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): November 4, 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 November 4, 2021, Zogenix, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 4, 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: November 4, 2021

By: /s/ Michael P. Smith
Micheal P. Smith
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 99.1

Zogenix Provides Corporate Update and Reports Third Quarter 2021 Financial Results

- *FINTEPLA® net product sales of $21.4 million and total revenue of $22.6 million in the third quarter, representing quarter-over-quarter increases of 22% and 20%, respectively*
- *Submitted supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for FINTEPLA in Lennox-Gastaut Syndrome (LGS)*
- *Continuing to advance late-stage development programs for FINTEPLA and MT1621*

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

“In the third quarter, we made significant progress against our corporate objectives in commercial operations and late-stage clinical development programs. We are pleased with the ongoing launch of FINTEPLA in the U.S. and EU and are encouraged with the positive trends that support continued adoption in Dravet syndrome. With the sNDA submitted for LGS, we are moving forward with regulatory submissions for LGS in the EU and a J-NDA in Japan for Dravet syndrome by the end of the year. We are excited to have the opportunity to potentially serve more patients who could benefit from FINTEPLA,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix.

“Concurrently, we are advancing our late-stage development pipeline, notably our global Phase 3 study of FINTEPLA in CDD and concluding studies of MT1621 for the treatment of Tk2 deficiency,” concluded Dr. Farr.

Corporate Update

- FINTEPLA for the treatment of seizures associated with Dravet syndrome:
    - As of September 30, 2021, the total number of unique prescribers was 334
    - As of September 30, 2021, over 990 patients in the U.S. were prescribed FINTEPLA and referred to the REMS program
    - Continuing momentum and increasing adoption of FINTEPLA among prescribers and patients in ongoing launch in Germany and Temporary Authorization of Use in France
    - Continuing to pursue country-by-country reimbursement in Europe
    - Zogenix Access Program is now providing FINTEPLA to patients in 8 countries where the therapy is not yet commercially reimbursed
    - On track for submission of an NDA in Japan (J-NDA) to Japan’s Pharmaceutical and Medical Devices Agency by the end of 2021; received Orphan Drug Designation from the Japanese Ministry of Health, Labour & Welfare
- FINTEPLA for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS):
    - Submitted a supplemental NDA (sNDA) to the FDA in late September

- Presented data from the interim analysis of its ongoing 12-month Phase 3 open-label extension study of FINTEPLA in LGS at the Child Neurology 2021 Annual Meeting; the results demonstrate that treatment with FINTEPLA resulted in highly statistically significant improvements in drop seizure frequency
    - Median reduction in drop seizure frequency was 39.4% at 3 months (n=247; p<0.0001) and 51.8% for patients assessed over months 10 to 12 (n=170; p<0.0001)
    - Of the 170 patients assessed in this analysis, most (51.2%) responded with a clinically meaningful (≥50%) reduction in drop seizures, while 25.3% of patients demonstrated a profound (≥75%) reduction
- Expect to submit type II variation application to Marketing Authorization in EU for approval of LGS indication in fourth quarter of 2021
- Initiated preparations for potential U.S. commercial launch for FINTEPLA in LGS as early as first half of 2022

- FINTEPLA for the treatment of seizures associated with CDKL5 deficiency disorder (CDD):
    - On track to initiate two-arm, fixed-dose Phase 3 trial to investigate the efficacy and safety of FINTEPLA in controlling convulsive seizure frequency at a dose of 0.7 mg/kg/day in fourth quarter of 2021
    - Confirmed with FDA that a single Phase 3 study would be sufficient to support an sNDA submission, following positive meeting with FDA

- MT1621 for the treatment of thymidine kinase 2 (TK2) deficiency:
    - Updated data from Study 101, a global retrospective study of pyrimidine nucleoside substrate enhancement therapy, a fixed combination treatment of two pyrimidine nucleosides
        - Primary efficacy endpoint, an updated survival analysis using a time-dependent Cox regression model, demonstrated that the difference in probability of survival between treated patients and untreated natural history control patients was highly statistically significant (p=0.0007)
        - Vast majority of treated patients also continued to have improvements in motor, respiratory and/or feeding abilities, and the others with stabilization in these major functional domains, with many patients re-acquiring previously lost motor milestones
        - MT1621 was generally safe and well-tolerated, consistent with previously reported results
    - Recent Type B meeting with FDA confirmed planned data packages for an NDA submission based on the rare and serious nature of TK2 deficiency and the unmet medical need
    - Remaining studies continue to proceed as planned and the Company is working towards a pre-NDA meeting with FDA, ahead of the anticipated NDA submission in the second half of 2022

