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): May 6, 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 2.02 Results of Operations and Financial Condition.

On May 6, 2021, Zogenix, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2021. 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 May 6, 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: May 6, 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 First Quarter 2021 Financial Results

- *Continued positive momentum for U.S. launch of FINTEPLA® (fenfluramine) oral solution in Dravet syndrome, with total net product sales of $12.3 million and total revenue of $13.7 million in the first quarter, representing quarter-over-quarter increases of 53% and 61%, respectively*
- *As of March 31, 2021, in the U.S., over 700 patients referred to the FINTEPLA REMS program, with over 560 patients receiving reimbursed therapy*
- *Successfully launched FINTEPLA in Germany in February and commenced the Zogenix Access Program to expand global access to FINTEPLA, including in European countries where reimbursement has not yet been established*
- *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*
- *Intend to meet with FDA in current quarter to discuss Phase 3 study of FINTEPLA for the treatment of seizures associated with CDKL5 Deficiency Disorder (CDD)*

EMERYVILLE, Calif., – May 6, 2021 – Zogenix (NASDAQ: ZGNX), a global biopharmaceutical company developing and commercializing rare disease therapies, today announced financial results for the three months ended March 31, 2021, and provided a corporate update. The Company will host a conference call today, Thursday, May 6, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

“We are pleased with the continued positive momentum in our U.S. launch of FINTEPLA® in Dravet Syndrome, where we see increased adoption by existing and new prescribers and patients,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “Our dialogue with U.S. payors is progressing very well, as we work to expand access for patients who could benefit from FINTEPLA treatment. In Europe, our initial launch in Germany has begun in an encouragingly strong manner and our recently established Zogenix Access Program will expand access to FINTEPLA for physicians globally, including in European countries where reimbursement has not yet been established. Additionally, we are working to submit an NDA in Japan for FINTEPLA in the second half of this year.”

“We have the opportunity to potentially make FINTEPLA available to additional patients in need in multiple additional indications, and remain on track to submit global regulatory filings in Lennox-Gastaut syndrome (LGS) later this year and anticipate meeting with the FDA this quarter to discuss the planned Phase 3 trial for CDKL5 deficiency disorder,” continued Dr. Farr. “Lastly, in our MT1621 program for TK2 deficiency, we continue to prepare for an NDA filing in the first half of 2022.”

Corporate Update

- FINTEPLA for the treatment of seizures associated with Dravet syndrome:
  - As of March 31, 2021, approximately 570 prescribers in the U.S. had successfully completed the Risk Evaluation and Mitigation Strategy (REMS) certification process

- As of March 31, 2021, over 700 patients in the U.S. had been referred to the FINTEPLA REMS program to become eligible to receive therapy, and over 560 patients were receiving reimbursed therapy.
- Received European Commission approval in December 2020; FINTEPLA commercially available in Germany as of February 1, 2021
- Received temporary authorization to use FINTEPLA in France from the French National Agency for Medicines and Health Products Safety in January 2021; currently onboarding patients
- Continued to advance reimbursement and pricing discussions with other major European countries, including the UK, Italy and France
- Launched Zogenix Access Program to expand access to FINTEPLA for physicians in other parts of the world, where local regulations allow, including European countries where reimbursement has not yet been established
- Anticipate submission of an NDA in Japan (J-NDA) to Japan's Pharmaceutical and Medical Devices Agency in the second half of 2021
- Presented new data from an investigator-initiated study of FINTEPLA in Dravet syndrome at American Academy of Neurology (AAN) Annual Meeting in April 2021, which highlighted certain quality-of-life benefits for patients and caregivers after patients received treatment with FINTEPLA
- In March, two additional issued patents were listed in the Orange Book , bringing the total number of Orange Book listed patents for FINTEPLA to 10.

- FINTEPLA for the treatment of seizures associated with LGS:
  - Compilation of data package is ongoing with anticipated submission of supplemental NDA in the third quarter of 2021
  - Anticipate submitting Marketing Authorization Application with European Medicines Agency in fourth quarter of 2021
  - Presented new data for FINTEPLA in LGS at AAN Annual Meeting, demonstrating that patients treated with FINTEPLA showed improvements in everyday executive function
- FINTEPLA for the treatment of seizures associated with CDKL5 Deficiency Disorder:
  - Anticipate meeting with U.S. Food and Drug Administration (FDA) in the second quarter of 2021 to discuss plans for upcoming Phase 3 safety and efficacy study
  - Expect to initiate a Phase 3 study of FINTEPLA for the treatment of CDKL5 Deficiency Disorder during the second half of 2021
- MT1621 for the treatment of TK2 deficiency:
  - Studies continue to proceed as planned and Company anticipates the submission of an NDA in the first half of 2022

