

# ZOGENIX

## Zogenix Provides Corporate Update and Reports Fourth Quarter and Full-Year 2017 Financial Results

March 6, 2018

- **ZX008 Granted Breakthrough Therapy Designation in Dravet syndrome by FDA**
- **Last patient randomized into second Phase 3 clinical trial of ZX008 in patients with Dravet syndrome, Study 1504**
- **Initiated global Phase 3 clinical trial for ZX008 in Lennox-Gastaut syndrome**

EMERYVILLE, Calif., March 06, 2018 (GLOBE NEWSWIRE) -- 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 fourth quarter and year ended December 31, 2017.

"Following positive results from our first global Phase 3 trial, Study 1, evaluating ZX008 in Dravet syndrome, Zogenix entered 2018 in strong operating and financial positions," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "Based on the results from Study 1, we were recently granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for ZX008 in Dravet syndrome. We now look forward to the availability of top-line results towards the end of the second quarter of this year from our second pivotal Phase 3 trial, Study 1504, which recently completed enrollment. Assuming a successful outcome for Study 1504, we intend to submit applications for regulatory approvals of ZX008 as adjunctive treatment for Dravet syndrome in the U.S. and Europe in the fourth quarter of 2018."

"Our second target indication for ZX008, Lennox-Gastaut syndrome (LGS), an indication that affects more patients than Dravet syndrome, also continues to advance. During the fourth quarter, we announced the initiation of a single global Phase 3 trial in LGS required for future regulatory submissions in the U.S. and EU for this indication. Finally, we are supported by a strong balance sheet that was further fortified in the fourth quarter through our secondary public offering of common stock, which culminated in a capital raise of \$271 million in net proceeds."

### Corporate Update

- Breakthrough Therapy Designation granted by FDA for ZX008 in Dravet syndrome
- Completed enrollment of Study 1504; expect top-line results in late second quarter
- Initiated global Phase 3 clinical trial of ZX008 in children and adults with Lennox-Gastaut syndrome
- Presented additional efficacy and safety results from Study 1 at the 71<sup>st</sup> American Epilepsy Society Annual Meeting. The new Study 1 results presented showed the odds of achieving a clinically meaningful ( $\geq 50\%$ ) or substantial ( $\geq 75\%$ ) reduction in convulsive seizure frequency were 29 and 50 times higher, respectively, in patients treated with ZX008 0.8 mg/kg/day as compared to patients treated with placebo. Additionally, 55% of patients treated with ZX008 0.8 mg/kg/day were rated by parents/caregivers as very much improved or much improved in overall condition on the Clinical Global Impression (CGI-C) rating scale compared to 10% of the placebo group ( $p=0.001$ ) and 62.5% of patients treated with ZX008 0.8 mg/kg/day were rated by investigators as very much improved or much improved in overall condition on the CGI-C compared to 10% of the placebo group ( $p=0.001$ ). In addition, the safety profile demonstrated that the drug was generally well-tolerated and there were no clinical or echocardiographic signs of any cardiac abnormality, including no valvulopathy or pulmonary hypertension.
  - 11 additional posters supporting the ongoing open-label trials of ZX008 in refractory epilepsies, and the burden of these conditions, were also presented
- Completed year ended December 31, 2017, with \$293.5 million in cash and cash equivalents

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

- Due to the wind-down of Sumavel DosePro manufacturing operations, the Company recorded no revenue for the three months ended December 31, 2017. This compares with total revenue of \$11.0 million in the fourth quarter ended December 31, 2016, consisting entirely of contract manufacturing revenue for Sumavel DosePro.
- Research and development expenses for the fourth quarter ended December 31, 2017, totaled \$18.1 million, up from \$13.4 million in the fourth quarter ended December 31, 2016, as the Company continued enrollment and expanded the scope of its Phase 3 clinical trials for ZX008 in Dravet syndrome and initiated its global Phase 3 study in LGS.
- Selling, general and administrative expenses for the fourth quarter ended December 31, 2017, totaled \$7.8 million, compared with \$7.5 million in the fourth quarter ended December 31, 2016.
- Net loss from continuing operations for the fourth quarter ended December 31, 2017, was \$39.8 million, compared with a net loss of \$23.6 million in the fourth quarter ended December 31, 2016.
- Total net loss for the fourth quarter ended December 31, 2017, was \$39.7 million, or \$1.17 per share, compared with a net loss of \$23.5 million, or

\$0.95 per share, in the fourth quarter ended December 31, 2016.

