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): November 8, 2018

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.)

5858 Horton Street, Ste. 455, Emeryville, CA	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.)

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 8, 2018, Zogenix, Inc. issued a press release announcing its financial results for the third quarter September 30, 2018. 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 8, 2018

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 8, 2018

By: /s/ Michael P. Smith

Name: Michael P. Smith

Title: Executive Vice President, Chief Financial Officer, Treasurer and Secretary

Exhibit 99.1

Zogenix Provides Corporate Update and Reports Third Quarter Financial Results

- ***Reported positive top-line results from second pivotal Phase 3 trial of FINTEPLA® (ZX008) in patients with Dravet syndrome, Study 1504***
- ***Initiated rolling NDA submission to FDA for FINTEPLA***
- ***Continued to advance enrollment of global Phase 3 trial of FINTEPLA for treatment of Lennox-Gastaut syndrome, Study 1601***
- ***Completed successful public offering of $293 million in net proceeds to position Company well for next stage of growth***

EMERYVILLE, California, November 8, 2018—Zogenix, Inc. (NASDAQ: ZGNX), a pharmaceutical company developing therapies for the treatment of rare central nervous system (CNS) disorders, today provided a corporate update and announced financial results for the third quarter and nine months ended September 30, 2018.

"Following the completion of our positive, confirmatory Study 1504 Phase 3 trial of our investigational drug, FINTEPLA, in patients with Dravet syndrome, we began submission of a New Drug Application (NDA) for rolling review by the U.S. Food and Drug Administration (FDA) under a previously agreed NDA rolling submission plan," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "We also recently held a successful pre-NDA meeting with the FDA to discuss certain aspects of the FINTEPLA NDA. Based on discussions at the meeting, we will conduct some additional analyses of our clinical data that could positively impact our product label. As a result, we now anticipate that the submission of the final sections of the NDA will occur in early first quarter 2019 versus the previously anticipated end of this year. Our centralized Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) will occur shortly following the NDA submission."

"In parallel to our work on regulatory submissions, we continue to actively prepare for the potential launch of FINTEPLA in the U.S. and Europe," continued Dr. Farr. "Moreover, we are pleased with the pace of enrollment in our Phase 3 trial of FINTEPLA in Lennox-Gastaut Syndrome (LGS), Study 1601. There are over 30 sites open for patient enrollment, primarily located in the U.S, and we are now focused on the addition of study sites in Europe and Japan over the next several months. With our recently completed public offering raising $293 million in net proceeds, we believe Zogenix is now in a strong position to create significant long-term shareholder value with our advancing FINTEPLA programs in Dravet syndrome, Lennox Gastaut syndrome and other pipeline program opportunities."

Corporate Update

- Reported positive top-line results from Study 1504, the second pivotal Phase 3 clinical trial of FINTEPLA in Dravet syndrome. The study achieved statistical significance on the primary and all key secondary endpoints.
- Conducted positive pre-NDA meeting with FDA; began rolling submission of NDA for FINTEPLA for the treatment of seizures associated with Dravet syndrome.
- Continued U.S. and European commercial preparations for FINTEPLA.
- Continued enrollment in global Phase 3 trial of FINTEPLA for treatment of seizures associated with LGS, Study 1601.
- Successfully raised approximately $293 million in net proceeds in a public offering of common stock.
- Presented new findings from multiple studies assessing the psychological and socioeconomic impact of epileptic encephalopathies, such as Dravet syndrome, in the U.S. and Europe, as well as new results from an

ongoing open-label prospective study of FINTEPLA in Dravet syndrome, at the 13th European Congress on Epileptology.

- Detailed results of the Phase 2, open-label study evaluating FINTEPLA for the treatment of refractory patients with LGS were published in the September 2018 issue of *Epilepsia.*

Third Quarter 2018 Financial Results

- Research and development expenses for the third quarter ended September 30, 2018, totaled $27.6 million, up from $21.2 million in the third quarter ended September 30, 2017, as the Company expanded clinical trial activities related to its ongoing Phase 3 development programs of FINTEPLA in Dravet syndrome and LGS.

- Selling, general and administrative expenses for the third quarter ended September 30, 2018, totaled $11.0 million, compared with $6.1 million in the third quarter ended September 30, 2017.

- Net loss for the third quarter ended September 30, 2018, was $42.3 million, or a net loss of $1.08 per share, compared with a net loss of $42.8 million, or a net loss of $1.68 per share, in the third quarter ended September 30, 2017.

Nine Months Ended September 30, 2018 Financial Results Compared to Nine Months Ended September 30, 2017

- Due to the wind-down of Sumavel DosePro manufacturing operations in September 2017, the Company recorded no revenue for the nine months ended September 30, 2018. This compares with total revenue of $9.8 million in the nine month period ended September 30, 2017, consisting entirely of contract manufacturing revenue for Sumavel DosePro.

- Research and development expenses for the nine months ended September 30, 2018, totaled $77.3 million, up from $49.4 million in the nine months ended September 30, 2017, as the Company expanded clinical trial activities related to its ongoing Phase 3 development programs of FINTEPLA in Dravet syndrome and LGS.

