

---

**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 8, 2017**

---

**ZOGENIX, INC.**  
(Exact Name of Registrant as Specified in its Charter)

---

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-34962**  
(Commission  
File Number)

**20-5300780**  
(IRS Employer  
Identification No.)

**5858 Horton Street, Suite 455, Emeryville, CA**  
(Address of Principal Executive Offices)

**94608**  
(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 8, 2017, Zogenix, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 8, 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: August 8, 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 August 8, 2017

## Zogenix Provides Corporate Update and Reports Second Quarter 2017 Financial Results

*Top-Line Results of First Phase 3 Clinical Trial of ZX008 in Dravet Syndrome Expected in Third Quarter 2017*

*Second Phase 3 Clinical Trial in Dravet Syndrome, Study 1504, Enrolling According to Plan*

*Orphan Drug Designation Granted by FDA for ZX008 in Lennox Gastaut Syndrome; Phase 3 Clinical Trial Expected to Begin in Fourth Quarter of 2017*

*Company Will Host a Conference Call Today at 4:30 p.m. EST/1:30 p.m. PST*

**EMERYVILLE, California, August 8, 2017**—Zogenix, Inc. (NASDAQ: ZGNX), a pharmaceutical company developing therapies for the treatment of orphan and central nervous system (CNS) disorders, today provided a corporate update and announced financial results for the second quarter and six months ended June 30, 2017.

“We remain on target to announce Study 1 top-line results from our ZX008 Phase 3 program in Dravet syndrome late in the third quarter of this year,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “The completion of Study 1 will be a significant milestone for our company, as it will represent the culmination of over two years of effort at Zogenix. Importantly, these will be the first results from one of our placebo-controlled, clinical trial evaluating the potential of low-dose fenfluramine as a safe and effective treatment for Dravet syndrome. In addition, our second planned pivotal Phase 3 data readout for Dravet syndrome, Study 1504, has enrolled approximately two-thirds of the total number of subjects targeted for inclusion. We are focused on completing enrollment in Study 1504 by the end of the current quarter.”

“Beyond Dravet syndrome, we were pleased most recently to receive orphan drug designation in the U.S. for ZX008 in Lennox Gastaut Syndrome (LGS), which follows the same distinction received in the EU earlier this year,” continued Dr. Farr. “We have begun preparations that will allow us to initiate a Phase 3 clinical trial for ZX008 in LGS once we announce the top-line data from Study 1.”

### Corporate Update

- Completed enrollment of Study 1 in the Phase 3 program of ZX008 in Dravet syndrome; remain on track to announce top-line safety and efficacy results in the third quarter of 2017
  - Enrollment of second pivotal Phase 3 trial, Study 1504, is now approximately two-thirds complete; focused effort on completing enrollment in the third quarter of 2017
  - Investigational New Drug Application (IND) accepted by U.S. Food and Drug Administration (FDA) to commence Phase 3 clinical trial of ZX008 in LGS in children and adults; preparations underway to initiate trial in the fourth quarter of 2017, following the availability of top-line data from Study 1 in Dravet syndrome
  - Granted orphan drug designation by FDA for ZX008 for the treatment of LGS
  - Presented new data on the mechanism of action of ZX008 at the 72<sup>nd</sup> Annual Meeting of the Society of Biological Psychiatry
  - Completed second quarter ended June 30, 2017, with \$65.8 million in cash and cash equivalents
-

## **Second Quarter 2017 Financial Results Compared to Second Quarter 2016**

- Total revenue for the second quarter ended June 30, 2017, was \$7.1 million, consisting entirely of contract manufacturing revenue. This compared with total revenue of \$2.1 million in the second quarter ended June 30, 2016, consisting almost entirely of contract manufacturing revenue. The \$5.0 million increase in contract manufacturing revenue in the second quarter of 2017 was primarily due to more Sumavel DosePro units delivered to Endo International.
- Research and development expenses for the second quarter ended June 30, 2017, totaled \$14.9 million, up from \$10.4 million in the second quarter ended June 30, 2016, as the Company progressed enrollment and expanded the scope of its Phase 3 clinical trials for ZX008 in Dravet syndrome.
- Selling, general and administrative expenses for the second quarter ended June 30, 2017, totaled \$5.5 million, compared with \$6.8 million in the second quarter ended June 30, 2016.
- Net loss from continuing operations for the second quarter ended June 30, 2017, was \$22.5 million, compared with \$18.2 million in the second quarter ended June 30, 2016.
- Net loss from discontinued operations for both the second quarter ended June 30, 2017, and June 30, 2016, was \$0.6 million.
- Total net loss for the second quarter ended June 30, 2017, was \$23.0 million, or \$0.93 per share, compared with a net loss of \$18.8 million, or \$0.76 per share, in the second quarter ended June 30, 2016.

## **Six Months Ended June 30, 2017 Financial Results Compared to Six Months Ended June 30, 2016**

- Total revenue for the six months ended June 30, 2017, was \$9.8 million, consisting entirely of contract manufacturing revenue. This compared with total revenue of \$11.3 million in the six months ended June 30, 2016, consisting nearly entirely of contract manufacturing revenue. The decrease was primarily attributable to lower reimbursed production costs under the agreement with Endo. In April 2017, we completed fulfillment of the remaining open orders and ceased all manufacturing activities related to Sumavel DosePro.
  - Research and development expenses for the six months ended June 30, 2017, totaled \$28.2 million, up from \$18.4 million in the six months ended June 30, 2016, as the Company progressed enrollment and expanded the scope of its Phase 3 clinical trials for ZX008 in Dravet syndrome.
  - Selling, general and administrative expenses for the six months ended June 30, 2017, totaled \$12.1 million, compared with \$13.0 million in the six months ended June 30, 2016.
  - Net loss from continuing operations for the six months ended June 30, 2017, was \$43.6 million, compared with \$28.5 million in the six months ended June 30, 2016.
  - Net loss from discontinued operations for the six months ended June 30, 2017, was \$0.7 million, compared with \$0.8 million in the six months ended June 30, 2016.
  - Total net loss for the six months ended June 30, 2017 was \$44.3 million, or \$1.79 per share, compared with a net loss of \$29.2 million, or \$1.18 per share, in the six months ended June 30, 2016.
  - At June 30, 2017, the Company had cash and cash equivalents of \$65.8 million, compared to \$91.6 million at December 31, 2016. The Company believes that it has sufficient funds to support operations into the first half of 2018.
-

