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): August 6, 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 August 6, 2018, Zogenix, Inc. issued a press release announcing its financial results for the second quarter June 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 August 6, 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: August 6, 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 Second Quarter Financial Results

- ***Reported positive top-line results from second pivotal Phase 3 trial of ZX008 in patients with Dravet syndrome, Study 1504***
- ***Submission of U.S. and EU regulatory filings for ZX008 in Dravet syndrome anticipated by year-end 2018***
- ***Actively enrolling global Phase 3 trial of ZX008 for treatment of Lennox-Gastaut syndrome, Study 1601***
- ***Appointed Global Chief Commercial Officer***

EMERYVILLE, California, August 6, 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 second quarter and six months ended June 30, 2018.

"We were thrilled to recently announce positive top-line data from our second global Phase 3 trial of ZX008, Study 1504, for the control of convulsive seizures in children and young adults with Dravet syndrome," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "Study 1504 met the primary efficacy endpoint, and all key secondary objectives, with high statistical significance. This confirmatory study corroborated the positive data from Study 1, our first pivotal Phase 3 trial of ZX008 in Dravet syndrome."

"Looking ahead, Study 1 and Study 1504 will provide the basis for regulatory submissions in both the U.S. and EU with data that reflect global clinical practice for the treatment of Dravet syndrome," continued Dr. Farr. "We are now focused on submitting applications for registration in the U.S. and EU before the end of the year."

"We also continue to be pleased with the rate of enrollment in our ongoing global Phase 3 trial of ZX008 in Lennox-Gastaut syndrome (LGS), Study 1601, in the U.S. We will continue to add sites in Europe and Australia to this global study as we advance through the rest of the year," concluded Dr. Farr.

Corporate Update

- Reported positive top-line results from Study 1504, the second pivotal Phase 3 clinical trial of ZX008 in Dravet syndrome in July.
  - Patients taking ZX008 achieved a 54.7% greater reduction in mean monthly convulsive seizures compared to placebo ($p<0.001$). The study also met all key secondary efficacy endpoints.
  - ZX008 was generally well-tolerated with the adverse events consistent with those observed in Study 1 and the known safety profile of fenfluramine. The incidence of overall rates of treatment-emergent adverse events was similar in the ZX008 and placebo groups. No clinical or echocardiographic evidence of the development of valvulopathy or pulmonary hypertension was observed in any subject.
- New Drug Application and Marketing Authorization Application preparations ongoing for ZX008 in Dravet syndrome, targeting submissions by year-end 2018.
- Continued enrollment in global Phase 3 trial of ZX008 for treatment of LGS, Study 1601.
- Appointed Ashish Sagrolikar, an industry veteran with over 25 years of global pharmaceutical sales, marketing and operations experience in rare disease and specialty pharmaceutical products, as Executive Vice President and Chief Commercial Officer, as the Company continues to build its commercial operations in preparation for anticipated launches in the U.S. and Europe.

Second 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 June 30, 2018. This compares with total revenue of $7.1 million in the second quarter ended June 30, 2017, consisting entirely of contract manufacturing revenue for Sumavel DosePro.

- Research and development expenses for the second quarter ended June 30, 2018, totaled $26.7 million, up from $14.9 million in the second quarter ended June 30, 2017, as the Company expanded clinical trial activities related to its ongoing Phase 3 development programs of ZX008 in Dravet syndrome and LGS.

- Selling, general and administrative expenses for the second quarter ended June 30, 2018, totaled $8.6 million, compared with $5.5 million in the second quarter ended June 30, 2017.

- Net loss from continuing operations for the second quarter ended June 30, 2018, was $28.8 million, compared with a net loss from continuing operations of $22.5 million in the second quarter ended June 30, 2017.

- Total net loss for the second quarter ended June 30, 2018, was $29.0 million, or a net loss of $0.83 per share, compared with a total net loss of $23.0 million, or a net loss of $0.93 per share, in the second quarter ended June 30, 2017.

Six Months Ended June 30, 2018 Financial Results Compared to Six Months Ended June 30, 2017

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

- Research and development expenses for the six months ended June 30, 2018, totaled $49.7 million, up from $28.2 million in the six months ended June 30, 2017, as the Company expanded clinical trial activities related to its ongoing Phase 3 development programs of ZX008 in Dravet syndrome and LGS.

- Selling, general and administrative expenses for the six months ended June 30, 2018, totaled $16.6 million, compared with $12.1 million in the six months ended June 30, 2017.

