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 9, 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 May 9, 2018, Zogenix, Inc. issued a press release announcing its financial results for the first quarter March 31, 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 May 9, 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: May 9, 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 First Quarter Financial Results

- ***Following receipt of Breakthrough Therapy Designation, conducted successful Type B meeting with FDA confirming adequacy of Phase 3 program for ZX008 NDA in Dravet syndrome***
- ***Study 1504 fully enrolled with 87 randomized patients; top-line results expected late June/early July***
- ***On-track to submit U.S. and EU regulatory approval filings for ZX008 in Dravet syndrome in fourth quarter of 2018***

EMERYVILLE, California, May 9, 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 first quarter ended March 31, 2018.

"We continue to advance towards multiple key catalysts in our late-stage lead program, ZX008 for the treatment of Dravet syndrome, including results from our second Phase 3 trial, Study 1504, and U.S. and EU regulatory filings targeted for the fourth quarter of 2018," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "To this end, following receipt of Breakthrough Therapy designation in the first quarter, we recently conducted a successful Type B meeting with the U.S. Food and Drug Administration (FDA) to discuss our ZX008 clinical development program and planned New Drug Application (NDA) content for ZX008 in Dravet syndrome."

"In addition, we continued to add to the positive efficacy data set for ZX008 in Dravet syndrome through the presentation of further analyses of Study 1, our first Phase 3 trial, in two poster presentations at the 2018 American Academy of Neurology (AAN) Annual Meeting," continued Dr. Farr. "Importantly, the results of a post-hoc analysis evaluating the effect of ZX008 in a subset of patients who had previously failed treatment with stiripentol, a commonly used antiepileptic drug, showed that the efficacy and tolerability results in this subgroup were robust and comparable to those achieved in the full Study 1 population."

"We also continued to enroll patients in our ongoing global Phase 3 trial of ZX008 in Lennox-Gastaut syndrome (LGS) in children and adults up to age 35, and had 16 open sites in the U.S. and Canada at the end of April and are focused on opening others in North America and completing Ethics Committee submissions to several European countries," concluded Dr. Farr.

Corporate Update

- Conducted a successful Breakthrough Therapy Type B meeting with the FDA regarding the ZX008 clinical development program and planned NDA submission in Dravet syndrome. Key outcomes included:
  - Reaffirmation of Study 1 and Study 1504 as the clinical basis for the NDA submission;
  - Concurrence that the anticipated ZX008 exposures in the Dravet syndrome program at the time of the NDA submission are likely to be sufficient to support the filing; and
  - Agreement on the schedule for a rolling NDA submission.
- Enrolled and randomized a total of 87 patients into the efficacy cohort of Study 1504, with last patient scheduled to exit the treatment period at the end of May and top-line results expected end of June/early July.
- Presented new efficacy and safety results from Study 1 at the AAN 2018 Annual Meeting:
  - Positive results of a post-hoc analysis evaluating the effect of ZX008 on controlling convulsive seizures in patients in Study 1 who had previously failed therapy with stiripentol. The data demonstrated that patients taking ZX008 0.8 mg/kg/day (max. 30 mg/day) achieved a 60.8% greater reduction in mean monthly convulsive seizures compared to placebo (p=0.002). Additionally, in the 0.8 mg/kg/day group, 72.7% of patients achieved an equal or greater than 50% reduction in convulsive seiz

ures (p=0.006), and 50.0% achieved an equal or greater than 75% reduction (p=0.036). Across these and other efficacy measures, the results from the subset analysis of stiripentol non-responders were comparable to the full Study 1 population, indicating that a history of non-responsiveness to stiripentol is not a predictor of negative response to treatment with ZX008 in Dravet syndrome.

  - Positive results of a prespecified secondary analysis evaluating the effect of ZX008 on total seizure frequency, showing that treatment with ZX008 at doses of 0.2 mg/kg/day and 0.8 mg/kg/day (max. 30 mg/day) resulted in significantly greater reductions in median monthly total seizure frequency compared to placebo (p=0.031 and p<0.001, respectively).
  - Encouraging preliminary quality of life and cognitive function data showing that patients treated with ZX008 over the 14-week double-blind treatment period experienced significant improvements on select measures of quality of life and executive function compared to those on placebo.

- Continued enrollment in global Phase 3 trial of ZX008 for treatment of LGS, Study 1601. At the end of April, 16 sites in the U.S. and Canada were open to recruit patients and Ethics Committee submissions to several European countries have been completed.

First Quarter 2018 Financial Results

- Due to the wind-down of Sumavel DosePro manufacturing operations in September 2017, the Company recorded no revenue for the three months ended March 31, 2018. This compares with total revenue of $2.7 million in the first quarter ended March 31, 2017, consisting entirely of contract manufacturing revenue for Sumavel DosePro.

