UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 5, 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 May 5, 2020, Zogenix, Inc. issued a press release announcing its financial results for the first quarter ended March 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 May 5, 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: May 5, 2020

By: /s/ Michael P. Smith

Name: Michael P. Smith

Title: Executive Vice President, Chief Financial Officer and Treasurer

Exhibit 99.1

ZOGENIX

Zogenix Provides Corporate Update and Reports First Quarter 2020 Financial Results

- *FDA PDUFA target action date of June 25, 2020, for FINTEPLA® NDA in Dravet syndrome*
- *Plan to meet with FDA in second half of 2020 to discuss planned FINTEPLA Lennox-Gastaut syndrome sNDA*
- *Closed public offering of common stock for net proceeds of $221.7 million; approximately $420 million in cash and marketable securities at March 31, 2020*

EMERYVILLE, Calif. – May 5, 2020 – Zogenix, Inc. (Nasdaq: ZGNX), a global pharmaceutical company developing rare disease therapies, today announced financial results for the three months ended March 31, 2020, and provided a corporate update. The Company will host a conference call today, Tuesday, May 5, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

“We continue to make progress on several key initiatives to support Zogenix’s growth and transition to a commercial-stage company,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “During the pandemic, our priority has been to ensure that the approximately 530 Dravet syndrome patients currently taking FINTEPLA® in our clinical studies and expanded access program continue to receive this investigational product. As we approach the June 25th PDUFA date for FINTEPLA in Dravet syndrome, we continue to support the FDA’s review of our application and advance our commercial preparations in parallel. Our plans now also address potential ongoing pandemic-related circumstances that could impact how we launch FINTEPLA, if approved, in the third quarter.

“Recently, we were very pleased to share additional compelling clinical efficacy and safety data from an interim analysis of our ongoing open-label extension (OLE) study in Dravet syndrome,” continued Dr. Farr. “These data demonstrated significant, lasting and clinically meaningful reductions in convulsive seizure frequency in patients after up to two years of treatment with FINTEPLA.”

“Following positive top-line results from our global pivotal Phase 3 trial (Study 1601) of FINTEPLA in Lennox-Gastaut syndrome (LGS), a notoriously difficult to treat rare epilepsy, we are now focused on finalizing the studies and data required to support a supplemental NDA (sNDA) and intend to meet with the FDA later this year to discuss our planned submission,” concluded Dr. Farr.

Corporate Update

- FINTEPLA for the treatment of seizures associated with Dravet syndrome:
  - FDA has established a PDUFA target action date of June 25, 2020
  - FINTEPLA Marketing Authorization Application (MAA) under active review by the European Medicines Agency (EMA)
  - Commercial readiness activities ongoing in the U.S. and Europe
  - An interim analysis of the OLE study with a cutoff date of February 15, 2019, which includes results for a total of 330 patients and a median treatment duration of 445 days (range 7-899 days), was presented and showed continued clinically meaningful reductions in convulsive seizure frequency after up to two years of treatment. The most common adverse events (AEs) were pyrexia, nasopharyngitis, decreased appetite, and diarrhea. There were no cases of valvular heart disease or pulmonary arterial hypertension.

- FINTEPLA for the treatment of seizures associated with LGS:
  - Primary endpoint achieved in Study 1601; patients taking FINTEPLA 0.7 mg/kg/day demonstrated a statistically significant median reduction of 26.5% in monthly drop seizure frequency (p=0.0012). FINTEPLA was generally well-tolerated; the most common AEs were decreased appetite, somnolence, fatigue, vomiting, diarrhea, and pyrexia. No cases of valvular heart disease or pulmonary arterial hypertension were observed.
  - Intend to meet with the FDA second half of 2020 to confirm plan for sNDA submission
- FINTEPLA for the treatment of other rare epilepsy disorders:
  - Start-up activities for our planned Phase 2 basket study (Study 1901) temporarily paused due to COVID-19; will resume when COVID-19 measures are eased, and healthcare systems return to more normal operations
  - Positive interim data from an investigator-initiated study were presented in Sunflower syndrome, a rare, drug-resistant epileptic disorder with photo-induced seizures characterized by episodes of hand-waving while looking towards bright light
- MT1621 for the treatment of TK2 deficiency:
  - Held constructive End of Phase 2 meeting with FDA regarding MT1621 clinical and non-clinical programs; awaiting official minutes from the FDA
  - Additional FDA meeting scheduled in June to focus on CMC matters
- Financing
  - Successfully closed an underwritten public offering of 9,798,000 shares of common stock for net proceeds of approximately $221.7 million
- Executive Team
  - Appointed Shawnte M. Mitchell to the role of Executive Vice President, General Counsel and Secretary, to lead the Company's Legal and Compliance functions, manage corporate affairs and serve as a member of the Zogenix Executive Team

First Quarter 2020 Financial Results

- The Company recorded $1.2 million in revenue for the first quarter ended March 31, 2020, as a result of its March 2019 collaboration with Nippon Shinyaku Co., Ltd. for FINTEPLA in Dravet syndrome and LGS in Japan. Zogenix recorded no revenue for the corresponding period of 2019.
- Research and development expenses for the first quarter ended March 31, 2020, totaled $33.2 million, up from $24.4 million in the first quarter ended March 31, 2019.
- Selling, general and administrative expenses for the first quarter ended March 31, 2020, totaled $21.3 million, compared with $10.9 million in the first quarter ended March 31, 2019
- Net loss for the first quarter ended March 31, 2020, was $25.8 million, or a net loss of $0.54 per share, reflective of a net operating loss of $46.9 million, partially offset by $19.7 million in non-operating income recognized related to rebate claims submitted under the United Kingdom's small and medium-sized enterprise research and development tax relief program, compared with a net loss of $35.2 million, or a net loss of $0.83 per share, in the first quarter ended March 31, 2019.
- As of March 31, 2020, the Company had $420.2 million in cash, cash equivalents, and marketable securities, compared to $251.2 million at December 31, 2019.

