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 7, 2017

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, Suite 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 7, 2017, Zogenix, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2017. 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 No.	Description
99.1	Press Release, dated November 7, 2017

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 7, 2017

By: /s/ Michael P. Smith

Name: Michael P. Smith

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated November 7, 2017

Exhibit 99.1

Zogenix Provides Corporate Update and Reports Third Quarter 2017 Financial Results

- ***During the third quarter, the Company announced positive top-line results from its Phase 3 Study 1 of ZX008 in patients with Dravet syndrome***
- ***Study 1 met primary endpoint of reduction in frequency of convulsive seizures (p<0.001), as well as all key secondary endpoints***
- ***Zogenix strengthened cash position by raising $290.7 million in net proceeds through common stock offerings***

EMERYVILLE, California, November 7, 2017—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, 2017.

"We are extremely pleased with our third quarter accomplishments, culminating with the positive top-line data from Study 1 of our global Phase 3 program of ZX008 in Dravet syndrome," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "As we announced on September 29, Study 1 met the primary efficacy endpoint and all key secondary objectives representing a significant step forward in our objectives to advance ZX008 as a potential adjunctive therapy for Dravet syndrome and help positively impact the lives of patients and their families. We look forward to presenting further data from Study 1 at the American Epilepsy Society Annual Meeting in December in Washington, D.C."

"We expect that our second planned pivotal trial in our Phase 3 Dravet syndrome program, Study 1504, will be fully enrolled shortly and anticipate announcing top-line data from Study 1504 in the second quarter 2018," continued Dr. Farr. "Beyond Dravet syndrome, we anticipate enrolling patients into a global Phase 3 study in Lennox-Gastaut syndrome, another severe, catastrophic childhood onset epilepsy with a high unmet need, soon. Our recently completed successful common stock offerings position us well financially to execute on these programs as we expect a number of significant clinical and regulatory milestones in the next several quarters."

Corporate Update

- Reported positive top-line results from pivotal Phase 3 clinical trial of ZX008 in Dravet syndrome; patients receiving the 0.8 mg/kg/day dose of ZX008 achieved a 63.9% greater reduction in mean monthly convulsive seizures compared to placebo (the study's primary endpoint), which was statistically significant (p<0.001). The study also met all key secondary endpoints.
- Targeting completion of enrollment of Study 1504 in the fourth quarter of 2017
- Continued preparations to initiate Phase 3 clinical trial of ZX008 in children and adults with Lennox-Gastaut syndrome during fourth quarter of 2017
- Strengthened financial position through common stock offerings in the third quarter and October 2017 raising net proceeds of approximately $290.7 million
- Announced results from multiple surveys focused on impact of pediatric epilepsies:
    - Sibling Voices Survey evaluated psychosocial impact on the siblings of patients with severe childhood epilepsies; results presented at the National Organization for Rare Disorders and Orphan Products Breakthrough Summit
    - DISCUSS survey evaluated clinical, social and economic consequences of Dravet syndrome on children, young adults and their families; results published in Developmental Medicine & Child Neurology

Third Quarter 2017 Financial Results Compared to Third Quarter 2016

- Due to the wind-down of Sumavel DosePro manufacturing operations, the Company recorded no revenue for the three months ended September 30, 2017. This compares with total revenue of $6.6 million in the third quarter ended September 30, 2016, consisting almost entirely of contract manufacturing revenue for Sumavel DosePro.
- Research and development expenses for the third quarter ended September 30, 2017, totaled $21.2 million, up from $10.1 million in the third quarter ended September 30, 2016, as the Company continued enrollment and expanded the scope of its Phase 3 clinical trials for ZX008 in Dravet syndrome.
- Selling, general and administrative expenses for the third quarter ended September 30, 2017, totaled $6.1 million, compared with $6.5 million in the third quarter ended September 30, 2016.
- Net loss from continuing operations for the third quarter ended September 30, 2017, was $42.7 million, compared with a net loss of $16.6 million in the third quarter ended September 30, 2016.
- Net loss from discontinued operations for the third quarter ended September 30, 2017, was $0.1 million, compared with $0.4 million in the third quarter ended September 30, 2016.
- Total net loss for the third quarter ended September 30, 2017, was $42.8 million, or $1.68 per share, compared with a net loss of $17.0 million, or $0.69 per share, in the third quarter ended September 30, 2016.

Nine Months Ended September 30, 2017 Financial Results Compared to Nine Months Ended September 30, 2016

