ZOGENIX, INC.
Form 8-K
January 03, 2013

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 3, 2013

ZOGENIX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-34962**	**20-5300780**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12400 High Bluff Drive, Suite 650, San Diego, CA **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 8.01 Other Events.

On January 3, 2013, Zogenix, Inc. (the Company or Zogenix) announced positive single-dose pharmacokinetic (PK) results from the Phase 1 clinical trial of Relday , an investigational candidate of a proprietary, once-monthly subcutaneous formulation of risperidone for the treatment of schizophrenia. The Phase 1 clinical trial was conducted as a single-center, open-label, safety and PK trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. Adverse events in the Phase 1 trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other risperidone products.

Based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, Zogenix has extended the study to include an additional cohort of 10 patients at a 100 mg dose of the same formulation. The addition of this dose arm to the study will enable evaluation of dose proportionality across the full dose range that would be anticipated to be used in clinical practice. Positive results from this study extension would better position Zogenix to begin a multi-dose clinical trial, which would provide the required steady-state PK and safety data prior to initiating Phase 3 development studies. Zogenix expects to complete the extension of the Phase 1 clinical trial during the second quarter of 2013.

The development of Relday will first focus on its delivery by conventional needle and syringe in order to allow the administration of different volumes of the same formulation of Relday by a healthcare professional. Zogenix anticipates that the introduction of its DosePro needle-free technology for administration of Relday can occur later in development or as part of life cycle management after further work involving formulation development, technology enhancements, and applicable regulatory approvals.

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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 and similar expressions are identify forward-looking statements. These statements are based on the Company s current beliefs and expectations. These forward-looking statements include statements regarding: initiation of a multi-dose clinical trial and Phase 3 development studies for Relday; timing of completion of the extension of the Phase 1 trial; and the introduction of DosePro technology for Relday and the timing thereof. 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: 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; Zogenix s dependence on its collaboration with DURECT Corporation to develop Relday; inadequate therapeutic efficacy or unexpected adverse side effects relating to Relday that could prevent its development or commercialization; 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; ability to obtain and the validity and duration of patent protection and other intellectual property rights for Relday; and other risks described in 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: January 3, 2013

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