# Zogenix Reports First Quarter 2014 Financial Results

May 8, 2014

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

**Recent Business Highlights**

- Commercial and medical affairs organization began educational efforts to prescribers and pharmacists for Zohydro™ ER (hydrocodone bitartrate) extended-release capsules the first week in March
- Continued efforts to support patient access to Zohydro ER in all States
- Entered definitive agreement to sell SUMAVEL® DosePro® migraine therapy business to Endo International plc for $85 million in cash, milestone payments of up to $20 million, and approximately $11 million for working capital advance and purchase of finished goods inventory

**First Quarter 2014 Highlights**

- Total net revenue of $7.7 million, up 10% year-over-year
- Zohydro ER net revenue of $286,000 on prescription demand and deferred revenue of $6.0 million for shipments to wholesalers
- Zohydro ER prescriptions were 1,141 for the first quarter and 660 for the most recent week ending April 25[1]
- The vast majority, more than 80%, of prescriptions for Zohydro ER are for the 30 mg strength or less

SAN DIEGO, May 8, 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 first quarter ended March 31, 2014.

Roger Hawley, chief executive officer of Zogenix, stated, "During the first quarter we successfully expanded our medical affairs and commercial teams with a focus on training as well as educational and voluntary initiatives to support the introduction and appropriate use of Zohydro ER. We are pleased with the early response to these efforts, including a steady sequential increase in weekly prescriptions, meaningful use of our safe storage offerings, and positive feedback from prescribers and patients."

Mr. Hawley concluded, "In April, we announced a definitive agreement to sell SUMAVEL DosePro that will add more than $95 million in cash to our balance sheet, plus $20 million in potential milestone payments. This is a significant transaction for the Company as it will allow our team to have a greater level of focus on Zohydro ER and the ongoing development of abuse deterrent formulations of Zohydro ER. The additional capital will support our other innovative pipeline products, including Relday and opportunities that leverage our DosePro technology."

**First Quarter 2014 Financial Results**

Total revenues for the first quarter 2014, which consisted of net product revenue and service and other revenue, were $7.7 million, up 10% from $7.0 million in the first quarter 2013. Net product revenue on sales of Zohydro ER for the first quarter 2014 was $286,000. 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 March 31, 2014, the Company had $6.0 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 first quarter 2014 was $6.5 million, compared to $6.9 million in the first quarter 2013. Service and other revenue for the first quarter 2014 was $0.9 million, which was primarily comprised of fees from Valeant Pharmaceuticals for the Company's co-promotion of Migranal® Nasal Spray, which began in August 2013.

Cost of sales for the first quarter 2014 was $3.4 million, compared to $4.2 million in the first quarter 2013. Product gross margin was 50% in the first quarter 2014, compared to 40% in the first quarter 2013. The increase in product gross margin was primarily due to lower cost per unit and higher net selling price for SUMAVEL DosePro.

Royalty expense for the first quarter 2014 was $363,000, an increase from $282,000 in the first quarter 2013, reflecting the launch of Zohydro ER.

Research and development expenses for the first quarter 2014 were $3.5 million, representing a 9% increase from $3.2 million in the first quarter 2013. The increase in research and development expenses was primarily due to an increase in development expenses for Zohdyro ER abuse-deterrent formulations and Relday development expenses.

Selling, general and administrative expenses were $27.7 million for the first quarter 2014, representing a 91% increase from $14.5 million for the first quarter 2013. The increase in selling, general and administrative expenses was primarily the result of the expansion of the Company's sales force to 150 field sales representatives from 47 representatives at the end of 2013, the addition of a medical affairs team, and the launch of Zohydro ER. 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.

Other income for the first quarter 2014 totaled $6.3 million, compared to other expense of $5.9 million in the first 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 loss for the first quarter 2014 was $20.9 million, or $0.20 per share on a diluted basis, compared to a net loss of $21.1 million, or $0.21 per share, for the first quarter 2013. Non-GAAP net loss adjusted for certain non-cash items for the first quarter 2014 was $0.20 per share compared to a loss of $0.17 per share for the first quarter 2013. The adjustments are detailed in the non-GAAP financial results table included in this release.

