Zogenix Provides Corporate Update and Reports Fourth Quarter and Full-Year 2015 Financial Results

March 10, 2016

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

EMERYVILLE, Calif., March 10, 2016 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ:ZGNX), a pharmaceutical company developing therapies for the treatment of central nervous system (CNS) disorders, today provided a corporate update and announced financial results for the fourth quarter and year ended December 31, 2015.

Corporate Update

- Investigational New Drug (IND) Application for the Phase 3 program for ZX008 for the treatment of Dravet syndrome, a rare and debilitating form of epilepsy that begins in infancy, accepted by the U.S. Food and Drug Administration (FDA).
- Initiated the first Phase 3 clinical trial of ZX008 in the U.S.
- Recently received first national approvals towards commencing the second Phase 3 clinical trial for ZX008 in Europe.
- Received Fast Track designation from the FDA for ZX008 in Dravet syndrome.
- Announced new data demonstrating sustained effectiveness and cardiovascular-related safety in a new cohort of 7 Dravet syndrome patients who began add-on treatment with ZX008 at various starting points between 2010 and 2014.
- Completed the year ended December 31, 2015, with $155.3 million in cash and cash equivalents. Zogenix's expected cash runway extends through 2017.

"With the ZX008 Phase 3 program for Dravet syndrome now underway, and a solid cash position that should take the Company through 2017, Zogenix is in an extremely strong operating position," said Stephen J. Farr, Ph.D., President and CEO. "As we look forward to the remainder of 2016, we have a number of exciting milestones, including the initiation of the European portion of the ZX008 Phase 3 program in Dravet syndrome shortly, and targeting the availability of top-line data from the first phase 3 study by year-end. In addition, we will continue to look to expand the use of ZX008 into additional pediatric orphan refractory epilepsy conditions. To this end, we anticipate the commencement of an Investigator Initiated Study of ZX008 in Lennox Gastaut in the first quarter, with data expected in the fourth quarter of 2016."

Fourth Quarter 2015 Financial Results Compared to Fourth Quarter 2014 Financial Results

As a result of the sale of the Zohydro ER business, all Zohydro ER revenue and expenses have been excluded from continuing operations for all periods herein and reported as discontinued operations. All prior period information has been recast to conform to this presentation.

- Total revenue for the fourth quarter of 2015 was $6.1 million, and reflected $5.3 million of contract manufacturing revenue and $0.8 million of service and other product revenue. This compared with total revenue of $9.9 million in the same quarter last year, which included $8.9 million of contract manufacturing revenue and $1.0 million of service and other product revenue. The decrease in contract manufacturing revenue in the fourth quarter of 2015 was due to the timing of shipments of Sumavel® DosePro® to Endo International Plc under the supply agreement between the two companies.
- Fourth quarter 2015 research and development expenses totaled $8.6 million, up from $3.3 million in the fourth quarter a year ago, as the Company continued preparations for its two Phase 3 studies for ZX008.
- Fourth quarter 2015 selling, general and administrative expenses totaled $6.8 million, compared with $5.8 million in the fourth quarter a year ago.
- Net loss from continuing operations for the fourth quarter of 2015 was $11.9 million, compared with $9.6 million in the same quarter a year ago.
- Net income from discontinued operations was $3.0 million for the fourth quarter of 2015, compared with a net loss of $10.9 million in the fourth quarter a year ago, and reflects revenues recorded from Zohydro prescriptions and final allocation of income taxes between continuing and discontinued operations.
- Total net loss for the fourth quarter of 2015 was $8.8 million, or $0.36 per share, compared with a net loss of $20.5 million, or $1.09 per share, for the fourth quarter a year ago.

Year Ended December 31, 2015 Financial Results Compared to Year Ended December 31, 2014 Financial Results

As a result of the sale of the Zohydro ER business, all Zohydro ER revenue and expenses have been excluded from continuing operations for all periods herein and reported as discontinued operations. All prior period information has been recast to conform to this presentation.

- Total revenue for the year ended December 31, 2015 was $27.2 million, and reflected $24.4 million of contract manufacturing revenue and $2.8 million of service and other product revenue. This compared with total revenue of $28.9 million in the same period last year, which included $15.4 million of contract manufacturing revenue and $13.6 million of net product and service revenue. The increase in contract manufacturing revenue and decrease

in net product revenue in the year ended December 31, 2015 was due to the sale of Sumavel DosePro to Endo International Plc in May 2014 and subsequent performance under the supply agreement between the two companies.

- Research and development expenses for the year ended December 31, 2015 totaled $27.9 million, up from $11.9 million in the year ago period, as the Company continued preparations for its two Phase 3 studies for ZX008 and the multi-dose clinical study for Relday™.

- Selling, general and administrative expenses for the year ended December 31, 2015 totaled $26.3 million, compared with $34.6 million in the year ago period. The Company incurred selling expenses for Sumavel DosePro prior to its sale in May 2014.

- Net loss from continuing operations for the year ended December 31, 2015 was $41.7 million, compared with net income from continuing operations of $61.5 million in the same period a year ago, which includes the pre-tax gain on the sale of Sumavel DosePro.

- Net income from discontinued operations for the year ended December 31, 2015 was $67.8 million, compared to a net loss of $52.9 million in the year ago period. Income from discontinued operations in 2015 includes a gain on the sale of the Zohydro business of $75.4 million, net of applicable tax expense.

- Total net income for the year ended December 31, 2015 was $26.1 million, or $1.22 per share, compared with net income of $8.6 million, or $0.48 per share, for the year ended December 31, 2014.

