Zogenix Provides Corporate Update and Reports Third Quarter 2015 Financial Results

November 9, 2015

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

SAN DIEGO, Nov. 9, 2015 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ:ZGNX), a pharmaceutical company developing therapies for the treatment of central nervous system (CNS) disorders, provided a corporate update, and announced financial results for the third quarter ended September 30, 2015.

Corporate Update

- Continued preparations for the Phase 3 program for ZX008, which is expected to begin in the fourth quarter of 2015 for the treatment of Dravet syndrome, a rare and debilitating form of epilepsy that begins in infancy. Key recent activities include:
    - Submitted Investigational New Drug (IND) Application to the U.S. Food and Drug Administration (FDA)
    - Initiated pre-study qualification visits in 11 countries with 34 study sites selected for participation in the Phase 3 studies
    - Convened International Pediatric Cardiovascular Advisory Board
- Reported positive top-line pharmacokinetic results from a Phase 1b multi-dose clinical trial of Relday ™, a proprietary, once-monthly subcutaneous investigational formulation of risperidone for the treatment of schizophrenia. Zogenix has retained Locust Walk Partners of Cambridge, MA, a transaction advisory firm for life sciences companies, to provide transaction advisory and support services for Relday. Efforts to secure a global strategic development and commercialization partner for Relday are ongoing.
- Closed public equity offering resulting in approximately $92 million in net proceeds.
- Completed the nine-months ended September 30, 2015, with $162.7 million in cash and cash equivalents. Zogenix's expected cash runway now extends through 2017.
- Participated in the Wells Fargo 2015 Healthcare Conference and the Leerink Partners 4th Annual Rare Disease Roundtable.

"Over the past few months, we have made significant progress towards initiation of the Phase 3 program for ZX008 in the treatment of uncontrolled seizures in children with Dravet syndrome. While we are engaged in an ongoing information exchange with FDA to establish normal/abnormal values for interpretation of echocardiograms to be collected during the Phase 3 program, we continue to expect the U.S. pivotal efficacy and safety trial will proceed later this year," said Stephen J. Farr, Ph.D., President and CEO. "We also continue to move ahead with Relday, having recently announced positive top-line pharmacokinetic results from a Phase 1b multi-dose clinical trial, and are actively seeking a global strategic development and commercialization partner for this program, which would represent another value creating event for Zogenix and the Company's shareholders."

Third Quarter 2015 Financial Results Compared to Third 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 third quarter of 2015 was $9.1 million, and reflected $8.9 million of contract manufacturing revenue and $0.3 million of service and other product revenue. This compared with total revenue of $4.9 million in the same quarter last year, which included $4.2 million of contract manufacturing revenue and $0.7 million of service and other product revenue. The increase in contract manufacturing revenue in the 2015 third quarter was due to an increase in shipments of Sumavel® DosePro® to Endo International Plc under the supply agreement between the two companies.
- Third quarter 2015 research and development expenses totaled $7.9 million, up from $2.9 million in the third quarter a year ago, as the Company continued preparations for its two Phase 3 studies for ZX008, and completed its multi-dose clinical study for Relday.
- Third quarter 2015 selling, general and administrative expense totaled $5.7 million, compared with $7.2 million in the third quarter a year ago.
- Net loss from continuing operations for the third quarter of 2015 was $13.0 million, compared with $1.5 million in the same quarter a year ago.
- Net loss from discontinued operations was $1.6 million for the third quarter of 2015, compared with a net loss of $11.4 million in the third quarter a year ago, which reflected the operating loss related to the Zohydro business.
- Total net loss for the third quarter of 2015 was $14.6 million, or $0.65 per basic share and fully diluted, compared with a net loss of $12.8 million, or $0.73 per basic share and fully diluted, for the third quarter a year ago.

Nine-Months Ended September 30, 2015 Financial Results Compared to Nine-Months Ended September 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 nine-months ended September 30, 2015 was $21.1 million, and reflected $19.0 million of contract manufacturing revenue and $2.1 million of service and other product revenue. This compared with total revenue of $19.0 million in the same period last year, which included $6.5 million of contract manufacturing revenue and $12.5 million of net product and service revenue. The increase in contract manufacturing revenue and decrease in net product revenue in the 2015 nine-months ended September 30, 2015 was due to the sale of Sumavel DosePro to Endo International Plc in May 2014 and subsequent performance under the supply agreement between the two companies.

- Research and development expenses for the nine-months ended September 30, 2015 totaled $19.3 million, up from $8.6 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 nine-months ended September 30, 2015 totaled $19.5 million, compared with $28.9 million in the year ago period. The Company incurred selling expenses for Sumavel DosePro prior to its sale in May 2014.

- Net loss from continuing operations for the nine-months ended September 30, 2015 was $29.8 million, compared with net income from continuing operations of $71.1 million in the same period a year ago, which includes the gain on the sale of Sumavel DosePro.

- Net income from discontinued operations for the nine-months ended September 30, 2015 was $64.8 million, compared to a loss of $42.0 million in the year ago period. Income from discontinued operations in 2015 includes a gain on the sale of the Zohydro business of $73.1 million net of applicable tax expense.

