Zogenix Reports Third Quarter 2013 Financial Results

November 4, 2013

Business Highlights and Milestones

- Received FDA Approval for Zohydro™ ER (hydrocodone bitartrate), an extended-release oral formulation of hydrocodone without acetaminophen
- Announced development and option agreement with Altus Formulation Inc. for abuse deterrent formulations of Zohydro ER
- Began co-promotion of Migranal® (dihydroergotamine mesylate, USP) Nasal Spray in August

SUMAVEL® DosePro® (sumatriptan injection) Third Quarter 2013 Highlights

- Net product revenue of $6.9 million, which reflected a $2.4 million increase to future product returns reserve
- Generated approximately 21,000 total prescriptions, 4% growth over the second quarter 2013
- Sold approximately 139,000 units, up 4% over the third quarter 2012 and 10% over second quarter 2013
- Maintained positive quarterly refill rate at 45%*

SAN DIEGO, Nov. 4, 2013 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of central nervous system disorders and pain, today reported financial results for the third quarter ended September 30, 2013.

On October 25, 2013, Zogenix announced that the U.S. Food and Drug Administration (FDA) approved Zohydro™ ER (hydrocodone bitartrate), an extended-release oral formulation of hydrocodone without acetaminophen, for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Zogenix expects to launch Zohydro ER in March 2014.

Roger Hawley, chief executive officer of Zogenix, stated, "The recent FDA approval of Zohydro ER is a testament to the dedication and expertise of our employees, and fulfills a critical need for patients suffering with chronic pain. Zohydro, the second product that Zogenix has taken through clinical development, regulatory review and approval, will allow us to further leverage our established sales and marketing infrastructure. Over the next several months, we will focus on evaluating potential co-marketing opportunities and completing pre-commercial activities for Zohydro ER. We expect to launch Zohydro ER in March 2014."

On November 1, 2013, Zogenix also announced a Development and Option Agreement with Altus Formulation Inc. to develop abuse deterrent formulations of Zohydro ER, which is consistent with FDA draft guidance on the evaluation and labeling of abuse deterrent opioids. The Company believes Altus' technology can be customized to match the current pharmacokinetic profile of Zohydro ER, enabling Zogenix to bridge to the safety and efficacy established in the recently approved NDA.

Third Quarter 2013 Financial Results

Total revenues for the third quarter 2013, which consists of net product revenue and service and other revenue, were $7.2 million, compared to $8.5 million in the third quarter 2012. Net product revenue on sales of Sumavel DosePro for the third quarter 2013 was $6.9 million, which included a $2.4 million increase to the Company's estimate of future product returns. This compares to net product revenue of $8.5 million in the third quarter 2012. The decrease in net product revenue was primarily driven by the increase to the return reserve, partially offset by a 4% increase in unit volume. Service and other revenue for the third quarter 2013 was $271,000, which was primarily comprised of fees from Valeant Pharmaceuticals for the Company's co-promotion of Migranal® Nasal Spray, which began in August 2013.

Mr. Hawley noted, "During the quarter, we continued to maintain demand for Sumavel DosePro despite the reduction in force announced in June that decreased the number of Zogenix sales reps in the field. In August, we began co-promoting Migranal, further expanding our migraine business with another important treatment option to offer physicians and the patients they serve."

Cost of sales for the third quarter 2013 was $5.4 million, compared to $4.2 million in the third quarter 2012. Product gross margin was 22% in the third quarter 2013, compared to 50% in the third quarter 2012. The decrease in product gross margin in the third quarter 2013 was primarily due to a lower average net selling price resulting from the returns reserve adjustment as well as a one-time scrap charge and excess capacity charge during the quarter.

Royalty expense for the third quarter 2013 was $281,000 compared to $325,000 in the third quarter 2012, reflecting the impact of decreased net product revenue.

Research and development expenses for the third quarter 2013 were $2.5 million, representing a 30% decrease from $3.7 million in the third quarter 2012. The decrease in research and development expenses was primarily the result of lower development costs for Relday and Zohydro ER.

Selling, general and administrative expenses were $10.0 million for the third quarter 2013, representing an 8% decrease from $10.9 million for the third quarter 2012. The decrease in selling, general and administrative expenses was primarily the result of the Company's cost control initiatives initiated in June 2013.

Other income for the third quarter 2013 totaled $170,000, compared to other expense of $8.6 million in the third quarter 2012. For both periods, other income and expense was primarily comprised of interest expense related to the Company's financing agreements and non-cash income or expense related to fair value adjustments of the Company's warrant and derivative liabilities. A table with a full description of other income and expense is included in this release.