First Quarter 2021 Financial Results

- The Company recorded $13.7 million in revenue for the first quarter ended March 31, 2021, which was an increase of 61% as compared to the $8.5 million recorded in the fourth quarter of 2020. This included total net product sales of FINTEPLA of $12.3 million, which were an increase of 53% as compared to the $8.1 million reported in the fourth quarter of 2020, in

addition to $1.3 million in collaboration 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 total revenue of $1.2 million for the three months ended March 31, 2020, which consisted solely of collaboration revenue.

- Research and development expenses for the first quarter ended March 31, 2021, totaled $31.0 million, compared to $33.2 million in the first quarter ended March 31, 2020.
- Selling, general and administrative expenses for the first quarter ended March 31, 2021, totaled $ 31.3 million, up from $21.3 million in the first quarter ended March 31, 2020. The increase was driven by the commercial launch of FINTEPLA in the U.S. and launch preparations in Europe.
- Net loss for the first quarter ended March 31, 2021, was $55.6 million, or a net loss of $1.00 per share, compared with a net loss of $25.8 million, or a net loss of $0.54 per share, in the first quarter ended March 31, 2020.
- As of March 31, 2021, the Company had $435.2 million in cash, cash equivalents, and marketable securities, compared to $505.1 million at December 31, 2020.

Conference Call Details

Thursday, May 6, at 4:30 PM Eastern Time / 1:30 PM Pacific Time

Toll Free: 877-846-2690

International: 416-981-9029

Conference ID: 21993693

Webcast: http://public.viavid.com/index.php?id=144590

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, one in a rare epilepsy called Lennox-Gastaut syndrome and one in a mitochondrial disease called TK2 deficiency. Zogenix plans to initiate a study of FINTEPLA in a genetic epilepsy called CDKL5 Deficiency Disorder (CDD) and 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: the timing of commercial launch of FINTEPLA for the treatment of Dravet syndrome in additional countries in Europe; 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 U.S. and the European 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 CDD and investigator-initiated clinical trials in other indications; and Zogenix's expectations regarding meeting with the FDA to discuss FINTEPLA in CDD. 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; patient outcomes may differ from 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)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 86,317	$ 166,916
Marketable securities	348,905	338,193
Accounts receivable, net	6,119	3,824
Inventory	2,324	1,026
Prepaid expenses and other current assets	11,065	12,215
Total current assets	454,730	522,174
Property and equipment, net	8,377	8,724
Operating lease right-of-use assets	7,452	7,748
Intangible asset, net	96,587	98,558
Goodwill	6,234	6,234
Other non-current assets	7,584	7,692
Total assets	$ 580,964	$ 651,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,964	$ 11,945
Accrued and other current liabilities	30,749	54,964
Deferred revenue, current	5,297	5,318
Current portion of operating lease liabilities	1,621	1,688
Current portion of contingent consideration	8,900	8,800
Total current liabilities	58,531	82,715
Deferred revenue, noncurrent	5,664	5,479
Operating lease liabilities, net of current portion	9,937	10,314
Contingent consideration, net of current portion	34,100	33,600
Convertible senior notes	151,451	149,353
Total liabilities	259,683	281,461
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	1,701,788	1,694,580
Accumulated deficit	(1,380,470)	(1,324,840)
Accumulated other comprehensive loss	(37)	(71)
Total stockholders' equity	321,281	369,669
Total liabilities and stockholders' equity	$ 580,964	$ 651,130

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

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Net product sales	$ 12,349	$ —
Collaboration revenue	1,335	1,249
Total revenues	13,684	1,249
Costs and expenses:		
Cost of product sales (excluding amortization of intangible asset)	676	—
Research and development	30,969	33,240
Selling, general and administrative	31,272	21,318
Intangible asset amortization	1,971	—
Acquired in-process research and development costs	—	1,500
Change in fair value of contingent consideration	600	(7,900)
Total costs and expenses	65,488	48,158
Loss from operations	(51,804)	(46,909)
Interest income	308	1,088
Interest expense	(3,737)	—
Other (expense) income, net	(397)	20,021
Net loss	$ (55,630)	$ (25,800)
Net loss per share, basic and diluted	$ (1.00)	$ (0.54)
Weighted average number of shares used in the calculation of basic and diluted net loss per common share	55,750	48,185