

# ZOGENIX

## Zogenix Reports Second Quarter 2014 Financial Results

August 5, 2014

Conference Call and Webcast Today, August 5, at 4:30 p.m. ET

### Recent Business Highlights

- Provided updated timeline for abuse deterrent formulations of Zohydro<sup>®</sup> ER (hydrocodone bitartrate) Extended-Release Capsules, CII, with sNDA for first candidate expected to be filed by October, with potential approval in early 2015
- Completed sale of SUMAVEL<sup>®</sup> DosePro<sup>®</sup> migraine therapy business to Endo International plc for \$89.6 million in cash, milestone payments of up to \$20 million, and approximately \$7 million for working capital advance
- Repaid outstanding debt of approximately \$40 million to HealthCare Royalty Partners; cash position at June 30, 2014 was \$81.2 million plus restricted cash of \$8.5 million held in escrow

### Second Quarter 2014 Highlights

- Total prescriptions for Zohydro ER were 10,299 for the second quarter; 4,076 for the first four weeks of July, up 74% compared to the first four weeks of April; and 1,088 for the most recent week ended July 25<sup>1</sup>
- Total net revenue of \$9.2 million
- Zohydro ER net revenue of \$2.4 million on prescription demand
- Zohydro ER gross factory sales to wholesalers of \$4.8 million during the second quarter; \$11.6 million year-to-date

SAN DIEGO, Aug. 5, 2014 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of pain-related and central nervous system (CNS) disorders, today reported financial results for the second quarter ended June 30, 2014.

Roger Hawley, chief executive officer of Zogenix, stated, "In the first full quarter of the launch of Zohydro ER there continues to be steady growth in prescriptions and positive feedback from prescribers and patients on Zohydro ER and our safe use offerings. With only 5 months of product availability, we have approximately 2,800 prescribers and 15,000 prescriptions. We also announced an updated development timeline for our abuse deterrent formulations of Zohydro ER, and remain on track to file the supplemental New Drug Application by October 2014 for the first formulation, with potential approval in early 2015."

Mr. Hawley added, "Despite misrepresentations of the facts, the data reported to our External Safe Use Board thus far has demonstrated a lack of signal of misuse and diversion of Zohydro ER. Similarly, we have resolved issues in most of the limited number of states that had taken a narrow focus on Zohydro ER. The focus has now shifted appropriately to implementing class-wide prescribing guidelines to reduce the risk of opioid abuse, instead of singling out Zohydro ER. In Massachusetts, we have resolved all matters in Federal court with the exception of resolution of the State Board of Registration in Pharmacy's requirements specific to Zohydro ER. We remain committed to maintaining appropriate patient access to Zohydro ER in all States."

### Second Quarter 2014 Financial Results

Total revenues for the second quarter 2014, which consisted of net product revenue, contract manufacturing revenue, and service and other revenue, were \$9.2 million, up 2% from \$8.9 million in the second quarter 2013. Net product revenue on sales of Zohydro ER for the second quarter 2014 was \$2.4 million. The Company began commercializing Zohydro ER in March 2014, with recognized revenue based on product dispensed through patient prescriptions as estimated by Source Healthcare Analytics. As of June 30, 2014, the Company had \$7.0 million in deferred revenue for Zohydro ER sold to wholesalers but not yet dispensed through patient prescriptions. Gross-to-net sales deductions will be recorded at the time the prescription units are dispensed.

Net product revenue on sales of SUMAVEL DosePro for the second quarter 2014 was \$3.4 million, compared to \$8.9 million in the second quarter 2013. In May 2014, the Company completed the sale of the SUMAVEL DosePro business to Endo International plc ("Endo"). In connection with the sale of the business, the Company and Endo executed a supply agreement whereby the Company will act as the exclusive supplier of SUMAVEL DosePro to Endo. As a result of the sale, the Company will no longer report net product revenue on sales of SUMAVEL DosePro and will instead report contract manufacturing revenue consisting of the supply of SUMAVEL DosePro to Endo under the companies' supply agreement.

Contract manufacturing revenue on sales of SUMAVEL DosePro to Endo under the companies' supply agreement for the second quarter 2014 was \$2.2 million. It excludes the transfer of SUMAVEL DosePro finished goods inventory to Endo at the closing of the transaction, which was accounted for as part of the sale of the SUMAVEL DosePro business.

Service and other revenue for the second quarter 2014 was \$1.1 million, which was primarily comprised of fees from Valeant Pharmaceuticals for the Company's co-promotion of Migranal<sup>®</sup> Nasal Spray, which began in August 2013.

