

ZOGENIX, INC.
Form 8-K
May 02, 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): May 2, 2013

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 May 2, 2013, Zogenix, Inc. (the Company or Zogenix) announced positive top-line results from its extended 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 pharmacokinetic (PK) trial of 40 patients with chronic, stable schizophrenia or schizoaffective disorder across a dose range of 25, 50 and 100 mg. Adverse events in the Phase 1 trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other *risperidone* products.

The extended Phase 1 clinical trial included a 100 mg dose of Relday, following previously reported positive results with 25 and 50 mg doses. The results for the extended Phase 1 clinical trial showed *risperidone* blood concentrations in the therapeutic range were achieved on the first day of dosing and maintained throughout the one-month period. In addition, dose proportionality has now been established across the full dose range that would be anticipated to be used in clinical practice (50 to 100 mg). The positive results from this study extension 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, subject to Zogenix securing a development and commercialization partner prior to initiation of the multi-dose trial.

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 the 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.

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 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: initiation of a multi-dose clinical trial and Phase 3 development studies for Relday; the identification of a development and commercialization partner for Relday; 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: May 2, 2013

By: /s/ Ann D. Rhoads

Name: Ann D. Rhoads

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