Zogenix Reports Second Quarter 2013 Financial Results

August 8, 2013

Conference Call and Webcast Today, August 8, at 4:30 p.m. ET

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

- Net product revenue of $8.9 million, up 11% over the second quarter 2012
- Generated approximately 20,000 total prescriptions
- Maintained positive quarterly refill rate at 43%*

Recent Highlights and Milestones

- Zohydro™ ER New Drug Application (NDA) still under review with FDA
- Entered exclusive U.S. co-promotion agreement for Migranal® (dihydroergotamine mesylate, USP) Nasal Spray and launched product through Zogenix sales force in August
- Implemented significant cost control initiatives to extend cash runway to reach key business milestones that may occur over the remainder of the year

SAN DIEGO, Aug. 8, 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 second quarter ended June 30, 2013.

Roger Hawley, chief executive officer of Zogenix, stated, "Based on our recent interactions, the FDA is working on the Zohyrdo ER NDA and has indicated that it is reviewing the NDA as fast as possible and that nothing has changed with respect to reaching an action letter this summer. We have been reassured again that there are no deficiencies in the application. If approved, Zogenix will be prepared to launch Zohydro ER approximately three to four months after approval."

Mr. Hawley added, "We had commercial success with SUMAVEL DosePro in the second quarter and in early June we took important actions to extend our cash runway in anticipation of potential key business milestones that may occur over the remainder of the year. Since then, we have signed, and already commenced our activities under, our exclusive U.S. co-promotion agreement for Migranal, which leverages our sales force and expertise in migraine. We will continue to explore other opportunities to build a leading specialty migraine franchise and expect the Migranal co-promotion agreement will have a positive impact on our commercial operations. During the quarter we also made good progress with our partnering discussions for Relday™ and out-licensing initiatives for the DosePro needle-free delivery system, both of which represent significant opportunities to build shareholder value."

Second Quarter 2013 Financial Results

Net product revenue for the second quarter 2013 was $8.9 million, up 11% compared to $8.0 million in the second quarter 2012. The increase in net product revenue was primarily driven by a higher net selling price in the second quarter compared to the prior year period.

Cost of sales for the second quarter 2013 was $4.6 million, compared to $4.2 million in the second quarter 2012. Product gross margin of 48% in the second quarter 2013 was unchanged from the second quarter 2012.

Royalty expense for the second quarter 2013 was $338,000 compared to $315,000 in the second quarter 2012, reflecting the impact of increased net product revenue.

Research and development expenses for the second quarter 2013 were $3.6 million, representing a 44% decrease from $6.4 million in the second quarter 2012. The decrease in research and development expenses was primarily the result of lower development costs for Zohydro ER, for which the Company completed an NDA submission during the second quarter 2012.

Selling, general and administrative expenses were $12.0 million for the second quarter 2013, down slightly compared to $12.1 million for the second quarter 2012.

Second quarter 2013 operating expenses included an $876,000 restructuring charge related to the Company's previously announced cost control initiatives.

Other expense for the second quarter 2013 totaled $0.9 million, compared to $2.3 million in the second quarter 2012. For both periods, other expense is 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 second quarter 2013 was $13.3 million, or $0.13 per share, compared to a net loss of $17.2 million, or $0.26 per share, for the second quarter 2012. There were 100.9 million weighted average shares outstanding for the second quarter 2013 compared to 65.4 million for the second quarter 2012. Non-GAAP net loss adjusted for certain non-cash or non-recurring items for the second quarter 2013 was $0.13 per share as detailed in the non-GAAP financial results table included in this release.

Cash and cash equivalents as of June 30, 2013 were $16.1 million. 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. As of August 7, 2013, the Company had agreed to sell 3,013,724 shares of its common stock pursuant to this program at a weighted average price of $1.66 per share, for a total of $5.0 million in gross proceeds. None of the proceeds are included in the Company's cash and cash equivalents as of June 30, 2013.

Ann Rhoads, chief financial officer of Zogenix, said, "In conjunction with our cost control initiatives, we decided to raise capital under our controlled equity offering program in an effort to maintain an adequate cash position as we wait for the FDA's decision on Zohydro ER."

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 financial guidance at this time.

Conference Call and Web Cast

Zogenix will hold a conference call today, August 8, 2013 at 4:30 p.m. ET to discuss financial results and operational highlights for the second quarter ended June 30, 2013.

To participate, please dial (800) 322-2803 (U.S.) or (617) 614-4925 (International); participant passcode: 66351191. 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 August 8, 2013 at 6:30 p.m. ET until August 15, 2013 by dialing (888) 286-8010 (U.S.) or (617) 801-6888 (International); passcode: 21413433. A replay of the webcast will also be accessible on the Investor Relations website for one month, through September 8, 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 co-promotion of Migranal, the Company's efforts to secure a development and commercialization partner for Relday, the Company's out-licensing initiatives for the DosePro needle-free delivery system, 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; the expected launch timing of Zohydro ER, if approved; the potential for the co-promotion of Migranal to help the Company achieve profitability; the possibility of adding complementary migraine therapies to the Company's product portfolio; efforts to secure a strategic development and commercialization partner for Relday; and efforts to out-license the DosePro needle-free delivery system. 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 ER 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 and recent FDA determinations concerning abuse deterrent properties of existing opioid drugs; 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; Zogenix's ability to successfully sell Migranal to Zogenix's customer base of prescribers; unexpected adverse side effects relating to Migranal that could prevent its ongoing commercialization, or that could result in recalls or product liability claims; the potential early termination of the Migranal co-promotion agreement; the inherent risks of clinical development of Relday, including potential delays in enrollment and completion of clinical trials; and Zogenix's dependence on its existing collaboration with DURECT Corporation and potential new partners 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 ended on June 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.

