Zogenix Provides Corporate Update and Reports Second Quarter 2015 Financial Results

August 10, 2015

Company Will Host a Conference Call Today at 4:30 p.m. EDT/1:30 p.m. PDT

SAN DIEGO, Aug. 10, 2015 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of central nervous system (CNS) disorders, provided a corporate update, and announced financial results for the second quarter ended June 30, 2015.

Corporate Update

- Presented new data at European Paediatric Neurology Society Congress in Vienna, Austria, demonstrating sustained efficacy and tolerability for patients treated with low-dose fenfluramine as an adjunctive therapy for Dravet syndrome. During the 5-year follow-up period from 2010-2014, over 80% of patients experienced a greater than or equal to 75% reduction in seizure frequency every year, and a majority of patients experienced long periods of seizure freedom. The drug was well tolerated and no patient discontinued treatment due to adverse events.

- Following recent correspondence with the U.S. Food and Drug Administration (FDA), the Company is on track to commence its Phase 3 program for ZX008 in the fourth quarter of 2015. The FDA agreed that Zogenix's proposal of two double-blind, randomized, controlled Phase 3 studies, plus one long-term, open label extension study, should be sufficient to support registration, pending review of study outcomes.

- Hosted a Key Opinion Leader meeting focused on Dravet syndrome, including an overview of ZX008, the Company's investigational proprietary pediatric formulation of low-dose fenfluramine, that featured keynote presentations by Lieven Lagae, M.D., Ph.D., Professor at the University of Leuven, Belgium (KUL), Head of the Paediatric Neurology Department of the KUL University Hospitals and Director of the Childhood Epilepsy Program at the KUL University Hospitals, and current President of the European Pediatric Neurology Society and an elected board Member of the International Child Neurology Association, and Joseph Sullivan, M.D., Associate Professor of Neurology and Pediatrics at the University of California - San Francisco (UCSF), Director of the UCSF Pediatric Epilepsy Center. Dr. Sullivan also serves on the Pediatric Epilepsy Consortium Steering Committee, the Dravet Syndrome Association Medical Advisory Board and the PCDH19 Alliance Scientific Advisory Board. The archived webcast of this event is available on Zogenix's website.

- Expanded senior leadership team to further drive strategic focus on CNS disorders and orphan drug development through appointments of Gail M. Farfel, Ph.D., as Executive Vice President and Chief Development Officer, and Thierry Darcis, M.D., M.B.A., as Executive Vice President and General Manager, Europe.

- Raised net proceeds of approximately $92.0 million through an underwritten public offering of common stock.

- Executed a reverse stock split of Zogenix's outstanding common shares at an exchange ratio of 1-for-8 in order to support a per share valuation for the Company that is more in line with Zogenix's peers.

"With further positive data from the Belgian study of low-dose fenfluramine in Dravet syndrome, a clear development path for Phase 3 that now includes significant input from the FDA and the successful execution of a Dravet syndrome-focused KOL event, we have generated significant momentum over the past several months," said Stephen J. Farr, Ph.D., President and CEO. "From a clinical development standpoint, we are well-positioned to begin our Phase 3 program for ZX008 in the fourth quarter of 2015. In addition, following our recent capital raise, Zogenix is now in the strongest financial position in our company's history, and our cash should be sufficient to take us through the regulatory submissions, and potential approvals, of ZX008 in the U.S. and Europe."

Second Quarter 2015 Financial Results Compared to Second Quarter 2014 Financial Results

As a result of the sale of the Zohydro ER business, all Zohydro ER revenue and expenses have been excluded from continuing operations for all periods herein and reported as discontinued operations. All prior period information has been recast to conform to this presentation.

- Total revenue for the second quarter of 2015 was $7.4 million, and reflected $6.0 million of contract manufacturing revenue and $1.4 million of service and other product revenue (including Migranal®-related co-promotion fees earned under the Company's co-promotion agreement with Valeant Pharmaceuticals). This compared with total revenue of $6.7 million in the same quarter last year, which included $2.2 million of contract manufacturing revenue and $4.5 million of net product and other service revenue. The increase in contract manufacturing revenue and decrease in net product revenue in the 2015 second quarter was due to the sale of the Sumavel® DosePro® business to Endo International Plc in May 2014 and subsequent performance under the related supply agreement.

- Second quarter 2015 research and development expenses totaled $6.2 million, up from $3.2 million in the second quarter a year ago, as the Company continued preparations for its two Phase 3 studies for ZX008, and a multi-dose clinical study for Relday®, which commenced in February 2015.

- Second quarter 2015 selling, general and administrative expense totaled $7.6 million, compared with $9.1 million in the second quarter a year ago. The Company incurred selling expenses for Sumavel DosePro prior to its sale in May 2014.