- Zogenix will host a key opinion leader webinar on TK2 deficiency and MT-1621 on Monday, November 8, 2021, at 12:00 PM Eastern Time; to register for the webinar, please visit https://lifesci.rampard.com/WebcastingAppv5/Events/Registration/registration.jsp?Y2lk=MTQxNw==&Y2lk=MTQxNw==

Third Quarter 2021 Financial Results

- The Company recorded $22.6 million in revenue for the third quarter ended September 30, 2021, which was an increase of 20% as compared to the $18.8 million recorded in the second quarter of 2021. This included total net product sales of FINTEPLA of $21.4 million, which was an increase of 22% as compared to the $17.5 million reported in the second quarter of 2021, in addition to $1.2 million in collaboration revenue. Zogenix recorded total revenue of $2.9 million for the three months ended September 30, 2020, which included product sales of FINTEPLA in the U.S. of $1.5 million, in addition to $1.4 million in collaboration revenue.

- The Company incurred a one-time $7.0 million charge to research and development expense associated with an agreement to amend Zogenix's original FINTPELA license and collaboration agreement regarding our collaboration arrangement with Nippon Shinyaku in Japan.

- Research and development expenses for the third quarter ended September 30, 2021, totaled $33.3 million, versus $34.4 million in the third quarter ended September 30, 2020. Exclusive of the one-time $7.0 million charge, research and development expenses in the current quarter decreased 24% to $26.3 million as the Company decreased spending in FINTEPLA and recorded increased research and development costs and activities in its MT1621, and Tevard gene therapy programs.

- Selling, general and administrative expenses for the third quarter ended September 30, 2021, totaled $39.6 million, compared with $24.6 million in the third quarter ended September 30, 2020, as the Company continued investment related to the launches of FINTEPLA for the treatment of Dravet syndrome in the U.S. and Europe.

- Net loss for the third quarter ended September 30, 2021, was $58.0 million, or a net loss of $1.04 per share, compared with a net loss of $60.1 million, or a net loss of $1.08 per share, in the third quarter ended September 30, 2020.

Nine Months Ended September 30, 2021 Financial Results Compared to Nine Months Ended September 30, 2020

- The Company recorded $55.1 million in revenue for the nine months ended September 30, 2021. This included total net product sales of FINTEPLA of $51.3 million and $3.8 million in collaboration revenue. Zogenix recorded $5.1 million in revenue for the corresponding period of 2020, which included product sales of FINTEPLA in the U.S. of $1.5 million, in addition to $3.6 million in collaboration revenue.

- Research and development expenses for the nine months ended September 30, 2021, totaled $100.9 million, a slight decrease from $102.0 million in the nine months ended September 30, 2020, as the Company decreased spending in FINTEPLA and had increased research and development costs and activities in its MT1621, and Tevard gene therapy programs.

- Selling, general and administrative expenses for the nine months ended September 30, 2021, totaled $104.7 million, up from $70.3 million in the nine months ended September 30, 2020, as the Company continued to expand its commercial footprint and investment related to the launch of FINTEPLA for the treatment of Dravet syndrome in the U.S. and Europe.

- Net loss for the nine months ended September 30, 2021, was $172.5 million, or a net loss of $3.09 per share, compared with a net loss of $139.2 million, or a net loss of $2.62 per share, in the nine months ended September 30, 2020.

- As of September 30, 2021, the Company had $343.0 million in cash, cash equivalents, and marketable securities, compared to $505.1 million at December 31, 2020.

