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): August 5, 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 August 5, 2021, Zogenix, Inc. issued a press release announcing its financial results for the third quarter ended June 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 August 5, 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: August 5, 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 Second Quarter 2021 Financial Results

- *Commercial launches of FINTEPLA in the U.S. and Europe progressing strongly, with total net product sales of $17.5 million and total revenue of $18.8 million in the second quarter, representing quarter-over-quarter increases of 42% and 37%, respectively*

- *As of June 30, 2021, over 860 patients have been prescribed FINTEPLA and referred to the REMS program, and there were 290 unique prescribers, an increase of 22% quarter-over-quarter*

- *On track to submit supplemental New Drug Application (NDA) seeking to expand FINTEPLA's label for treatment of Lennox-Gastaut syndrome (LGS) in Q3 2021, following positive meeting with U.S. Food and Drug Administration (FDA)*
- *Anticipate NDA submission for MT1621 in TK2 deficiency during first half of 2022 following positive FDA meeting confirming adequacy of proposed data packages*

- *Finalized study design and confirmed with FDA the adequacy of a single Phase 3 study of FINTEPLA for the treatment of CDKL5 Deficiency Disorder; enrollment expected to begin later this year*

EMERYVILLE, Calif., – August 5, 2021 (GLOBE NEWSWIRE) – Zogenix (NASDAQ: ZGNX), a global biopharmaceutical company developing and commercializing rare disease therapies, today announced financial results for the three and six months ended June 30, 2021, and provided a corporate update. The Company will host a conference call today, Thursday, August 5, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

"We are encouraged by the continued momentum of our launch of FINTEPLA® in Dravet syndrome in the U.S. and Europe and remain focused on driving broader adoption of FINTEPLA as in-person physician visits increase and physicians and families move forward with new treatment decisions," said Stephen J. Farr, Ph.D., President and CEO of Zogenix.

"In addition to our growing commercial presence, we continue to expand and achieve significant progress in advancing our late-stage development portfolio. Following three productive meetings with the FDA recently, we remain on track with our pipeline initiatives for FINTEPLA and MT1621," concluded Dr. Farr.

Corporate Update

- FINTEPLA for the treatment of seizures associated with Dravet syndrome:
-
    - As of June 30, 2021, the total number of unique prescribers was 290, an increase of 22% quarter-over-quarter

- As of June 30, 2021, approximately 860 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 launches in Germany and France.
- FINTEPLA recognized for setting a new standard for Dravet syndrome treatment outcomes by two distinguished clinicians in an *Epilepsy & Behavior* editorial titled, "*Raising the Bar: Fenfluramine Sets New Treatment Standards for Dravet Syndrome*
- Anticipate submission of an NDA in Japan (J-NDA) to Japan's Pharmaceutical and Medical Devices Agency by the end of 2021

- FINTEPLA for the treatment of seizures associated with LGS:
  - On track to submit supplemental NDA (sNDA) by the end of third quarter of 2021 following outcomes from a pre-NDA meeting with the FDA in June
  - Submission will include efficacy and safety data from a single randomized controlled trial and two long-term open-label extension studies
  - Expect to submit Marketing Authorization Application with European Medicines Agency in fourth quarter of 2021
  - Initiated U.S. commercial preparations for potential launch as early as first half of 2022
- FINTEPLA for the treatment of seizures associated with CDD:
  - Confirmed design and endpoints for a randomized controlled Phase 3 registrational study following positive meeting with FDA
  - Confirmed that a single Phase 3 study would be sufficient to support an sNDA
  - On track to initiate a randomized, two-arm, placebo-controlled Phase 3 study later this year
- MT1621 for the treatment of TK2 deficiency:
  - Recent Type B meeting with FDA confirmed the adequacy of the proposed 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 expects to submit an NDA in the first half of 2022

Second Quarter 2021 Financial Results

- The Company recorded $18.8 million in revenue for the second quarter ended June 30, 2021, which was an increase of 37% as compared to the $13.7 million recorded in the first quarter of 2021. This included total net product sales of FINTEPLA of $17.5 million, which was an increase of 42% as compared to the $12.3 million reported in the first quarter of 2021, in addition to $1.3 million in collaboration revenue. Zogenix recorded total revenue of $1.0 million for the three months ended June 31, 2020, which consisted solely of collaboration revenue.

- Research and development expenses for the second quarter ended June 30, 2021, totaled $36.6 million, up from $34.4 million in the second quarter ended June 30, 2020, as spending for FINTEPLA across all indications remained relatively flat, and the Company incurred increased costs in its MT1621 program.

- Selling, general and administrative expenses for the second quarter ended June 30, 2021, totaled $33.9 million, compared with $24.4 million in the second quarter ended June 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 second quarter ended June 30, 2021, was $58.9 million, or a net loss of $1.05 per share compared with a net loss of $53.3 million, or a net loss of $0.96 per share, in the second quarter ended June 30, 2020.

