Zogenix Reports Second Quarter 2011 Financial Results

August 10, 2011

Zohydro Pivotal Phase 3 Results Expected By End of August

Conference Call and Web Cast Today, August 10th, at 4:30 p.m. ET

SUMAVEL(R) DosePro(R) Highlights

- Achieved second quarter 2011 U.S. net product revenue of $8.7 million, representing 16% growth over the first quarter
- Zogenix sales force generated 69% of the sales growth during second quarter
- Total prescriptions for the second quarter 2011 were over 17,000, an increase of 22% above the first quarter*
- Refill rate for SUMAVEL DosePro was 39% up from 34% previous quarter
- Expanding Zogenix sales force by approximately 20% from 80 to 95 representatives by the end of third quarter

Recent Highlights and Milestones

- Expecting top-line results of Phase 3 pivotal efficacy Study 801 for Zohydro(TM) (hydrocodone bitartrate) extended-release capsules by the end of August
- Entered exclusive global licensing agreement for second DosePro product, Relday(TM) (risperidone), a proprietary long-acting antipsychotic and expect to initiate clinical trials in early 2012
- Completed $31.5 million royalty and equity financing agreement

SAN DIEGO, Aug. 10, 2011 (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, 2011.

Roger Hawley, chief executive officer of Zogenix, stated, "SUMAVEL DosePro adoption continued to increase during the second quarter. Based on encouraging adoption with neurologists and headache specialists, we are expanding the Zogenix sales force from 80 to 95 representatives by the end of the third quarter. These additional representatives will allow us to call on more neurologists and play a larger role in the highest prescribing primary care offices. Today, the primary care market represents 40% of our total business, and we expect the primary care market to eventually grow to 60%. The strong growth achieved by the Zogenix sales force in the quarter was somewhat offset by the near-term impact of a realignment of the Astellas co-promotion sales force. We are supportive of these changes and believe it will be beneficial in the months ahead."

Stephen Farr, Ph.D., president and chief operating officer of Zogenix, commented, "We expect to report top-line Zohydro Phase 3 study results later this month. If approved, Zohydro has the potential to be the first hydrocodone product which provides for 12-hour dosing and is not combined with an analgesic such as acetaminophen. A positive outcome could position Zogenix to launch a product in the largest prescription category in the U.S. by leveraging our sales force."

As previously reported, Zogenix has completed patient enrollment in two Phase 3 clinical trials of Zohydro (formerly ZX002) and expects to announce top-line results from its single, pivotal efficacy study (Study 801) by the end of this month. The Company expects to submit a New Drug Application (NDA) with the United States Food and Drug Administration (FDA) by early 2012 for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy for an extended period of time. If approved, Zohydro has the potential to be the first oral extended-release version of hydrocodone and also the first hydrocodone product that is not combined with acetaminophen or another analgesic. This novel single-entity formulation has the potential to address safety concerns outlined by the FDA regarding the use of certain combination prescription pain products that contain acetaminophen, which can cause liver toxicity at high doses over time.

Dr. Farr continued, "In addition, in July, we entered into an exclusive global license agreement to develop a new CNS product candidate, Relday, utilizing our proprietary DosePro delivery system. Relday combines our needle-free injection technology with a long-acting formulation of the antipsychotic risperidone. The product provides Zogenix with entry into the $16 billion worldwide antipsychotic market. Relday allows us to leverage our investment in the DosePro technology platform and also validates our ability to deliver highly viscous formulations. Strategically, we believe Relday provides a significant opportunity for value creation given the expected relatively low investment required to advance the product through clinical proof of concept followed by development via a 505(b)(2) regulatory pathway. We expect to initiate U.S. clinical trials for once-monthly Relday in early 2012."

Second Quarter 2011 Financial Results

Total revenues for the second quarter 2011, which consists of net product revenue and contract revenue, were $10.2 million, up 99% from $5.1 million in the second quarter 2010. Net product revenue on sales of SUMAVEL DosePro for the second quarter 2011 was $8.7 million, up 106% from $4.2 million in the second quarter 2010, and up 16% from $7.5 million in

the first quarter 2011. Contract revenue for the second quarter 2011 was $1.6 million, reflecting the amortization of license and milestone payments received from Astellas.

Cost of sales for the second quarter 2011 was $4.0 million compared to $3.2 million in the second quarter 2010. Product gross margin was 54% in the second quarter 2011 compared to 24% in the second quarter 2010. The increase in product gross margin reflects the impact of higher net product revenues.

Royalty expense for the second quarter 2011 was $333,000 compared to $310,000 in the second quarter 2010, reflecting the impact of increased net product revenues. This only reflects royalties to Aradigm; royalty payments to Cowen Healthcare Partners related to the financing agreement will be reflected as interest expense beginning in the third quarter 2011.

