looking statements, and are based on the Company s current beliefs and expectations. Such statements include, without limitation, statements regarding the expected timing of FDA review of the sNDA and, if approved, introduction of the new product into the marketplace. Actual results may differ from those set forth in this filing due to the risk and uncertainties inherent in the Company s business, including, without limitation: risks and uncertainties associated with regulatory review and approval of the sNDA, including the risk that additional information or data requests from the FDA could significantly delay the FDA s review period beyond four months; unexpected adverse side effects or inadequate therapeutic efficacy of the modified formulation that could limit approval and/or commercialization, or that could result in recalls or product liability claims; 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; competition from other pharmaceutical or biotechnology companies; other difficulties or delays relating to the development, testing, manufacturing and marketing of and obtaining regulatory approval for an abuse deterrent formulation of Zohydro ER; and other risks detailed under Risk Factors and elsewhere in the Company s periodic reports and other filings made with the Securities and Exchange Commission from time to time. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, and Zogenix undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof.

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 1, 2014

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

Chief Financial Officer,
Treasurer and Secretary