UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): December 18, 2020

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, California 94608
(Address of Principal Executive Offices and Zip Code)

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

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**ZGNX**	**The Nasdaq Global Market**

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 December 18, 2020, Zogenix, Inc. ("Zogenix") announced that the European Commission ("EC") has granted marketing authorization for FINTEPLA® (fenfluramine) oral solution for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients two years of age and older.

The EC's approval of FINTEPLA was based on positive safety and efficacy results from two randomized, international, multi-center, placebo-controlled Phase 3 trials (Study 1 and Study 2), as well as data from an interim analysis of a long-term, open-label extension study in 330 Dravet syndrome patients treated up to 3 years.

When added to other antiepileptic therapies, including stiripentol, FINTEPLA provided a highly statistically significant and clinically meaningful reduction in convulsive seizure frequency. The most commonly reported adverse events that occurred in patients treated with this included decreased appetite, diarrhea, pyrexia, fatigue, upper respiratory tract infection, lethargy, somnolence and bronchitis.

With this approval, and subject to price and reimbursement being implemented according to national regulations, Zogenix will be able to market FINTEPLA in all European Union member countries, and in the United Kingdom, Norway, Iceland, and Liechtenstein. Zogenix expects its first European Union market launch to occur in Germany in the first quarter of 2021.

FINTEPLA will be available in Europe under a controlled access program requested by the European Medicines Agency to prevent off-label use for weight management and to confirm that prescribing physicians have been informed of the need for periodic cardiac monitoring in patients taking FINTEPLA.

Zogenix will also conduct the FINTEPLA Registry, an observational registry to provide data on long-term safety of FINTEPLA and frequency of echocardiographic monitoring in routine practice.

Earlier this year, FINTEPLA was approved by the U.S. Food & Drug Administration ("FDA") for the treatment of seizures associated with Dravet syndrome in patients aged two years and older. In addition, Zogenix recently reported positive results of a third Phase 3 study of FINTEPLA in Dravet syndrome to support planned registration in Japan, which corroborated the highly statistically significant and clinically meaningful convulsive seizure reductions seen in earlier multinational Phase 3 studies. FINTEPLA is also being studied for the potential treatment of seizures associated with other rare epilepsies.

Forward-Looking Statements

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," "designed," and similar expressions are intended to identify forward-looking statements. These statements include the potential that fenfluramine oral solution will be an important new treatment option for Dravet syndrome patients; Zogenix's plans to commercialize fenfluramine in Europe, including the timing of the launch. These statements are based on Zogenix's current beliefs and expectations. 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: Zogenix's ability to successfully launch FINTEPLA, including launching a controlled access program implemented due to risks related to valvular heart disease and pulmonary arterial hypertension, and the conduct of the FINTEPLA Registry, and the timing thereof; the COVID-19 pandemic may disrupt Zogenix's business operations, impairing the ability to commercialize FINTEPLA in Europe and Zogenix's ability to generate product revenue in Europe; Zogenix may not be successful in executing its sales and marketing strategy for the commercialization of FINTEPLA in Europe; unexpected adverse side effects or inadequate therapeutic efficacy of fenfluramine that could limit commercialization, or that could result in recalls or product liability claims; and other risks described in Zogenix's public periodic filings with the U.S. Securities & 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, unless required by law. 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: December 21, 2020

By: /s/ Shawnte M. Mitchell
Name: Shawnte M. Mitchell
Title: Executive Vice President, General Counsel and Secretary