

# ZOGENIX

## Zogenix Reports Second Quarter 2012 Financial Results

August 8, 2012

*Reiterates 2012 Financial Guidance*

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

### *SUMAVEL® DosePro® (sumatriptan injection) Second Quarter 2012 Highlights*

- Successfully retained prescribers called on by the Zogenix sales force, increasing their total prescriptions by 6% over the first quarter 2012\*
- Generated more than 20,000 total prescriptions in the second quarter, the first period without the primary care co-promotion efforts of Astellas, down 6% from the first quarter 2012\*
- Entered exclusive co-promotion agreement with Mallinckrodt LLC (Covidien) with their pain management sales force on track to begin promoting SUMAVEL DosePro to a specified list of high prescribers of triptans in late August
- Continued strong refill rate for SUMAVEL DosePro at 43% from 39% in the previous quarter\*

### *Recent Highlights and Milestones*

- The FDA accepted for review the New Drug Application (NDA) for Zohydro™ ER (hydrocodone bitartrate extended-release capsules) providing a PDUFA date of March 1, 2013
- Initiated first clinical trial for Relday™ and remain on track to obtain study results by the end of 2012
- Formally launched DosePro® technology co-marketing campaign with Battelle, focused on potential out-licensing opportunities
- Raised net proceeds of \$65.5 million in an equity offering, extending cash runway beyond potential Zohydro ER approval and launch
- Repaid \$21.2 million for all outstanding loans with Oxford Finance LLC and Silicon Valley Bank resulting in an elimination of approximately \$3.5 million per quarter in principal and interest payments

SAN DIEGO, Aug. 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 second quarter ended June 30, 2012.

Roger Hawley, chief executive officer of Zogenix, stated, "During the second quarter, our sales representatives continued to drive demand for SUMAVEL DosePro in the neurology segment while also assuming coverage of key primary care physicians formerly called on by our previous co-promotion partner, Astellas. We are pleased with the productivity levels from our sales representatives in their first quarter promoting the brand on their own. While revenue was down from the first quarter, we incurred no co-promotion service fee in the second quarter. Moving forward, we expect to accelerate growth with our new co-promotion partner, Mallinckrodt, which will double our reach into internal medicine and primary care and allow our team to focus on neurologists, headache specialists and high-prescribing physicians. The Mallinckrodt team has extensive experience in the pain market and we are excited to have them begin promoting SUMAVEL DosePro to their customers in late August."

Stephen J. Farr, Ph.D., president and chief operating officer of Zogenix, said, "In mid-July, the FDA accepted for review our NDA for Zohydro ER and provided a PDUFA date of March 1, 2013, in-line with our expectations for potential launch in the second quarter of 2013. For Relday, we enrolled the first patient in our open-label, safety and pharmacokinetic (PK) trial in July, keeping us on track with our goal to obtain the study data by year-end 2012. We believe that both Zohydro ER and Relday represent large new market opportunities for Zogenix and we continue to evaluate all potential commercialization options in order to maximize their value and potential for success. Finally, we recently announced the initiation of the DosePro technology co-marketing campaign with Battelle, which we believe will accelerate our partnership and out-licensing opportunities for DosePro within the biopharmaceutical industry."

### *Second Quarter 2012 Financial Results*

Net product revenues for the second quarter were \$8.0 million, reduced by a \$630,000 net increase in the reserve for future product returns bringing the reserve balance to \$2.9 million at June 30, 2012. This compares to net product revenues of \$8.7 million in the second quarter 2011. In addition, total revenues for the second quarter 2011 included \$1.6 million in contract revenue, reflecting the amortization of license and milestone payments received from the Company's co-promotion agreement with Astellas which ended March 31, 2012.

Cost of sales for the second quarter 2012 was \$4.2 million, compared to \$4.0 million in the second quarter 2011. Product gross margin was 48% in the second quarter 2012, compared to 54% in the second quarter 2011. The decrease in gross margin was driven primarily by a lower average net selling price, partially offset by lower per unit cost of sales.

Royalty expense for the second quarter 2012 was \$315,000, compared to \$333,000 in the second quarter 2011, reflecting the impact of decreased net product revenue.

Research and development expenses for the second quarter 2012 were \$6.4 million, representing a 28% decrease from \$8.9 million in the second 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.