- Net loss from continuing operations for the six months ended June 30, 2018, was $59.0 million, compared with a net loss from continuing operations of $43.6 million in the six months ended June 30, 2017.

- Total net loss for the six months ended June 30, 2018, was $59.2 million, or a net loss of $1.69 per share, compared with a total net loss of $44.3 million, or a net loss of $1.79 per share, in the six months ended June 30, 2017.

- As of June 30, 2018, the Company had cash and cash equivalents of $272.1 million, compared to $293.5 million at December 31, 2017.

Conference Call Details

Monday, August 6th @ 4:30 PM Eastern Time/1:30 PM Pacific Time

Toll Free:	800-263-0877
International:	323-794-2094
Conference ID:	1390518
Webcast:	http://public.viavid.com/index.php?id=130329

Replays, Available through August 20th:

Domestic:	844-512-2921
International:	412-317-6671
Replay PIN:	1390518

About Zogenix

Zogenix, Inc. (Nasdaq: ZGNX) is a pharmaceutical company dedicated to developing therapies for people living with severe central nervous system (CNS) disorders who have limited or no treatment options. Led by a team of experts in rare disease development and CNS conditions, Zogenix is rapidly advancing the clinical investigation and development of ZX008 (fenfluramine hydrochloride) for patients with severe, rare epilepsies, including Dravet and Lennox-Gastaut syndromes.

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 Study 1 and Study 1504 providing the basis for regulatory submissions in both the U.S. and EU for ZX008 in Dravet syndrome and the timing of such submissions; continued enrollment and the addition of clinical sites for Study 1601; and potential regulatory approval and launches of ZX008 in the U.S. and Europe. 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 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 ZX008 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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CONTACTS:
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Zogenix, Inc.
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands, except par value)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 272,103	$ 293,503
Prepaid expenses	9,089	5,994
Other current assets	3,933	5,206
Total current assets	285,125	304,703
Property and equipment, net	279	245
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	1,040	3,931
Total assets	$ 395,178	$ 417,613
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,434	$ 3,356
Accrued clinical trial expenses	12,160	8,657
Accrued compensation	3,267	6,616
Other accrued liabilities	2,501	1,842
Contingent consideration, current portion	18,500	—
Common stock warrant liabilities	543	512
Total current liabilities	41,405	20,983
Contingent consideration	55,900	76,900
Deferred income taxes	17,425	17,425
Other long-term liabilities	582	784
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; 35,827 and 34,808 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	36	35
Additional paid-in capital	911,087	873,526
Accumulated deficit	(631,257)	(572,040)
Total stockholders' equity	279,866	301,521
Total liabilities and stockholders' equity	$ 395,178	$ 417,613

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Contract manufacturing revenue	$ —	$ 7,125	$ —	$ 9,821
Costs and expenses:				
Cost of contract manufacturing	—	8,242	—	10,729
Research and development	26,741	14,850	49,721	28,191
Selling, general and administrative	8,577	5,502	16,647	12,056
Asset impairment charges	—	107	—	920
Change in fair value of contingent consideration	(2,500)	500	(2,500)	1,100
Total costs and expenses	32,818	29,201	63,868	52,996
Loss from operations	(32,818)	(22,076)	(63,868)	(43,175)
Other income (expense):				
Interest income	1,029	117	1,862	211
Interest expense	—	(692)	(6)	(1,363)
Change in fair value of common stock warrant liabilities	(48)	153	(31)	740
Other income, net	2,998	29	3,024	9
Total other income (expense)	3,979	(393)	4,849	(403)
Loss from continuing operations before income taxes	(28,839)	(22,469)	(59,019)	(43,578)
Income tax benefit (expense)	—	16	—	(1)
Net loss from continuing operations	(28,839)	(22,453)	(59,019)	(43,579)
Loss from discontinued operations, net of taxes	(198)	(555)	(198)	(736)
Net loss	$ (29,037)	$ (23,008)	$ (59,217)	$ (44,315)
Net loss per share, basic and diluted:				
Continuing operations	$ (0.82)	$ (0.90)	$ (1.68)	$ (1.76)
Discontinued operations	$ (0.01)	$ (0.03)	$ (0.01)	$ (0.03)
Total	$ (0.83)	$ (0.93)	$ (1.69)	$ (1.79)
Weighted average common shares used in the calculation of basic and diluted net loss per common share	35,355	24,822	35,099	24,817