

ZOGENIX

Zogenix Reports Third Quarter 2012 Financial Results

November 8, 2012

Growth Continues in Product Sales and Pipeline Remains on Track

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

SUMAVEL[®] DosePro[®] (sumatriptan injection) Third Quarter 2012 Highlights

- \$8.5 million net product revenue, 5% increase over the second quarter 2012
- Zogenix team generated approximately 20,000 total prescriptions in the third quarter*
- Trained Mallinckrodt (Covidien) pain management sales force, who began full scale promotion of SUMAVEL DosePro in October
- Maintained consistent refill rate for SUMAVEL DosePro at 43% from the second quarter 2012*

Recent Highlights and Milestones

- On track with new product pipeline
- Food and Drug Administration (FDA) Advisory Committee meeting for Zohydro[™] ER (hydrocodone bitartrate extended-release capsules) on December 7, 2012; assigned PDUFA date of March 1, 2013
- Relday[™] phase 1 study completion expected by end of 2012
- Strengthened financial position through \$65.4 million equity offering and repayment of all outstanding loans with Oxford Finance LLC and Silicon Valley Bank

SAN DIEGO, Nov. 8, 2012 (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 third quarter ended September 30, 2012.

Roger Hawley, chief executive officer of Zogenix, stated, "The next several months represent key developments for the Company's products. Our team continues to drive SUMAVEL DosePro prescription growth while devoting time to support the product launch with the Mallinckrodt sales force. Following the close of their fiscal year end in September, the Mallinckrodt team has scaled up promotion efforts on the brand and are excited to have the opportunity to introduce the unique benefits of SUMAVEL DosePro to their customers." Hawley continued, "During the quarter, we strengthened the Company through an equity offering and debt repayment while also making significant progress on our product pipeline and planning the commercialization of Zohydro ER."

Stephen J. Farr, Ph.D., president and chief operating officer of Zogenix, said, "We continue to believe we are well positioned for the FDA Advisory Committee meeting for Zohydro ER next month and the potential FDA approval in March, followed by the commercial launch planned for late in the second quarter of 2013. The Relday open-label, safety and pharmacokinetic (PK) trial is ongoing and we remain on track to complete the study by year-end 2012. These important upcoming milestones provide potential opportunities with strategic commercialization partners for Zohydro ER and Relday."

Third Quarter 2012 Financial Results

Net product revenues for the third quarter 2012 were \$8.5 million, compared to \$8.8 million in the third quarter 2011. During the third quarter 2011, total revenues of \$10.4 million also included \$1.6 million in contract revenue related to the Company's previous co-promotion agreement with Astellas which ended March 31, 2012.

Cost of sales for the third quarter 2012 was \$4.2 million, compared to \$5.5 million in the third quarter 2011. Product gross margin was 50% in the third quarter 2012, compared to 38% in the third quarter 2011. This improvement in gross product margin is primarily due to a decrease in excess capacity charges.

Royalty expense for the third quarter 2012 was \$325,000, compared to \$343,000 in the third quarter 2011, reflecting the impact of decreased net product revenue.

Research and development expenses for the third quarter 2012 were \$3.7 million, representing a 64% decrease from \$10.1 million in the third quarter 2011. The decrease in research and development expenses was the result of lower costs associated with the Phase 3 clinical trials for Zohydro ER, which were completed in 2011. The third quarter 2011 also included a one-time \$2.25 million up-front license payment to Durect made in connection with the execution of the Relday development and license agreement and a \$750,000 milestone payment to Alkermes made in connection with the completion of the Phase 3 study (801) for Zohydro ER.

Selling, general and administrative expenses for the third quarter 2012 were \$10.9 million, representing a 26% decrease from \$14.7 million in the third quarter 2011. The decrease in selling, general and administrative expenses was primarily the result of a \$3.7 million decrease in service fees to Astellas due to the termination of the co-promotion agreement on March 31, 2012 and a decrease in advertising and promotional expenses. This was partially offset by an increase in product sampling costs and field sales force costs.

Other expenses for the third quarter 2012 were \$8.6 million, which includes a \$3.6 million non-cash mark to market adjustment in the fair value of the Company's outstanding warrants. Also included are non-recurring costs associated with repayment of the Company's debt obligations and issuance of warrants in its July 2012 public equity offering. A table with a full description of other expenses is included in this release.

Net loss for the third quarter 2012 was \$19.3 million, or \$0.21 per share, compared to a net loss of \$22.0 million, or \$0.59 per share, for the third quarter 2011. The weighted average shares outstanding were 90,370,000 for the third quarter 2012. Non-GAAP net loss adjusted for certain non-cash or non-recurring items for the third quarter 2012 was \$0.16 per share as detailed in the non-GAAP financial results table included in this release.

