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): September 28, 2021

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 September 28, 2021, Zogenix, Inc. (the "Company") announced that it has submitted a supplemental New Drug Application ("sNDA") for FINTEPLA for the treatment of seizures associated with Lennox-Gastaut Syndrome ("LGS") to the U.S. Food and Drug Administration ("FDA").

The sNDA is supported by data from a global randomized, placebo-controlled Phase 3 clinical trial Study 1601 in 263 patients (age 2-35 years) that demonstrated FINTEPLA at a dose of 0.7/mg/kg/day was superior to placebo in reducing the frequency of drop seizures (p=0.0012). The same dose of FINTEPLA (0.7 mg/kg/day) also demonstrated statistically significant improvement versus placebo in the key secondary efficacy measure, the proportion of patients with a clinically meaningful reduction (³50%) in drop seizure frequency. The submission also includes long-term safety and efficacy data from Zogenix's on-going open-label extension trials. FINTEPLA has been generally well-tolerated, with the adverse events observed to date consistent with those observed in the Company's prior Phase 3 studies in Dravet syndrome.

LGS is a rare and highly refractory form of childhood-onset epilepsy that is difficult to treat. Patients suffer from significant intellectual, behavioral, and motor disabilities, and have a high risk of status epilepticus or sudden unexpected death in epilepsy. The Company estimates that there are 30,000-50,000 LGS patients in the United States. The vast majority of patients do not have well-controlled seizures, despite a regimen of two to five antiepileptic drugs.

FINTEPLA is approved by the FDA and European Commission for the treatment of seizures associated with Dravet syndrome, a rare infant- and childhood-onset epilepsy marked by frequent and severe treatment-resistant seizures, in patients 2 years of age and older. The Japanese Ministry of Health, Labour & Welfare has also granted Orphan Drug Designation to FINTEPLA for the treatment of seizures associated with Dravet syndrome, which Zogenix is developing in Japan.

Forward-Looking Statement

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 for FINTEPLA to reduce the frequency of seizures and provide clinical benefit to LGS patients, if approved, and statements regarding the Company's clinical development plans. 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 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 the Company's business, including, without limitation: the potential for the FDA to issue a "refuse to file" letter with respect to our sNDA submission if the FDA does not believe the sNDA is ready for review; the potential for the FDA to delay timing of review of the sNDA due to the FDA's internal resource constraints or other reasons; interim data from Part 2 of Study 1601 and other clinical trials may change as more patient data become available and could result in material changes in the final data, impairing regulatory submissions and approvals; unexpected adverse side effects or inadequate therapeutic efficacy of fenfluramine that could limit approval in Japan or commercialization in the United states or Europe, or that could result in recalls or product liability claims; and other risks described in the Company's prior 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: September 28, 2021

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