ZOGENIX, INC. Form 8-K January 09, 2012

# 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): January 9, 2012

# **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.)

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12671 High Bluff Drive, Suite 200, 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 at the following provisions ( <i>see</i> 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 2.02. Results of Operations and Financial Condition.

During the week of January 9, 2012, representatives of Zogenix, Inc. will be attending meetings with investors, analysts and others in connection with the JP Morgan Healthcare conference in San Francisco, California. During these meetings, Zogenix will present the slides attached as Exhibit 99.1 to this Current Report on Form 8-K. Although Zogenix has not finalized its full financial results for the fiscal year ended December 31, 2011, Zogenix will announce on these slides that it had approximately \$56.5 million of cash and cash equivalents as of December 31, 2011. This amount is unaudited and preliminary, and does not present all information necessary for an understanding of Zogenix s financial condition as of December 31, 2011. The audit of Zogenix s financial statements for the year ended December 31, 2011 is ongoing and could result in changes to this amount.

#### Item 7.01. Regulation FD Disclosure.

The slides attached as Exhibit 99.1 to this Current Report on Form 8-K are incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, 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 liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

\* \* \*

By filing this Current Report on Form 8-K and furnishing this information, Zogenix makes no admission as to the materiality of any information in this report. The information contained in this Current Report on Form 8-K is intended to be considered in the context of Zogenix s filings with the SEC and other public announcements that Zogenix makes, by press release or otherwise, from time to time. Zogenix undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

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. These forward-looking statements include statements regarding: estimates of Zogenix s cash position as of December 31, 2011; the ability to successfully commercialize Sumayel DosePro and its expected sales growth; the progress and timing of clinical trials for Zohydro and planned development of Relday; the potential for, and timing of, an NDA submission for Zohydro and an IND submission for Relday; the potential for Zohydro to be the first approved oral, single-entity extended release formulation of hydrocodone; the expansion of Zogenix s existing sales force; the potential to broaden the application of the DosePro technology; and the potential market penetration of Sumavel DosePro and Zohydro. 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 and the attached exhibit due to the risk and uncertainties inherent in Zogenix s business, including, without limitation: risks related to changes in estimated financial amounts based on the completion of Zogenix s audit; the market potential for migraine treatments, and Zogenix s ability to compete within that market; inadequate therapeutic efficacy or unexpected adverse side effects relating to Sumavel DosePro that could delay or prevent commercialization, or that could result in recalls or product liability claims; Zogenix s dependence on its collaboration with Astellas Pharma US, Inc. to promote Sumavel DosePro; Zogenix s ability to secure another co-promotion partner to promote Sumavel DosePro on acceptable terms, or at all; the ability of Zogenix to ensure adequate and continued supply of Sumavel DosePro to successfully meet anticipated market demand; the progress and timing of Zogenix s clinical trials; the potential that earlier clinical trials may not be predictive of future results; the potential for Zohydro to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to Zohydro to delay or prevent regulatory approval or commercialization; the ability of Zogenix and its licensors to obtain,

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maintain and successfully enforce adequate patent and other intellectual property protection of its products and product candidates and the ability to operate its business without infringing the intellectual property rights of others; the inherent risks of clinical development of Relday and Zogenix s dependence on its collaboration with DURECT Corporation to develop Relday; and other risks described in Zogenix s filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Zogenix undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Exchange Act.

# 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: January 9, 2012 By: /s/ Ann D. Rhoads Name: Ann D. Rhoads

Title: Executive Vice President, Chief Financial Officer,

Treasurer and Secretary

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### EXHIBIT INDEX

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