ZOGENIX, INC.
Form 8-K
September 04, 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 3, 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 3, 2014, Daravita Limited ("Daravita") filed suit in the United States District Court for the District of Delaware against Actavis Laboratories FL, Inc. and certain of its affiliates ("Actavis"). Daravita has licensed rights under certain patents covering Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules, CII to Zogenix, Inc. ("Zogenix"). Under the Zohydro ER license agreement, Daravita has the right to control the enforcement of these patents and related proceedings involving Zohydro ER and any prospective generic entrant.

As previously reported, on August 13, 2014, Zogenix received a notice from Actavis concerning its filing of an Abbreviated New Drug Application ("ANDA") containing a "Paragraph IV" patent certification with the U.S. Food and Drug Administration (the "FDA") for a generic version of Zohydro ER. The FDA will determine whether Actavis may be eligible for the 180-day exclusivity period described in 21 U.S.C. § 355(j)(5)(B)(iv).

The lawsuit filed by Daravita alleges that Actavis has infringed U.S. Patent Nos. 6,228,398 (the "'398 patent") and 6,902,742 (the "'742 patent") by filing its ANDA seeking approval from the FDA to market a generic version of Zohydro ER prior to the expiration of these patents. The '398 patent and '742 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The patent infringement lawsuit was filed within 45 days of receipt of the notice letter, thereby triggering a stay of FDA approval of the Actavis ANDA until the earlier of the expiration of a 30-month period from the receipt of the notice letter, the expiration of the '398 patent and '742 patent, the entry of a settlement order or consent decree stating that the '398 patent and '742 patent are invalid or not infringed, a decision in the infringement case that is favorable to Actavis, or such shorter or longer period as the court may order.

Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for Zohydro ER. Specifically, the FDA has granted Zohydro three years of regulatory exclusivity, which expires in October 2016.

Daravita and Zogenix intend to vigorously enforce the intellectual property rights relating to Zohydro ER to prevent the marketing of infringing generic products prior to the expiration of their patents. The '398 patent and the '742 patent each expire on November 1, 2019. However, given the unpredictability inherent in litigation, Zogenix cannot predict the outcome of this matter or guarantee the outcome of any litigation.

For a discussion of risks related to the ANDA filing by Actavis, see the "Risk Factors" section and the discussion of "Intellectual Property" under the "Business" section of Zogenix's Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission (the "SEC") on March 7, 2014 and the "Risk Factors" section of Zogenix's Quarterly Report on Form 10-Q for the period ended June 30, 2014 filed with the SEC on August 6, 2014, including the risks described under the headings "The patent rights that we have in-licensed covering Zohydro ER are limited to a modified release composition containing hydrocodone. As a result, our market opportunity for this product may be limited by the lack of patent protection for the active ingredient itself and other formulations of hydrocodone" and "We face intense competition, including from generic products, and if our competitors market and/or develop treatments for migraine, pain or psychotic disorders that are marketed more effectively, approved more quickly than our product candidates or demonstrated to be safer or more effective than our products, our commercial opportunities will be reduced or eliminated," as well as any updates to such sections contained in Zogenix's subsequent reports filed with the SEC.

* * *

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, a 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 the intellectual property rights relating to Zohydro ER. 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 Daravita to control enforcement proceedings for the Zohydro ER patents; 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: September 4, 2014

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