Cost of sales for the second quarter 2014 was \$2.4 million, compared to \$4.6 million in the second quarter 2013. Product gross margin was 59% in the second quarter 2014, compared to 48% in the second quarter 2013. The increase in product gross margin was primarily due to product mix, as higher margin Zohydro ER comprised a higher proportion of net product revenue in the second quarter 2014. Cost of manufacturing services for SUMAVEL DosePro supplied to Endo during the second quarter 2014 was \$1.9 million.

Royalty expense for the second quarter 2014 was \$435,000, an increase from \$338,000 in the second quarter 2013, reflecting the launch of Zohydro ER in March 2014.

Research and development expenses for the second quarter 2014 were \$4.1 million, representing a 15% increase from \$3.6 million in the second quarter 2013. The increase in research and development expenses was primarily due to an increase in development expenses for Zohydro ER abuse-deterrent formulations and Relday development expenses.

Selling, general and administrative expenses were \$24.5 million for the second quarter 2014, representing a 104% increase from \$12.0 million for the second quarter 2013. The increase in selling, general and administrative expenses was primarily the result of the launch of Zohydro ER, including expansion of the Company's sales force and the addition of its medical affairs team. It also reflects the implementation of the FDA required ER/LA opioids REMS program and the Company's voluntary initiatives to support the responsible commercialization of Zohydro ER.

A net gain on the sale of the SUMAVEL DosePro business was booked in the second quarter. The aggregate consideration received by the Company was \$89.6 million. The net gain

on sale was calculated as the difference between the allocated consideration for the SUMAVEL DosePro business, in accordance with authoritative accounting guidance, of \$80.0 million, and the net carrying amount of the assets transferred to Endo. The undelivered elements of this transaction were deferred and will primarily be recognized as contract manufacturing revenue based on proportional performance of contract manufacturing services under the supply agreement.

Impairment of long-lived assets of \$838,000 was booked in connection with the sale of the Company's SUMAVEL DosePro business. The Company tested the recoverability of its manufacturing machinery and equipment and construction in progress that relates to SUMAVEL DosePro manufacturing.

Other income for the second quarter 2014 totaled \$7.9 million, compared to other expense of \$853,000 in the second quarter 2013, reflecting a non-cash mark-to-market adjustment to the fair value of the Company's outstanding warrants driven primarily by changes in the Company's stock price.

Net income for the second quarter 2014 was \$62.9 million, or \$0.45 per share on a diluted basis, compared to a net loss of \$13.3 million, or \$0.13 per share, for the second quarter 2013. Non-GAAP net loss adjusted for certain non-cash items for the second quarter 2014 was \$0.19 per share compared to a loss of \$0.13 per share for the second quarter 2013. The adjustments are detailed in the non-GAAP financial results table included in this release.

Cash and cash equivalents as of June 30, 2014 were \$81.2 million. Additionally, restricted cash was \$8.5 million as of June 30, 2014, consisting of the portion of proceeds from the sale of the SUMAVEL DosePro business to Endo required to be held in escrow until May 2015. In May 2014, the Company completed the sale to Endo for \$89.6 million and subsequently repaid its outstanding debt of approximately \$40 million to HealthCare Royalty Partners. Also at closing, Endo provided Zogenix a working capital advance of \$7 million to support the manufacturing operations for SUMAVEL DosePro.

Ann Rhoads, chief financial officer of Zogenix, said, "As expected, our second quarter SG&A expenses declined sequentially from the first quarter, reflecting the Zohydro ER launch related expenses that only occurred in the first quarter. This was partially offset by increased costs in the second quarter associated with additional legal and public relations expenses related to Zohydro ER and the development of abuse deterrent formulations of Zohydro ER. Looking forward, we intend to continue to closely manage our expenses, and have lowered the top end of our expectations for our annual R&D and SG&A spend by \$5 million."

#### 2014 Financial Guidance

Below is the Company's updated financial guidance for the remainder of the year reflecting changes in the business as a result of the Endo transaction and the current outlook for Zohydro ER commercial activities.

- Net product revenue:
  - Continue on sell-through revenue recognition methodology for Zohydro ER at least through the remainder of 2014
  - Expecting \$240 average net selling price per prescription for Zohydro ER for the remainder of 2014
  - No further net product revenue for SUMAVEL DosePro
- Contract manufacturing revenue:
  - Continued manufacture and supply of SUMAVEL DosePro to Endo
  - Expecting high single-digit effective markup rate over manufacturing cost, reflecting recognition of revenue deferred at closing of the Endo transaction
- Service and other revenue:
  - Continued fees for co-promotion of Migranal® Nasal Spray
- Cost of goods sold and product gross margin:
  - Expecting product gross margin of approximately 80% for Zohydro ER, reflecting a manufacturing fee of 15% on Zohydro ER net product revenue, plus internal manufacturing overhead and other costs
- Cost of contract manufacturing:
  - Cost of supplying SUMAVEL DosePro to Endo under supply agreement
- Royalty expense:
  - 6% royalty on Zohydro ER net product revenue
- Research and development and selling, general and administrative expenses:
  - Expecting full-year spend of \$110 - \$115 million, down \$5 million on the high-end
  - \$50 - \$55 million during second half of 2014, with third quarter slightly higher than fourth quarter
- Interest expense:
  - No interest expense for the HealthCare Royalty Partners debt, which has been repaid

