ZOGENIX, INC.
Form 8-K
September 30, 2015

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): September 30, 2015

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 September 30, 2015, Zogenix, Inc. (the Company or Zogenix) announced positive top-line pharmacokinetic results from its Phase 1b multi-dose clinical trial of Relday, a proprietary, once-monthly subcutaneous investigational formulation of risperidone for the treatment of schizophrenia. If approved, Relday has the potential to be the first subcutaneous antipsychotic product that achieves therapeutic drug levels on the first day of administration, allows for once-monthly dosing and does not require reconstitution. Zogenix has retained Locust Walk Partners of Cambridge, MA, a transaction advisory firm for life sciences companies, to provide transaction advisory and support services for Relday, and has now initiated efforts to secure a global strategic development and commercialization partner for Relday.

The Phase 1b multi-dose parallel group clinical trial enrolled 60 subjects comprised of three cohorts of patients receiving four monthly injections of Relday, at dose levels of either 60, 90 or 120 mg of risperidone per month. A fourth cohort received five bi-weekly intramuscular injections of Risperdal® Consta. Risperdal Consta requires oral supplementation for the first three weeks following dosing initiation, and at least four Risperdal Consta doses are required to reach steady state. The results for Relday demonstrated that risperidone plasma concentrations in the therapeutic range were achieved on the first day of dosing, reached steady state levels following the second dose and consistently maintained therapeutic levels throughout the four-month period. In addition, dose proportionality was confirmed across the dose range intended for clinical practice (60 to 120 mg). Relday was generally safe and well-tolerated, with results consistent with the profile of risperidone and the Company s previous Phase 1 single-dose clinical trial.

Risperidone is one of the most widely prescribed medications used to treat the symptoms of schizophrenia in adults and teenagers 13 years of age and older. The injectable formulation of risperidone, Risperdal Consta, requires twice-a-month dosing, oral supplementation during therapy initiation, intramuscular injection and drug reconstitution prior to use.

***

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, indicates, will, plans, designed and similar expressions are intended to identify forward-looking statements. These statements are based on the Company s current beliefs and expectations. These forward-looking statements include statements regarding: delivery and dosing benefits of Relday to both the patient and clinician, the viability of Relday, Zogenix s ability to secure a global strategic development partner for rest-of-world development and commercialization of Relday, and the ability of such product to address the global anti-psychotic market. 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; 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 terms of any development or commercialization partnership for Relday may not be favorable, and the partner may not perform as expected; the market potential for anti-psychotics, and Zogenix s ability to compete within that market; Zogenix s 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: September 30, 2015

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