Cash and cash equivalents as of March 31, 2014 were $50.7 million. Additionally, the Company expects to receive $85 million in cash in the second quarter upon the closing of its sale of its SUMAVEL DosePro migraine therapy business to Endo International. Also at closing, Endo International will purchase approximately $4 million in finished goods inventory and support the manufacturing operations with a working capital advance of approximately $7 million.

Ann Rhoads, chief financial officer of Zogenix, said, "In conjunction with the sale of SUMAVEL DosePro, we plan to use approximately $40 million of the proceeds to repay our debt obligation with HealthCare Royalty Partners, which will eliminate the ongoing quarterly royalty obligation and scheduled principal payments. As of March 31, 2014, our cash position was $50.7 million, and given pro forma for the transaction and expected debt repayment, our cash position would have been approximately $100 million."

**2014 Full Year Expense Guidance**

Zogenix is reaffirming its full year 2014 expense guidance of $110 - $120 million in combined research and development and selling, general and administrative expenses.

Zogenix is not providing specific guidance on expected 2014 revenues, however the Company is providing guidance on expected gross margin on Zohydro ER net revenue in the low eighties on a percentage basis. Additionally, the Company will record royalty expense for royalties payable to Alkermes at a mid single-digit percentage of net Zohydro ER sales.

Subsequent to the closing of the sale of its SUMAVEL DosePro migraine therapy business, the Company also expects to record revenues for the ongoing manufacture and supply of SUMAVEL DosePro to Endo at a low single-digit markup to its cost of manufacturing, with such costs recorded as a component of cost of goods sold. Also, subsequent to closing, the Company will not record ongoing interest expense on its debt obligation to HealthCare Royalty Partners, which will be repaid at closing.

**Conference Call and Web Cast**

Zogenix will hold a conference call today, May 8, 2014 at 4:30 p.m. ET to discuss financial results and operational highlights for the first quarter ended March 31, 2014. To participate, please dial (866) 515-2911 (U.S.) or (617) 399-5125 (International); participant passcode: 56018502. 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 May 8, 2014 at 8:30 p.m. ET until May 15, 2014, by dialing (888) 286-8010 (U.S.) or (617) 801-6888 (International); passcode: 31346863. A replay of the webcast will also be accessible on the Investor Relations website for one month, through June 8, 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, SUMAVEL DosePro 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 projected research and development and selling, general and administrative expenses in 2014, and progress with 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: securing final agreement with regards to the sale of SUMAVEL DosePro to Endo; 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 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 loss and net loss per share for the three months ended on March 31, 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.



[1] Source Healthcare Analytics, Source® PHAST Prescription Monthly, January – March 2014; and Source Healthcare Analytics, Source® PHAST Prescription Weekly, week ending April 25, 2014

**Zogenix, Inc.**

**Consolidated Statements of Operations**

**(in thousands, except per share amounts)**

| | **Three Months Ended March 31,** | |
|---|---|---|
| | **2014** | **2013** |
| | **(unaudited)** | |
| Revenues: | | |
| Net product revenue | $ 6,770 | $ 6,893 |
| Service and other revenue | 904 | 88 |
| Total revenue | 7,674 | 6,981 |
| Operating expenses: | | |
| Cost of sales | 3,382 | 4,158 |
| Royalty expense | 363 | 282 |
| Research and development | 3,538 | 3,236 |
| Selling, general & administrative | 27,651 | 14,482 |
| Total operating expenses | 34,934 | 22,158 |
| Loss from operations | (27,260) | (15,177) |

| | | |
|---|---|---|
| Other income (expense): | | |
| Interest income | 6 | 8 |
| Interest expense | (1,886) | (1,613) |
| Change in fair value of warrant liabilities | 8,269 | (4,258) |
| Change in fair value of embedded derivatives | (14) | (81) |
| Other income (expense) | (47) | 66 |
| Total other income (expense), net | 6,328 | (5,878) |
| Net loss before income taxes | (20,932) | (21,055) |
| Provision for income taxes | -- | -- |
| Net loss | $ (20,932) | $ (21,055) |
| | | |
| Net loss per share, basic | $ (0.15) | $ (0.21) |
| Net loss per share, diluted | $ (0.20) | $ (0.21) |
| | | |
| Weighted average shares outstanding, basic | 139,309 | 100,809 |
| Weighted average shares outstanding, diluted | 145,323 | 100,809 |