Selling, general and administrative expenses for the second quarter 2012 were \$12.1 million, representing a 20% decrease from \$15.0 million in the second quarter 2011. The decrease in selling, general and administrative expenses was due primarily to the March 31, 2012 termination of the Company's co-promotion agreement with Astellas resulting in no service fee being incurred in the second quarter compared to a service fee of \$1.7 million in the second quarter of 2011. Also, sampling costs were lower, with decreases partially offset by the expansion of the Zogenix sales force completed in the fourth quarter 2011.

Other expenses for the second quarter 2012 were \$2.3 million, which included the cost of interest expense on the Company's debt obligations with Oxford Finance LLC and Silicon Valley Bank, as well as royalty payments and non-cash mark-to-market adjustments for derivatives and warrant liabilities related to the Company's July 2011 financing agreement with Healthcare Royalty Partners (previously called Cowen Healthcare Royalty Partners). The Company records interest expense on the Healthcare Royalty Partners debt obligation on an effective interest method at a rate in the mid-to-high teens, while actual quarterly royalty payments are made at a rate of 5.75% of net product revenues.

Net loss for the second quarter 2012 was \$17.2 million, or \$0.26 per share, compared to a net loss of \$19.2 million, or \$0.56 per share, for the second quarter 2011.

The weighted average shares outstanding were 65,449,000 for the second quarter 2012. This does not include the 35,058,300 shares issued in conjunction with the recently completed equity offering.

Cash and cash equivalents as of June 30, 2012, were \$22.0 million, which excludes net proceeds of \$65.5 million from the recently completed equity offering and the subsequent repayment of our debt obligations to Oxford and Silicon Valley Bank of \$21.2 million.

Ann Rhoads, executive vice president and chief financial officer said, "The equity offering we recently completed will provide us with resources to continue driving SUMAVEL DosePro growth and advance our research and development programs. It also allowed us to repay our term debt, which eliminates over \$3.5 million in quarterly principal and interest payments. We expect the net proceeds of this financing after debt repayment to provide us with funding beyond the potential approval and commercial launch of Zohydro ER."

#### *2012 Full Year Financial Guidance*

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

- Total revenue expected to be \$45.5 - \$48.5 million
- Prescription growth expected to be 25% - 30% over 2011
- Net product revenue expected to be \$37 - \$40 million
- Product gross margin expected to increase to 46% - 50% from 37% for 2011
- Research and development expenses expected to be \$20 - \$22 million
- Selling, general and administrative expenses expected to decline to \$48 - \$50 million from \$60.4 million in 2011 due to lower fees to Astellas
- Net interest expense to be approximately \$10 million for 2012, reflecting the payoff of the debt obligation with Oxford Finance LLC and Silicon Valley Bank resulting in a reduction of ongoing interest expense offset by a one-time charge in the third quarter of 2012 for the write off of unamortized debt discounts and debt acquisition costs relating to the loan, as well as prepayment premiums.

#### *Conference Call and Web Cast*

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

To participate, please dial (866) 356-4123 (U.S.) or (617) 597-5393 (International); participant passcode: 10031996. 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, 2012 at 6:30 p.m. ET (3:30 p.m. PT) until August 15, 2012, by dialing (888) 286-8010 (U.S.) or (617) 801-6888 (International); passcode: 81231537. A replay of the webcast will also be accessible on the Investor Relations website for one month, through September 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. (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<sup>®</sup> DosePro<sup>®</sup> (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<sup>™</sup> ER (hydrocodone bitartrate) is an oral, single-entity (without acetaminophen) novel extended-release formulation of various strengths of hydrocodone 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<sup>™</sup>, 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](http://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 clinical trials for Relday and results from such trials; the potential for the co-promotion arrangement with Mallinckrodt to increase sales of SUMAVEL DosePro; Zogenix's ability to be successful in the primary care and specialist markets; the expected sales growth of SUMAVEL DosePro; statements regarding the benefit that the elimination of amounts outstanding under the loan agreement will have on Zogenix's financial results; the extent and ability of Zogenix's current cash position to advance its current product and product candidates; the potential growth opportunity for Zogenix; the target action date for the FDA to complete its review of the Zohydro ER NDA; the potential for Zohydro ER to be the first approved oral, single-entity extended-release formulation of hydrocodone and the timing thereof; the launch of Battelle's marketing campaign and the ability to successfully out-license the DosePro technology; 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, including as a result of the termination of its collaboration with Astellas; 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 ability of Zogenix to ensure adequate and continued supply of SUMAVEL DosePro to successfully meet anticipated market demand; the potential for Zohydro to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to Zohydro 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 impact of any inability to raise sufficient capital to fund ongoing operations; 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 the DosePro technology and obtaining regulatory approval for other DosePro products; 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.

