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 9, 2020

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 9, 2020, Zogenix, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 9, 2020

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 9, 2020

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 Third Quarter 2020 Financial Results

- *FINTEPLA® (fenfluramine) oral solution launched in the U.S. in late July for Dravet syndrome with high enrollment of physicians and patients into the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) program*
- *More than 300 patients prescribed FINTEPLA and enrolled in the FINTEPLA REMS program in the third quarter; over half of the patients were new to FINTEPLA*
- *Received a positive opinion from the Committee for Medicinal Products for Human Use for FINTEPLA in Dravet syndrome; European approval of the Marketing Authorization Application anticipated by the end of 2020*
- *Announced highly positive top-line results from third Phase 3 trial of FINTEPLA in Dravet syndrome (Study 3) to support a planned submission of a Japan New Drug Application in the third quarter of 2021*
- *Ended the third quarter with $525 million in cash, cash equivalents, and marketable securities*

EMERYVILLE, Calif. – November 9, 2020 – Zogenix (Nasdaq: ZGNX), a global biopharmaceutical company developing and commercializing rare disease therapies, today announced financial results for the three and nine months ended September 30, 2020 and provided a corporate update. The Company will host a conference call today, Monday, November 9, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

“This continues to be a very positive and rewarding year for Zogenix as our deeply experienced international teams successfully advance key clinical, regulatory, and commercial programs,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “The strong physician and patient adoption of FINTEPLA® in this early stage of our U.S. launch and the recent positive opinion from the Committee for Medicinal Products for Human Use *(*CHMP) speak to FINTEPLA’s effectiveness, safety, and potential to provide meaningful and lasting seizure control for more Dravet syndrome patients. This increases our excitement for our next set of major FINTEPLA milestones – anticipated approval for Dravet syndrome in Europe later this year, regulatory submission for Dravet syndrome in Japan next year, and regulatory submissions for Lennox-Gastaut syndrome (LGS) in the U.S. and Europe, also next year.”

“Equally important,” said Dr. Farr, “following a productive meeting with the U.S. Food and Drug Administration (FDA), we believe we have a clearly defined development and regulatory path for MT1621, our late-stage investigational therapy for the treatment of the often-fatal mitochondrial disease thymidine kinase 2 deficiency (TK2d), for which no approved therapies currently exist. Our goal is to have all required data in hand by the end of 2021 to enable a planned New Drug Application (NDA) submission in 2022.”

Corporate Update

- FINTEPLA for the treatment of seizures associated with Dravet syndrome:
  - Received FDA approval on June 25, 2020 and initiated U.S. commercial launch on July 27, 2020
  - More than 360 prescribers had successfully completed Risk Evaluation and Mitigation Strategy (REMS) certification process by the end of September
  - During the third quarter, more than 300 patients were prescribed FINTEPLA and enrolled in the FINTEPLA REMS program to become eligible to receive therapy, with approximately 90% completing echocardiograms. More than half of these patients were new to FINTEPLA.
  - Received positive CHMP opinion in October 2020 for FINTEPLA in Dravet syndrome; anticipate European Medicines Agency approval by the end of 2020, and have ramped up preparations for a potential commercial launch in Europe in the first quarter of 2021
  - Announced positive top-line results from third multinational (including Japan) Phase 3 study in Dravet syndrome; results corroborate highly statistically significant reductions in convulsive seizure frequency seen in two earlier Phase 3 studies of FINTEPLA in Dravet. Anticipate submission of a Japan NDA to Japan’s Pharmaceutical and Medical Devices Agency in the third quarter of 2021
- FINTEPLA for the treatment of seizures associated with LGS:

- Anticipate submitting supplemental NDA in the second quarter of 2021 following a successful Type C meeting in September clarifying regulatory path
- Anticipate submitting MAA with EMA in the third quarter of 2021

- MT1621 for the treatment of TK2d:
  - Recently held positive FDA meetings to discuss development path and data required to support planned NDA submission
  - Company expects availability of all required data by end of 2021, and anticipates the submission of an NDA in first half of 2022

Third Quarter 2020 Financial Results

- The Company recorded $2.9 million in revenue for the third quarter ended September 30, 2020. This included product sales of FINTEPLA in the U.S. of $1.5 million, in addition to $1.4 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 $0.6 million in revenue for the corresponding period of 2019.
- Research and development expenses for the third quarter ended September 30, 2020, totaled $34.4 million, up from $28.4 million in the third quarter ended September 30, 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 third quarter ended September 30, 2020, totaled $24.6 million, compared with $15.8 million in the third quarter ended September 30, 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 potential launch in Europe.
- Net loss for the third quarter ended September 30, 2020, was $60.1 million, or a net loss of $1.08 per share, compared with a net loss of $290.5 million, or a net loss of $6.75 per share, in the third quarter ended September 30, 2019. Net loss for the three months ended September 30, 2019, included $249.4 million of acquired in-process research and development consisting of existing research and development projects at the time of the Modis acquisition.