- Cash and cash equivalents at December 31, 2015 totaled $155.3 million.

2016 Financial Guidance

Below is the Company's financial guidance for the full year 2016.

- Research and development expenses are expected to be $54-59 million, reflecting initiation and ramp-up of ZX008 clinical studies;
- Selling, general and administrative expenses are expected to be $25-27 million; and
- Contract manufacturing revenue from the supply of Sumavel DosePro to Endo is expected at a low single-digit markup over cost of contract manufacturing.

Conference Call Details
Investors interested in participating in today's live call can dial 888-337-8198 from the U.S. and international callers can dial 719-325-2308 and use conference ID: 5464024. A telephone replay will be available approximately two hours after the call and will run through March 24, 2016, by dialing 877-870-5176 from the U.S., or 858-384-5517 from international locations, and entering Replay Pin Number: 5464024. The conference call will be broadcast live and will be available for replay for 60 days at: http://public.viavid.com/index.php?id=118497 and on the IR section of the company's website at: Zogenix IR.

About Zogenix
Zogenix, Inc. (NASDAQ:ZGNX) is an innovative pharmaceutical company committed to providing unique therapeutic solutions for people living with rare and burdensome disease conditions. Our focused strategy centers on advancing late-stage, high-value products for CNS disorders that will significantly improve outcomes for patients and physicians.

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: the Company's financial guidance for the remainder of 2016; the Company's cash position related to operating expenses and planned development activities; the timing of the commencement and results of Phase 3 clinical studies for ZX008; Zogenix's strategy on advancing its novel pipeline in CNS disorders; and the expected timing of, and Zogenix's ability to achieve, key clinical milestones and regulatory meetings and submissions for Zogenix's development pipeline. 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 and Relday, including potential delays in enrollment and completion of clinical trials; the potential that earlier clinical trials 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 that apply to its product development activities; Zogenix could spend its available financial resources faster than it currently expects and may be unable to raise additional capital if and when needed, on acceptable terms or at all; 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 December 31,		Twelve Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
Revenues:				
Contract manufacturing revenue	$ 5,325	$ 8,929	$ 24,369	$ 15,392
Net product revenue	-	-	-	9,840
Service and other product revenue	756	1,009	2,813	3,715
Total revenue	6,081	9,938	27,182	28,947
Operating (income) expense:				

Cost of contract manufacturing	4,850	8,423	22,356	14,342
Cost of goods sold	-	-	-	5,263
Royalty expense	96	80	345	591
Research and development	8,550	3,278	27,860	11,893
Selling, general & administrative	6,801	5,836	26,347	34,639
Change in fair value of contingent consideration	(100)	-	(2,000)	-
Impairment of long-lived assets	-	-	-	838
Net gain on sale of business	-	-	-	(79,980)
Total operating (income) expense	20,197	17,617	74,908	(12,414)
Income (loss) from operations	(14,116)	(7,679)	(47,726)	41,361
Other income (expense):				
Interest expense, net	(700)	(89)	(2,959)	(3,070)
Loss on early extinguishment of debt	-	-	-	(1,254)
Change in fair value of warrant liabilities	(242)	(1,086)	(1,103)	25,332
Change in fair value of embedded derivatives	-	-	-	(14)
Investment loss	(261)	-	(5,746)	-
Other income (expense)	(15)	(743)	(71)	(784)
Total other income (expense)	(1,218)	(1,918)	(9,879)	20,210
Net income (loss) from continuing operations before income taxes	(15,334)	(9,597)	(57,605)	61,571
Benefit (expense) for income taxes	3,472	(39)	15,901	(84)
Net income (loss) from continuing operations	(11,862)	(9,636)	(41,704)	61,487
Income (loss) from discontinued operations, net of applicable tax	3,019	(10,884)	67,848	(52,900)
Net income (loss)	$ (8,843)	$ (20,520)	$ 26,144	$ 8,587
Net income per share, basic	$ (0.36)	$ (1.09)	$ 1.22	$ 0.48
Net income per share, diluted	$ (0.36)	$ (1.09)	$ 1.22	$ 0.48
Weighted average shares outstanding, basic	24,764	18,752	21,449	17,825
Weighted average shares outstanding, diluted	24,764	18,752	21,449	17,855

Zogenix, Inc.
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 155,349	$ 42,205
Restricted cash	10,002	8,500
Trade accounts receivable, net	1,396	6,078
Inventory	12,030	11,444
Prepaid expenses and other current assets	5,611	2,555
Current assets of discontinued operations	208	7,196
Total current assets	184,596	77,978
Property and equipment, net	9,254	10,618
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	3,403	2,832
Noncurrent assets of discontinued operations	-	2,673
Total assets	$ 305,987	$ 202,835
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,290	$ 4,742
Accrued expenses	8,328	9,173
Common stock warrant liabilities	6,196	5,093
Revolving credit facility	-	1,450
Long-term debt, current portion	6,414	-
Deferred revenue	945	1,472
Current liabilities of discontinued operations	2,906	22,307
Total current liabilities	30,079	44,237

Long-term debt, less current portion	15,971	21,703
Deferred revenue, less current portion	6,139	7,063
Contingent purchase consideration	51,000	53,000
Deferred income taxes	18,450	20,500
Other long-term liabilities	1,588	1,053
Stockholders' equity	182,760	55,279
Total liabilities and stockholders' equity	$ 305,987	$ 202,835

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