
**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): March 9, 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, #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 (see General Instruction A.2. below):

- 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))
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Item 2.02 Results of Operations and Financial Condition.

On March 9, 2017, Zogenix, Inc. issued a press release announcing its financial results for the fourth quarter and full-year ended December 31, 2016. 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 March 9, 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.

Date: March 9, 2017

ZOGENIX, INC.

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 March 9, 2017

**Zogenix Provides Corporate Update and Reports
Fourth Quarter and Full-Year 2016 Financial Results**

Top-Line Data for First Phase 3 Study Expected in 3Q 2017

ZX008 Phase 3 Pivotal Study 1504 Initiated – Target Data Readout by End of 2017

Planned Initiation of Phase 3 study of ZX008 in Lennox Gastaut Syndrome in 2H 2017

Company will host a conference call today at 4:30 p.m. EST/1:30 p.m. PST

EMERYVILLE, California, March 9, 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 fourth quarter and year ended December 31, 2016.

“Zogenix is in a strong operating position, and 2017 has the potential to be a transformative year for the Company,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “We have a clear regulatory pathway for ZX008 in Dravet syndrome and anticipate top-line data readouts from our Phase 3 program this year, the first being in the third quarter. In addition, we intend to initiate a Phase 3 clinical trial for ZX008 in Lennox Gastaut Syndrome (LGS), another rare and severe childhood-onset epilepsy disorder, in the second half of 2017. Our development program is well supported by a strong balance sheet that allows the Company to move forward with no plans to raise capital ahead of the initial Phase 3 data in Dravet syndrome. Zogenix remains confident in ZX008’s therapeutic potential in Dravet syndrome and other refractory orphan epilepsy disorders, and we look forward to leveraging the significant opportunities that lie ahead of us.”

CORPORATE UPDATE

- Established global development plan and regulatory pathway for ZX008 (low-dose fenfluramine) in Dravet syndrome to expedite Phase 3 data readouts for U.S. and European regulatory submissions
 - Three ongoing Phase 3 double-blind, randomized clinical trials evaluating ZX008 as an adjunctive treatment for seizures in children and young adults with Dravet syndrome, having enrolled more than 180 patients to date
 - Identically designed Study 1501 (U.S. and Canada) and Study 1502 (Europe and Australia) will be combined into one adequately powered study (Study 1)
 - Full enrollment of Study 1 expected by end of 1Q 2017
 - Top-line data readout targeted for 3Q 2017
 - Efficacy and safety portion of Study 1504 (Cohort 2) currently enrolling patients in Europe and has been expanded to include sites in U.S. and Canada
 - Study 1504 designed to meet requirements of a Phase 3 pivotal trial in U.S.
 - Enrollment proceeding with a target data readout by end of 2017
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- Received conditional approval from U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for FINTEPLA™ as proprietary name for ZX008
- Method of use patent issued in U.S. for ZX008 in Dravet syndrome that is expected to provide protection of associated claims through 2033
- Granted “orphan drug” designation by European Commission for ZX008 to treat patients with LGS
- Presented new data at 70th American Epilepsy Society Annual Meeting demonstrating effectiveness and safety, including cardiovascular-related safety, for patients treated with ZX008 as an adjunctive therapy for seizures associated with LGS, and continued effectiveness and safety for ongoing open-label patients with Dravet syndrome
- Initiation of Phase 3 clinical trial for ZX008 in LGS planned for second half 2017
- Appointed Michael Smith, a senior executive with more than 18 years of experience in biotechnology industry, as Company’s new Chief Financial Officer
- Completed year ended December 31, 2016, with \$91.6 million in cash and cash equivalents

FINANCIAL RESULTS

Fourth Quarter Financial Results

As a result of the sale of the Zohydro ER business in April 2015, all Zohydro ER revenue and expenses have been excluded from continuing operations for all periods herein and reported as discontinued operations.

