ZOGENIX, INC.
Form 8-K
April 08, 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): April 8, 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.)**

5959 Horton Street, Suite 500, 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 (*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 April 8, 2019, Zogenix, Inc. (the Company), announced that it received a Refusal to File (RTF) letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for FINTEPLA (ZX0008, fenfluramine hydrochloride) for the treatment of seizures associated with Dravet syndrome. Upon its preliminary review, the FDA determined that the NDA, submitted on February 5, 2019, was not sufficiently complete to permit a substantive review. In the letter, the FDA cited two reasons for the RTF decision: first, certain non-clinical studies were not submitted to allow assessment of the chronic administration of fenfluramine; and, second, the application contained an incorrect version of a clinical dataset, which prevented the completion of the review process that is necessary to support the filing of the NDA. The FDA has not requested or recommended additional clinical efficacy or safety studies.

The Company will seek immediate guidance, including a Type A meeting with the FDA, to clarify and respond to the issues identified in the RTF letter in order to re-file the NDA.

The Company s Marketing Authorization Application (MAA) for FINTEPLA for the treatment of seizures associated with Dravet syndrome was previously accepted for review by the European Medicines Agency (EMA), and the Company anticipates an approvability decision could be reached by the EMA in the first quarter of 2020.

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 Company s plans to seek immediate guidance from, and a Type A meeting with, the FDA and to address the issues identified in the RTF letter and re-file the NDA; and a potential approvability decision by the EMA on the MAA in the first quarter of 2020. 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 timing, occurrence and outcome of the planned Type A meeting with the FDA to discuss the RTF letter; the Company s ability to address the identified issues and successfully meet the FDA s requirements for resubmission of the NDA and the timing thereof; the FDA may require additional non-clinical or clinical studies and the potential for the FDA to impose other requirements to be completed before or after approval of the NDA; the FDA or EMA may disagree that the existing safety and efficacy data is sufficient to allow an NDA or MAA, respectively, approval; the Company s reliance on third parties for the preparation of clinical study reports and data analyses; the FDA and/or the EMA 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 and MAA for FINTEPLA; the uncertainties associated with the clinical development and regulatory approval of product candidates such as FINTEPLA; potential delays by the EMA on an approvability decision, including as a result of the RTF letter; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit approval and/or commercialization; 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: April 8, 2019

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