Zogenix Reports Fourth Quarter and Full Year 2014 Financial Results

March 10, 2015

Conference Call and Webcast to Discuss Fourth Quarter Results and Definitive Agreement to Sell Zohydro ER to Pernix; Scheduled for Today, March 10, at 4:30 p.m. ET

Clinical and Regulatory Update

- Received FDA approval for new formulation of Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules, CII, with BeadTek™
- On track to begin Phase 3 clinical study for ZX008 (orphan drug candidate for Dravet syndrome) in the third quarter 2015; data expected in 2016
- Enrolled first patient in Relday (novel long-acting injectable formulation of risperidone for schizophrenia) multi-dose clinical study; data on track for third quarter 2015

Fourth Quarter 2014 Highlights

- Total prescriptions for Zohydro ER were 18,956, up 25% compared to the third quarter[1]
- Total net revenue of $14.9 million
- Net product revenue of $5.0 million
- Zohydro ER gross factory sales to wholesalers of $9.2 million during the fourth quarter; $27.3 million for full year 2014

SAN DIEGO, March 10, 2015 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of central nervous system (CNS) disorders, today reported financial results for the fourth quarter ended December 31, 2014.

Roger Hawley, chief executive officer of Zogenix, stated, "As we enter 2015, we are very excited about the prospects for our differentiated clinical pipeline featuring ZX008 and Relday. We are confident in our ability to execute on these development programs based on our proven success obtaining product approvals, including the recent approval of the new formulation of Zohydro ER with BeadTek. As a result of this recent approval, our discussions for Zohydro ER evolved into broader strategic interest in the brand, which led to the sale of the Zohydro ER business to Pernix announced today in a separate press release."

[1] Symphony Health Solutions, Source® PHAST Prescription Monthly, October – December 2014

Stephen Farr, president of Zogenix, said, "This year we expect to make significant advancements in our clinical pipeline. We are making excellent progress in preparing for the Phase 3 clinical trial for ZX008, our orphan drug candidate for the treatment of Dravet syndrome, which we expect to begin in the third quarter. The existing long-term data on ZX008 from the open-label European study showed that 67% of patients were seizure-free and 87% had a greater than 90% reduction in seizure frequency, during an average treatment period of greater than 12 years. These are very positive effectiveness data in a disease with significant unmet patient need. We also recently enrolled the first patient with schizophrenia in our multi-dose clinical study for Relday, the successful completion of which will position this asset to be Phase 3 ready and for potential international partnering opportunities. ZX008 and Relday represent significant opportunities for the Company and we look forward to advancing these programs over the course of the year."

Fourth Quarter and Full Year 2014 Financial Results

Total revenues for the fourth quarter 2014, which consisted of net product revenue, contract manufacturing revenue, and service and other revenue, were $14.9 million, up 50% from $9.9 million in the fourth quarter 2013.

Net product revenue for the fourth quarter 2014 was $5.0 million, compared to $9.0 million in the fourth quarter 2013. The Company launched Zohydro ER in March 2014, with revenue recognized based on product dispensed through patient prescriptions as estimated by Source Healthcare Analytics. The fourth quarter 2013 net product revenue consisted of sales from the SUMAVEL DosePro business, which the Company sold in May 2014 to Endo International plc (Endo).

As of December 31, 2014, the Company had $7.1 million in deferred revenue for Zohydro ER sold to wholesalers but not yet dispensed through patient prescriptions. Gross-to-net sales deductions will be recorded at the time the prescription units are dispensed.

Contract manufacturing revenue on SUMAVEL DosePro supplied to Endo under the companies' supply agreement for the fourth quarter 2014 was $8.9 million.

Service and other revenue for the fourth quarter 2014 was $930,000, compared to $915,000 in the fourth quarter 2013, and was primarily comprised of fees from Valeant Pharmaceuticals for the Company's co-promotion of Migranal® Nasal Spray, which began in August 2013.

Total revenues for the full year 2014 were $40.5 million, up 23% from $33.0 million in the full year 2013. Net product revenue for the full year 2014 was $21.7 million, compared to $31.7 million in the full year 2013. Contract manufacturing revenue for the full year 2014 was $15.4 million. Service and other revenue for the full year 2014 was $3.4 million, compared to $1.3 million in the full year 2013.

