

# ZOGENIX

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

May 4, 2017

*Completed Enrollment of Study 1, First Phase 3 Clinical Trial of ZX008 in Dravet Syndrome;*

*Top-Line Results Expected in Third Quarter 2017*

*IND Accepted by FDA for Phase 3 Clinical Trial of ZX008 in Lennox Gastaut Syndrome*

*Company will host a conference call today at 4:30 p.m. EDT/1:30 p.m. PDT*

EMERYVILLE, Calif., May 04, 2017 (GLOBE NEWSWIRE) -- 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 first quarter ended March 31, 2017.

"Zogenix has a clear development pathway to regulatory submissions for ZX008 in the U.S. and Europe in Dravet syndrome," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "With enrollment now complete in Study 1, our first Phase 3 trial, we look forward to the availability of top-line data in the third quarter of this year. We believe ZX008 has the potential to transform the lives of children and their families with Dravet syndrome. Beyond this indication, following the acceptance of our Investigational New Drug Application (IND) by the U.S. Food and Drug Administration (FDA), we are pleased to be in a position to initiate our Phase 3 clinical trial for ZX008 in Lennox Gastaut Syndrome (LGS) after we have the top-line data from Study 1."

### Corporate Update

- Completed enrollment of Study 1 in the Phase 3 program of ZX008 in Dravet syndrome; top-line safety and efficacy results expected in the third quarter of 2017
- Continued enrollment in Phase 3 Study 1504 for ZX008 in patients with Dravet syndrome on background therapy, including stiripentol
- Issued three additional U.S. patents related to ZX008 method of use in Dravet syndrome
- IND accepted by FDA to commence Phase 3 clinical trial of ZX008 in LGS; Phase 3 trial expected to begin in the second half of 2017, following the availability of top-line data from Study 1 in Dravet syndrome
- Completed first quarter ended March 31, 2017, with \$80.1 million in cash and cash equivalents

### First Quarter 2017 Financial Results Compared to First Quarter 2016

- Total revenue for the first quarter ended March 31, 2017, was \$2.7 million, consisting entirely of contract manufacturing revenue. This compared with total revenue of \$9.2 million in the first quarter ended March 31, 2016, also consisting entirely of contract manufacturing revenue. The decrease in contract manufacturing revenue in the first quarter of 2017 was due to a decrease in the number of Sumavel DosePro units delivered to Endo International.
- Research and development expenses for the first quarter ended March 31, 2017 totaled \$13.3 million, up from \$8.0 million in the first quarter ended March 31, 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 first quarter ended March 31, 2017 totaled \$6.6 million, compared with \$6.1 million in the first quarter ended March 31, 2016.
- Net loss from continuing operations for the first quarter ended March 31, 2017 was \$21.1 million, compared with \$10.2 million in the first quarter ended March 31, 2016.
- Net loss from discontinued operations for the first quarter ended March 31, 2017 was \$0.2 million, compared with \$0.2 million in the first quarter ended March 31, 2016.
- Total net loss for the first quarter ended March 31, 2017 was \$21.3 million, or \$0.86 per share, compared with a net loss of \$10.4 million, or \$0.42 per share, in the first quarter ended March 31, 2016.
- At March 31, 2017, the Company had cash and cash equivalents of \$80.1 million. The Company believes that it has sufficient funds to support operations into the first half of 2018.

### Conference Call Details

**Thursday, May 4<sup>th</sup> @ 4:30 PM Eastern Time/1:30 PM Pacific Time**

Toll Free: 888-287-5516

International: 719-325-2436

Conference ID: 2588025

Webcast: <http://public.viaavid.com/index.php?id=123895>

Replays, available through May 18, 2017:

Domestic: 844-512-2921

International: 412-317-6671

Replay PIN: 2588025

## 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.

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

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Contract manufacturing revenue	\$ 2,696	\$ 9,206
Costs and expenses:		
Cost of contract manufacturing	2,487	7,804
Royalty expense	—	71
Research and development	13,341	7,987
Selling, general and administrative	6,554	6,124
Impairment charges	813	—
Change in fair value of contingent consideration	600	1,300
Total costs and expenses	23,795	23,286
Loss from operations	(21,099)	(14,080)
Other income (expense):		
Interest expense, net	(577)	(598)
Change in fair value of common stock warrant liabilities	587	4,527
Other expense	(20)	(7)
Total other (expense) income	(10)	3,922
Loss from continuing operations before income taxes	(21,109)	(10,158)
Income tax expense	(17)	(62)
Net loss from continuing operations	(21,126)	(10,220)
Net loss from discontinued operations	(181)	(169)
Net loss	\$ (21,307)	\$ (10,389)
Net loss per share, basic and diluted:		
Continuing operations	\$ (0.85)	\$ (0.41)
Discontinued operations	\$ (0.01)	\$ (0.01)
Total	\$ (0.86)	\$ (0.42)
Weighted average shares outstanding, basic and diluted	24,813	24,722

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

	<b>March 31, 2017</b>	<b>December 31, 2016</b>
Assets		
Current assets:		

Cash and cash equivalents	\$ 80,108	\$ 91,551
Trade accounts receivable, net	1,027	12,577
Inventory	9,099	7,047
Prepaid expenses and other current assets	8,584	8,739
Total current assets	98,818	119,914
Property and equipment, net	710	1,710
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	1,076	1,147
Total assets	\$ 209,338	\$ 231,505
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,625	\$ 4,549
Accrued expenses	7,427	6,374
Accrued compensation	1,941	3,652
Common stock warrant liabilities	222	809
Working capital advance note payable, net of discount	3,385	3,267
Current portion of long-term debt	1,333	—
Deferred revenue	972	1,245
Current liabilities of discontinued operations	439	414
Total current liabilities	18,344	20,310
Long term debt	17,625	18,824
Contingent consideration	53,400	52,800
Deferred income taxes	17,425	17,425
Other long-term liabilities	1,422	1,390
Stockholders' equity:		
Common stock	25	25
Additional paid-in capital	567,627	565,954
Accumulated deficit	(466,530 )	(445,223 )
Total stockholders' equity	101,122	120,756
Total liabilities and stockholders' equity	\$ 209,338	\$ 231,505

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Zogenix, Inc.