Zogenix Reports Third Quarter 2014 Financial Results

November 6, 2014

Conference Call and Webcast Today, November 6, at 4:30 p.m. ET

Recent Business Highlights

- Submitted a supplemental New Drug Application (sNDA) for a modified formulation with potential abuse deterrent properties of Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules, CII, on September 30, with a target action date in late January 2015
- Acquired Brabant Pharma, obtaining global rights for a Phase 3 product candidate with orphan drug designation in the U.S. and Europe for the treatment of Dravet syndrome
- Exchanged waivers of regulatory exclusivity for extended-release hydrocodone products with Purdue Pharma, which includes $10 million in payments and potential sales royalties from Purdue
- Signed a non-binding term sheet that is anticipated to provide a $20 million term loan plus an additional $4 million in a revolving line of credit

Third Quarter 2014 Highlights

- Total prescriptions for Zohydro ER were 15,134 for the third quarter, up 47% compared to the second quarter; and 1,385 for the most recent week ended October 24[(1)]
- Total net revenue of $8.8 million
- Net product revenue of $4.1 million
- Zohydro ER gross factory sales to wholesalers of $6.5 million during the third quarter; $18.1 million year-to-date

SAN DIEGO, Nov. 6, 2014 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of pain-related and central nervous system (CNS) disorders, today reported financial results for the third quarter ended September 30, 2014.

Roger Hawley, chief executive officer of Zogenix, stated, "During the third quarter we continued to execute on our strategy for Zohydro ER, and remain on track for potential approval in the first quarter of 2015 for a formulation of Zohydro ER with potential abuse deterrent properties. We further strengthened our long-term position with the recent waiver exchange with Purdue, which reduces risk and provides greater clarity on the regulatory pathway for our abuse deterrent extended-release hydrocodone product candidates."

Mr. Hawley added, "In late October, we completed the transformative acquisition of Brabant Pharma and its product candidate, Brabafen™, which has already received orphan drug status in both the U.S. and Europe. Our research and development team has begun planning for the Phase 3 program, which will begin in the second quarter of 2015, to help bring this important new treatment option to Dravet syndrome patients. In addition, the Relday multi-dose clinical and safety study for schizophrenia is on track to begin in January, progressing further our CNS pipeline."

Third Quarter 2014 Financial Results

Total revenues for the third quarter 2014, which consisted of net product revenue, contract manufacturing revenue, and service and other revenue, were $8.8 million, up 23% from $7.2 million in the third quarter 2013.

Net product revenue for the third quarter 2014 was $4.1 million, compared to $6.9 million in the third quarter 2013. The third 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).

The Company began commercializing Zohydro ER in March 2014, with recognized revenue based on product dispensed through patient prescriptions as estimated by Source Healthcare Analytics. As of September 30, 2014, the Company had $7.9 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 sales of SUMAVEL DosePro to Endo under the companies' supply agreement for the third quarter 2014 was $4.2 million.

Service and other revenue for the third quarter 2014 was $447,000, compared to $271,000 in the third quarter 2013. Service and other revenue in both periods was primarily comprised of fees from Valeant Pharmaceuticals for the Company's co-promotion of Migranal® Nasal Spray, which began in August 2013.

Cost of sales for the third quarter 2014 was $706,000, compared to $5.4 million in the third quarter 2013. Product gross margin was 83% in the third quarter 2014, compared to 22% in the third quarter 2013. The increase in product gross margin was primarily due to product mix, as the Company's only commercial product in the third quarter 2014 was Zohydro ER and the only commercial product in the third quarter 2013 was SUMAVEL DosePro. Cost of manufacturing services for SUMAVEL DosePro supplied to Endo during the third quarter 2014 was $4.0 million.

Royalty expense for the third quarter 2014 was $425,000, an increase from $281,000 in the third quarter 2013, reflecting the launch of Zohydro ER in March 2014.

Research and development expenses for the third quarter 2014 were $5.3 million, representing a 108% increase from $2.5 million in the third quarter 2013. The increase in research and development expenses was primarily due to an increase in development expenses for Zohydro ER abuse-deterrent formulations and Relday.

Selling, general and administrative expenses were $19.1 million for the third quarter 2014, representing a 90% increase from $10.0 million for the third quarter 2013. The increase in selling, general and administrative expenses 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 third quarter 2014 totaled $7.9 million, compared to $170,000 in the third quarter 2013, reflecting 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.