Cost of goods sold for the fourth quarter 2014 was $9.4 million, compared to $7.1 million in the fourth quarter 2013. Cost of goods sold or the full year 2014 was $15.8 million, compared to $21.2 million in the full year 2013. Cost of sales in the fourth quarter 2014 included an $8.4 million charge for excess and obsolete inventory primarily related to the transition from the original formulation of Zohydro ER to the new formulation with BeadTek technology planned for the second quarter 2015. Excluding this charge, product gross margin for fourth quarter 2014 was 80% compared to 21% in the fourth quarter 2013, and was 66% for full year 2014, compared to 33% for full year 2013. The year-over-year improvement was primarily due to product mix, as the Company launched Zohydro ER in March 2014, and sold the SUMAVEL DosePro business in May 2014.

Cost of contract manufacturing for SUMAVEL DosePro supplied to Endo during the fourth quarter 2014 was $8.4 million, and $14.3 million for full year 2014.

Royalty expense for the fourth quarter 2014 was $495,000, an increase from $341,000 in the fourth quarter 2013. Royalty expense for the full year 2014 was $1.7 million, an increase from $1.2 million in the full year 2013. The increase in royalty expense for the quarter and year reflect the launch of Zohydro ER in March 2014.

Research and development expenses for the fourth quarter 2014 were $6.0 million, up 74% from $3.4 million in the fourth quarter 2013. Research and development expenses for the

full year 2014 were $18.9 million, up 48% from $12.8 million for the full year 2013. The increase in research and development expenses for the quarter and year was primarily due to development expenses for abuse-deterrent formulations and Relday, and, to a lesser degree, the acquisition of Brabant Pharma in October 2014.

Selling, general and administrative expenses were $17.7 million for the fourth quarter 2014, up 31% from $13.5 million for the fourth quarter 2013. Selling, general and administrative expenses were $88.9 million for the full year 2014, up 78% from $50.0 million for the full year 2013. The increase in selling, general and administrative expenses for the quarter and the year was primarily the result of the launch of Zohydro ER, including expansion of the Company's sales force and the addition of its medical affairs team. It also reflects the implementation of the FDA required ER/LA opioids REMS program and the Company's voluntary initiatives to support the responsible commercialization of Zohydro ER.

Other income for the fourth quarter 2014 totaled $6.6 million, compared to expense of $21.1 million in the fourth quarter 2013. Other income for the full year 2014 totaled $28.7 million, compared to expense of $27.7 million in the full year 2013. The other income and expense in 2013 and 2014 reflects a non-cash mark-to-market adjustment to the fair value of the Company's outstanding warrants driven primarily by changes in the Company's stock price. Additionally, in the fourth quarter 2014, the Company recorded $5.0 million income from consideration received for its exclusivity waiver exchange with Purdue Pharma L.P. and $3.5 million income for sale of right to reference its carcinogenicity data to Teva Pharmaceuticals USA, Inc., both related to Zohydro ER.

Net loss for the fourth quarter 2014 was $20.5 million, or $0.14 per share compared to a net loss of $35.6 million, or $0.28 per share, for the fourth quarter 2013. Non-GAAP net loss adjusted for certain non-cash and non-recurring items for the fourth quarter 2014 was $0.13 per share compared to a loss of $0.13 per share for the fourth quarter 2013. Net income for the full year 2014 was $8.6 million, or $0.06 per share compared to a net loss of $80.9 million, or $0.74 per share, for the full year 2013. Non-GAAP net loss adjusted for certain non-cash and non-recurring items for the full year 2014 was $0.65 per share compared to a loss of $0.54 per share for the full year 2013. The adjustments are detailed in the non-GAAP financial results table included in this release.

Cash and cash equivalents as of December 31, 2014 were $42.2 million. Additionally, restricted cash was $8.5 million as of December 31, 2014, consisting of the portion of proceeds from the sale of the SUMAVEL DosePro business to Endo required to be held in escrow until May 2015. On December 30, 2014, the Company secured $20 million in term loans and $4 million in revolving line commitments for working capital and general business purposes.

Ann Rhoads, chief financial officer of Zogenix, said, "Our research and development and selling, general and administrative expenses came in lower than expected for the fourth quarter and full year. We achieved this while also generating positive revenue trends for Zohydro ER."

