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): October 16, 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 October 16, 2020, Zogenix, Inc. (the "Company") announced that the Committee for Medicinal Products for Human Use ("CHMP"), a part of the European Medicines Agency, has adopted a positive opinion recommending the marketing authorization of FINTEPLA (fenfluramine) oral solution for the treatment of seizures associated with Dravet syndrome, a rare and devastating infant- and childhood-onset epilepsy, as an add-on therapy to other antiepileptic medicines for patients two years of age and older. The European Commission ("EC") is expected to make a final decision on the Company's Marketing Authorization Application ("MAA") by the end of the year.

The MAA for FINTEPLA included positive results from two randomized, controlled Phase 3 trials (Study 1 and Study 2), together with an interim analysis of an ongoing long-term, open-label extension study involving a total of 330 Dravet syndrome patients. These studies demonstrated that adjunctive fenfluramine treatment provided a highly statistically significant and clinically meaningful reduction in convulsive seizure frequency compared to placebo and was generally well-tolerated. In one of the trials, Study 2, all subjects were treated with a background regimen that included stiripentol, with significant improvement observed for FINTEPLA over placebo. The long-term, open-label extension study demonstrated durable efficacy, with patients in that study treated for up to three years with FINTEPLA. The most commonly reported adverse events experienced during these studies were decreased appetite, diarrhea, pyrexia, fatigue, upper respiratory tract infection, lethargy, somnolence and bronchitis. No patient developed any cardiovascular adverse events, including valvular heart disease or pulmonary arterial hypertension.

If authorized by the EC, FINTEPLA will be approved for use by patients with Dravet syndrome aged two years and older in all European Union member states, as well as the United Kingdom, Iceland, Liechtenstein and Norway. The product is expected to be made available under a controlled access program to ensure regular cardiac monitoring and to mitigate potential off-label use for weight management.

Earlier this year, FINTEPLA was approved by the U.S. Food and Drug Administration for the treatment of seizures associated with Dravet syndrome in patients aged two years and older. A third positive Phase 3 clinical trial (Study 3) was recently reported to support registration of FINTEPLA in Japan.

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 include: the potential that FINTEPLA, if approved by the EC, will be an important new treatment option for Dravet syndrome patients; and the timing and results of any decision regarding the MAA for FINTEPLA for the treatment of seizures associated with Dravet syndrome. 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 release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the EC may not agree with the Company's interpretation of the clinical data submitted in the MAA; the EC may not affirm the CHMP opinion and grant a centralized marketing authorization; additional data from the Company's ongoing studies may contradict or undermine the data submitted in the Dravet syndrome MAA for FINTEPLA or reported for LGS; 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 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 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: October 16, 2020

By: /s/ Shawnte M. Mitchell

Name: Shawnte M. Mitchell

Title: Executive Vice President, General Counsel and Secretary