

ZOGENIX, INC.
Form 8-K
October 31, 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 29, 2014

ZOGENIX, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-34962
(Commission
File Number)

20-5300780
(IRS Employer
Identification No.)

12400 High Bluff Drive, Suite 650, San Diego, CA
(Address of Principal Executive Offices)

92130
(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 1.01. Entry into a Material Definitive Agreement.

On October 29, 2014, Zogenix, Inc. (“Zogenix”) entered into a Waiver Agreement (the “Agreement”) with Purdue Pharma L.P. (“Purdue”), pursuant to which Zogenix granted to Purdue a permanent, irrevocable, non-transferable and exclusive waiver of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER® capsules in support of Purdue’s single-entity, extended-release hydrocodone product which is the subject of pending NDA 206627 and any single-entity, once-daily hydrocodone successor products or NDAs filed by Purdue (“Purdue Product”). In addition, Purdue granted to Zogenix a permanent, irrevocable, non-transferable and exclusive waiver of the Hatch-Waxman regulatory exclusivity period with respect to Purdue Products in support of Zogenix’s single-entity, twice-a-day hydrocodone product, including Zohydro ER and any successor products with any abuse deterrent properties or labeling claims.

Under the terms of the Agreement, Purdue will pay to Zogenix (i) \$5.0 million within fifteen (15) days of the date of the Agreement, (ii) \$5.0 million on July 1, 2015, and (iii) a percentage royalty in the low single-digits on Purdue’s net sales of Purdue Product commencing on October 1, 2015 and ending on October 25, 2016, only to the extent such royalty payment by Purdue in the aggregate would exceed \$5.0 million and then only with respect to royalties in excess of such amount.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the provisions of the Agreement. Zogenix expects to file the Agreement with its Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, requesting confidential treatment for certain portions.

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 31, 2014

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