SUMAVEL<sup>®</sup>, DosePro<sup>®</sup>, Relday<sup>™</sup> and Zohydro<sup>™</sup> ER are trademarks of Zogenix, Inc.

\*Wolters Kluwer Pharma Solutions, Source<sup>®</sup> PHAST Prescription Monthly (Retail + Mail), January 2012 – June 2012

*Zogenix, Inc.*

*Condensed Consolidated Statements of Operations*

(in thousands, except per share amounts)

	<i>Three Months Ended</i>		<i>Six Months Ended</i>	
	<i>June 30,</i>		<i>June 30,</i>	
	<i>2012</i>	<i>2011</i>	<i>2012</i>	<i>2011</i>
	<i>(unaudited)</i>		<i>(unaudited)</i>	
Revenues:				
Net product revenue	\$ 8,030	\$ 8,674	\$ 17,915	\$ 16,151
Contract revenue	--	1,563	8,462	3,126
Total revenues	8,030	10,237	26,377	19,277
Operating expenses:				
Cost of sales	4,167	3,975	9,229	8,850
Royalty expense	315	333	672	630
Research and development	6,381	8,882	12,345	17,406
Selling, general & administrative	12,068	15,039	26,717	27,940
Total operating expenses	22,931	28,229	48,963	54,826
Loss from operations	(14,901)	(17,992)	(22,586)	(35,549)
Total other income (expense)	(2,268)	(1,179)	(4,870)	(2,599)
Loss before income taxes	(17,169)	(19,171)	(27,456)	(38,148)
Income tax	--	(6)	(5)	(13)
Net loss	\$ (17,169)	\$ (19,177)	\$ (27,461)	\$ (38,161)
Net loss per share, basic and diluted	\$ (0.26)	\$ (0.56)	\$ (0.42)	\$ (1.12)
Weighted average shares outstanding, basic and diluted	65,449	34,018	65,409	34,015

Zogenix, Inc.

Condensed Consolidated Balance Sheets

(in thousands)

	<i>June 30,</i>	<i>December 31,</i>
	<i>2012</i>	<i>2011</i>
	<i>(unaudited)</i>	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 21,974	\$ 56,525
Trade accounts receivable, net	4,894	4,913
Inventory, net	15,014	16,251
Prepaid expenses and other current assets	2,451	2,210
Total current assets	44,333	79,899
Property and equipment, net	14,091	14,590
Other assets	6,472	6,151
Total assets	\$ 64,896	\$ 100,640

**LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)**

Current liabilities		
Accounts payable	\$ 4,733	\$ 5,168
Accrued expenses	15,767	14,898
Revolving credit facility	4,694	5,081
Long-term debt, current portion	11,627	9,758
Deferred revenue	--	8,462
Total current liabilities	36,821	43,367
Long-term debt, less current portion	36,120	42,070
Other long-term liabilities	6,963	5,891
Stockholders' equity (deficit)		
Common stock	66	65

Additional paid-in capital	294,392	291,252
Accumulated deficit	(309,466)	(282,005)
Total stockholders' equity (deficit)	(15,008)	9,312
Total liabilities and stockholders' equity (deficit)	\$ 64,896	\$ 100,640

Zogenix, Inc.

Net Product Revenue

(\$ in thousands)

	<i>Three Months Ended June 30, 2012</i>	<i>Six Months Ended June 30, 2012</i>
U.S. Units Shipped	138,120	287,460
U.S. Gross Product Sales	\$ 12,389	\$ 25,785
Product Sales Allowances:		
Allowance for Product Sales Discounts	3,006	6,390
Allowance for Product Returns	1,355	1,879
Total Product Sales Allowances	4,361	8,269
U.S. Net Product Revenue	8,028	17,516
EU Net Product Revenue	2	399
Total Net Product Revenue	\$ 8,030	\$ 17,915

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