- Total revenue for the fourth quarter ended December 31, 2016, was \$11.0 million, consisting entirely of contract manufacturing revenue. This compared with total revenue of \$6.1 million in the fourth quarter ended December 31, 2015, which included \$5.3 million of contract manufacturing revenue.
 - Research and development expenses for the fourth quarter ended December 31, 2016, totaled \$13.4 million, up from \$8.6 million in the fourth quarter ended December 31, 2015, as the Company progressed enrollment in its Phase 3 clinical trials for ZX008 in Dravet syndrome.
 - Selling, general and administrative expenses for the fourth quarter ended December 31, 2016, totaled \$7.5 million, compared with \$6.8 million in the fourth quarter ended December 31, 2015.
 - Net loss from continuing operations for the fourth quarter ended December 31, 2016, was \$23.6 million, compared with \$11.9 million in the fourth quarter ended December 31, 2015.
 - Net income from discontinued operations for the fourth quarter ended December 31, 2016, was \$0.1 million, compared with net income of \$3.0 million in the fourth quarter ended December 31, 2015.
 - Total net loss for the fourth quarter ended December 31, 2016, was \$23.5 million, or \$0.95 per share, compared with a net loss of \$8.8 million, or \$0.36 per share, in the fourth quarter ended December 31, 2015.
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Full-Year Financial Results

As a result of the sale of the Zohydro ER business in April 2015, all Zohydro ER revenue and expenses have been excluded from continuing operations for all periods herein and reported as discontinued operations.

Zogenix and Endo International recently entered into a letter agreement acknowledging Endo's decision to have Zogenix discontinue the manufacturing and supply of the Sumavel DosePro product while the parties finalize the termination of the agreement. Zogenix expects to fulfill orders during the first half of 2017 and to cease to supply Endo with additional Sumavel DosePro following such time. Based on these actions, Zogenix recorded a non-cash \$8.4 million impairment charge under its 2016 operating expenses, which was partially offset by the acceleration of approximately \$4.9 million of previously deferred revenues.

- Total revenue for the year ended December 31, 2016 was \$28.9 million, consisting almost entirely of contract manufacturing revenue. This compared with total revenue of \$27.2 million in the year ended December 31, 2015, which included \$24.4 million in contract revenue and \$2.8 million in service and other product revenue. The increase in contract manufacturing revenue in 2016 as compared to 2015 was primarily due to the impending termination of Zogenix's contract manufacturing supply agreement with Endo and corresponding acceleration of deferred revenue.
 - Research and development expenses for the year ended December 31, 2016, totaled \$41.8 million, up from \$27.9 million in the year ended December 31, 2015, as the Company increased development activities related to the Company's Phase 3 clinical trials in Dravet syndrome and funding of the open-label dose-ranging investigator initiated study in LGS.
 - Selling, general and administrative expenses for the year ended December 31, 2016, totaled \$27.0 million, compared with \$26.3 million in the year ended December 31, 2015.
 - Net loss from continuing operations for the year ended December 31, 2016 was \$68.7 million, compared with \$41.7 million in the year ended December 31, 2015.
 - Net loss from discontinued operations for the year ended December 31, 2016 was \$1.0 million, compared with net income of \$67.8 million in the year ended December 31, 2015, which included the net gain on the sale of the Zohydro ER business.
 - Total net loss for the year ended December 31, 2016, was \$69.7 million, or \$2.81 per share, compared with net income of \$26.1 million, or \$1.22 per share in the year ended December 31, 2015, which included the net gain on the sale of the Zohydro ER business.
 - As of December 31, 2016, the Company had cash and cash equivalents totaling \$91.6 million, as compared to \$155.3 million as of December 31, 2015. Zogenix believes it has sufficient funds to support operations into the first half of 2018.
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CONFERENCE CALL DETAILS

Investors interested in participating in today's live call can dial 877-675-4750 from the U.S. and international callers can dial 719-325-4867 and use conference ID: 1061121. A telephone replay will be available approximately two hours after the call and will run through March 23, by dialing 844-512-2921 from the U.S., or 412-317-6671 from international locations, and entering Replay Pin Number: 1061121. The conference call will be broadcast live and will be available for replay for 60 days at: <http://public.viavid.com/index.php?id=122985> and on the IR section of the Company's website at: <http://www.ir.zogenix.com>.

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.