2015 Financial Guidance

Zogenix is not providing financial guidance on expected 2015 revenues and expenses at this time. However, the Company expects its current financial resources and the expected proceeds from the sale of the Zohydro ER business to provide a cash runway through three significant clinical milestones: the end of phase 2 meeting for Relday, followed by the regulatory submissions in the U.S. and Europe for ZX008, which are anticipated in the fourth quarter 2016. The Company expects to provide updated financial guidance after the transaction is closed on its first quarter 2015 conference call.

Conference Call and Web Cast

Zogenix will hold a conference call today, March 10, 2015 at 4:30 p.m. ET to discuss financial results and operational highlights for the fourth quarter ended December 31, 2014. To participate, please dial (877) 417-5253 (U.S.) or (315) 625-3082 (International); participant passcode: 85134635. To access the live webcast please visit the Zogenix Investor Relations website at http://ir.zogenix.com.

A replay of the conference call will be available beginning March 10, 2015 at 7:30 p.m. ET until March 17, 2015, by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (International); passcode: 85134635. A replay of the webcast will also be accessible on the Investor Relations website for one month, through April 10, 2015.

Discussion during the conference call may include forward-looking statements regarding such topics as, but not limited to, the Company's commercial activities, the Company's financial status and performance, development programs and any comments the Company may make about its future plans or prospects in response to questions from participants on the conference call.

About Zogenix

Zogenix, Inc. (Nasdaq:ZGNX) is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with CNS disorders who need innovative treatment alternatives to help them return to normal daily functioning.

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," "plans," "expects," "will," "potential" 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: Zogenix's cash runway; the timing and likelihood of closing the Zohydro ER transaction; the expected timing of, and Zogenix's ability to achieve, key clinical milestones and regulatory submissions for Zogenix's development pipeline; and the expected timeframes for initiation of and results from clinical trials and other clinical development plans for ZX008 and Relday. Actual results may differ from those set forth in this release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the uncertainty of approval under the Hart Scott Rodino Antitrust Improvements Act for the proposed sale of Zohydro ER; the parties' ability to satisfy the conditions to closing for the proposed transaction on the anticipated timeline or at all; 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; Zogenix's ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its product development and commercial activities; Zogenix's ability to obtain additional financing in order to complete the development and commercialization of its product candidates; and other risks detailed under "Risk Factors" and elsewhere in Zogenix's periodic reports and other filings made with the Securities and Exchange Commission from time to time.

In this press release, Zogenix's financial results are provided both in accordance with accounting principles generally accepted in the United States (GAAP) and using certain non-GAAP financial measures. In particular, Zogenix provides its net income (loss) and net income (loss) per share for the three and twelve months ended on December 31, 2014 and 2013 adjusted for certain non-cash or non-recurring items, which are non-GAAP financial measures. Management believes these non-GAAP financial results reflect the Company's ongoing business in a manner that allows for meaningful period-to-period comparisons and analysis of trends in the Company's business, as they exclude certain income or other expenses that are not reflective of ongoing operating results. Management also believes that these non-GAAP financial results provide useful information to investors and others in understanding and evaluating the Company's operating results and future prospects in the same manner as management, and in comparing financial results across accounting periods and to those of peer companies. Non-GAAP financial measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with GAAP. A reconciliation of the non-GAAP financial results to GAAP financial results is included in the attached financial statements.

DosePro® and Zohydro® ER are registered trademarks of Zogenix, Inc.
BeadTek™ is a trademark used by Zogenix under license.
SUMAVEL® is a registered trademark of Endo International, plc.
MIGRANAL® is a registered trademark of Valeant Pharmaceuticals International, Inc. or its affiliates.

Zogenix, Inc.

Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
	(unaudited)			
Revenues:				
Net product revenue	$ 5,040	$ 9,006	$ 21,715	$ 31,699
Contract manufacturing revenue	8,929	--	15,392	--
Service and other revenue	930	915	3,424	1,313
Total revenue	14,899	9,921	40,531	33,012
Operating (income) expense:				
Cost of goods sold	9,354	7,097	15,817	21,241
Cost of contract manufacturing	8,421	--	14,342	--
Royalty expense	495	341	1,718	1,242
Research and development	5,989	3,447	18,936	12,805
Selling, general & administrative	17,702	13,549	88,899	50,040
Restructuring	--	--	--	876
Impairment of long-lived assets	--	--	838	--
Net gain on sale of business	--	--	(79,980)	--
Total operating expense	41,961	24,434	60,570	86,204
Income (loss) from operations	(27,062)	(14,513)	(20,039)	(53,192)
Other income (expense):				
Interest income	2	6	20	18
Interest expense	(91)	(1,815)	(3,090)	(6,610)
Loss on early extinguishment of debt	--	--	(1,254)	--
Change in fair value of warrant liabilities	(1,086)	(19,147)	25,332	(21,927)
Change in fair value of embedded derivatives	--	(153)	(14)	759
Other income (expense)	7,755	6	7,716	96
Total other income (expense)	6,580	(21,103)	28,710	(27,664)
Net income (loss) before income taxes	(20,482)	(35,616)	8,671	(80,856)
Provision for income taxes	(39)	--	(84)	--
Net income (loss)	$ (20,521)	$ (35,616)	$ 8,587	$ (80,856)
Net income (loss) per share, basic and diluted	$ (0.14)	$ (0.28)	$ 0.06	$ (0.74)
Weighted average shares outstanding, basic	150,016	127,869	142,607	108,568
Weighted average shares outstanding, diluted	150,016	127,869	145,046	108,568

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

	December 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,205	$ 72,021
Restricted cash	8,500	--
Trade accounts receivable, net	8,877	6,665
Inventory	13,439	9,936
Prepaid expenses and other current assets	4,957	4,257
Total current assets	77,978	92,879
Property and equipment, net	10,618	13,011
Intangible assets	102,500	--
Goodwill	6,234	--
Other assets	5,505	6,614
Total assets	$ 202,835	$ 112,504
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	$ 8,523	$ 4,622
Accrued expenses	20,576	22,817
Common stock warrant liabilities	5,093	31,341
Revolving credit facility	1,450	--
Deferred revenue	8,595	--
Total current liabilities	44,237	58,780
Long term debt	21,703	28,802
Contingent purchase consideration	53,000	--
Deferred tax liability	20,500	--
Other long-term liabilities	8,116	6,496
Stockholders' equity	55,279	18,426
Total liabilities and stockholders' equity	$ 202,835	$ 112,504

Zogenix, Inc.

Non-GAAP Financial Results[(1)]

(in thousands, except per share amounts)

	Three Months Ended December 31,		**Twelve Months Ended December 31,**	
	2014	**2013**	**2014**	**2013**
	(unaudited)		**(unaudited)**	
Net income (loss) (as reported, GAAP)	$ (20,521)	$ (35,616)	$ 8,587	$ (80,856)
Net income (loss) per share (as reported, GAAP)	**$ (0.14)**	**$ (0.28)**	**$ 0.06**	**$ (0.74)**
Adjustments for certain non-cash or non-recurring items:				
Change in fair value of warrant liabilities	$ 1,086	$ 19,147	$ (25,332)	$ 21,927
Change in fair value of embedded derivatives	--	153	14	(759)
Charge for excess and obsolete inventory	8,363	--	8,363	--
Consideration received for exclusivity waiver exchange	(5,000)	--	(5,000)	--
Sale of right to reference carcinogenicity data	(3,500)	--	(3,500)	--
Restructuring expenses	--	--	--	876
Impairment of long-lived assets	--	--	838	--
Net gain on sale of business	--	--	(79,980)	--
Loss on extinguishment of debt	--	--	1,254	--
UK stamp duty on Brabant	692	--	692	--
Total adjustments to net loss	$ 1,641	$ 19,300	$ (102,651)	$ 22,044
Net loss adjusted for certain non-cash or non-recurring items	$ (18,880)	$ (16,316)	$ (94,064)	$ (58,812)
Adjusted net loss per share (non-GAAP)	**$ (0.13)**	**$ (0.13)**	**$ (0.65)**	**$ (0.54)**
Weighted average shares outstanding diluted	150,016	127,869	145,046	108,568

(1) Management believes these non-GAAP financial results reflect the Company's ongoing business in a manner that allows for meaningful period-to-period comparisons and analysis of trends in the Company's business, as they exclude certain income or other expenses that are not reflective of ongoing operating results. Management also believes that these non-GAAP financial results provide useful information to investors and others in understanding and evaluating the Company's operating results and future prospects in the same manner as management, and in comparing financial results across accounting periods and to those of peer companies.

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