- Total net income for the nine-months ended September 30, 2015 was $35.0 million, or $1.72 per basic share and fully diluted, compared with net income of $29.1 million, or $1.66 per basic share and $0.17 fully diluted, for the nine-months ended September 30, 2014.

- Cash and cash equivalents at September 30, 2015 totaled $162.7 million, which includes the net proceeds of $92.0 million received from the public offering that closed on August 5, 2015.

2015 Financial Guidance

Below is the Company's financial guidance for the remainder of 2015, which reflects spending towards the low end of the annual guidance ranges previously provided.

- Research and development expenses are expected to be $10 to $12 million for the fourth quarter of 2015, reflecting the initiation of ZX008 clinical studies.
- Selling, general and administrative expenses are expected to be $7 to $8 million for the fourth quarter of 2015.
- Contract manufacturing revenue from the supply of Sumavel DosePro to Endo is expected 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 fourth quarter 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 719-325-2308 and use conference ID: 660434. A telephone replay will be available approximately two hours after the call and will run through November 23, 2015, by dialing 877-870-5176 from the U.S., or 858-384-5517 from international locations, and entering Replay Pin Number: 660434. The conference call will be broadcast live and will be available for replay for 60 days at: http://public.viavid.com/player/index.php?id=116611 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 CNS therapies that address specific clinical needs for people living with orphan and other 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.

Zogenix, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,	Nine Months Ended September 30,

	2015	2014	2015	2014
Revenues:				
Contract manufacturing revenue	$ 8,860	$ 4,225	$ 19,044	$ 6,463
Net product revenue	--		--	9,840
Service and other product revenue	260	658	2,057	2,705
Total revenue	9,120	4,883	21,101	19,008
Operating (income) expense:				
Cost of contract manufacturing	7,780	3,986	17,506	5,921
Cost of goods sold	--	--	--	5,262
Royalty expense	106	72	249	511
Research and development	7,919	2,912	19,310	8,616
Selling, general & administrative	5,696	7,213	19,547	28,865
Change in fair value of contingent consideration	(300)	--	(1,900)	--
Impairment of long-lived assets	--	--	--	838
Net gain on sale of business	--	--	--	(79,980)
Total operating (income) expense	21,201	14,183	54,712	(29,967)
Income (loss) from operations	(12,081)	(9,300)	(33,611)	48,975
Other income (expense):				
Interest income	33	6	47	18
Interest expense	(751)	(84)	(2,306)	(2,999)
Loss on early extinguishment of debt	--	--	--	(1,254)
Change in fair value of warrant liabilities	(296)	7,948	(861)	26,418
Change in fair value of embedded derivatives	--	--	--	(14)
Investment loss	(5,485)		(5,485)	
Other income (expense)	103	14	(55)	(39)
Total other income (expense)	(6,396)	7,884	(8,660)	22,130
Net income (loss) from continuing operations before income taxes	(18,477)	(1,416)	(42,271)	71,105
Benefit for income taxes	5,496	(45)	12,428	(45)
Net income (loss) from continuing operations	(12,981)	(1,461)	(29,843)	71,060
Income (loss) from discontinued operations, net of applicable tax	(1,635)	(11,364)	64,829	(41,952)
Net income	$ (14,616)	$ (12,825)	$ 34,986	$ 29,108
Net income per share, basic	$ (0.65)	$ (0.73)	$ 1.72	$ 1.66
Net income per share, diluted	$ (0.65)	$ (0.73)	$ 1.72	$ 0.17
Weighted average shares outstanding, basic	22,613	17,630	20,332	17,513
Weighted average shares outstanding, diluted	22,613	17,630	20,332	17,909

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

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 162,683	$ 42,205
Restricted cash	10,001	8,500
Short-term investments	5,129	--
Trade accounts receivable, net	3,906	6,078
Inventory	10,341	11,444
Prepaid expenses and other current assets	4,782	2,555
Current assets of discontinued operations	3,782	7,196
Total current assets	200,624	77,978
Property and equipment, net	9,537	10,618
Intangible assets	102,500	102,500

Goodwill	6,234	6,234
Other assets	2,664	2,832
Noncurrent assets of discontinued operations	4	2,673
Total assets	$ 321,563	$ 202,835
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,328	$ 4,742
Accrued expenses	8,216	9,173
Accrued income taxes	3,535	--
Common stock warrant liabilities	5,954	5,093
Revolving credit facility	--	1,450
Long-term debt, current portion	4,724	--
Deferred revenue	1,116	1,472
Current liabilities of discontinued operations	5,153	22,307
Total current liabilities	35,026	44,237
Note payable	2,737	2,461
Long-term debt, less current portion	14,750	19,242
Deferred revenue, less current portion	6,320	7,063
Contingent purchase consideration	51,100	53,000
Deferred income taxes	20,500	20,500
Other long-term liabilities	1,316	1,053
Stockholders' equity	189,814	55,279
Total liabilities and stockholders' equity	$ 321,563	$ 202,835

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