ZOGENIX, INC.
Form 8-K
February 06, 2019

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): February 6, 2019

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, #455,		**94608**

Emeryville, CA
(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 (*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))
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 February 6, 2019, Zogenix, Inc. (the Company), issued a press release announcing that it has completed its rolling submission of a New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) and submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for FINTEPLA (ZX008, low-dose fenfluramine) for the treatment of seizures associated with Dravet syndrome. Both applications are based on data from two pivotal Phase 3 trials in Dravet syndrome and an interim analysis from an ongoing open-label extension study, which included 232 patients treated for up to 21 months.

Zogenix is also investigating FINTEPLA in Lennox-Gastaut syndrome, another rare childhood-onset epilepsy, for which a Phase 3 trial is ongoing.

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, suggests, assuming, designed, and similar expressions are intended to identify forward-looking statements. These statements include the potential timing of acceptance and approval, if any, by the FDA and the EMA of the NDA and MAA, respectively, for FINTEPLA; the Company s plans regarding the development of FINTEPLA in Lennox-Gastaut syndrome; the need for FINTEPLA to address unmet medical need; and the patient population. These statements are based on the Company s current beliefs and expectations. 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 report due to the risks and uncertainties inherent in the Company s business, including, without limitation: the FDA may disagree that the existing safety and efficacy data is sufficient to allow an NDA review and approval, the FDA may not agree with the Company s interpretation of the results of the clinical trials of FINTEPLA; additional data from the Company s ongoing studies may contradict or undermine the data submitted in the NDA for FINTEPLA; the uncertainties associated with the clinical development and regulatory approval of product candidates such as FINTEPLA; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit approval and/or commercialization, or that could result in recalls or product liability claims; and other risks described in the Company s prior filings with the U.S. 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.

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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: February 6, 2019

By: /s/ Michael P. Smith
Name: Michael P. Smith
Title: Executive Vice President, Chief Financial Officer,

Treasurer and Secretary