Net loss for the third quarter 2014 was $12.8 million, or $0.09 per share compared to a net loss of $10.9 million, or $0.10 per share, for the third quarter 2013. Non-GAAP net loss adjusted for certain non-cash items for the third quarter 2014 was $0.15 per share compared to a loss of $0.12 per share for the third quarter 2013. The adjustments are detailed in the non-GAAP financial results table included in this release.

Cash and cash equivalents as of September 30, 2014 were $50.5 million. Additionally, restricted cash was $8.5 million as of September 30, 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.

Ann Rhoads, chief financial officer of Zogenix, said, "In conjunction with the acquisition of Brabant Pharma, we signed a non-binding term sheet for a $20 million term loan and a $4 million revolving line of credit. We expect to receive $10 million in funding over the next eight months from our waiver exchange with Purdue in addition to a $3.5 million payment from Teva Pharmaceuticals for the right to reference our carcinogenicity data for their pending NDA for extended-release hydrocodone (which has no impact on their review timeline). This additional non-dilutive capital will fund the initial $20 million payment to Brabant and help support our ongoing commercial and clinical activities."

2014 Financial Guidance

The Company reiterates its 2014 financial guidance with the following update:

- Expecting combined research and development and selling, general and administrative expenses of $25 million to $27 million for the fourth quarter, resulting in 2014 spending at the low end of the full-year range previously provided.

Conference Call and Web Cast

Zogenix will hold a conference call today, November 6, 2014 at 4:30 p.m. ET to discuss financial results and operational highlights for the third quarter ended September 30, 2014. To participate, please dial (877) 417-5253 (U.S.) or (315) 625-3082 (International); participant passcode: 18407877. 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 November 6, 2014 at 7:30 p.m. ET until November 13, 2014, by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (International); passcode: 18407877. A replay of the webcast will also be accessible on the Investor Relations website for one month, through December 6, 2014.

Discussion during the conference call may include forward-looking statements regarding such topics as, but not limited to, the Company's commercial activities relating to Zohydro ER and Migranal, prescription trends, the Company's financial status and performance, the Brabafen development program, the Relday development program 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 pain-related conditions and 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: the expected timing of the FDA review and action date and potential approval of the sNDA for Zohydro ER; the timing of the commencement of Phase 3 clinical trials for Brabafen and a multi-dose clinical and safety study for Relday; the exchange of waivers with Purdue Pharma reducing risk and providing greater clarity on the regulatory pathway for the abuse deterrent extended-release hydrocodone pipeline and the receipt of future payments from Purdue Pharma and Teva Pharmaceutical Industries; updated financial guidance for 2014; and the ability to secure debt financing based on the non-binding term sheet. 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: risks and uncertainties associated with regulatory review and approval of the sNDA, including the risk that additional information or data requests from the FDA could significantly delay the FDA's review period; Zogenix's dependence on the successful commercialization of Zohydro ER; Zogenix's ability to achieve broad market acceptance and generate revenues from sales of Zohydro ER; public concern regarding the safety of drug products such as Zohydro ER and the impact of negative publicity and political influences relating to the regulation of the pain management market in general and opioids and Zohydro ER in particular; competition from other pharmaceutical or biotechnology companies; risks associated with the acquisition of Brabant and integration of Brabant's operations into Zogenix's business, including an increase in near and long-term expenditures, exposure to unknown liabilities and diversion of Zogenix's management's time and attention; Zogenix's dependence on its contract manufacturers and its ability to ensure an adequate and continued supply of Zohydro ER to meet market demand; Zogenix's dependence on third parties to develop an abuse deterrent formulation of Zohydro ER, Relday and Brabafen; the potential that earlier clinical trials may not be predictive of future results; Zogenix's ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend the patents covering Zohydro ER, including the potential for Paragraph IV litigation relating to the product; the potential product liability exposure associated with pharmaceutical products such as Zohydro ER and Sumavel DosePro and other products Zogenix may in-license or acquire; Zogenix's ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its commercial activities; the risk that Zogenix will be unable to negotiate and enter into definitive agreements for a potential debt financing, on acceptable terms, or at all; Zogenix's ability to raise additional funding that it may need to continue to pursue its commercial and business development plans; 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 nine months ended on September 30, 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.

(1) Symphony Health Solutions, Source® PHAST Prescription Monthly, July – September 2014; and Symphony Health Solutions, Source® PHAST Prescription Weekly, week ending October 24, 2014

Zogenix, Inc.

Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014 (unaudited)	2013	2014 (unaudited)	2013
Revenues:				
Net product revenue	$ 4,125	$ 6,897	$ 16,675	$ 22,693
Contract manufacturing revenue	4,225	--	6,463	--
Service and other revenue	447	271	2,494	398
Total revenue	8,797	7,168	25,632	23,091
Operating (income) expense:				
Cost of goods sold	706	5,354	6,463	14,144
Cost of contract manufacturing	3,986	--	5,921	--
Royalty expense	425	281	1,223	901
Research and development	5,289	2,544	12,947	9,358
Selling, general & administrative	19,056	10,011	71,197	36,491
Restructuring	--	--	--	876
Impairment of long-lived assets	--	--	838	--
Net gain on sale of business	--	--	(79,980)	--
Total operating expense	29,462	18,190	18,609	61,770
Income (loss) from operations	(20,665)	(11,022)	7,023	(38,679)
Other income (expense):				
Interest income	6	1	18	12
Interest expense	(84)	(1,587)	(2,999)	(4,795)
Loss on early extinguishment of debt	--	--	(1,254)	--
Change in fair value of warrant liabilities	7,948	215	26,418	(2,780)
Change in fair value of embedded derivatives	--	1,474	(14)	912
Other income (expense)	15	67	(39)	90
Total other income (expense)	7,885	170	22,130	(6,561)
Net income (loss) before income taxes	(12,780)	(10,852)	29,153	(45,240)
Provision for income taxes	(45)	--	(45)	--
Net income (loss)	$ (12,825)	$ (10,852)	$ 29,108	$ (45,240)
Net income (loss) per share, basic	$ (0.09)	$ (0.10)	$ 0.21	$ (0.44)
Net income (loss) per share, diluted	$ (0.09)	$ (0.10)	$ 0.02	$ (0.44)
Weighted average shares outstanding, basic	141,045	104,682	140,110	102,136
Weighted average shares outstanding, diluted	141,045	104,682	140,474	102,136

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

	September 30, 2014 (unaudited)	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 50,527	$ 72,021
Restricted cash	8,500	--
Trade accounts receivable, net	5,886	6,665
Inventory	19,271	9,936
Prepaid expenses and other current assets	6,406	4,257
Total current assets	90,590	92,879
Property and equipment, net	10,615	13,011
Other assets	5,821	6,614
Total assets	$ 107,026	$ 112,504

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 8,177	$ 4,622
Accrued expenses	17,856	22,817
Common stock warrant liabilities	4,007	31,341
Deferred revenue	9,303	--
Total current liabilities	39,343	58,780
Note payable	2,375	--
Long term debt	--	28,802
Other long-term liabilities	7,773	6,496
Stockholders' equity	57,535	18,426
Total liabilities and stockholders' equity	$ 107,026	$ 112,504

Zogenix, Inc.

Non-GAAP Financial Results[(1)]

(in thousands, except per share amounts)

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2014	**2013**	**2014**	**2013**
	(unaudited)		**(unaudited)**	
Net loss for basic EPS (as reported, GAAP)	$ (12,825)	$ (10,852)	$ 29,108	$ (45,240)
Effect of dilutive securities:				
Common stock warrants [(2)]	$ --	$ --	$ (26,418)	$ --
Total adjustments to net loss for dilutive EPS	$ --	$ --	$ (26,418)	$ --
Net income (loss) for diluted EPS (as reported, GAAP)	$ (12,825)	$ (10,852)	$ 2,690	$ (45,240)
Net income (loss) per share, diluted (as reported, GAAP)	**$ (0.09)**	**$ (0.10)**	**$ 0.02**	**$ (0.44)**
Adjustments for certain non-cash or non-recurring items:				
Change in fair value of warrant liabilities	$ (7,948)	$ (215)	$ --	$ 2,780
Change in fair value of embedded derivatives	--	(1,474)	14	(912)
Restructuring expenses	--	--	--	876
Impairment of long-lived assets	--	--	838	--
Net gain on sale of business	--	--	(79,980)	--
Total adjustments to net loss	$ (7,948)	$ (1,689)	$ (79,128)	$ 2,744
Net loss adjusted for certain non-cash or non-recurring items	$ (20,773)	$ (12,541)	$ (76,438)	$ (42,496)
Adjusted net loss per share, diluted (non-GAAP)	**$ (0.15)**	**$ (0.12)**	**$ (0.54)**	**$ (0.42)**
Weighted average shares outstanding, diluted	141,045	104,682	140,474	102,136

(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.

(2) Common stock warrants were included in the dilutive net loss per share calculation only in the period for which their effect was dilutive

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