Nine Months Ended September 30, 2020 Financial Results Compared to Nine Months Ended September 30, 2019

- The Company recorded $5.1 million in revenue for the nine months ended September 30, 2020. This included product sales of FINTEPLA in the U.S. of $1.5 million, in addition to $3.6 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 $1.7 million in revenue for the corresponding period of 2019.
- Research and development expenses for the nine months ended September 30, 2020, totaled $102.0 million, up from $79.8 million in the nine months ended September 30, 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 nine months ended September 30, 2020, totaled $70.3 million, up from $42.1 million in the nine months ended September 30, 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 nine months ended September 30, 2020, was $139.2 million, or a net loss of $2.62 per share, compared with a net loss of $363.4 million, or a net loss of $8.54 per share, in the nine months ended September 30, 2019.
- As of September 30, 2020, the Company had $525.2 million in cash, cash equivalents, and marketable securities, reflecting the issuance of a $200 million convertible bond on September 28, 2020, compared to $251.2 million at December 31, 2019.

Conference Call
Monday, November 9 at 4:30 PM Easter Time / 1:30 PM Pacific Time

Toll Free: 877-407-9716

International: 201-493-6779

Conference ID: 13711927

Webcast: http://public.viavid.com/index.php?id=141969

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 received a positive CHMP opinion in Europe for the treatment of seizures associated with Dravet syndrome, a rare, severe childhood onset epilepsy. The company has two additional late-stage development programs underway: one for FINTEPLA for the treatment of seizures associated with Lennox-Gastaut syndrome, a different rare childhood-onset epilepsy and another for MT1621, an investigational novel substrate enhancement therapy for the treatment of TK2 deficiency, a rare genetic disorder. MT1621 is being developed through Modis Therapeutics, a Zogenix company.

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 potential that FINTEPLA, if approved by the EC, will be an important new treatment option for Dravet syndrome patients; and the timing and results of any decision regarding the MAA for FINTEPLA for the treatment of seizures associated with Dravet syndrome. 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: the EC may not agree with the Company's interpretation of the clinical data submitted in the MAA; the EC may not affirm the CHMP opinion and grant a centralized marketing authorization; additional data from Zogenix's ongoing studies may contradict or undermine the data submitted in the Dravet syndrome MAA for FINTEPLA or reported for LGS; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit approval and/or 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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Zogenix, Inc.
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands)

	September 30, 2020	December 31, 2019
Assets:		
Current assets:		
Cash and cash equivalents	$ 297,460	$ 62,070
Marketable securities	227,707	189,085
Accounts receivable, net	1,309	—
Inventory	1,010	—
Prepaid expenses and other current assets	12,905	11,084
Acquisition holdback placed in escrow	25,000	25,000
Total current assets	565,391	287,239
Property and equipment, net	9,050	9,424
Operating lease right-of-use assets	8,002	7,774
Intangible asset, net	100,529	102,500
Goodwill	6,234	6,234
Other noncurrent assets	2,840	1,079
Total assets	$ 692,046	$ 414,250
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	$ 7,223	$ 7,979
Accrued and other current liabilities	31,882	30,117
Acquisition holdback liability	24,444	24,444
Deferred revenue, current	4,900	5,927
Current portion of operating lease liabilities	1,654	1,322
Current portion of contingent consideration	22,200	25,600
Total current liabilities	92,303	95,389
Deferred revenue, noncurrent	6,331	7,425
Operating lease liabilities, net of current portion	10,660	10,752
Contingent consideration, net of current portion	32,700	38,200
Convertible senior notes	127,960	—
Deferred tax liability	—	17,425
Total liabilities	269,954	169,191
Commitments and contingencies		
Stockholders' equity:		
Common stock	56	45
Additional paid-in capital	1,676,408	1,360,092
Accumulated deficit	(1,254,670)	(1,115,457)
Accumulated other comprehensive income	298	379
Total stockholders' equity	422,092	245,059
Total liabilities and stockholders' equity	$ 692,046	$ 414,250

Zogenix, Inc.
Condensed Consolidated Statements of Operations (Unaudited)
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Net product sales	$ 1,520	$ —	$ 1,520	$ —
Collaboration revenue	1,340	630	3,621	1,699
Total revenues	2,860	630	5,141	1,699
Costs and expenses:				
Cost of product sales (excluding amortization of intangible asset)	140	—	140	—
Research and development	34,425	28,372	102,038	79,820
Selling, general and administrative	24,583	15,762	70,332	42,139
Amortization of intangible asset	1,971	—	1,971	—
Acquired in-process research and development and acquisition-related costs	1,500	249,437	4,500	249,437
Change in fair value of contingent consideration	1,800	400	6,100	2,700
Total costs and expenses	64,419	293,971	185,081	374,096
Loss from operations	(61,559)	(293,341)	(179,940)	(372,397)
Other income, net	934	481	20,798	433
Interest income, net	536	2,382	2,504	8,521
Loss before income taxes	(60,089)	(290,478)	(156,638)	(363,443)
Income tax benefit	—	—	(17,425)	—
Net loss	$ (60,089)	$ (290,478)	$ (139,213)	$ (363,443)
Net loss per share, basic and diluted	$ (1.08)	$ (6.75)	$ (2.62)	$ (8.54)
Weighted average number of shares used in the calculation of basic and diluted net loss per common share	55,548	43,029	53,039	42,577