#### Year Ended December 31, 2017, Financial Results Compared to Year Ended December 31, 2016

- Total revenue for the year ended December 31, 2017, was \$9.8 million, consisting entirely of contract manufacturing revenue for Sumavel DosePro. This compared with total revenue of \$28.9 million in the year ended December 31, 2016, substantially all of which was 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 year ended December 31, 2017, totaled \$67.4 million, up from \$41.8 million in the year ended December 31, 2016, and was primarily attributable to the progression and expansion of the Company's clinical trial activities related to its Phase 3 development program for ZX008 in Dravet syndrome and LGS.
- Selling, general and administrative expenses for the year ended December 31, 2017, totaled \$25.9 million, compared with \$27.0 million in the year ended December 31, 2016.
- Net loss from continuing operations for the year ended December 31, 2017, was \$126.0 million, compared with \$68.7 million in the year ended December 31, 2016.
- Net loss from discontinued operations for the year ended December 31, 2017, was \$0.8 million, compared with \$1.0 million in the year ended December 31, 2016.
- Total net loss for the year ended December 31, 2017 was \$126.8 million, or \$4.65 per share, compared with a net loss of \$69.7 million, or \$2.81 per share, in the year ended December 31, 2016.
- At December 31, 2017, the Company had cash and cash equivalents of \$293.5 million, compared to \$91.6 million at December 31, 2016. 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, March 6<sup>th</sup> @ 4:30pm Eastern Time/1:30pm Pacific Time**

Toll Free: 800-239-9838  
International: 323-794-2551  
Conference ID: 5092266  
Webcast: <http://public.viavid.com/index.php?id=128365>

Replays, available through March 20:

Domestic: 844-512-2921  
International: 412-317-6671  
Replay PIN: 5092266

#### 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).

Investors: Andrew McDonald  
Founding Partner, LifeSci Advisors LLC  
646-597-6987 | [Andrew@lifesciadvisors.com](mailto: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 enrollment of patients in the planned global Phase 3 clinical trial in Lennox Gastaut Syndrome; the timing of top line results for the Study 1504 clinical trial; the timing or results of regulatory submissions for ZX008 for Dravet syndrome in the U.S. and Europe; the timing of the enrollment of patients or results in our Phase 3 trial in LGS; the timing of our regulatory submissions of ZX008 to treat 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; 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. Consolidated Balance Sheets (In thousands) (Unaudited)

	December 31, 2017	2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 293,503	\$ 91,551
Trade accounts receivable	—	12,577

Inventory	—	7,047
Prepaid expenses	5,994	7,404
Other current assets	5,206	1,335
Total current assets	304,703	119,914
Property and equipment, net	245	1,710
Indefinite-lived intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	3,931	1,147
Total assets	\$ 417,613	\$ 231,505
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,356	\$ 4,549
Accrued expenses	10,499	6,374
Common stock warrant liabilities	512	809
Accrued compensation	6,616	3,652
Working capital advance note payable, net of discount	—	3,267
Deferred revenue	—	1,245
Current liabilities of discontinued operations	—	414
Total current liabilities	20,983	20,310
Long-term debt	—	18,824
Contingent consideration	76,900	52,800
Deferred tax liability	17,425	17,425
Other long-term liabilities	784	1,390
Commitments and contingencies		
Stockholders' equity:		
Common stock	35	25
Additional paid-in capital	873,526	565,954
Accumulated deficit	(572,040)	(445,223)
Total stockholders' equity	301,521	120,756
Total liabilities and stockholders' equity	\$ 417,613	\$ 231,505

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

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
Revenue:				
Contract manufacturing revenue	\$ —	\$ 10,988	\$ 9,821	\$ 28,525
Service and other product revenue	—	(2)	—	325
Total revenue	—	10,986	9,821	28,850
Operating expenses (income):				
Cost of contract manufacturing	—	5,988	10,729	22,468
Research and development	18,080	13,393	67,449	41,840
Selling, general and administrative	7,756	7,491	25,885	26,996
Loss on contract termination	—	—	478	—
Change in fair value of contingent consideration	12,500	(1,000)	24,100	1,800
Asset impairment charges	—	8,431	1,116	8,431
Total operating expenses	38,336	34,303	129,757	101,535
Loss from operations	(38,336)	(23,317)	(119,936)	(72,685)
Other income (expense):				
Interest income	758	81	1,090	443
Interest expense	(579)	(675)	(2,644)	(2,825)
Loss on extinguishment of debt	(1,498)	—	(4,876)	—
Change in fair value of warrant liabilities	(63)	239	297	5,387
Other income (expense)	(24)	45	47	46
Total other (expense) income	(1,406)	(310)	(6,086)	3,051
Net loss from continuing operations before income taxes	(39,742)	(23,627)	(126,022)	(69,634)
Income tax (expense) benefit	(41)	25	—	948
Net loss from continuing operations	(39,783)	(23,602)	(126,022)	(68,686)
Net income (loss) from discontinued operations, net of taxes	75	109	(795)	(1,021)
Net (loss) income	\$ (39,708)	\$ (23,493)	\$ (126,817)	\$ (69,707)
Net (loss) income per share, basic and diluted	\$ (1.17)	\$ (0.95)	\$ (4.65)	\$ (2.81)
Weighted average shares outstanding, basic and diluted	34,057	24,799	27,301	24,785

 [Primary Logo](#)

Source: Zogenix, Inc.