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): February 25, 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 February 25, 2021, Zogenix, Inc. issued a press release reporting the Company's results for the fourth quarter and full-year ended December 31, 2020. A copy of this press release is attached hereto as Exhibit 99.1.

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 February 25, 2021

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: February 25, 2021

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

Exhibit 99.1

Zogenix Provides Corporate Update and Reports Fourth Quarter and Full-Year 2020 Financial Results

- *Positive momentum continues for U.S. launch of FINTEPLA® (fenfluramine) oral solution in Dravet syndrome, with total net product sales of $8.1 million in the fourth quarter; total net sales of $9.6 million since launch in July 2020*
- *As of December 31, 2020, over 550 Dravet syndrome patients referred to the FINTEPLA REMS program, with 416 patients receiving reimbursed therapy, approximately 60% were new to FINTEPLA*
- *FINTEPLA for Dravet syndrome approved by European Commission in December 2020 and launched in Germany this month*
- *On track to submit applications for FINTEPLA in Lennox-Gastaut syndrome in the U.S. in Q3 2021 and in Europe in Q4 2021*
- *Planned New Drug Application (NDA) submission in first half of 2022 for MT1621 in TK2 deficiency*
- *Ended 2020 with $505.1 million in cash, cash equivalents and marketable securities*

EMERYVILLE, Calif., February 25, 2021 — Zogenix (NASDAQ: ZGNX), a global biopharmaceutical company developing and commercializing rare disease therapies, today provided a corporate update and announced financial results for the fourth quarter and full-year ended December 31, 2020. The Company will host a conference call today, Thursday, February 25, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

“We are very pleased to have concluded 2020 with strong momentum across all of our programs, especially the robust U.S. launch of FINTEPLA® in Dravet syndrome, where we saw strong adoption by existing and new prescribing physicians and patients, and partnerships with U.S. payors to provide optimal access for all appropriate patients,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “We expect several additional key catalysts for FINTEPLA in Dravet syndrome in the year ahead in the U.S. and in Europe, where we recently launched FINTEPLA in Germany and are actively preparing for additional European country launches and, with our partner Nippon Shinyaku, are preparing to submit a J-NDA in the second half of the year.”

“Our goal is also to continue expanding the eligible patient population for FINTEPLA in other indications, based on strong safety and efficacy data from our clinical trials,” continued Dr. Farr. “In the U.S. and Europe, we are advancing FINTEPLA for multiple other treatment-resistant epilepsies, including Lennox-Gastaut syndrome (LGS), for which we anticipate submitting global regulatory filings. We are also planning to initiate a Phase 3 trial for CDKL5 in the second half of 2021, and assess additional severe, treatment-resistant epilepsies through the initiation of other investigator-initiated clinical studies.”

Corporate Update

- FINTEPLA for the treatment of seizures associated with Dravet syndrome:
    - As of December 31, 2020, 492 prescribers had successfully completed the Risk Evaluation and Mitigation Strategy (REMS) certification process
    - As of December 31, 2020, over 550 Dravet syndrome patients had been referred to the FINTEPLA REMS program to become eligible to receive therapy, and 416 patients were receiving reimbursed therapy, of which approximately 60% were new to FINTEPLA
    - Received European Commission approval on December 21, 2020; FINTEPLA commercially available in Germany as of February 1, 2021

- Received temporary authorisation to use in France from the French National Agency for Medicines and Health Products Safety in January 2021; expect patients to begin treatment with FINTEPLA in France during current quarter
- Anticipate submission of a Japan-NDA to Japan's Pharmaceutical and Medical Devices Agency in the second half of 2021
- Presented new long-term (3 year) safety and efficacy data for FINTEPLA in Dravet syndrome at American Epilepsy Society (AES) Annual Meeting in December 2020, which demonstrated durable effectiveness in significantly reducing seizures

