Zogenix Reports Fourth Quarter and Full Year 2012 Financial Results

March 15, 2013

Conference Call and Webcast Today, March 15, at 8:30 a.m. ET

SUMAVEL® DosePro® (sumatriptan injection) Highlights

- 2012 net product revenue of $35.9 million, up 18% over 2011
- Fourth quarter net product revenue of $9.5 million, up 12% over third quarter
- Increased total prescriptions to over 83,000 in 2012, up 16% over 2011*
- Transitioned co-promotion responsibilities to Mallinckrodt's (Covidien) sales force, which began focused co-promotion at the beginning of October 2012
- Maintained consistent quarterly refill rate at approximately 44%*

Recent Highlights and Milestones

- Completion of the FDA review of the New Drug Application for Zohydro™ ER (hydrocodone bitartrate extended-release capsules) delayed past the Prescription Drug User Fee Act (PDUFA) target action date of March 1, 2013, with FDA indication that delay would likely be brief and last only several weeks
- Reported positive results for Relday™ phase 1 study; extended study to potentially accelerate development and partnering opportunities

SAN DIEGO, March 15, 2013 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain, today reported financial results for the fourth quarter and full year ended December 31, 2012.

Roger Hawley, chief executive officer of Zogenix, stated, "2012 was an important year of development for the Company. We drove 18% growth in net product sales of SUMAVEL DosePro and transitioned to a new co-promotion partner, Mallinckrodt, that is well positioned to work with our team to further expand product adoption in 2013.

"We continue to move forward with launch preparations for Zohydro ER while we wait for further communication from the FDA on the NDA. We believe that Zohydro ER, an extended-release hydrocodone formulation without acetaminophen, meets an important medical need based on its safety and efficacy profile. If approved, we anticipate launching the product three to four months after approval."

Fourth Quarter and Full Year 2012 Financial Results

Total revenues for the fourth quarter 2012 of $9.5 million consisted solely of net product revenue. During the fourth quarter 2011, total revenues of $7.9 million also included $2.5 million in contract revenue related to the Company's previous co-promotion agreement with Astellas which ended March 31, 2012. Net product revenues for the fourth quarter 2012 of $9.5 million were up 75% from $5.4 million in the fourth quarter 2011. Total revenues for the full year 2012, which consist of net product revenue and contract revenue, were $44.3 million, up 18% from $37.6 million in 2011. Net product revenues for the full year 2012 were $35.9 million, up 18% from $30.4 million in 2011. Contract revenue for the full year 2012 was $8.5 million, and includes the final amortization of license and milestone payments received from Astellas, the amortization of which was accelerated due to the earlier termination date of the co-promotion agreement. This compares to contract revenue of $7.2 million in 2011.

Cost of sales for the fourth quarter 2012 was $6.0 million, compared to $5.0 million in the fourth quarter 2011. Product gross margin was 37% in the fourth quarter 2012, compared to 9% in the fourth quarter 2011. This improvement in product gross margin was primarily due to an increase in average net selling price.

Cost of sales for the full year 2012 was $19.5 million, compared to $19.3 million in 2011. Product gross margin was 46% in the full year 2012, compared to 37% in 2011. This improvement in product gross margin was primarily due to a decrease in average unit cost.

Royalty expense for the fourth quarter and full year 2012 was $0.4 million and $1.4 million, compared to $0.2 million and $1.2 million in the fourth quarter and full year 2011, reflecting the impact of increased net product revenue.

Research and development expenses for the fourth quarter 2012 were $5.4 million, compared to $5.5 million in the fourth quarter 2011. Research and development expenses for the full year 2012 were $21.4 million, a 35% decrease from $33.0 million in 2011. The decrease in research and development expenses was primarily the result of lower costs associated with the Phase 3 clinical trials for Zohydro ER, which were completed in 2011, and an upfront fee paid in July 2011 upon execution of the Relday license agreement.

Selling, general and administrative expenses for the fourth quarter 2012 were $11.9 million, a 33% decrease from $17.8 million in the fourth quarter 2011. The decrease in selling, general and administrative expenses was primarily the result of a $5.7 million decrease in service fees to Astellas due to the termination of the co-promotion agreement on March 31, 2012.

Selling, general and administrative expenses for the full year 2012 were $49.5 million, an 18% decrease from $60.5 million in 2011. The decrease in selling, general and administrative expenses was primarily the result of a $10.8 million decrease in service fees to Astellas due to the March 31, 2012 termination of the co-promotion agreement and a decrease in advertising and promotional expenses. This was partially offset by an increase in field sales force costs.

Other income for the fourth quarter was $13.6 million, which includes a $15.4 million non-cash mark-to-market adjustment in the fair value of the Company's outstanding warrants. Other income for the full year 2012 was not significant on a net basis. A table with a full description of other income and expense is included in this release.