- Research and development expenses for the first quarter ended Mach 31, 2018, totaled $23.0 million, up from $13.3 million in the first quarter ended March 31, 2017, as the Company continued enrollment and expanded the scope of its Phase 3 clinical trials for ZX008 in Dravet syndrome and LGS.

- Selling, general and administrative expenses for the first quarter ended March 31, 2018, totaled $8.1 million, compared with $6.6 million in the first quarter ended March 31, 2017.

- Net loss from continuing operations for the first quarter ended March 31, 2018, was $30.2 million, compared with a net loss from continuing operations of $21.1 million in the first quarter ended March 31, 2017.

- Total net loss for the first quarter ended March 31, 2018, was $30.2 million, or a net loss of $0.87 per share, compared with a total net loss of $21.3 million, or a net loss of $0.86 per share, in the first quarter ended March 31, 2017.

- As of March 31, 2018, the Company had cash and cash equivalents of $272.0 million, compared to $293.5 million at December 31, 2017.

Conference Call Details
Wednesday, May 9th at 4:30pm Eastern Time/1:30pm Pacific Time

Toll Free: 866-548-4713
International: 323-794-2093
Conference ID: 7186111
Webcast: http://public.viavid.com/index.php?id=129538

Replays, available through May 23rd
Domestic: 844-512-2921
International: 412-317-6671
Replay PIN: 7186111

About Zogenix

Zogenix, Inc. (Nasdaq: ZGNX) is a pharmaceutical company committed to developing and commercializing CNS therapies that address specific clinical needs for people living with orphan and other CNS disorders who need innovative treatment alternatives to improve their daily functioning.

For more information, visit www.zogenix.com.

CONTACTS:
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Founding Partner, LifeSci Advisors LLC
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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 are based on the Company's current beliefs and expectations. These forward-looking statements include statements regarding ZX008’s potential as a treatment for seizures associated with Dravet syndrome; the enrollment of patients in the planned global Phase 3 clinical trial in Lennox Gastaut Syndrome; the timing of top line results for the Study 1504 clinical trial; the timing or results of regulatory submissions for ZX008 for Dravet syndrome in the U.S. and Europe; the timing of the enrollment of patients or results in our Phase 3 trial in LGS; the timing of our regulatory submissions of ZX008 to treat LGS; and the commercial potential of ZX008. 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 ZX008, including potential delays in the commencement, enrollment and completion of clinical trials; the potential that earlier clinical trials and studies, and analyses of such clinical trials and studies, may not be predictive of future results; top-line data is based on preliminary analysis of clinical data, and such data may change following a more comprehensive review of the data related and such top-line data may not accurately reflect the complete results of a clinical trial; 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 ZX008 that could limit approval and/or commercialization, or that could result in recalls or product liability claims; Zogenix's ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities; Breakthrough Therapy designation and Fast Track designation may not result in an expedited regulatory review process; 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.

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

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 271,953	$ 293,503
Prepaid expenses	8,547	5,994
Other current assets	827	5,206
Total current assets	281,327	304,703
Property and equipment, net	287	245
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	1,509	3,931
Total assets	$ 391,857	$ 417,613
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,866	$ 3,356
Accrued expenses	16,024	10,499
Accrued compensation	3,691	6,616
Common stock warrant liabilities	495	512
Total current liabilities	23,076	20,983
Contingent consideration	76,900	76,900
Deferred income taxes	17,425	17,425
Other long-term liabilities	684	784
Stockholders' equity:		
Common stock	35	35
Additional paid-in capital	875,957	873,526
Accumulated deficit	(602,220)	(572,040)
Total stockholders' equity	273,772	301,521
Total liabilities and stockholders' equity	$ 391,857	$ 417,613

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

	Three Months Ended March 31,	
	2018	2017
Contract manufacturing revenue	$ —	$ 2,696
Costs and expenses:		
Cost of contract manufacturing	—	2,487
Research and development	22,980	13,341
Selling, general and administrative	8,070	6,554
Asset impairment charges	—	813
Change in fair value of contingent consideration	—	600
Total costs and expenses	31,050	23,795
Loss from operations	(31,050)	(21,099)
Other income (expense):		
Interest income	833	94
Interest expense	(6)	(671)
Change in fair value of common stock warrant liabilities	17	587
Other income (expense)	26	(20)
Total other income (expense)	870	(10)
Loss from continuing operations before income taxes	(30,180)	(21,109)
Income tax expense	—	(17)
Net loss from continuing operations	(30,180)	(21,126)
Loss from discontinued operations, net of tax	—	(181)
Net loss	$ (30,180)	$ (21,307)
Net loss per share, basic and diluted:		
Continuing operations	$ (0.87)	$ (0.85)
Discontinued operations	$ —	$ (0.01)
Total	$ (0.87)	$ (0.86)
Weighted-average shares used in computing net loss per share, basic and diluted	34,841	24,813