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 two on-going Phase 3 clinical trials for ZX008; the timing of top line results for the two on-going Phase 3 clinical trials; the timing of any NDA submission; the timing of the commencement of Cohort 2 of Study 1504; the presentation of data at the American Epilepsy Society Annual Meeting; 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 ability of the EMA to reevaluate Orphan Drug Designation for ZX008 for treatment of patients with LGS; the EMA may modify or eliminate the benefits of Orphan Drug Designations generally; 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.

CONTACT:

Investors:

Andrew McDonald

Founding Partner, LifeSci Advisors LLC

646-597-6987 | Andrew@lifesciadvisors.com

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
Revenue:				
Contract manufacturing revenue	\$ 10,988	\$ 5,325	\$ 28,525	\$ 24,369
Service and other product revenue	(2)	756	325	2,813
Total revenue	10,986	6,081	28,850	27,182
Operating expenses (income):				
Cost of contract manufacturing	5,917	4,850	22,173	22,356
Royalty expense	71	96	295	345
Research and development	13,393	8,550	41,840	27,860
Selling, general and administrative	7,490	6,801	26,996	26,347
Change in fair value of contingent consideration	(1,000)	(100)	1,800	(2,000)
Impairment charges	8,431	—	8,431	—
Total operating expenses	34,302	20,197	101,535	74,908
Loss from operations	(23,316)	(14,116)	(72,685)	(47,726)
Other income (expense):				
Interest expense, net	(594)	(700)	(2,382)	(2,959)
Loss on sale of short-term investments	—	(261)	—	(5,746)
Change in fair value of warrant liabilities	239	(242)	5,387	(1,103)
Other income (expense)	44	(15)	46	(71)
Total other (expense) income	(311)	(1,218)	3,051	(9,879)
Net loss from continuing operations before income taxes	(23,627)	(15,334)	(69,634)	(57,605)
Income tax benefit	26	3,472	948	15,901
Net loss from continuing operations	(23,601)	(11,862)	(68,686)	(41,704)
Income (loss) from discontinued operations, net of taxes	109	3,019	(1,021)	67,848
Net (loss) income	\$ (23,492)	\$ (8,843)	\$ (69,707)	\$ 26,144
Net (loss) income per share, basic	\$ (0.95)	\$ (0.36)	\$ (2.81)	\$ 1.22
Net (loss) income per share, diluted	\$ (0.95)	\$ (0.36)	\$ (2.81)	\$ 1.22
Weighted average shares outstanding, basic	24,799	24,764	24,785	21,449
Weighted average shares outstanding, diluted	24,799	24,764	24,785	21,449

Zogenix, Inc.
Consolidated Balance Sheets
(In Thousands, except Per Share Amounts)(Unaudited)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 91,551	\$ 155,349
Restricted cash	—	10,002
Trade accounts receivable	12,577	1,396
Inventory	7,047	12,030
Prepaid expenses	7,404	1,707
Other current assets	1,335	3,811
Current assets of discontinued operations	—	208
Total current assets	119,914	184,503
Property and equipment, net	1,710	9,254
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	1,147	3,331
Total assets	<u>\$ 231,505</u>	<u>\$ 305,822</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,549	\$ 5,290
Accrued expenses	6,374	4,617
Common stock warrant liabilities	809	6,196
Accrued compensation	3,652	3,711
Working capital advance note payable, net of discount of \$3,733	3,267	—
Current portion of long-term debt	—	6,321
Deferred revenue	1,245	945
Current liabilities of discontinued operations	414	2,906
Total current liabilities	20,310	29,986
Long-term debt	18,824	15,899
Deferred revenue, noncurrent	—	6,139
Contingent purchase consideration	52,800	51,000
Deferred tax liability	17,425	18,450
Other long-term liabilities	1,390	1,588
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 50,000 shares authorized; 24,813 and 24,772 shares issued and outstanding at December 31, 2016 and 2015, respectively.	25	25
Additional paid-in capital	565,954	558,251
Accumulated deficit	(445,223)	(375,516)
Total stockholders' equity	<u>120,756</u>	<u>182,760</u>
Total liabilities and stockholders' equity	<u>\$ 231,505</u>	<u>\$ 305,822</u>