- Income from discontinued operations was $79.2 million, compared to a loss of $14.7 million in the second quarter a year ago. Income from

discontinued operations includes a gain on the sale of the Zohydro business of $75.6 million net of tax expense and the $5.0 million for the Purdue waiver agreement received on June 29, 2015.

- Net loss from continuing operations was $6.7 million, compared with net income of $77.5 million in the same quarter a year ago. Net income, including discontinued operations, for the second quarter of 2015 was $72.5 million, or $3.78 per basic share and fully diluted, which includes the pre-tax net gain on the sale of Zohydro ER, which was sold in April 2015, compared with net income of $62.9 million, or $3.59 per basic share and fully diluted, for the second quarter a year ago, which includes the pre-tax gain on the sale of Sumavel DosePro.

Six-Months Ended June 30, 2015 Financial Results Compared to Six-Months Ended June 30, 2014 Financial Results

As a result of the sale of the Zohydro ER business, all Zohydro ER revenue and expenses have been excluded from continuing operations for all periods herein and reported as discontinued operations. All prior period information has been recast to conform to this presentation.

- Total revenue for the six months ended June 30, 2015 was $12.0 million, and reflected $10.2 million of contract manufacturing revenue and $1.8 million of service and other product revenue (including Migranal®-related co-promotion fees earned). This compared with total revenue of $14.1 million in the same period last year, which included $2.2 million of contract manufacturing revenue and $11.9 million of net product and other service revenue. The increase in contract manufacturing revenue and decrease in net product revenue in the 2015 second quarter was due to the sale of the Sumavel® DosePro® business to Endo International Plc in May 2014 and subsequent performance under the related supply agreement.

- Research and development expenses for the six months ended June 30, 2015 totaled $11.4 million, up from $5.7 million in the year ago period, as the Company continued preparations for its two Phase 3 studies for ZX008, and the multi-dose clinical study for Relday.

- Selling, general and administrative expense for the six months ended June 30, 2015 totaled $13.9 million, compared with $21.6 million in the year ago period. The Company incurred selling expenses for Sumavel DosePro prior to its sale in May 2014.

- Income from discontinued operations was $66.5 million, compared to a loss of $30.7 million in the year ago period. Income from discontinued operations includes a gain on the sale of the Zohydro business of $75.6 million net of tax expense and the $5.0 million for the Purdue waiver agreement received on June 29, 2015.

- Net loss from continuing operations was $16.9 million, compared with net income of $72.6 million in the same period a year ago. Net income, including discontinued operations, for the six-months ended June 30, 2015 was $49.6 million, or $2.59 per basic share and fully diluted, which includes the pre-tax net gain on the sale of Zohydro ER, compared with net income of $41.9 million, or $2.40 per basic share and $1.31 fully diluted, for the six months ended June 30, 2014, which includes the pre-tax gain on the sale of Sumavel DosePro.

- Cash and cash equivalents at June 30, 2015 totaled $77.4 million, which did not reflect the net proceeds of $92.0 million received subsequent to quarter's end related to the public offering that closed on August 5, 2015.

The Company anticipates that its current financial resources, including the net proceeds from the recently closed public offering, will provide sufficient cash to fund operations through several significant milestones, including the U.S. and European Phase 3 studies for ZX008 and potential regulatory approvals in the U.S. and Europe for ZX008.

2015 Financial Guidance

Below is the Company's financial guidance for the remainder of 2015.

- Research and development expenses are expected to be $19 to $22 million for the second half of 2015, reflecting the initiation of ZX008 clinical studies and the recent commencement of the Relday multi-dose clinical study.
- Selling, general and administrative expenses are expected to be $14 to $16 million for the second half of 2015.
- Contract manufacturing revenue from the supply of Sumavel DosePro to Endo will continue at a low single-digit markup over cost of contract manufacturing.

Additionally, the Company does not expect gain or loss from discontinued operations to be significant in the second half of 2015.

Conference Call Details

Investors interested in participating in today's live call can dial 888-523-1228 from the U.S. and international callers can dial 719-325-2177 and use conference ID: 9869696. A telephone replay will be available approximately two hours after the call and will run through August 24 by dialing 877-870-5176 from the U.S., or 858-384-5517 from international locations, and entering Replay Pin Number: 9869696. The conference call will be broadcast live and will be available for replay for 60 days at: Conference Call Link and on the IR section of the company's website at: Zogenix IR.