## Conference Call Details

**Tuesday, August 8th @ 4:30 PM Eastern Time/1:30 PM Pacific Time**

Toll Free: 800-279-9534

International: 719-325-2450

Conference ID: 6341528

Webcast: <http://public.viavid.com/index.php?id=125147>

Replays, available through August 22, 2017:

Domestic: 844-512-2921

International: 412-317-6671

Replay PIN: 6341528

## 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](http://www.zogenix.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 enrollment of patients in the on-going Phase 3 clinical trials for ZX008; the timing of top line results for the on-going Phase 3 clinical trials (including Study 1); any IND submission and commencement of a Phase 3 clinical trial in 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 may not be predictive of future results; top-line data from Study 1 may not support our NDA for ZX008 in Dravet syndrome; negative top-line data from Study 1 may delay or prevent commencement of the Phase 3 clinical trial in LGS; 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.

## CONTACT:

Investors:

Andrew McDonald

Founding Partner, LifeSci Advisors LLC

646-597-6987 | [Andrew@lifesciadvisors.com](mailto:Andrew@lifesciadvisors.com)

---

**Zogenix, Inc.**  
**Condensed Consolidated Statements of Operations**  
(In Thousands, except Per Share Amounts)  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
<b>Revenue:</b>				
Contract manufacturing revenue	\$ 7,125	\$ 1,986	\$ 9,821	\$ 11,192
Service and other product revenue	—	102	—	102
<b>Total revenue</b>	<b>7,125</b>	<b>2,088</b>	<b>9,821</b>	<b>11,294</b>
<b>Costs and expenses:</b>				
Cost of contract manufacturing	8,242	2,136	10,729	10,011
Research and development	14,850	10,384	28,191	18,371
Selling, general and administrative	5,502	6,844	12,056	12,968
Impairment charges	107	—	920	—
Change in fair value of contingent consideration	500	1,300	1,100	2,600
<b>Total costs and expenses</b>	<b>29,201</b>	<b>20,664</b>	<b>52,996</b>	<b>43,950</b>
Loss from operations	(22,076)	(18,576)	(43,175)	(32,656)
<b>Other income (expense):</b>				
Interest expense, net	(575)	(623)	(1,152)	(1,221)
Change in fair value of common stock warrant liabilities	153	977	740	5,504
Other income (expense)	29	(15)	9	(23)
<b>Total other (expense) income</b>	<b>(393)</b>	<b>339</b>	<b>(403)</b>	<b>4,260</b>
Loss from continuing operations before income taxes	(22,469)	(18,237)	(43,578)	(28,396)
Income tax benefit (expense)	16	(9)	(1)	(71)
Net loss from continuing operations	(22,453)	(18,246)	(43,579)	(28,467)
Net loss from discontinued operations	(555)	(582)	(736)	(751)
<b>Net loss</b>	<b>\$ (23,008)</b>	<b>\$ (18,828)</b>	<b>\$ (44,315)</b>	<b>\$ (29,218)</b>
<b>Net loss per share, basic and diluted:</b>				
Continuing operations	\$ (0.90)	\$ (0.74)	\$ (1.76)	\$ (1.15)
Discontinued operations	\$ (0.03)	\$ (0.02)	\$ (0.03)	\$ (0.03)
<b>Total</b>	<b>\$ (0.93)</b>	<b>\$ (0.76)</b>	<b>\$ (1.79)</b>	<b>\$ (1.18)</b>
Weighted average shares outstanding, basic and diluted	24,822	24,777	24,817	24,774

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

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 65,761	\$ 91,551
Trade accounts receivable	4,684	12,577
Inventory	2,232	7,047
Prepaid expenses and other current assets	6,137	8,739
Total current assets	78,814	119,914
Property and equipment, net	459	1,710
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	1,995	1,147
Total assets	<u>\$ 190,002</u>	<u>\$ 231,505</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,791	\$ 4,549
Accrued expenses	9,551	6,374
Accrued compensation	2,639	3,652
Common stock warrant liabilities	69	809
Working capital advance note payable, net of discount of \$3,493 and \$3,733 at June 30, 2017 and December 31, 2016, respectively	3,507	3,267
Current portion of long-term debt	3,333	—
Deferred revenue	—	1,245
Current liabilities of discontinued operations	1,093	414
Total current liabilities	21,983	20,310
Long term debt	15,757	18,824
Contingent consideration	53,900	52,800
Deferred income taxes	17,425	17,425
Other long-term liabilities	1,455	1,390
Stockholders' equity:		
Common stock, \$0.001 par value; 50,000 shares authorized; 24,839 and 24,813 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	25	25
Additional paid-in capital	568,995	565,954
Accumulated deficit	(489,538)	(445,223)
Total stockholders' equity	79,482	120,756
Total liabilities and stockholders' equity	<u>\$ 190,002</u>	<u>\$ 231,505</u>