Net loss for the third quarter 2013 was $10.9 million, or $0.10 per share, compared to a net loss of $19.3 million, or $0.21 per share, for the third quarter 2012. There were 104.7 million weighted average shares outstanding for the third quarter 2013 compared to 90.4 million for the third quarter 2012. Non-GAAP net loss adjusted for certain non-cash or non-recurring items for the third quarter 2013 was $0.12 per share as detailed in the non-GAAP financial results table included in this release.

Cash and cash equivalents as of September 30, 2013 were $17.4 million, compared to $16.1 million in cash and cash equivalents on June 30, 2013. In March 2013, Zogenix established a controlled equity offering program, pursuant to which Zogenix may from time to time sell up to $25.0 million of its common stock through Cantor Fitzgerald & Co. During the third quarter 2013, the Company sold 6.8 million shares of its common stock pursuant to this program at a weighted average price of $1.66 per share, resulting in net proceeds of approximately $10.9 million.

About Zogenix

Zogenix, Inc. (Nasdaq:ZGNX), with offices in San Diego and Emeryville, California, is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with CNS and pain-related conditions who need innovative treatment alternatives to help them return to normal daily functioning. Zogenix developed and commercialized the first needle-free subcutaneous injection, SUMAVEL® DosePro® (sumatriptan injection) for migraine and cluster headache. Zogenix recently received FDA approval for Zohydro ER (hydrocodone bitartrate) extended-release capsules, the first extended-release oral formulation of hydrocodone without acetaminophen. The development pipeline for Zogenix includes a once-monthly subcutaneous injection for schizophrenia.

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 timing of the launch of Zohydro ER, leveraging Zogenix's existing sales and marketing infrastructure for Zohydro ER, Zogenix's evaluation of potential co-marketing opportunities for Zohydro ER, the potential of Zohydro ER to provide a significant new management alternative in the chronic pain market and the potential to develop abuse deterrent formulations of Zohydro ER with Altus, including the ability to customize the Altus technology to match the current pharmacokinetic profile of Zohydro ER. 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 press release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the timing and success of the commercial launch of Zohydro ER and Zogenix's ability to drive market demand for Zohydro ER; the market potential for migraine and pain treatments, and Zogenix's ability to compete within those markets; Zogenix's ability to obtain additional financing as needed to support its operations; Zogenix's ability to successfully execute its sales and marketing strategy for the commercialization of SUMAVEL DosePro and Zohydro ER; inadequate therapeutic efficacy or unexpected adverse side effects relating to SUMAVEL DosePro, Migranal or, once launched, Zohydro ER that could prevent their ongoing commercialization, or that could result in recalls or product liability claims; the ability of Zogenix and its licensors to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of its products and product candidates and the ability to operate its business without infringing the intellectual property rights of others; difficulties in identifying, negotiating and carrying out co-marketing or similar strategic transactions relating to Zohydro ER; risks and uncertainties associated with the development and regulatory approval of an abuse deterrent formulation of Zohydro ER and Zogenix's reliance on Altus and its drug delivery platform in such development efforts; Zogenix's ability to successfully sell Migranal to Zogenix's customer base of prescribers; the inherent risks of clinical development of Relday, including potential delays in enrollment and completion of clinical trials; competition from other pharmaceutical or biotechnology companies; and other risks detailed 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.

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 loss and net loss per share for the three months ended on September 30, 2013 and 2012 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.

ZohydroTM ER is a trademark and SUMAVEL® and DosePro® are registered trademarks of Zogenix, Inc.

Migranal® is a registered trademark of Valeant Pharmaceuticals International, Inc. or its affiliates.

*Source Healthcare Analytics, Source® PHAST Prescription Monthly, July – September 2013

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Zogenix, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2013	**2012**	**2013**	**2012**
	(unaudited)		**(unaudited)**	
Revenues:				
Net product revenue	$ 6,897	$ 8,453	$ 22,693	$ 26,368
Contract revenue	--	--	--	8,462
Service and other revenue	271	--	398	--
Total revenues	7,168	8,453	23,091	34,830
Operating expenses:				
Cost of sales	5,354	4,249	14,144	13,478
Royalty expense	281	325	901	997
Research and development	2,544	3,660	9,358	16,005
Selling, general & administrative	10,011	10,857	36,491	37,574
Restructuring	--	--	876	--
Total operating expenses	18,190	19,091	61,770	68,054
Loss from operations	(11,022)	(10,638)	(38,679)	(33,224)
Total other expense, net	170	(8,644)	(6,561)	(13,514)
Net loss before income taxes	(10,852)	(19,282)	(45,240)	(46,738)
Provision for income taxes	--	--	--	(5)
Net loss	$ (10,852)	$ (19,282)	$ (45,240)	$ (46,743)

Net loss per share, basic and diluted	$ (0.10)	$ (0.21)	$ (0.44)	$ (0.63)
Weighted average shares outstanding, basic and diluted	104,682	90,370	102,136	73,790

