ZOGENIX, INC.
Form 8-K
August 14, 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): August 13, 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 August 13, 2014, Zogenix, Inc. (Zogenix) received a paragraph IV certification from Actavis Laboratories FL, Inc. (Actavis) advising Zogenix of the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (the FDA) for a generic version of Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules, CII.

The certification notice alleges that the two U.S. patents listed in the FDA s Orange Book for Zohydro ER, with an expiration date in November 2019, will not be infringed by Actavis s proposed product, are invalid and/or are unenforceable. Zogenix and its licensor are evaluating the paragraph IV certification and intend to vigorously enforce the intellectual property rights relating to Zohydro ER.

Zohydro ER was granted exclusivity by the FDA through October 2016; Zogenix plans to submit a supplemental New Drug Application for the next-generation capsule formulation of Zohydro ER by October 2014.

The parties have 45 days from the receipt of the paragraph IV certification to commence a patent infringement lawsuit against Actavis that would automatically stay, or bar, the FDA from approving Actavis s ANDA for 30 months or until a district court decision that is adverse to the asserted patents, whichever is earlier.

* * *

Zogenix cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. Words such as plans, believes, expects, anticipates, and will, and similar expressions intended to identify forward-looking statements, and are based on Zogenix s current beliefs and expectations. Such statements include, without limitation, statements regarding Zogenix s intention to vigorously enforce its intellectual property rights. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Zogenix s actual future results may differ materially from its current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: Zogenix s ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend its patents; Zogenix s reliance on its licensor to control enforcement proceedings for the Zohydro ER patents; the possibility that Zogenix and its licensor may be required to file lawsuits to defend the patent rights from challenges by companies seeking to market generic versions of Zohydro ER, and the substantial costs associated with such lawsuits; the possible introduction of generic competition to Zohydro ER; the risk that Zogenix may not be able to raise sufficient capital when needed, or at all; and other risks detailed under Risk Factors and elsewhere in Zogenix 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: August 14, 2014

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

Chief Financial Officer,

Treasurer and Secretary