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): June 25, 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)	(Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report.)

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**

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 June 25, 2020, Zogenix, Inc. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") has approved FINTEPLA (fenfluramine) oral solution, CIV for the treatment of seizures associated with Dravet syndrome in patients two years of age and older. FINTEPLA will be launched through a restricted distribution program, called the FINTEPLA Risk Evaluation and Mitigation Strategy ("REMS") Program, and is expected to be available through Zogenix's specialty pharmacy partner by the end of July 2020.

The FDA's approval of FINTEPLA in Dravet syndrome was based on data from two randomized, double-blinded, placebo-controlled Phase 3 clinical trials, published in *The Lancet* (Volume 394, Issue 10216, P2243-2254, December 21, 2019) and *JAMA Neurology* (2020 Mar; 77(3): 300–308), and safety data from an open-label extension trial in which many patients received FINTEPLA for up to three years. When added to existing treatment regimens, FINTEPLA significantly reduced the monthly convulsive seizure frequency compared to placebo in study patients whose seizures were not adequately controlled on one or more antiepileptic drugs. In addition, most study patients responded to treatment with FINTEPLA within three to four weeks and effects remained consistent over the treatment period.

FINTEPLA will be available to certified prescribers in the U.S. in July 2020. Zogenix is launching Zogenix Central™, a comprehensive support service that will provide ongoing product assistance to patients, caregivers, and their medical teams.

As a result of the FDA approval of FINTEPLA, the Company will pay a milestone of $15.0 million pursuant to the sale and purchase agreement with Brabant Pharma Limited, dated October 24, 2014.

Forward Looking Statements

The Company cautions you that statements included in this report and the conference call 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: Zogenix's plans to commercialize FINTEPLA, including the timing of the launch of the restricted distribution program, FINTEPLA REMS Program, and the launch of Zogenix Central and the availability of product assistance to patients, caregivers, and their medical teams. 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 establishing the restricted distribution program, FINTEPLA REMS Program, and Zogenix Central, and the timing thereof; the COVID-19 pandemic may disrupt Zogenix's business operations, impairing the ability to commercialize FINTEPLA and Zogenix's ability to generate product revenue; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit commercialization, or that could result in recalls or product liability claims; Zogenix may not be successful in executing its sales and marketing strategy for the commercialization of FINTEPLA; Zogenix's dependence on third parties for the manufacture of FINTEPLA; Zogenix's ability to achieve and maintain adequate levels of coverage and reimbursement for FINTEPLA; the scope and validity of patent protection or regulatory exclusivity protection for FINTEPLA and Zogenix's ability to commercialize FINTEPLA without infringing the patent rights of others; and other risks described in Zogenix's press releases as well as in 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. 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: June 25, 2020

By: /s/ Shawnte M. Mitchell

Name: Shawnte M. Mitchell

Title: Executive Vice President, General Counsel and Secretary