Net loss for the fourth quarter 2012 was $0.6 million, or $0.01 per share, compared to a net loss of $23.7 million, or $0.36 per share, for the fourth quarter 2011. There were 100.7 million weighted average shares outstanding for the fourth quarter 2012 compared to 65.2 million for the fourth quarter of 2011. Non-GAAP net loss adjusted for certain non-cash or non-recurring items for the fourth quarter 2012 was $0.16 per share as detailed in the non-GAAP financial results table included in this release.

Net loss for the full year 2012 was $47.4 million, or $0.59 per share, compared to a net loss of $83.9 million, or $1.96 per share, for 2011. There were 80.6 million weighted average shares outstanding for the full year 2012 compared to 42.7 million for the full year 2011. Non-GAAP net loss adjusted for certain non-cash or non-recurring items for the full year 2012 was $0.72 per share as detailed in the non-GAAP financial results table included in this release.

Cash and cash equivalents as of December 31, 2012, were $41.2 million.

Because of the pending decision from the FDA regarding the potential approval of Zohydro ER, and the related business implications, the Company is not providing full year 2013 financial guidance at this time.

Conference Call and Web Cast

Zogenix will hold a conference call today, March 15, 2013 at 8:30 a.m. ET to discuss financial results and operational highlights for the fourth quarter and full year ended December 31, 2012.

To participate, please dial (866) 202-3048 (U.S.) or (617) 213-8843 (International); participant passcode: 73489853. 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 15, 2013 at 10:30 a.m. ET (7:30 a.m. PT) until March 22, 2013, by dialing (888) 286-8010 (U.S.) or (617) 801-6888 (International); passcode: 78479681. A replay of the webcast will also be accessible on the Investor Relations website for one month, through April 15, 2013.

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 SUMAVEL DosePro, prescription trends, the Company's financial status and performance, the Zohydro ER 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), with offices in San Diego and Emeryville, California, is a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Zogenix's first commercial product, SUMAVEL® DosePro® (sumatriptan injection) Needle-free Delivery System, was launched in January 2010 for the acute treatment of migraine and cluster headache. Zogenix's lead investigational product candidate, Zohydro™ ER (hydrocodone bitartrate), is an oral, extended-release formulation of various strengths of hydrocodone, without acetaminophen, intended for administration every 12 hours for around the clock management of moderate to severe chronic pain. In May 2012, Zogenix submitted to the FDA a New Drug Application for Zohydro ER. Zogenix's second investigational product candidate, Relday™, is a proprietary, long-acting injectable formulation of risperidone for the treatment of schizophrenia; an investigational new drug application was submitted to the FDA in May 2012.

For additional information, please visit www.zogenix.com.

Forward Looking Statements

Zogenix cautions you that statements included in this press release and the conference call 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 potential to accelerate development and partnering opportunities for Relday; the expected sales growth and adoption of SUMAVEL DosePro, including through the efforts of Mallinckrodt; the delay in the target action date for the FDA to complete its review of the Zohydro ER NDA; and the expected launch timing of Zohydro ER, if approved. 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 market potential for migraine treatments, and Zogenix's ability to compete within that market; Zogenix's ability to successfully execute its sales and marketing strategy for the commercialization of SUMAVEL DosePro; Zogenix's reliance on Mallinckrodt to co-promote SUMAVEL DosePro; inadequate therapeutic efficacy or unexpected adverse side effects relating to SUMAVEL DosePro that could prevent its ongoing commercialization, or that could result in recalls or product liability claims; the potential for Zohydro to receive regulatory approval on a timely basis or at all, including as a result of the delay in the PDUFA target action date for the Zohydro ER NDA; the potential for adverse safety findings relating to Zohydro ER or negative publicity concerning opioids in general to delay or prevent regulatory approval or commercialization; the potential for delays associated with any additional data required by the FDA to be submitted by Zogenix in support of the NDA; 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 strategic transactions relating to Zohydro ER and Relday; the inherent risks of clinical development of Relday, including potential delays in enrollment and completion of clinical trials, and Zogenix's dependence on its collaboration with DURECT Corporation to develop Relday; and other risks described in Zogenix's 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 and twelve months ended on December 31, 2012 and 2011, 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.

*Source Healthcare Analytics, Source® PHAST Prescription Monthly, January – December 2012

Zogenix, Inc.

Consolidated Financial Results

(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
	(unaudited)			
Revenues:				
Net product revenue	$ 9,496	$ 5,425	$ 35,864	$ 30,411
Contract revenue	--	2,476	8,462	7,165
Total revenues	9,496	7,901	44,326	37,576
Operating expenses:				
Cost of sales	6,018	4,961	19,496	19,293
Royalty expense	357	232	1,353	1,205

Research and development	5,409	5,503	21,414	33,043
Selling, general & administrative	11,920	17,818	49,494	60,459
Total operating expenses	23,704	28,514	91,757	114,000
Loss from operations	(14,208)	(20,613)	(47,431)	(76,424)
Total other income (expense)	13,565	(3,121)	50	(7,488)
Loss before income taxes	(643)	(23,734)	(47,381)	(83,912)
Income tax	--	29	(5)	9
Net loss	$ (643)	$ (23,705)	$ (47,386)	$ (83,903)
Net loss per share, basic and diluted	$ (0.01)	$ (0.36)	$ (0.59)	$ (1.96)
Weighted average shares outstanding, basic and diluted	100,714	65,215	80,558	42,712