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

| | **March 31, 2014 (unaudited)** | **December 31, 2013** |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 50,684 | $ 72,021 |
| Trade accounts receivable, net | 11,680 | 6,665 |
| Inventory | 14,854 | 9,936 |
| Prepaid expenses and other current assets | 3,767 | 4,257 |
| Total current assets | 80,985 | 92,879 |
| Property and equipment, net | 12,310 | 13,011 |
| Other assets | 6,685 | 6,614 |
| Total assets | $ 99,980 | $ 112,504 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 10,569 | $ 4,622 |
| Accrued expenses | 22,515 | 22,817 |
| Common stock warrant liabilities | 22,156 | 31,341 |
| Long term debt, current portion | 9,579 | -- |
| Deferred revenue | 5,963 | -- |
| Total current liabilities | 70,782 | 58,780 |
| Long-term debt, less current | 19,313 | 28,802 |
| Other long-term liabilities | 7,466 | 6,496 |
| Stockholders' equity | 2,419 | 18,426 |
| Total liabilities and stockholders' equity | $ 99,980 | $ 112,504 |

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

| | **Three Months Ended March 31,** | |
|---|---|---|
| | **2014** | **2013** |
| | **(unaudited)** | |

| | | |
|---|---|---|
| Sumavel DosePro Units Shipped | 96,600 | 120,540 |
| Sumavel DosePro Gross Product Sales | $ 9,558 | $ 11,357 |
| Allowance for Sales Discounts | (2,484) | (2,807) |
| Allowance for Product Returns | (590) | (1,657) |
| Sumavel DosePro Net Product Revenue | $ 6,484 | $ 6,893 |
| Zohydro Bottles Shipped (100 capsules/bottle) | 10,826 | -- |
| Zohydro Total Prescriptions | 1,141 | -- |
| Average Capsules per Prescription | 55.7 | -- |
| Zohydro Shipments | $ 6,831 | $ -- |
| Gross Revenue Deferred[1] | 6,426 | -- |
| Zohydro Gross Revenue Based on Prescriptions | 405 | -- |
| Allowance for Sales Discounts | (119) | -- |
| Allowance for Product Returns | -- | -- |
| Zohydro Net Product Revenue | 286 | -- |
| Total Net Product Revenue | $ 6,770 | $ 6,893 |

(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[1]**

**(in thousands, except per share amounts)**

| | **Three Months Ended March 31,** | |
|---|---|---|
| | **2014** | **2013** |
| | **(unaudited)** | |
| Net loss for basic EPS (as reported, GAAP) | $ (20,932) | $ (21,055) |
| Effect of dilutive securities: | | |
| Change in fair value of warrant liabilities[2] | $ (8,269) | $ -- |
| Change in fair value of non-employee stock options and restricted stock units[2] | (132) | -- |
| Total adjustments to net loss for dilutive EPS | $ (8,401) | $ -- |
| Net loss for diluted EPS (as reported, GAAP) | $ (29,333) | $ (21,055) |
| **Net loss per share, diluted (as reported, GAAP)** | **$ (0.20)** | **$ (0.21)** |
| Adjustments for certain non-cash or non-recurring items not included above: | | |
| Change in fair value of warrant liabilities | $ -- | $ 4,258 |
| Change in fair value of embedded derivatives | 14 | 81 |
| Additional adjustments to net loss | $ 14 | $ 4,339 |
| Net loss adjusted for certain non-cash or non-recurring items | $ (29,319) | $ (16,716) |
| **Adjusted net loss per share, diluted (non-GAAP)** | **$ (0.20)** | **$ (0.17)** |
| Weighted average shares outstanding, diluted | 145,323 | 100,809 |

(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) These changes in fair value were excluded from the dilutive net loss per share calculation for the three months ended March 31, 2013 as their effect was anti-dilutive

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