Cash and cash equivalents as of September 30, 2012, were \$49.6 million. During the third quarter 2012 the Company raised net proceeds of \$65.4 million in an equity offering and repaid \$21.2 million of debt obligations to Oxford Finance LLC and Silicon Valley Bank.

Ann Rhoads, chief financial officer of Zogenix, commented, "We have reduced our loss from operations by nearly half as compared to the third quarter of 2011. Following the

successful equity raise and debt repayment early in this quarter, we are advancing our development programs while continuing to invest in the growth of our commercial product, SUMAVEL DosePro, with the support of our new co-promotion partner."

2012 Full Year Financial Guidance

The Company is refining its full year 2012 financial guidance as follows:

- Total revenue expected to be approximately \$45.5 million, at the low end of the previous guidance range
- Net product revenue expected to be approximately \$37 million, at the low end of the previous guidance range due to the disruption in sales focus during the co-promotion transition and prescription growth expected to be approximately 20% over 2011
- Product gross margin expected to be approximately 48% - 49%, towards the high end of the previous guidance range
- Research and development expenses expected to be approximately \$22 million, at the high end of the previous guidance range primarily due to expenses associated with preparing for the FDA Advisory Committee meeting for Zohydro ER
- Selling, general and administrative expenses expected to be approximately \$50 million, at the high end of the previous guidance range
- Net interest expense to be approximately \$10 million for 2012, unchanged from the previous guidance, reflecting the payoff of the debt obligation with Oxford Finance LLC and Silicon Valley Bank

Conference Call and Web Cast

Zogenix will hold a conference call today, November 8, 2012 at 4:30 p.m. ET to discuss financial results and operational highlights for the third quarter ended September 30, 2012.

To participate, please dial (866) 700-6293 (U.S.) or (617) 213-8835 (International); participant passcode: 68096593. 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 8, 2012 at 6:30 p.m. ET (3:30 p.m. PT) until November 15, 2012, by dialing (888) 286-8010 (U.S.) or (617) 801-6888 (International); passcode: 41905564. A replay of the webcast will also be accessible on the Investor Relations website for one month, through December 8, 2012.

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, including 2012 financial guidance, 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., 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, novel 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. Zogenix's second DosePro investigational product candidate, Relday[™], is a proprietary, long-acting injectable formulation of risperidone for the treatment of schizophrenia. In May 2012, Zogenix submitted to the FDA a New Drug Application for Zohydro ER and an Investigational New Drug Application for Relday. The FDA assigned a PDUFA target action date of March 1, 2013 for the Zohydro ER NDA.

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 progress and timing of the ongoing clinical trial for Relday and results from such trial; the expected sales growth of SUMAVEL DosePro; the benefit that the elimination of amounts outstanding under the loan agreement will have on Zogenix's financial results; the potential opportunities to partner Zohydro ER and Relday; the timing of the FDA advisory committee meeting; the target action date for the FDA to complete its review of the Zohydro ER NDA; the potential approval of Zohydro ER and, if approved, its commercial launch and the timing thereof; and financial guidance for 2012. 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; 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 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 nine months ended on September 30, 2012 and 2011, adjusted for certain non-cash or non-recurring items, which are non-GAAP financial measures. These results are provided as a complement to results provided in accordance with GAAP because management believes these non-GAAP financial measures help illustrate underlying trends in the Company's business, are important in comparing current results with prior period results and provide additional information regarding its financial position. Management also uses these non-GAAP financial measures to establish budgets and operational goals that are communicated internally, to manage the Company's business and to evaluate its performance. 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 other non-GAAP financial results to GAAP financial results is included in the attached financial statements.

SUMAVEL[®], DosePro[®], Relday[™] and Zohydro[™] ER are trademarks of Zogenix, Inc.

*Source Healthcare Analytics, Source[®] PHAST Prescription Monthly, July – September 2012

Zogenix, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

	<i>Three Months Ended</i>		<i>Nine Months Ended</i>	
	<i>September 30,</i>		<i>September 30,</i>	
	<i>2012</i>	<i>2011</i>	<i>2012</i>	<i>2011</i>
	<i>(unaudited)</i>		<i>(unaudited)</i>	
Revenues:				
Net product revenue	\$ 8,453	\$ 8,835	\$ 26,368	\$ 24,986
Contract revenue	--	1,563	8,462	4,688
Total revenues	8,453	10,398	34,830	29,674
Operating expenses:				
Cost of sales	4,249	5,482	13,478	14,333
Royalty expense	325	343	997	972
Research and development	3,660	10,134	16,005	27,540
Selling, general & administrative	10,857	14,701	37,574	42,642
Total operating expenses	19,091	30,660	68,054	85,487
Loss from operations	(10,638)	(20,262)	(33,224)	(55,813)
Total other income (expense)	(8,644)	(1,769)	(13,514)	(4,366)
Loss before income taxes	(19,282)	(22,031)	(46,738)	(60,179)
Income tax	--	(7)	(5)	(20)
Net loss	\$ (19,282)	\$ (22,038)	\$ (46,743)	\$ (60,199)
Net loss per share, basic and diluted	\$ (0.21)	\$ (0.59)	\$ (0.63)	\$ (1.71)
Weighted average shares outstanding, basic and diluted	90,370	37,320	73,790	35,127

Zogenix, Inc.