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

	December 31, 2012	**December 31, 2011**
ASSETS		
Current assets		
Cash and cash equivalents	$ 41,228	$ 56,525
Trade accounts receivable, net	5,643	4,913
Inventory, net	12,886	16,776
Prepaid expenses and other current assets	1,968	2,210
Total current assets	61,725	80,424
Property and equipment, net	13,561	14,590
Other assets	5,400	5,626
Total assets	$ 80,686	$ 100,640
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 4,592	$ 5,168
Accrued expenses	18,569	14,553
Common stock warrant liabilities	9,493	345
Revolving credit facility	--	5,081
Long-term debt, current portion	--	9,758
Deferred revenue	--	8,462
Current liabilities	32,654	43,367
Long-term debt, less current portion	28,481	42,070
Other long-term liabilities	5,078	5,891
Stockholders' equity	14,473	9,312
Total liabilities and stockholders' equity	$ 80,686	$ 100,640

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

	Three Months Ended December 31,		**Twelve Months Ended December 31,**	
	2012 (unaudited)	**2011**	**2012 (unaudited)**	**2011**
U.S. Units Shipped	145,020	115,440	565,980	438,720
2010 Deferred Product Revenue Units	--	--	--	50,053
Total Product Revenue Units	145,020	115,440	565,980	488,773

Gross U.S. Wholesaler Product Sales	$ 13,549	$ 10,353	$ 51,309	$ 38,483
Gross 2010 Deferred Product Revenue	--	--	--	4,190
Total Gross U.S. Product Sales	13,549	10,353	51,309	42,673
Product Sales Allowances:				
Allowance for Product Sales Discounts	3,575	2,543	12,951	7,873
Allowance for Product Returns	518	2,387	2,934	4,394
Total Product Sales Allowances	4,093	4,930	15,885	12,267
U.S. Net Product Revenue	9,456	5,423	35,424	30,406
EU and Other Net Product Revenue	40	2	440	5
Total Net Product Revenue	$ 9,496	$ 5,425	$ 35,864	$ 30,411

Zogenix, Inc.
Other Income (Expense)
(in thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012 (unaudited)	2011	2012 (unaudited)	2011
Interest income	$ 13	$ 16	$ 53	$ 37
Interest expense:				
Healthcare Royalty Partners interest expense[1]	(1,444)	(1,442)	(5,577)	(2,666)
Imputed interest expense on Astellas tail payments	(136)	--	(550)	--
Oxford/SVB interest expense[2]	--	(1,216)	(4,176)	(4,953)
Other interest expense	(3)	(2)	(10)	(25)
Total interest expense	(1,583)	(2,660)	(10,313)	(7,644)
Change in fair value of warrant liabilities[3]	15,422	(101)	11,811	445
Change in fair value of embedded derivatives	(313)	(377)	(147)	(240)
Other income (expense)				
Warrant issuance costs[4]	--	--	(1,423)	--
Other	26	1	69	(86)
Other income (expense), net	26	1	(1,354)	(86)
Total other income (expense)	$ 13,565	$ (3,121)	$ 50	$ (7,488)

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 and twelve months ending December 31, 2012 were $546,000 and $1,968,000, respectively.

2. The Company's debt obligations with Oxford Finance LLC and Silicon Valley Bank were repaid in July 2012, and the expenses relating to these obligations will not recur in future periods.

3. Change in fair value of warrants issued in the July 2012 public equity offering and the July 2011 financing agreement with Healthcare Royalty Partners. Income from this item during the three and twelve months ended December 31, 2012 was driven primarily by the decrease in the Company's stock price in December 2012.

4. This non-recurring expense consists of offering costs, including underwriters discounts and commissions, allocated to the warrants issued in the Company's July 2012 public equity offering.

Zogenix, Inc.

Non-GAAP Financial Results*

(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	**2011**	**2012**	**2011**
	(unaudited)		**(unaudited)**	
Net loss (as reported, GAAP)	$ (643)	$ (23,705)	$ (47,386)	$ (83,903)
Net loss per share, basic and diluted (as reported, GAAP)	**$ (0.01)**	**$ (0.36)**	**$ (0.59)**	**$ (1.96)**
Adjustments for certain non-cash or non-recurring items:				
Change in fair value of warrant liability	$ 15,422	$ (101)	$ 11,811	$ 445
Change in fair value of derivatives	(313)	(377)	(147)	(240)
Warrant issuance costs	0	0	(1,423)	0
Total Adjustments to Net loss	15,109	(478)	10,241	205
Net loss adjusted for certain non-cash or non-recurring items	$ (15,752)	$ (23,227)	$ (57,627)	$ (84,108)
Adjusted net loss per share (non-GAAP)	**$ (0.16)**	**$ (0.36)**	**$ (0.72)**	**$ (1.97)**
Weighted average shares outstanding, basic and diluted	100,714	65,215	80,558	42,712

*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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