ZOGENIX, INC. Form 8-K March 28, 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): March 27, 2014

ZOGENIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction **001-34962** (Commission

20-5300780 (IRS Employer

of Incorporation)

File Number)

Identification No.)

Edgar Filing: ZOGENIX, INC. - Form 8-K

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

(Address of Principal Executive Offices)

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 March 27, 2014, Zogenix, Inc. (Zogenix or the Company) issued a statement addressing Massachusetts Governor Deval Patrick s ban on the Company s product, Zohydro ER (*hydrocodone bitartrate*) extended-release capsules, the first and only extended release *hydrocodone* product without *acetaminophen*, in the state of Massachusetts. The statement is 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 (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 Current Report on Form 8-K and the attached exhibit that are not a description of historical facts are forward-looking statements. Words such as believes, anticipates, indicates, suggests, assuming and similar expressions are intended to iden expects, will, intends, potential, forward-looking statements. These statements are based on the Company s current beliefs and expectations. These forward-looking statements include statements regarding the potential of Zohydro ER to provide a significant new management alternative within the chronic pain market, the ability to ensure that the risk of abuse, misuse and diversion of Zohydro ER is minimized and the amount of hydrocodone product that will be manufactured in the United States. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in Zogenix s business, including, without limitation: Zogenix s ability to adequately ensure that the risk of abuse, misuse and diversion of Zohydro ER is minimized; Zogenix s ability to successfully launch and drive market demand for Zohydro ER; unexpected adverse side effects or inadequate therapeutic efficacy of Zohydro ER that could limit commercialization, or that could result in recalls or product liability claims; competition from other pharmaceutical or biotechnology companies; and other risks detailed in Zogenix s public periodic filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

No. Description

99.1 Statement regarding Massachusetts ban on Zohydro ER, dated March 27, 2014

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: March 28, 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 Statement regarding Massachusetts ban on Zohydro ER, dated March 27, 2014