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): November 29, 2017

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.)

5858 Horton Street, Suite 455, Emeryville, CA	94608
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (510) 550-8300

(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:

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933(§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On November 29, 2017, Zogenix, Inc. (the "Company") announced that the first child has enrolled in the Phase 3 clinical trial for the Company's lead investigational therapy, ZX008, as an adjunctive treatment of seizures associated with Lennox-Gastaut syndrome ("LGS").

The Phase 3 multicenter global LGS trial is divided in two parts. Part 1 is a double-blind, placebo-controlled investigation to assess the safety, tolerability and efficacy of ZX008, low-dose fenfluramine, when added to a patient's current anti-epileptic therapy. The trial will include two dose levels of ZX008 (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg), as well as placebo. After establishing baseline seizure frequency for 4 weeks, randomized patients will be titrated to their dose over a 2-week titration period, followed by a 12-week fixed dose maintenance period. The Company is targeting a total of 225 patients (75 per treatment arm) in the trial. The primary endpoint of the clinical trial is change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.8 mg/kg/day dose. The key secondary endpoints include change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.2 mg/kg/day dose, and the proportion of patients achieving a 50 percent reduction in drop seizures. Part 2 of the clinical trial will be a 12-month open-label extension to evaluate the long-term safety, tolerability and effectiveness of ZX008.

The initiation of this Phase 3 program follows a Phase 2 open-label, dose-finding investigator-initiated clinical trial of ZX008 for the treatment of LGS that was conducted by Lieven Lagae, M.D., Ph.D., Professor at the University of Leuven, Belgium, Head of the Pediatric Neurology Department. The interim Phase 2 results were presented at the 70th Annual Meeting of the American Epilepsy Society in December 2016. Of the 13 subjects enrolled, seven (54 percent) achieved at least a 50 percent reduction in the number of major motor seizures, with a range of 50 percent to 90 percent improvement. In addition, there was an approximately 2-fold increase in the number of responders (with a reduction of 50 percent or greater) on a dose of 0.4 mg/kg/day vs. 0.2 mg/kg/day. Importantly, per protocol, dose escalation stopped when a patient's major motor seizure frequency was reduced by ≥50 percent of baseline.

ZX008 for the treatment of LGS has previously been designated as an orphan drug by both the U.S. Food and Drug Administration and the European Commission. The Phase 3 trial is planned for up to 85 sites in North America, Europe, Asia-Pacific, South America, South Africa and Australia.

Forward Looking Statements

The Company 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 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 the Phase 3 clinical trial in Lennox-Gastaut syndrome, including the number of patients to be enrolled. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the uncertainties associated with the clinical development and regulatory approval of product candidates such as ZX008, including potential delays in the commencement, enrollment and completion of clinical trials; the Company's reliance on third parties to conduct its clinical trials, enroll patients, manufacture its preclinical and clinical drug supplies and manufacture commercial supplies of its drug products, if approved; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 in LGS that could limit approval and/or commercialization, or that could result in recalls or product liability claims; the Company's ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities; and other risks described in the Company's prior press releases as well as in public periodic 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 the Company 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: November 29, 2017

By: /s/ Michael P. Smith

Name: Michael P. Smith

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