Six Months Ended June 30, 2021 Financial Results Compared to Six Months Ended June 30, 2020

- The Company recorded $32.5 million in revenue for the six months ended June 30, 2021. This included total net product sales of FINTEPLA of $29.9 million and $2.6 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 $2.3 million in revenue for the corresponding period of 2020, which consisted solely of collaboration revenue.

- Research and development expenses for the six months ended June 30, 2021, totaled $67.6 million, flat from $67.6 million in the six months ended June 30, 2020, as the Company decreased spending in Dravet syndrome and increased research and development costs and activities in its FINTEPLA LGS, MT1621, and Tevard gene therapy programs.

- Selling, general and administrative expenses for the six months ended June 30, 2021, totaled $65.2 million up from $45.7 million in the six months ended June 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 prepared for prospective launch in Europe.

- Net loss for the six months ended June 30, 2021, was $114.5 million, or a net loss of $2.05 per share, compared with a net loss of $79.1 million, or a net loss of $1.53 per share, in the six months ended June 30, 2020.
- As of June 30, 2021, the Company had $393.0 million in cash, cash equivalents, and marketable securities, compared to $505.1 million at December 31, 2020.

Conference Call Details

Thursday, August 5, at 4:30 PM Eastern Time / 1:30 PM Pacific Time

Toll Free: 800-347-6311

International: 323-994-21319

Conference ID: 6229003

Webcast: http://public.viavid.com/index.php?id=145894

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 Statement

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 submissions in the U.S. and Europe for its product candidates; the expected timing of initiation of clinical trials; potential future adoption of FINTEPLA and the potential impact of COVID-19; Zogenix's plans to commercialize fenfluramine in 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 the company'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 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 commercialization, or that could result in recalls or product liability claims; later developments with FDA that may be inconsistent with the already completed meetings; unexpected adverse side effects or

inadequate therapeutic efficacy of FINTEPLA that could limit approval for additional indications and/or commercialization; 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.

CONTACTS:

Zogenix
Melinda Baker
Senior Director, Corporate Communications
+1 (510) 788-8732 | 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)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 139,083	$ 166,916
Marketable securities	254,199	338,193
Accounts receivable, net	7,702	3,824
Inventory	2,923	1,026
Prepaid expenses and other current assets	12,487	12,215
Total current assets	416,394	522,174
Property and equipment, net	7,985	8,724
Operating lease right-of-use assets	7,103	7,748
Intangible asset, net	94,615	98,558
Goodwill	6,234	6,234
Other non-current assets	7,742	7,692
Total assets	$ 540,073	$ 651,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,831	$ 11,945
Accrued and other current liabilities	42,774	54,964
Deferred revenue, current	4,953	5,318
Current portion of operating lease liabilities	1,783	1,688
Current portion of contingent consideration	9,000	8,800
Total current liabilities	69,341	82,715
Deferred revenue, noncurrent	4,742	5,479
Operating lease liabilities, net of current portion	9,496	10,314
Contingent consideration, net of current portion	30,000	33,600
Convertible senior notes	153,634	149,353
Total liabilities	267,213	281,461
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	1,712,350	1,694,580
Accumulated deficit	(1,439,366)	(1,324,840)
Accumulated other comprehensive loss	(124)	(71)
Total stockholders' equity	272,860	369,669
Total liabilities and stockholders' equity	$ 540,073	$ 651,130

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Net product sales	$ 17,523	$ —	$ 29,871	$ —
Collaboration revenue	1,266	1,032	2,601	2,281
Total revenues	18,789	1,032	32,472	2,281
Costs and expenses:				
Cost of product sales (excluding amortization of intangible asset)	1,222	—	1,898	—
Research and development	36,644	34,373	67,613	67,613
Selling, general and administrative	33,883	24,431	65,154	45,749
Intangible asset amortization	1,971	—	3,942	—
Acquired in-process research and development costs	—	1,500	—	3,000
Change in fair value of contingent consideration	500	12,200	1,100	4,300
Total costs and expenses	74,220	72,504	139,707	120,662
Loss from operations	(55,431)	(71,472)	(107,235)	(118,381)
Other income (expense), net:				
Interest income	186	880	494	1,968
Interest expense	(3,789)	—	(7,525)	—
Other (expense) income, net	138	(157)	(260)	19,864
Total other (expense) income, net	(3,465)	723	(7,291)	21,832
Loss before income taxes	(58,896)	(70,749)	(114,526)	(96,549)
Income tax benefit	—	(17,425)	—	(17,425)
Net loss	$ (58,896)	$ (53,324)	$ (114,526)	$ (79,124)
Net loss per share, basic and diluted	$ (1.05)	$ (0.96)	$ (2.05)	$ (1.53)
Weighted average number of shares used in the calculation of basic and diluted net loss per common share	55,836	55,355	55,794	51,770