Conference Call

Tuesday, May 5, at 4:30 PM Eastern Time / 1:30 PM Pacific Time

Toll Free:	888-254-3590
International:	323-994-2093
Conference ID:	3810961
Webcast:	http://public.viavid.com/index.php?id=139572

About Zogenix

Zogenix is a global pharmaceutical 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 has two late-stage development programs underway: FINTEPLA for the treatment of seizures associated with Dravet and Lennox-Gastaut syndromes, two rare and often-catastrophic childhood-onset epilepsies, and MT1621, a novel substrate enhancement therapy for the treatment of a rare genetic disorder called TK2 deficiency.

Forward Looking Statements

Zogenix cautions you that statements included in this press release and the webcast 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 the FDA’s PDUFA target action date and the timing of review by the EMA with respect to the NDA and MAA, respectively, for FINTEPLA for the treatment of patients with Dravet syndrome; the potential that FINTEPLA, if approved, will provide treatment options for patients with Dravet syndrome and LGS; Zogenix’s plans to commercialize FINTEPLA, if approved; Zogenix’s plans to finalize the studies and data required to support an sNDA for FINTEPLA in LGS; and the timing of regulatory submissions and meetings or other interactions with regulatory agencies. 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 potential for the FDA to delay the PDUFA target goal date due to FDA's internal resource constraints or other reasons, including delays related to the COVID-19 pandemic; the FDA and EMA may disagree that the existing safety and efficacy data, or Zogenix’s analysis of such data, is sufficient to support marketing approval; interim results do not necessarily predict final results and one or more of the clinical outcomes may materially change as the trial continues, following more comprehensive reviews of the data, and as more patient data become available; additional data from Zogenix’s ongoing studies may contradict or undermine the data submitted in the Dravet syndrome NDA 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; Zogenix may not be successful in executing its sales and marketing strategy for the commercialization of FINTEPLA, if approved; Zogenix may encounter further delays or difficulties in enrolling patients in its clinical trials as a result of the COVID-19 pandemic; the COVID-19 pandemic may disrupt Zogenix’s business operations, increasing its costs or impairing its ability to prepare for potential commercialization of FINTEPLA and its ability to generate any product revenue, if approved; 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, 2020	December 31, 2019
Assets:		
Current assets:		
Cash and cash equivalents	$ 269,975	$ 62,070
Marketable securities	150,218	189,085
Other receivable	19,741	—
Prepaid expenses and other current assets	13,647	11,084
Acquisition holdback placed in escrow	25,000	25,000
Total current assets	478,581	287,239
Property and equipment, net	9,560	9,424
Operating lease right-of-use assets	8,546	7,774
Indefinite-lived intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other noncurrent assets	1,485	1,079
Total assets	$ 606,906	$ 414,250
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	$ 7,887	$ 7,979
Accrued and other current liabilities	25,803	30,117
Acquisition holdback liability	24,444	24,444
Deferred revenue, current	5,696	5,927
Current portion of operating lease liabilities	1,383	1,322
Current portion of contingent consideration	23,600	25,600
Total current liabilities	88,813	95,389
Deferred revenue, noncurrent	6,407	7,425
Operating lease liabilities, net of current portion	11,454	10,752
Contingent consideration, net of current portion	32,300	38,200
Deferred income taxes	17,425	17,425
Total liabilities	156,399	169,191
Commitments and contingencies		
Stockholders' equity:		
Common stock	55	45
Additional paid-in capital	1,591,497	1,360,092
Accumulated deficit	(1,141,257)	(1,115,457)
Accumulated other comprehensive income	212	379
Total stockholders' equity	450,507	245,059
Total liabilities and stockholders' equity	$ 606,906	$ 414,250

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

	Three Months Ended March 31,	
	2020	2019
Collaboration revenue	$ 1,249	$ —
Operating expenses:		
Research and development	33,240	24,352
Selling, general and administrative	21,318	10,918
Acquired in-process research and development expense	1,500	—
Change in fair value of contingent consideration	(7,900)	3,000
Total operating expenses	48,158	38,270
Loss from operations	(46,909)	(38,270)
Other income (expense):		
Interest income	1,088	3,156
Other income (expense), net	20,021	(88)
Total other income	21,109	3,068
Net loss	$ (25,800)	$ (35,202)
Net loss per share, basic and diluted	$ (0.54)	$ (0.83)
Weighted average number of shares used in the calculation of basic and diluted net loss per common share	48,185	42,236