*Source Healthcare Analytics, Source® PHAST Prescription Monthly, April – June 2013

FPR

Zogenix, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
	(unaudited)		(unaudited)	
Revenues:				
Net product revenue	$ 8,942	$ 8,030	$ 15,924	$ 17,915
Contract revenue	--	--	--	8,462
Total revenues	8,942	8,030	15,924	26,377
Operating expenses:				
Cost of sales	4,630	4,167	8,789	9,229
Royalty expense	338	315	620	672

Research and development	3,577	6,381	6,814	12,345
Selling, general & administrative	12,000	12,068	26,482	26,717
Restructuring	876	--	876	--
Total operating expenses	21,421	22,931	43,581	48,963
Loss from operations	(12,479)	(14,901)	(27,657)	(22,586)
Total other expense, net	(853)	(2,268)	(6,732)	(4,870)
Net loss before income taxes	(13,332)	(17,169)	(34,389)	(27,456)
Provision for income taxes	--	--	--	(5)
Net loss	$ (13,332)	$ (17,169)	$ (34,389)	$ (27,461)
Net loss per share, basic and diluted	$ (0.13)	$ (0.26)	$ (0.34)	$ (0.42)
Weighted average shares outstanding, basic and diluted	100,876	65,449	100,843	65,409

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

	June 30, 2013 (unaudited)	**December 31, 2012**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,121	$ 41,228
Trade accounts receivable, net	4,138	5,643
Inventory, net	13,185	12,886
Prepaid expenses and other current assets	2,044	2,254
Total current assets	35,488	62,011
Property and equipment, net	13,414	13,561
Other assets	4,496	5,114
Total assets	$ 53,398	$ 80,686
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 6,337	$ 4,592
Accrued expenses	14,570	18,569
Common stock warrant liabilities	12,488	9,493
Total current liabilities	33,395	32,654
Long-term debt, less current portion	28,638	28,481
Other long-term liabilities	7,452	5,078
Stockholders' equity (deficit)	(16,087)	14,473
Total liabilities and stockholders' equity (deficit)	$ 53,398	$ 80,686

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

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2013 (unaudited)	**2012**	**2013 (unaudited)**	**2012**
U.S. Units Shipped	126,600	138,120	247,140	287,460
U.S. Gross Product Sales	$ 12,310	$ 12,389	$ 23,756	$ 25,785
Product Sales Allowances:				
Allowance for Product Sales Discounts	2,931	3,006	5,738	6,390
Allowance for Product Returns	437	1,355	2,094	1,879

Total Product Sales Allowances	3,368	4,361	7,832	8,269
U.S. Net Product Revenue	8,942	8,028	15,924	17,516
EU Net Product Revenue	--	2	--	399
Total Net Product Revenue	$ 8,942	$ 8,030	$ 15,924	$ 17,915

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

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2013	**2012**	**2013**	**2012**
	(unaudited)		**(unaudited)**	
Interest income	$ 3	$ 10	$ 11	$ 29
Interest expense:				
Healthcare Royalty Partners interest expense[1]	(1,459)	(1,369)	(2,921)	(2,705)
Imputed interest expense on Astellas tail payments	(146)	(164)	(287)	(321)
Oxford/SVB interest expense[2]	--	(1,054)	--	(2,235)
Other interest expense	10	(2)	--	(6)
Total interest expense	(1,595)	(2,589)	(3,208)	(5,267)
Change in fair value of warrant liabilities[3]	1,264	(91)	(2,995)	(42)
Change in fair value of embedded derivatives	(480)	330	(562)	368
Other income (expense)	(45)	72	22	42
Total other income (expense)	$ (853)	$ (2,268)	$ (6,732)	$ (4,870)

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 June 30, 2013 and 2012 were $514,000 and $462,000, respectively, and for the six months ended June 30, 2013 and 2012 were $916,000 and $936,000, 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 six months ended June 30, 2013 was driven primarily by changes in the Company's stock price at the warrant liability measurement dates.

Zogenix, Inc.
Non-GAAP Financial Results*
(in thousands, except per share amounts)

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2013	**2012**	**2013**	**2012**
	(unaudited)		**(unaudited)**	
Net loss (as reported, GAAP)	$ (13,332)	$ (17,169)	$ (34,389)	$ (27,461)
Net loss per share, basic and diluted (as reported, GAAP)	$ (0.13)	$ (0.26)	$ (0.34)	$ (0.42)
Adjustments for certain non-cash or non-recurring items:				
Restructuring expenses	(876)	--	(876)	--
Change in fair value of warrant liabilities	1,264	(91)	(2,995)	(42)
Change in fair value of embedded derivatives	(480)	330	(562)	368
Total Adjustments to Net loss	(92)	239	(4,433)	326
Net loss adjusted for certain non-cash or non-recurring items	$ (13,240)	$ (17,408)	$ (29,956)	$ (27,787)

Adjusted net loss per share (non-GAAP)	**$ (0.13)**	**$ (0.27)**	**$ (0.30)**	**$ (0.42)**
Weighted average shares outstanding, basic and diluted	100,876	65,449	100,843	65,409

*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.

CONTACT: INVESTORS:
Zack Kubow | The Ruth Group
646.536.7020 | zkubow@theruthgroup.com

MEDIA:
Amy Wheeler | The Ruth Group
646.536.7025 | awheeler@theruthgroup.com

Zogenix