- FINTEPLA for the treatment of seizures associated with LGS:
  - Completed all required studies for submission. Compilation of data package is ongoing with anticipated filing of sNDA in the third quarter of 2021
  - Anticipate submitting Marketing Authorization Application with European Medicines Agency in fourth quarter of 2021
  - Presented full results from Phase 3 study of FINTEPLA in LGS and its efficacy in reducing convulsive seizure frequency at AES Annual Meeting
- FINTEPLA for the treatment of seizures associated with CDKL5 Deficiency Disorder:
  - New data presented from investigator-initiated study in CDKL5 Deficiency Disorder, an infantile-onset genetic seizure disorder, at AES Annual Meeting
  - Anticipate initiating a Phase 3 study of FINTEPLA for the treatment of CDKL5 Deficiency Disorder during the second half of 2021
- MT1621 for the treatment of TK2d:
  - Studies are proceeding as planned and Company anticipates the submission of an NDA in the first half of 2022
- Tevard Research Collaboration:
  - Zogenix and Tevard collaborating to identify and develop novel tRNA-based gene therapies for Dravet syndrome and other genetic epilepsies

Fourth Quarter 2020 Financial Results

- The Company recorded $8.5 million in revenue for the fourth quarter ended December 31, 2020. This included total net product sales of FINTEPLA of $8.1 million, in addition to $0.4 million in revenue as a result of the March 2019 collaboration with Nippon Shinyaku Co., Ltd. for FINTEPLA in Dravet syndrome and LGS in Japan. Zogenix recorded $1.9 million in revenue for the corresponding period of 2019.
- Research and development expenses for the fourth quarter ended December 31, 2020, totaled $36.0 million, compared to $35.8 million in the fourth quarter ended December 31, 2019.
- Selling, general and administrative expenses for the fourth quarter ended December 31, 2020, totaled $29.2 million, up from $18.7 million in the fourth quarter ended December 31, 2019. The increase was driven by commercial launch in the U.S. and launch preparations Europe.
- Net loss for the fourth quarter ended December 31, 2020, was $70.2 million, or a net loss of $1.26 per share, compared with a net loss of $56.1 million, or a net loss of $1.26 per share, in the fourth quarter ended December 31, 2019.

Year Ended December 31, 2020 Financial Results Compared to Year Ended December 31, 2019

- The Company recorded $13.6 million in revenue for the year ended December 31, 2020. This included total net product sales of FINTEPLA of $9.6 million, in addition to $4.0 million in revenue as a result of the March 2019 collaboration with Nippon Shinyaku Co., Ltd. for FINTEPLA in Dravet syndrome and LGS in Japan. Zogenix recorded in $3.6 million revenue for the corresponding period of 2019.

- Research and development expenses for the year ended December 31, 2020, totaled $138.0 million, up from $115.6 million in the year ended December 31, 2019, as the Company expanded clinical activities in LGS and MT1621, partially offset by decreased spending in Dravet syndrome.

- Selling, general and administrative expenses for the year ended December 31, 2020, totaled $99.6 million, up from $60.8 million in the year ended December 31, 2019, as the Company continued investment related to the launch of FINTEPLA for the treatment of Dravet syndrome in the U.S. and prepared for prospective launch in Europe.

- Net loss for the year ended December 31, 2020, was $209.4 million, or a net loss of $3.90 per share, compared with a net loss of $419.5 million, or a net loss of $9.74 per share, in the year ended December 31, 2019. The decrease in net loss was primarily attributable to the 2019 acquisition of Modis.

- As of December 31, 2020, the Company had $505.1 million in cash, cash equivalents, and marketable securities, compared to $251.2 million at December 31, 2019.

Conference Call Details
Thursday, February 25, at 4:30 PM Eastern Time / 1:30 PM Pacific Time
Toll Free: 877-407-9716
International: 201-493-6779
Conference ID: 13715661
Webcast: http://public.viavid.com/index.php?id=143250

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 Lennox-Gastaut syndrome, another rare epilepsy, and one for MT1621, an investigational therapy for the treatment of a rare genetic disorder called TK2 deficiency. Zogenix is also collaborating with Tevard Biosciences to identify and develop potential next-generation gene therapies for Dravet syndrome and other genetic epilepsies.