Conference Call Details

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

Toll Free: 855-327-6838
International: 604-235-2082
Conference ID: 10016695
Webcast: http://public.viavid.com/index.php?id=146849

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 also plans to initiate a study of FINTEPLA in a genetic epilepsy called CDKL5 Deficiency Disorder (CDD) and is 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 and ability of Zogenix to complete regulatory submission in the EU and Japan for its product candidates; the expected timing of reporting data from clinical trials; the expected timing of review of Zogenix's regulatory submissions including the sNDA for the treatment of seizures associated with LGS; Zogenix's commercialization plans in the U.S. and Europe; and Zogenix's plans with respect to its development programs. 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: FINTEPLA may not achieve broad market acceptance as a treatment option of Dravet syndrome which would limit Zogenix's ability to general revenues; 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 continue to disrupt Zogenix's business operations, impairing the ability to commercialize FINTEPLA in Europe and Zogenix's ability to generate product revenue in Europe and conduct its development programs; unexpected adverse side effects or inadequate therapeutic efficacy of fenfluramine that could limit regulatory approval or commercialization, or that could result in recalls or product liability claims; later developments with FDA that may be inconsistent with the already completed meetings; additional data from Zogenix's ongoing studies may contradict or undermine the data previously reported; the potential for the FDA to delay timing of review of the sNDA due to the FDA's internal resource constraints or other reasons; 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.

CONTACTS:

Zogenix
corpcomms@zogenix.com

Investors
Brian Ritchie
Managing Director, LifeSci Advisors LLC
+1 (212) 915-2578 | britchie@lifesciadvisors.com

Media
Trish McCall, Porter Novelli
+1 (805) 390-3279 | trish.mcall@porternovelli.com

ZOGENIX, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In thousands, except par value)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 106,138	$ 166,916
Marketable securities	236,886	338,193
Accounts receivable, net	9,486	3,824
Inventory	3,502	1,026
Prepaid expenses	13,950	7,279
Other current assets	5,500	4,936
Total current assets	375,462	522,174
Property and equipment, net	7,593	8,724
Operating lease right-of-use assets	6,862	7,748
Intangible asset, net	92,644	98,558
Goodwill	6,234	6,234
Other non-current assets	8,192	7,692
Total assets	$ 496,987	$ 651,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,113	$ 11,945
Accrued and other current liabilities	46,111	54,964
Deferred revenue, current	5,048	5,318
Current portion of operating lease liabilities	1,654	1,688
Current portion of contingent consideration	13,500	8,800
Total current liabilities	78,426	82,715
Deferred revenue, noncurrent	3,436	5,479
Operating lease liabilities, net of current portion	9,055	10,314
Contingent consideration, net of current portion	25,900	33,600
Convertible senior notes	155,871	149,353
Total liabilities	272,688	281,461
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	1,721,694	1,694,580
Accumulated deficit	(1,497,370)	(1,324,840)
Accumulated other comprehensive loss	(25)	(71)
Total stockholders' equity	224,299	369,669
Total liabilities and stockholders' equity	$ 496,987	$ 651,130

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Net product sales	$ 21,398	$ 1,520	$ 51,269	$ 1,520
Collaboration revenue	1,212	1,340	3,813	3,621
Total revenues	22,610	2,860	55,082	5,141
Costs and expenses:				
Cost of product sales (excluding amortization of intangible asset)	1,294	140	3,192	140
Research and development	33,255	34,425	100,868	102,038
Selling, general and administrative	39,559	24,583	104,713	70,332
Intangible asset amortization	1,972	1,971	5,914	1,971
Acquired in-process research and development costs	—	1,500	—	4,500
Change in fair value of contingent consideration	400	1,800	1,500	6,100
Total costs and expenses	76,480	64,419	216,187	185,081
Loss from operations	(53,870)	(61,559)	(161,105)	(179,940)
Other income (expense), net:				
Interest income	85	934	579	2,504
Interest expense	(3,848)	—	(11,373)	—
Other, net	(371)	536	(631)	20,798
Total other (expense) income, net	(4,134)	1,470	(11,425)	23,302
Loss before income taxes	(58,004)	(60,089)	(172,530)	(156,638)
Income tax benefit	—	—	—	(17,425)
Net loss	$ (58,004)	$ (60,089)	$ (172,530)	$ (139,213)
Net loss per share, basic and diluted	$ (1.04)	$ (1.08)	$ (3.09)	$ (2.62)
Weighted average number of shares used in the calculation of basic and diluted net loss per common share	55,905	55,548	55,831	53,039