

ZOGENIX, INC.
Form 8-K
July 12, 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): July 12, 2012

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.)

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

(Address of Principal Executive Offices)

Registrant's telephone number, including area code: (858) 259-1165

92130

(Zip Code)

(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 July 12, 2012, Zogenix, Inc. (the Company or Zogenix) announced that it initiated its first investigational new drug (IND) clinical trial for Relday , which is a product candidate based on a combination of the Company s DosePro needle-free, subcutaneous drug delivery system plus a proprietary, subcutaneous once-monthly formulation of risperidone for treating schizophrenia. The Phase 1 clinical trial for Relday is a single-center, open-label, safety and pharmacokinetic trial that will enroll thirty patients with chronic, stable schizophrenia or schizoaffective disorder. The Company expects that study results will be available by the end of 2012.

Zogenix cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. Words such as believes, anticipates, plans, expects, indicates, will, intends, potential, suggests, assuming, designed and similar expressions are used to identify forward-looking statements. These statements are based on the Company s current beliefs and expectations. These forward-looking statements include statements regarding the initiation of clinical trials and results from such trials and the timing thereof. The inclusion of forward-looking statements should not be regarded as 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 risk and uncertainties inherent in Zogenix s business, including, without limitation: the uncertainties associated with the clinical development and regulatory approval of product candidates such as Relday, including potential delays in enrollment and completion of clinical trials; difficulties in identifying, negotiating, executing and carrying out strategic transactions relating to Relday; the market potential for anti-psychotics, and Zogenix s ability to compete within that market; the ability to obtain and the validity and duration of patent protection and other intellectual property rights for Relday; and other risks described in the Zogenix s 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.

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: July 12, 2012

By: /s/ Ann D. Rhoads

Name: Ann D. Rhoads

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