Research and development expenses for the second quarter 2011 were $8.9 million, up 16% from $7.7 million in the second quarter 2010. The increase in research and development expenses primarily reflects the costs and timing associated with the Company's two concurrent, fully enrolled and ongoing Phase 3 clinical trials for Zohydro.

Selling, general and administrative expenses for the second quarter 2011 were $15.0 million, up 22% from $12.3 million in the second quarter 2010. The increase in selling, general and administrative expenses is primarily due to higher general and administrative costs associated with operating as a public company, higher service fees to Astellas as well as higher stock-based compensation charges.

Net loss for the second quarter 2011 was $19.2 million, or $0.56 per share, compared to a net loss of $27.8 million, or $20.65 per share, in the second quarter 2010. The majority of the Company's outstanding shares in the second quarter of 2010 consisted of preferred stock, which is not included in the weighted average shares outstanding. The weighted average shares outstanding for the second quarter 2011 reflect the conversion of the preferred stock and issuance of common stock in connection with the Company's initial public offering in November 2010.

Cash and cash equivalents as of June 30, 2011 were $7.7 million, which excludes net proceeds of $29.5 million from the royalty financing and equity investment agreement with Cowen Healthcare Royalty Partners announced June 30, 2011 and closed in July 2011.

Ann Rhoads, chief financial officer of Zogenix, commented, "In July, we raised gross proceeds of $31.5 million in a royalty and equity financing. This contributes to the capital required to continue investing in the launch of SUMAVEL DosePro, advance Zohydro towards an NDA and initiate the Relday development program. We are now in a position to broaden our product portfolio and further leverage our sales and manufacturing infrastructure."

2011 Full Year Financial Guidance

The Company is refining its revenue and gross margin guidance for the year, updating its R&D guidance, and providing SG&A guidance.

- Total revenue is expected to be $43 million to $47 million, which includes $6 million of contract revenue from the Astellas co-promotion agreement. The refined revenue guidance reflects the actual results for the first half of the year, the Zogenix sales force expansion and the anticipated impact of the realignment of the Astellas sales force in the second and third quarters of 2011 which is contributing to lower than our anticipated growth from the primary care market this year.
- Product gross margin is expected to be 48% to 52% for 2011 reflecting the change in revenue guidance.
- Research and development expenses are expected to be $37 million to $39 million reflecting costs associated with the Relday development program.
- Selling, general and administrative expenses are expected to be $57 million to $59 million which includes the planned addition of 15 sales representatives to the Zogenix sales force during the third quarter of 2011.

Conference Call and Web Cast

Zogenix will hold a conference call today, August 10, 2011 at 4:30 p.m. ET to discuss financial results and operational highlights for the second quarter ended June 30, 2011.

To participate, please dial 800-638-5439 (U.S.) or 617-614-3945 (International); participant passcode: 55963914. To access the live Web Cast please visit the Zogenix Investor Relations Web site at http://ir.zogenix.com.

A replay of the conference call will be available beginning August 10, 2011 at 8:30 p.m. ET (5:30 p.m. PT) and ending on September 10, 2011 by dialing 888-286-8010 (U.S.) or 617-801-6888 (International); passcode: 79535694. A replay of the Web Cast will also be available on the Zogenix Investor Relations Web site for one month, through September 10, 2011.

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 2011 financial guidance, the Zohydro 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 SUMAVEL DosePro

SUMAVEL DosePro (sumatriptan injection) is indicated for the acute treatment of migraine attacks, with or without aura, and the acute treatment of cluster headache episodes.

SUMAVEL DosePro should only be used where a clear diagnosis of migraine or cluster headache has been established. SUMAVEL DosePro is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine and should not be administered intravenously. For a given attack, if a patient does not respond to the first dose of SUMAVEL DosePro, the diagnosis of migraine or cluster headache should be reconsidered before administration of a second dose.

Important Safety Information

SUMAVEL DosePro is contraindicated in patients with uncontrolled hypertension, in patients with history, symptoms or signs of ischemic heart disease, coronary artery vasospasm, cerebrovascular or peripheral vascular disease including ischemic bowel disease and in patients with other significant underlying cardiovascular diseases or known hypersensitivity to sumatriptan. SUMAVEL DosePro should not be given to patients in whom unrecognized coronary artery disease is predicted by the presence of risk factors without a prior cardiovascular evaluation.

Serious cardiovascular events, including death, have been reported when taking sumatriptan, including patients with no findings of cardiovascular disease. Considering the extent of use of sumatriptan in patients with migraine, the incidence of these events is extremely low. Cerebrovascular events, some fatal, have been reported in patients treated with sumatriptan. In a number of cases, it appears possible that the cerebrovascular events were primary, sumatriptan having been administered in the incorrect belief the symptoms experienced were a consequence of migraine when they were not. It is important to advise patients not to administer SUMAVEL DosePro if a headache being experienced is atypical.

