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): January 11, 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**

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 2.02. Results of Operations and Financial Condition.

On January 11, 2021, Zogenix Inc. (the "Company") issued a press release ahead of the 39th Annual J.P. Morgan Healthcare Conference announcing certain preliminary, unaudited financial information for the fourth quarter ended December 31, 2020 based on currently available information, as well as other developments. A copy of the press release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press Release dated January 11, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: January 11, 2021

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

Exhibit 99.1

Zogenix Announces Preliminary, Unaudited Fourth Quarter 2020 Net Product Sales

- *Total FINTEPLA® preliminary, unaudited net product sales of approximately $8.1 million for the fourth quarter*
- *As of December 31, 2020, 492 healthcare prescribers had completed FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) certification process*
- *As of December 31, 2020, more than 550 patients had been prescribed FINTEPLA and were enrolled in the REMS program, and 416 patients were receiving reimbursed therapy*
- *Cash, cash equivalents and marketable securities at December 31, 2020, were approximately $505.8 million*

EMERYVILLE, Calif., January 11, 2021 — Zogenix (NASDAQ: ZGNX), a global biopharmaceutical company developing and commercializing rare disease therapies, today reported select preliminary, unaudited financial results for the fourth quarter and full-year 2020. In addition, the Company highlighted its key 2021 corporate objectives.

“2020 marked a year of tremendous achievements for Zogenix, highlighted by the successful commercial launch of FINTEPLA® in Dravet syndrome in the U.S.”, said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “We are extremely pleased with our launch progress and believe our strong results in the fourth quarter reinforce FINTEPLA’s potential to provide transformational and durable seizure reduction for many Dravet syndrome patients. We look forward to further increasing U.S. physician and patient adoption of FINTEPLA in the year ahead. Moreover, we are excited to launch FINTEPLA in the EU shortly, following recent receipt of marketing authorization.”

Preliminary, Unaudited Fourth Quarter FINTEPLA Net Product Sales

Based on preliminary, unaudited financial information, the Company expects total FINTEPLA net product sales to be approximately $8.1 million for the fourth quarter of 2020. Unaudited cash, cash equivalents and marketable securities at December 31, 2020, were approximately $505.8 million.

The financial information included in this press release is preliminary, unaudited and subject to adjustment. It does not present all information necessary for an understanding of the Company’s fourth quarter of 2020. Zogenix expects to report its complete financial results for the fourth quarter and full-year 2020 in February 2021.

As of December 31, 2020, 492 healthcare providers had completed the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) certification process. In addition, as of December 31, 2020, more than 550 patients had been prescribed FINTEPLA and were enrolled in the REMS program, and a total of 416 patients were receiving reimbursed therapy, of which approximately 60% were new to FINTEPLA.

Key 2021 Corporate Objectives

FINTEPLA Commercialization:

- Continue to drive adoption of FINTEPLA in the U.S. by building on the positive momentum with existing and new prescribing physicians
- Continue to work in partnership with U.S. payors to provide optimal access to FINTEPLA for all appropriate patients
- Launch FINTEPLA for the treatment of patients with Dravet syndrome in Europe, beginning with the planned launch in Germany in the first quarter of 2021
- Secure positive pricing and reimbursement decisions in major European countries
- Submit J-NDA in Japan for FINTEPLA for the treatment of patients with Dravet syndrome in collaboration with Zogenix’s partner, Nippon Shinyaku
- Significantly expand the eligible patient population for FINTEPLA by submitting an sNDA in the U.S. for FINTEPLA for the treatment of seizures associated with Lennox-Gastaut syndrome

Additional FINTEPLA Pipeline Programs:

- Initiate a Phase 3 study of FINTEPLA for the treatment of CDKL5 Deficiency Disorder, an infantile-onset genetic seizure disorder
- Continue to explore FINTEPLA as a potential treatment for additional severe, treatment-resistant rare epilepsies through the initiation of other company-sponsored clinical studies

MT1621

- Complete all clinical, non-clinical and CMC studies and assessments required to support planned 2022 U.S. NDA and EMA MAA submissions for MT1621, the Company's investigational treatment for patients with the mitochondrial disease, thymidine kinase 2 deficiency (TK2d)

Early-Stage R&D Activities

- Support research and drug discovery activities with Zogenix's partner, Tevard Biosciences, to advance novel gene therapy candidates for the treatment of Dravet syndrome and other serious, treatment-resistant genetic epilepsies

About Zogenix

Zogenix is a global biopharmaceutical company committed to developing and commercializing therapies with the potential to transform the lives of patients and their families living with rare diseases. The Company's first rare disease therapy, FINTEPLA® (fenfluramine) oral solution has been approved by the U.S. FDA and the European Medicines Agency and is in development in Japan for the treatment of seizures associated with Dravet syndrome, a rare, severe lifelong epilepsy. The company has two additional late-stage development programs underway: one for FINTEPLA for the treatment of seizures associated with the rare epilepsy, Lennox-Gastaut syndrome, and one for MT1621, an investigational therapy for the treatment of a rare genetic disorder called TK2 deficiency (being developed through its subsidiary Modis Therapeutics). Zogenix is also collaborating with Tevard Biosciences to identify and develop potential next-generation gene therapies for genetic rare epilepsies. Further information for FINTEPLA is available at www.FINTEPLA.com.

Forward-Looking Statements

Zogenix cautions you that statements included in this press release 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 preliminary, unaudited financial results for the fourth quarter 2020, expectations regarding U.S. FINTEPLA adoption growth; Zogenix's plans to commercialize FINTEPLA in Europe, including the timing of the launch; and Zogenix's 2021 corporate objectives. 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 release due to the risks and uncertainties inherent in Zogenix's business, including, without limitation: adjustments to the preliminary, unaudited financial results in connection with completion of financial closing procedures and an audit for the 2020 fiscal year; the timing of enrollment or results of Zogenix's clinical trials; the timing of planned regulatory submissions and Zogenix's dependence on its partner Nippon Shinyaku with respect to the J-NDA for FINTEPLA for the treatment of patients with Dravet syndrome; the COVID-19 pandemic may disrupt Zogenix's business operations, impairing the ability to commercialize FINTEPLA in the U.S. and Europe; Zogenix may not be successful in executing its sales and marketing strategy for the commercialization of FINTEPLA; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could delay submission of new drug applications, limit commercialization, or that could result in recalls or product liability claims; and other risks described in Zogenix's prior 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 press release 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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