Condensed Consolidated Balance Sheets

(in thousands)

	<i>September 30, December 31,</i>	
	<i>2012</i>	<i>2011</i>
	<i>(unaudited)</i>	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 49,552	\$ 56,525
Trade accounts receivable, net	5,504	4,913
Inventory, net	13,705	16,251
Prepaid expenses and other current assets	2,600	2,210
Total current assets	71,361	79,899
Property and equipment, net	13,673	14,590
Other assets	6,273	6,151
Total assets	\$ 91,307	\$ 100,640

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities		
Accounts payable	\$ 4,876	\$ 5,168
Accrued expenses	16,003	14,553
Common stock warrant liabilities	24,915	345
Revolving credit facility	--	5,081
Long-term debt, current portion	--	9,758
Deferred revenue	--	8,462
Total current liabilities	45,794	43,367
Long-term debt, less current portion	28,413	42,070
Other long-term liabilities	3,811	5,891
Stockholders' equity (deficit)		
Common stock	101	65
Additional paid-in capital	341,936	291,252
Accumulated deficit	(328,748)	(282,005)

Total stockholders' equity	13,289	9,312
Total liabilities and stockholders' equity	\$ 91,307	\$ 100,640

Zogenix, Inc.

Net Product Revenue

(\$ in thousands)

	Three Months Ended September 30, 2012 <i>(unaudited)</i>	Nine Months Ended September 30, 2012 <i>(unaudited)</i>
U.S. Units Shipped	133,500	420,960
U.S. Gross Product Sales	\$ 11,975	\$ 37,760
Product Sales Allowances:		
Allowance for Product Sales Discounts	2,986	9,376
Allowance for Product Returns	537	2,416
Total Product Sales Allowances	3,523	11,792
U.S. Net Product Revenue	8,452	25,968
EU Net Product Revenue	1	400
Total Net Product Revenue	\$ 8,453	\$ 26,368

Zogenix, Inc.

Other Income (Expense)

(in thousands)

	Three Months Ended September 30, 2012 <i>(unaudited)</i>	Nine Months Ended September 30, 2012 <i>(unaudited)</i>
Change in fair value of warrant liability ¹	\$ (3,569)	\$ (3,611)
Oxford/SVB interest expense ²	(1,940)	(4,176)
Healthcare Royalty Partners interest expense ³	(1,429)	(4,133)
Warrant issuance costs ⁴	(1,423)	(1,423)
Change in fair value of embedded derivatives	(202)	166
Imputed interest expense on Astellas tail payments	(93)	(414)
Other income, net	12	77
Total other income (expense)	\$ (8,644)	\$ (13,514)

1. Change in fair value of warrants issued in the July 2012 public equity offering and the July 2011 financing agreement with Healthcare Royalty Partners (previously called Cowen Healthcare Royalty Partners II, LP). This non-cash expense was driven primarily by the increase in the Company's stock price during the reporting periods.

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. The Company accrues interest expense on the Healthcare Royalty Partners 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. The revenue interest cash payments for the three and nine months ending September 30, 2012 were \$486,000 and \$1,516,000, respectively.

4. This non-recurring expense consists of offering costs, including underwriters discounts and commissions, allocated to 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		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
	(unaudited)		(unaudited)	
Net loss (as reported, GAAP)	\$ (19,282)	\$ (22,038)	\$ (46,743)	\$ (60,199)
Net loss per share, basic and diluted (as reported, GAAP)	\$ (0.21)	\$ (0.59)	\$ (0.63)	\$ (1.71)
Adjustments for certain non-cash or non-recurring items:				
Change in fair value of warrant liability	\$ (3,569)	\$ 546	\$ (3,611)	\$ 546
Change in fair value of derivatives	(202)	137	166	137
Warrant issuance costs	(1,423)	0	(1,423)	0
Total Adjustments to Other Income (Expense)	(5,194)	683	(4,868)	683
Net loss adjusted for certain non-cash or non-recurring items	\$ (14,088)	\$ (22,721)	\$ (41,875)	\$ (60,882)
Adjusted net loss per share (non-GAAP)	\$ (0.16)	\$ (0.61)	\$ (0.57)	\$ (1.73)
Weighted average shares outstanding, basic and diluted	90,370	37,320	73,790	35,127

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