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 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," "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 Company's financial guidance for the remainder of 2015; the Company's cash position related to operating expenses and planned development activities; the timing of the commencement of Phase 3 clinical studies for ZX008; Zogenix's strategy on advancing its novel pipeline in CNS disorders; and the expected timing of, and Zogenix's ability to achieve, key clinical milestones and regulatory meetings and submissions for Zogenix's development pipeline. 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 release due to the risks and uncertainties inherent in Zogenix's business, including, without limitation: the uncertainties associated with the clinical development and regulatory approval of product candidates such as ZX008 and Relday, including potential delays in enrollment and completion of clinical trials; the potential that earlier clinical trials may not be predictive of future results; Zogenix's reliance on third parties to conduct its clinical trials, enroll patients, manufacture its preclinical and clinical drug supplies and manufacture commercial supplies of its drug products, if approved; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 that could limit approval and/or commercialization, or that could result in recalls or product liability claims; Zogenix's ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its product development activities; Zogenix could spend its available financial resources faster than it currently expects and may be unable to raise additional capital if and when needed, on acceptable terms or at all; and other risks described in Zogenix's prior press releases as well as in public periodic 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.

DosePro® and Relday® are registered trademarks of Zogenix, Inc.

All other trademarks are of the associated companies.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	**2014**	**2015**	**2014**
Revenues:				
Contract manufacturing revenue	$ 6,003	$ 2,238	$ 10,184	$ 2,238
Net product revenue	--	3,355	--	9,840
Service and other product revenue	1,364	1,144	1,797	2,048
Total revenue	7,367	6,737	11,981	14,126
Operating (income) expense:				
Cost of contract manufacturing	5,803	1,935	9,726	1,935
Cost of goods sold	--	1,928	--	5,261
Royalty expense	71	172	143	439
Research and development	6,241	3,162	11,390	5,703
Selling, general & administrative	7,582	9,062	13,851	21,590
Change in fair value of contingent consideration	(600)	--	(1,600)	--
Impairment of long-lived assets	--	838	--	838
Net gain on sale of business	--	(79,980)	--	(79,980)
Total operating (income) expense	19,097	(62,883)	33,510	(44,214)
Income (loss) from operations	(11,730)	69,620	(21,529)	58,340
Other income (expense):				
Interest income	9	6	14	12
Interest expense	(907)	(1,029)	(1,555)	(2,915)
Loss on early extinguishment of debt	--	(1,254)	--	(1,254)
Change in fair value of warrant liabilities	(975)	10,201	(564)	18,470
Change in fair value of embedded derivatives	--	--	--	(14)
Other income (expense)	(39)	(8)	(160)	(55)
Total other income (expense)	(1,912)	7,916	(2,265)	14,244
Net income (loss) from continuing operations before income taxes	(13,642)	77,536	(23,794)	72,584
Benefit for income taxes	6,946	--	6,932	--
Net income (loss) from continuing operations	(6,696)	77,536	(16,862)	72,584
Income (loss) from discontinued operations, net of applicable tax	79,160	(14,672)	66,464	(30,651)
Net income	$ 72,464	$ 62,864	$ 49,602	$ 41,933
Net income per share, basic	$ 3.78	$ 3.59	$ 2.59	$ 2.40
Net income per share, diluted	$ 3.78	$ 3.59	$ 2.59	$ 1.31
Weighted average shares outstanding, basic	19,176	17,498	19,173	17,454
Weighted average shares outstanding, diluted	19,176	17,498	19,173	17,846

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

	June 30, 2015 unaudited	**December 31, 2014**
ASSETS		

Current assets:		
Cash and cash equivalents	$ 77,372	$ 42,205
Restricted cash	10,000	8,500
Short-term investments	9,062	--
Trade accounts receivable, net	5,954	6,078
Inventory	12,646	11,444
Prepaid expenses and other current assets	4,500	2,555
Current assets of discontinued operations	5,796	7,196
Total current assets	125,330	77,978
Property and equipment, net	9,823	10,618
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	2,579	2,832
Noncurrent assets of discontinued operations	231	2,673
Total assets	$ 246,697	$ 202,835
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,293	$ 4,742
Accrued expenses	8,669	9,173
Accrued income taxes	6,521	--
Common stock warrant liabilities	5,657	5,093
Revolving credit facility	--	1,450
Long-term debt, current portion	3,040	--
Deferred revenue	827	1,472
Current liabilities of discontinued operations	9,990	22,307
Total current liabilities	38,997	44,237
Note payable	2,641	2,461
Long-term debt, less current portion	16,357	19,242
Deferred revenue, less current portion	7,493	7,063
Contingent purchase consideration	51,400	53,000
Deferred income taxes	20,500	20,500
Other long-term liabilities	1,229	1,053
Stockholders' equity	108,080	55,279
Total liabilities and stockholders' equity	$ 246,697	$ 202,835

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