#### Conference Call and Web Cast

Zogenix will hold a conference call today, August 5, 2014 at 4:30 p.m. ET to discuss financial results and operational highlights for the second quarter ended June 30, 2014. To participate, please dial (877) 417-5253 (U.S.) or (315) 625-3082 (International); participant passcode: 76176599. 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 5, 2014 at 7:30 p.m. ET until August 12, 2014, by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (International); passcode: 76176599. A replay of the webcast will also be accessible on the Investor Relations website for one month, through September 5, 2014.

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 Zohydro ER and Migranal, prescription trends, the Company's financial status and performance, 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) is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with pain-related conditions and CNS disorders who need innovative treatment alternatives to help them return to normal daily functioning.

#### 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," "plans," "expects," "will," "potential" 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 updated financial guidance for 2014, and progress and potential timing for the development of an abuse deterrent formulation of Zohydro ER. Actual results may differ from those set forth in this release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: Zogenix's dependence on the successful commercialization of Zohydro ER; Zogenix's ability to achieve broad market acceptance and generate revenues from sales of Zohydro ER; public concern regarding the safety of drug products such as Zohydro ER and the impact of negative publicity and political influences relating to the regulation of the pain management market in general and opioids and Zohydro ER in particular; Zogenix's dependence on its contract manufacturers and its ability to ensure an adequate and continued supply of Zohydro ER to meet market demand; Zogenix's dependence on third parties to develop abuse deterrent formulation of Zohydro ER; Zogenix's ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend the patents covering Zohydro ER, including the potential for Paragraph IV litigation relating to the product; the potential product liability exposure associated with pharmaceutical products such as Zohydro ER and Sumavel DosePro and other products Zogenix may in-license or acquire; Zogenix's ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its commercial activities; and other risks detailed under "Risk Factors" and elsewhere in Zogenix's periodic reports and other filings made with the Securities and Exchange Commission from time to time.

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 income (loss) and net income (loss) per share for the three and six months ended on June 30, 2014 and 2013 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.

DosePro® and Zohydro® ER are registered trademarks of Zogenix, Inc.

SUMAVEL® is a registered trademark of Endo International, plc.

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

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<sup>1</sup> Source Healthcare Analytics, Source® PHAST Prescription Monthly, April – June 2014; and Source Healthcare Analytics, Source® PHAST Prescription Weekly, weeks ending April 4, 11, 18 and 25, 2014 and July 4, 11 18 and 25, 2014

## Zogenix, Inc.

### Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	June 30, 2014 (unaudited)	2013	June 30, 2014 (unaudited)	2013
Revenues:				
Net product revenue	\$ 5,780	\$ 8,903	\$ 12,550	\$ 15,797
Contract manufacturing revenue	2,238	--	2,238	--
Service and other revenue	1,143	39	2,048	127
Total revenue	9,161	8,942	16,836	15,924
Operating (income) expense:				
Cost of goods sold	2,375	4,630	5,756	8,789
Cost of contract manufacturing	1,935	--	1,935	--
Royalty expense	435	338	798	620
Research and development	4,120	3,577	7,657	6,814
Selling, general & administrative	24,490	12,000	52,143	26,482
Restructuring	--	876	--	876
Impairment of long-lived assets	838	--	838	--
Net gain on sale of business	(79,980)	--	(79,980)	--
Total operating (income) expense	(45,787)	21,421	(10,853)	43,581
Income (loss) from operations	54,948	(12,479)	27,689	(27,657)
Other income (expense):				
Interest income	6	3	12	11
Interest expense	(1,029)	(1,595)	(2,915)	(3,208)
Loss on early extinguishment of debt	(1,254)	--	(1,254)	--
Change in fair value of warrant liabilities	10,201	1,264	18,470	(2,995)
Change in fair value of embedded derivatives	--	(480)	(14)	(562)
Other income (expense)	(7)	(45)	(55)	22
Total other income (expense)	7,917	(853)	14,244	(6,732)
Net income (loss) before income taxes	62,865	(13,332)	41,933	(34,389)
Provision for income taxes	--	--	--	--
Net income (loss)	\$ 62,865	\$ (13,332)	\$ 41,933	\$ (34,389)
Net income (loss) per share, basic	\$ 0.45	\$ (0.13)	\$ 0.30	\$ (0.34)
Net income (loss) per share, diluted	\$ 0.45	\$ (0.13)	\$ 0.16	\$ (0.34)
Weighted average shares outstanding, basic	139,985	100,876	139,635	100,843
Weighted average shares outstanding, diluted	139,985	100,876	142,772	100,843