- Total revenue for the nine months ended September 30, 2017, was $9.8 million, consisting entirely of contract manufacturing revenue for Sumavel DosePro. This compared with total revenue of $17.9 million in the nine months ended September 30, 2016, substantially all of which were derived from contract manufacturing revenue for Sumavel DosePro. The decrease was primarily attributable to lower reimbursed production costs under the agreement with Endo. In April 2017, Zogenix completed fulfillment of the remaining open orders and ceased all manufacturing activities related to Sumavel DosePro.
- Research and development expenses for the nine months ended September 30, 2017, totaled $49.4 million, up from $28.4 million in the nine months ended September 30, 2016, as the Company continued enrollment and expanded the scope of its Phase 3 clinical trials for ZX008 in Dravet syndrome.
- Selling, general and administrative expenses for the nine months ended September 30, 2017, totaled $18.1 million, compared with $19.5 million in the nine months ended September 30, 2016.
- Net loss from continuing operations for the nine months ended September 30, 2017, was $86.2 million, compared with $45.1 million in the nine months ended September 30, 2016.
- Net loss from discontinued operations for the nine months ended September 30, 2017, was $0.9 million, compared with $1.1 million in the nine months ended September 30, 2016.
- Total net loss for the nine months ended September 30, 2017 was $87.1 million, or $3.48 per share, compared with a net loss of $46.2 million, or $1.87 per share, in the nine months ended September 30, 2016.
- At September 30, 2017, the Company had cash and cash equivalents of $64.7 million, compared to $91.6 million at December 31, 2016. During the three months ended September 30, 2017, the Company sold 1,550,880 shares of its common stock under an at-the-market (ATM) offering and raised net proceeds of approximately $19.4 million. In October 2017, Zogenix closed on an underwritten common stock offering in which the Company issued and sold 7,705,000 shares of common stock at a price of $37.50 per share and received net proceeds of approximately $271.3 million.

Conference Call Details

Tuesday, November 7th @ 4:30 PM Eastern Time/1:30 PM Pacific Time

Toll Free: 888-211-9963
International: 719-325-4773
Conference ID: 6163936
Webcast: http://public.viavid.com/index.php?id=126700

Replays, available through November 21, 2017:
Domestic: 844-512-2921
International: 412-317-6671
Replay PIN: 6163936

About Zogenix

Zogenix 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.

Investors: Andrew McDonald
Founding Partner, LifeSci Advisors LLC
646-597-6987 | Andrew@lifesciadvisors.com

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 timing of presenting further data regarding Study 1 at the American Epilepsy Society Annual Meeting; the enrollment of patients in the on-going Study 1504 clinical trial for ZX008 or the planned global Phase 3 clinical trial in Lennox Gastaut Syndrome; the timing of top line results for the Study 1504 clinical trial; 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 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 may not agree with Zogenix’s interpretation of such results; 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 may not be predictive of future results; 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; 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 Statements of Operations
(In Thousands, except Per Share Amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Contract manufacturing revenue	$ —	$ 6,345	$ 9,821	$ 17,537
Service and other product revenue	—	225	—	327
Total revenue	—	6,570	9,821	17,864
Costs and expenses:				
Cost of contract manufacturing	—	6,469	10,729	16,480
Research and development	21,178	10,076	49,369	28,447
Selling, general and administrative	6,073	6,538	18,129	19,506
Loss on contract termination	478	—	478	—
Asset impairment charges	196	—	1,116	—
Change in fair value of contingent consideration	10,500	200	11,600	2,800
Total costs and expenses	38,425	23,283	91,421	67,233
Loss from operations	(38,425)	(16,713)	(81,600)	(49,369)
Other income (expense):				
Interest expense, net	(581)	(567)	(1,733)	(1,788)
Loss on extinguishment of debt	(3,378)	—	(3,378)	—
Change in fair value of common stock warrant liabilities	(380)	(356)	360	5,148
Other income	62	25	71	2
Total other (expense) income	(4,277)	(898)	(4,680)	3,362
Loss from continuing operations before income taxes	(42,702)	(17,611)	(86,280)	(46,007)
Income tax benefit	42	993	41	922
Net loss from continuing operations	(42,660)	(16,618)	(86,239)	(45,085)
Net loss from discontinued operations	(134)	(379)	(870)	(1,130)
Net loss	$ (42,794)	$ (16,997)	$ (87,109)	$ (46,215)
Net loss per share, basic and diluted:				
Continuing operations	$ (1.68)	$ (0.67)	$ (3.45)	$ (1.82)
Discontinued operations	$ —	$ (0.02)	$ (0.03)	$ (0.05)
Total	$ (1.68)	$ (0.69)	$ (3.48)	$ (1.87)
Weighted average shares outstanding, basic and diluted	25,431	24,791	25,024	24,780

Zogenix, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In Thousands)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 64,730	$ 91,551
Trade accounts receivable	—	12,577
Inventory	—	7,047
Prepaid expenses and other current assets	6,000	8,739
Total current assets	70,730	119,914
Property and equipment, net	221	1,710
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	3,560	1,147
Total assets	$ 183,245	$ 231,505
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,040	$ 4,549
Accrued expenses	13,289	6,374
Accrued compensation	4,792	3,652
Common stock warrant liabilities	449	809
Working capital advance note payable, net of discount	—	3,267
Current portion of long-term debt	5,333	—
Deferred revenue	—	1,245
Current liabilities of discontinued operations	186	414
Total current liabilities	26,089	20,310
Long term debt	13,890	18,824
Contingent consideration	64,400	52,800
Deferred income taxes	17,425	17,425
Other long-term liabilities	1,823	1,390
Stockholders' equity:		
Common stock, $0.001 par value; 50,000 shares authorized; 26,545 and 24,813 shares issued and outstanding, respectively	27	25
Additional paid-in capital	591,923	565,954
Accumulated deficit	(532,332)	(445,223)
Total stockholders' equity	59,618	120,756
Total liabilities and stockholders' equity	$ 183,245	$ 231,505