- Selling, general and administrative expenses for the nine months ended September 30, 2018, totaled $27.7 million, compared with $18.1 million in the nine months ended September 30, 2017.

- Net loss for the nine months ended September 30, 2018, was $101.5 million, or a net loss of $2.78 per share, compared with a net loss of $87.1 million, or a net loss of $3.48 per share, in the nine months ended September 30, 2017.

- As of September 30, 2018, the Company had $539.1 million in cash and cash equivalents and marketable securities, compared to $293.5 million at December 31, 2017.

Conference Call

Thursday, November 8th @ 4:30 PM Eastern Time/1:30 PM Pacific Time

Toll Free:	877-407-9716
International:	201-493-6779
Conference ID:	13684016
Webcast:	http://public.viavid.com/index.php?id=131731

Replays available through November 22nd:

Domestic:	844-512-2921
International:	412-317-6671
Replay PIN:	13684016

About Zogenix

Zogenix (Nasdaq: ZGNX) is focused on developing therapies for patients with rare central nervous system (CNS) conditions that have limited or no treatment options, but face a critical need. For more information, visit www.zogenix.com.

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 are based on the Zogenix's current beliefs and expectations. These forward-looking statements include statements regarding the timing of the NDA and MAA submissions for FINTEPLA in Dravet syndrome; the potential that additional data analyses could lead to enhanced product labeling; continued enrollment and the addition of clinical sites for Study 1601; potential regulatory approval and commercial launches of FINTEPLA in the U.S. and Europe; and the potential for Zogenix to create significant long-term shareholder value. 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 uncertainties associated with the clinical development and regulatory approval of product candidates such as FINTEPLA, including potential delays in the timing of regulatory submissions; the top-line data Zogenix has reported is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such top-line data may not accurately reflect the complete results of the trial, and the FDA and other regulatory authorities may not agree with Zogenix’s interpretation of such results; potential delays in the commencement, enrollment and completion of clinical trials; Zogenix’s reliance on third parties to conduct its clinical trials, enroll patients, manufacture its preclinical and clinical drug supplies and manufacture commercial supplies of its drug products, if approved; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA may limit regulatory approval and/or commercialization, or may 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 Securities and 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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CONTACT:
Investors: Andrew McDonald
Founding Partner, LifeSci Advisors LLC
646-597-6987 | Andrew@lifesciadvisors.com

Media: David Polk
Senior Media Relations Strategist, Syneos Health
310-309-1029 | david.polk@syneoshealth.com

Zogenix, Inc.
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands, except par value)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 163,038	$ 293,503
Marketable securities	376,087	—
Prepaid expenses	6,861	5,994
Other current assets	1,286	5,206
Total current assets	547,272	304,703
Property and equipment, net	244	245
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	3,380	3,931
Total assets	$ 659,630	$ 417,613
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,110	$ 3,356
Accrued clinical trial expenses	10,674	8,657
Accrued compensation	5,039	6,616
Other accrued liabilities	2,413	1,842
Current portion of contingent consideration	32,500	—
Common stock warrant liabilities	607	512
Total current liabilities	55,343	20,983
Contingent consideration	47,600	76,900
Deferred income taxes	17,425	17,425
Other long-term liabilities	482	784
Total liabilities	120,850	116,092
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.001 par value; 50,000 shares authorized; 41,925 and 34,808 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	42	35
Additional paid-in capital	1,212,305	873,526
Accumulated deficit	(673,521)	(572,040)
Accumulated other comprehensive loss	(46)	—
Total stockholders' equity	538,780	301,521
Total liabilities and stockholders' equity	$ 659,630	$ 417,613

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Contract manufacturing revenue	$ —	$ —	$ —	$ 9,821
Costs and expenses:				
Cost of contract manufacturing	—	—	—	10,729
Research and development	27,608	21,178	77,329	49,369
Selling, general and administrative	11,016	6,073	27,663	18,129
Loss on contract termination	—	478	—	478
Asset impairment charges	—	196	—	1,116
Change in fair value of contingent consideration	5,700	10,500	3,200	11,600
Total costs and expenses	44,324	38,425	108,192	91,421
Loss from operations	(44,324)	(38,425)	(108,192)	(81,600)
Other income (expense):				
Interest income	2,133	121	3,995	332
Interest expense	—	(702)	(6)	(2,065)
Loss on extinguishment of debt	—	(3,378)	—	(3,378)
Change in fair value of common stock warrant liabilities	(64)	(380)	(95)	360
Other (expense) income, net	(9)	62	3,015	71
Total other income (expense)	2,060	(4,277)	6,909	(4,680)
Loss from continuing operations before income taxes	(42,264)	(42,702)	(101,283)	(86,280)
Income tax benefit	—	42	—	41
Net loss from continuing operations	(42,264)	(42,660)	(101,283)	(86,239)
Loss from discontinued operations, net of taxes	—	(134)	(198)	(870)
Net loss	$ (42,264)	$ (42,794)	$ (101,481)	$ (87,109)
Net loss per share, basic and diluted:				
Continuing operations	$ (1.08)	$ (1.68)	$ (2.78)	$ (3.45)
Discontinued operations	—	—	—	(0.03)
Total	$ (1.08)	$ (1.68)	$ (2.78)	$ (3.48)