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 timing of commercial launch of FINTEPLA for the treatment of Dravet syndrome in additional countries in Europe, including France; Zogenix's expectations on the submission of a J-NDA by Nippon Shinyaku in Japan; the timing and ability of Zogenix to complete regulatory submissions in the United States and the European Union for FINTEPLA in LGS; Zogenix's plans to expand FINTEPLA in other indications including the timing or success of a Phase 3 clinical trial in CDKL5 deficiency disorder and investigator-initiated clinical trials in other indications; Zogenix's belief that the recent Type B meeting with the FDA supports an NDA submission for MT1621 in TK2 deficiency and the timing of such submission. 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: Zogenix may not be successful in executing its sales and marketing strategy for the commercialization of FINTEPLA in the U.S. and Europe, including due to the costs and procedures related to the REMS certification process or controlled access program; the COVID-19 pandemic may disrupt Zogenix's business operations, impairing the ability to commercialize FINTEPLA and may delay Zogenix's development plans for FINTEPLA and MT1621; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA or MT1621 that could limit development or commercialization, or that could result in recalls or product liability claims; additional data from Zogenix's ongoing studies may contradict or undermine the data previously reported; 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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ZOGENIX INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(in thousands)

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 166,916	$ 62,070
Marketable securities	338,193	189,085
Accounts receivable, net	3,824	—
Inventory	1,026	—
Prepaid expenses	7,279	8,593
Acquisition holdback placed in escrow	—	25,000
Other current assets	4,936	2,491
Total current assets	522,174	287,239
Property and equipment, net	8,724	9,424
Operating lease right-of-use assets	7,748	7,774
Intangible asset, net	98,558	102,500
Goodwill	6,234	6,234
Other non-current assets	7,692	1,079
Total assets	$ 651,130	$ 414,250
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,945	$ 7,979
Accrued and other current liabilities	54,964	30,117
Acquisition holdback liability	—	24,444
Deferred revenue, current	5,318	5,927
Current portion of operating lease liabilities	1,688	1,322
Current portion of contingent consideration	8,800	25,600
Total current liabilities	82,715	95,389
Deferred revenue, non-current	5,479	7,425
Operating lease liabilities, net of current portion	10,314	10,752
Contingent consideration, net of current portion	33,600	38,200
Deferred tax liability	—	17,425
Convertible Senior Notes	149,353	—
Total liabilities	281,461	169,191
Stockholders' equity:		
Common stock	56	45
Additional paid-in capital	1,694,524	1,360,092
Accumulated other comprehensive (loss) income	(71)	379
Accumulated deficit	(1,324,840)	(1,115,457)
Total stockholders' equity	369,669	245,059
Total liabilities and stockholders' equity	$ 651,130	$ 414,250

ZOGENIX INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Net product sales	$ 8,067	$ —	$ 9,587	$ —
Collaboration revenue	435	1,949	4,056	3,648
Total revenues	8,502	1,949	13,643	3,648
Operating costs and expenses:				
Cost of product sales (excluding intangible asset amortization)	402	—	542	—
Research and development	35,964	35,820	138,002	115,639
Selling, general and administrative	29,242	18,653	99,574	60,792
Intangible asset amortization	1,971	—	3,942	—
Acquired IPR&D and related costs	6,200	2,000	10,700	251,438
Change in fair value of contingent consideration	2,500	2,900	8,600	5,600
Total operating expenses	76,279	59,373	261,360	433,469
Loss from operations	(67,777)	(57,424)	(247,717)	(429,821)
Other income (expense):				
Interest income	387	1,283	2,891	9,802
Interest expense	(3,759)	—	(3,759)	—
Other income, net	979	81	21,777	516
Loss from operations before income taxes	(70,170)	(56,060)	(226,808)	(419,503)
Income tax benefit	—	—	(17,425)	—
Net loss	$ (70,170)	$ (56,060)	$ (209,383)	$ (419,503)
Net loss per share, basic and diluted	$ (1.26)	$ (1.26)	$ (3.90)	$ (9.74)