

ZOGENIX, INC.
Form 8-K
November 18, 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): November 18, 2014

ZOGENIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

12400 High Bluff Drive, Suite 650, San Diego, CA

001-34962
(Commission

File Number)

20-5300780
(IRS Employer

Identification No.)

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 7.01. Regulation FD Disclosure.

On November 18, 2014, Zogenix, Inc. (Zogenix) management will be attending the Stifel Nicolaus 2014 Healthcare Conference in New York City, New York, and will present the slides attached as Exhibit 99.1 to this Current Report on Form 8-K, which is incorporated herein by reference.

The information in this report, including Exhibit 99.1, is being furnished pursuant to Item 7.01 and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

* * *

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 are intended to identify forward-looking statements, and are based on Zogenix's current beliefs and expectations. Such statements include, without limitation, statements regarding the expected timing of the FDA review and action date and potential approval of the sNDA and updated labels with abuse deterrent claims for Zohydro ER; the potential to develop an abuse deterrent formulation of Zohydro ER with Altus and the timing of related studies; the potential timing of negotiating and carrying out a co-promotion agreement for Zohydro ER; the timing of the commencement of Phase 3 clinical trials for Brabafen and a multi-dose clinical and safety study and Phase 3 clinical trials for Relday and the timing of the results; the potential timing of NDA submissions for each of the abuse deterrent formulation of Zohydro ER with Altus, Brabafen and Relday and the expected timing of the FDA review and potential approval of the NDA submissions; the size of the commercial opportunity for Zohydro ER and Relday; and the ability to secure debt financing based on the non-binding term sheet. 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: 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; risks and uncertainties associated with the development and regulatory approval of an abuse deterrent formulation with Altus and Zogenix's reliance on Altus and its drug delivery platform in such development efforts; unexpected adverse side effects or inadequate therapeutic efficacy of the abuse deterrent formulations that could limit approval and/or commercialization; Zogenix's dependence on the successful commercialization of Zohydro ER; Zogenix's ability to achieve broad market acceptance and generate revenues from sales 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; competition from other pharmaceutical or biotechnology companies; risks associated with the acquisition of Brabant and integration of Brabant's operations into Zogenix's business, including an increase in near and long-term expenditures, exposure to unknown liabilities and diversion of Zogenix's management's time and attention; Zogenix's dependence on its contract manufacturers and its ability to ensure an adequate and continued supply of Zohydro ER to meet market demand; Zogenix's dependence on third parties to

develop an abuse deterrent formulation of Zohydro ER, Relday and Brabafen; the potential that earlier clinical trials may not be predictive of future results; Zogenix's ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend the patents covering Zohydro ER, including the potential for Paragraph IV litigation relating to the product; the potential product liability exposure associated with pharmaceutical products such as Zohydro ER and other products Zogenix may in-license or acquire; difficulties in identifying, negotiating and carrying out a co-promotions agreement for Zohydro ER; Zogenix's ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its commercial activities; the risk that Zogenix will be unable to negotiate and enter into definitive agreements for a potential debt financing, on acceptable terms, or at all; Zogenix's ability to raise additional funding that it may need to continue to pursue its commercial and business development plans; 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

| No. | Description |
|------|--------------------|
| 99.1 | Slide Presentation |

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: November 18, 2014

By: /s/ Ann D. Rhoads

Name: Ann D. Rhoads

Title: Executive Vice President, Chief Financial Officer,
Treasurer and Secretary

EXHIBIT INDEX

Exhibit

| No. | Description |
|------|--------------------|
| 99.1 | Slide Presentation |