Do not use Sumavel DosePro and any ergotamine-containing or ergot-type medication within 24 hours of each other; do not use SUMAVEL DosePro and another 5-HT1 agonist (e.g. triptan) within 24 hours of each other (with the exception of a single dose of another sumatriptan product, provided the doses are separated by at least 1 hour). SUMAVEL DosePro is not generally recommended for use with MAO-A inhibitors. The development of a potentially life-threatening serotonin syndrome may occur with triptans, including treatment with SUMAVEL DosePro, particularly during combined use with selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). SUMAVEL DosePro should be used during pregnancy only if the potential benefit justifies the potential risk.

In controlled clinical trials with sumatriptan injection, the most common adverse reactions were injection site reactions, tingling, warm/hot sensation, burning sensation, feeling of heaviness, pressure sensation, feeling of tightness, numbness, feeling strange, tight feeling in head, flushing, tightness in chest, discomfort in nasal cavity/sinuses, jaw discomfort, dizziness/vertigo, drowsiness/sedation and headache.

For full prescribing information, please click here: http://www.zogenix.com/downloads/SV0468.0611_SDP_PI.pdf

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(R) DosePro(R) (sumatriptan injection) Needle-free Delivery System, was launched in January 2010 for the acute treatment of migraine and cluster headache. Zogenix's lead product candidate, Zohydro(TM) (hydrocodone bitartrate), is a novel, oral, single-entity extended-release capsule formulation currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. Zogenix's second DosePro product candidate, Relday(TM), is a proprietary, long-acting injectable formulation of risperidone for the treatment of schizophrenia. Zogenix expects to begin clinical studies of Relday in early 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 ability to successfully commercialize SUMAVEL DosePro and its expected sales growth; the mix of our business represented by the primary care and specialist markets; financial guidance for 2011; the timing of the release of results from the Phase 3 trials for Zohydro; the potential for, and timing of, an NDA submission for Zohydro; the potential for Zohydro to be the first approved oral, single-entity extended-release formulation of hydrocodone; the planned expansion of the Zogenix sales force; and the initiation of clinical trials for Relday in early 2012 and the relative investment amount required for its development and its expected regulatory pathway. 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 presentation 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; 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; Zogenix's dependence on its collaboration with Astellas Pharma US, Inc. to promote SUMAVEL DosePro; the impact of any inability to raise sufficient capital to fund ongoing operations; the ability of Zogenix to ensure adequate and continued supply of SUMAVEL DosePro to successfully meet anticipated market demand; the progress and timing of Zogenix's clinical trials; the potential that earlier clinical trials may not be predictive of future results; the potential for Zohydro to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to Zohydro to delay or prevent regulatory approval or commercialization; 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; 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 presentation 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.

*Wolters Kluwer Pharma Solutions, Source Pharmaceutical Audit Suite, January 2010 through June 2011

SUMAVEL (R), DosePro (R), Relday(TM) and Zohydro(TM) are trademarks of Zogenix, Inc.

Zogenix, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues:				
Net product revenue	$ 8,674	$ 4,215	$ 16,151	$ 6,118
Contract revenue	1,563	920	3,126	1,461
Total revenues	10,237	5,135	19,277	7,579
Operating expenses:				
Cost of sales	3,975	3,210	8,850	5,302
Royalty expense	333	310	630	382
Research and development	8,882	7,683	17,406	11,389
Selling, general & administrative	15,039	12,343	27,940	25,422
Total operating expenses	28,229	23,546	54,826	42,495
Loss from operations	(17,992)	(18,411)	(35,549)	(34,916)
Total other income (expense)	(1,179)	(9,428)	(2,599)	(14,389)
Net loss before income taxes	(19,171)	(27,839)	(38,148)	(49,305)
Provision for income tax	(6)	--	(13)	--

Net loss	$ (19,177)	$ (27,839)	$ (38,161)	$ (49,305)
Net loss per share, basic and diluted	$ (0.56)	$ (20.65)	$ (1.12)	$ (37.44)
Weighted average shares outstanding, basic and diluted	34,018	1,348	34,015	1,317

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

	June 30, 2011	December 31, 2010
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 7,672	$ 49,172
Trade accounts receivable	3,218	4,474
Inventory, net	18,556	18,293
Prepaid expenses and other current assets	2,355	2,251
Total current assets	31,801	74,190
Property and equipment, net	15,009	15,434
Other assets	4,583	4,644
Total assets	$ 51,393	$ 94,268
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 6,167	$ 5,580
Accrued expenses	11,599	13,043
Revolving credit facility	3,612	3,449
Long-term debt, current portion	3,504	3,519
Deferred revenue, current portion	6,980	9,973
Total current liabilities	31,862	35,564
Long-term debt, less current portion	19,547	19,934
Deferred revenue, less current portion	6,251	9,376
Other long-term liabilities	875	660
Total stockholders' equity (deficit)	(7,142)	28,734
Total liabilities and stockholders' equity	$ 51,393	$ 94,268

SOURCE: Zogenix

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