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

	September 30, 2013 (unaudited)	**December 31, 2012**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,352	$ 41,228
Trade accounts receivable, net	6,161	5,643
Inventory, net	12,089	12,886
Prepaid expenses and other current assets	1,772	2,254
Total current assets	37,374	62,011
Property and equipment, net	12,943	13,561
Other assets	4,316	5,114
Total assets	$ 54,633	$ 80,686
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 2,972	$ 4,592
Accrued expenses	19,046	18,569
Common stock warrant liabilities	12,273	9,493
Total current liabilities	34,291	32,654
Long-term debt, less current portion	28,719	28,481
Other long-term liabilities	5,512	5,078
Stockholders' (deficit) equity	(13,889)	14,473
Total liabilities and stockholders' equity	$ 54,633	$ 80,686

Zogenix, Inc.
Net Product Revenue
($ in thousands)

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2013 (unaudited)	**2012**	**2013 (unaudited)**	**2012**
U.S. Units Shipped	138,780	133,500	385,920	420,960
U.S. Gross Product Sales	$ 13,724	$ 11,975	$ 37,349	$ 37,760
Product Sales Allowances:				
Allowance for Product Sales Discounts	3,803	2,986	9,542	9,376
Allowance for Product Returns	3,048	537	5,142	2,416
Total Product Sales Allowances	6,851	3,523	14,684	11,792
U.S. Net Product Revenue	6,873	8,452	22,665	25,968
Non-U.S. Net Product Revenue	24	1	28	400

Total Net Product Revenue	$ 6,897	$ 8,453	$ 22,693	$ 26,368

Zogenix, Inc.

Other Income (Expense)

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	**2012**	**2013**	**2012**
	(unaudited)		**(unaudited)**	
Interest income	$ 1	$ 11	$ 12	$ 40
Interest expense:				
Healthcare Royalty Partners interest expense[1]	(1,547)	(1,429)	(4,468)	(4,133)
Imputed interest expense on Astellas tail payments	(40)	(93)	(327)	(414)
Oxford/SVB interest expense	--	(1,940)	--	(4,176)
Other interest expense	--	(1)	--	(7)
Total interest expense, net	(1,587)	(3,463)	(4,795)	(8,730)
Change in fair value of warrant liabilities[2]	215	(3,569)	(2,780)	(3,611)
Change in fair value of embedded derivatives[3]	1,474	(202)	912	166
Other income (expense)	67	(1,421)	90	(1,379)
Total other income (expense)	$ 170	$ (8,644)	$ (6,561)	$ (13,514)

1. The Company accrues interest expense on the Healthcare Royalty Partners (previously called Cowen Healthcare Royalty Partners II, LP) debt obligation using an effective interest method at a rate in the mid-to-high teens, while actual quarterly revenue interest payments are made at a rate of 5.75% of net product revenue (prior to April 1, 2012, the rate was 5.0%). The revenue interest cash payments owed for the three months ending September 30, 2013 and 2012 were $409,000 and $486,000, respectively, and for the nine months ended September 30, 2013 and 2012 were $1,324,000 and $1,422,000, respectively.

2. The change in fair value of warrant liabilities relates to a fair value adjustment recorded on the warrants to purchase common stock issued in connection with our July 2012 public offering and issued in connection with our Healthcare Royalty Partners financing agreement.

3. The change in fair value of embedded derivatives relates to a fair value adjustment recorded on the embedded derivatives associated with the Healthcare Royalty Partners financing agreement.

Zogenix, Inc.

Non-GAAP Financial Results*

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	**2012**	**2013**	**2012**
	(unaudited)		**(unaudited)**	
Net loss (as reported, GAAP)	$ (10,852)	$ (19,282)	$ (45,240)	$ (46,743)
Net loss per share, basic and diluted (as reported, GAAP)	$ (0.10)	$ (0.21)	$ (0.44)	$ (0.63)
Adjustments for certain non-cash or non-recurring items:				
Restructuring expenses	--	--	(876)	--
Change in fair value of warrant liabilities	215	(3,569)	(2,780)	(3,611)
Change in fair value of embedded derivatives	1,474	(202)	912	166
Warrant issuance costs	--	(1,423)	--	(1,423)
Total Adjustments to Net loss	1,689	(5,194)	(2,744)	(4,868)
Net loss adjusted for certain non-cash or non-recurring items	$ (12,541)	$ (14,088)	$ (42,496)	$ (41,875)
Adjusted net loss per share (non-GAAP)	**(0.12)**	**(0.16)**	**(0.42)**	**(0.57)**

Weighted average shares outstanding, basic and diluted	104,682	90,370	102,136	73,790

*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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