## Zogenix, Inc.

### Condensed Consolidated Balance Sheets

(in thousands)

	June 30, 2014	December 31, 2013
<b>(unaudited)</b>		
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 81,235	\$ 72,021
Restricted cash	8,500	--
Trade accounts receivable, net	5,920	6,665
Inventory	15,656	9,936
Prepaid expenses and other current assets	5,190	4,257
Total current assets	116,501	92,879
Property and equipment, net	10,960	13,011
Other assets	5,837	6,614
Total assets	\$ 133,298	\$ 112,504

**LIABILITIES AND STOCKHOLDERS' EQUITY**

Current liabilities:		
Accounts payable	\$ 13,546	\$ 4,622
Accrued expenses	20,866	22,817
Common stock warrant liabilities	11,955	31,341
Deferred revenue	8,424	--
Total current liabilities	54,791	58,780
Note payable	2,292	28,802
Other long-term liabilities	7,897	6,496
Stockholders' equity	68,318	18,426
Total liabilities and stockholders' equity	\$ 133,298	\$ 112,504

**Zogenix, Inc.**

**Net Product Revenue**

(\$ in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	<b>(unaudited)</b>		<b>(unaudited)</b>	
Zohydro Bottles Shipped (100 ct.)	7,403	--	18,229	--
Zohydro Total Prescriptions	10,299	--	11,440	--
Average Capsules per Prescription	55.6	--	55.7	--
Zohydro Gross Factory Sales	\$ 4,775	\$ --	\$ 11,607	\$ --
Gross Revenue Deferred <sup>(1)</sup>	(1,115)	--	(7,542)	--
Zohydro Gross Revenue Based on Prescriptions	3,660	--	4,065	--
Allowance for Sales Discounts	(1,235)	--	(1,355)	--
Allowance for Product Returns	--	--	--	--
Zohydro Net Product Revenue	\$ 2,425	\$ --	\$ 2,710	\$ --
Sumavel DosePro Units Shipped	55,740	126,600	152,340	247,140
Sumavel DosePro Gross Factory Sales	\$ 5,512	\$ 12,271	\$ 15,070	\$ 23,629
Allowance for Sales Discounts	(1,612)	(2,931)	(4,096)	(5,738)
Allowance for Product Returns	(545)	(437)	(1,134)	(2,094)
Sumavel DosePro Net Product Revenue	\$ 3,355	\$ 8,903	\$ 9,840	\$ 15,797

Total Net Product Revenue	\$ 5,780	\$ 8,903	\$ 12,550	\$ 15,797
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(1) The amount of revenue deferred does not have a direct correlation with future revenue recognition as the Company will record sales deductions at the time the prescription units are dispensed.

**Zogenix, Inc.**

**Non-GAAP Financial Results<sup>(1)</sup>**

(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(unaudited)		(unaudited)	
Net loss for basic EPS (as reported, GAAP)	\$ 62,865	\$ (13,332)	\$ 41,933	\$ (34,389)
Effect of dilutive securities:				
Change in fair value of warrant liabilities <sup>(2)</sup>	\$ --	\$ --	\$ (18,470)	\$ --
Total adjustments to net loss for dilutive EPS	\$ --	\$ --	\$ (18,470)	\$ --
Net income (loss) for diluted EPS (as reported, GAAP)	\$ 62,865	\$ (13,332)	\$ 23,463	\$ (34,389)
<b>Net income (loss) per share, diluted (as reported, GAAP)</b>	<b>\$ 0.45</b>	<b>\$ (0.13)</b>	<b>\$ 0.16</b>	<b>\$ (0.34)</b>
Adjustments for certain non-cash or non-recurring items:				
Change in fair value of warrant liabilities	\$ (10,201)	\$ (1,264)	\$ --	\$ 2,995
Change in fair value of embedded derivatives	--	480	14	562
Restructuring expenses	--	876	--	876
Impairment of long-lived assets	838	--	838	--
Net gain on sale of business	(79,980)	--	(79,980)	--
Total adjustments to net loss	\$ (89,343)	\$ 92	\$ (79,128)	\$ 4,433
Net loss adjusted for certain non-cash or non-recurring items	\$ (26,478)	\$ (13,240)	\$ (55,665)	\$ (29,956)
<b>Adjusted net loss per share, diluted (non-GAAP)</b>	<b>\$ (0.19)</b>	<b>\$ (0.13)</b>	<b>\$ (0.39)</b>	<b>\$ (0.30)</b>
Weighted average shares outstanding, diluted	139,985	100,876	142,772	100,843

(1) 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.

(2) The change in fair value was included in the dilutive net loss per share calculation only in the period for which its effect was dilutive

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