Zogenix Provides Corporate Update and Reports Third Quarter 2016 Financial Results

November 7, 2016

Company will host a conference call today at 4:30 p.m. EST/1:30 p.m. PST

EMERYVILLE, Calif., Nov. 07, 2016 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ:ZGNX), a pharmaceutical company developing therapies for the treatment of orphan and central nervous system (CNS) disorders, today provided a corporate update and announced financial results for the third quarter ended September 30, 2016.

CORPORATE UPDATE

- Continued enrollment in the two Phase 3 safety and efficacy clinical trials of ZX008 (low-dose fenfluramine) (Studies 1501 and 1502) in North America, Europe and Australia, with top-line results anticipated in Q2 2017.
- Company remains on-track for potential regulatory submissions by year-end 2017.
- Initiated Cohort 1 (pharmacokinetic assessment) in Study 1504, a trial evaluating the pharmacokinetics, efficacy and safety of ZX008 in patients who have responded poorly to a stiripentol regimen. Cohort 2 (efficacy and safety assessment) is expected to begin by the end of this year.
- Effectiveness and safety results of ZX008 from the ongoing open-label prospective study of patients with Dravet syndrome published in the *European Journal of Neurology*. The study demonstrated a robust median reduction in seizures of 75% (range, 28–100%) during the treatment period with no cardiovascular abnormalities. Schoonjans, A. S., Paelinck, B. P., Marchau, F., Gunning, B., Gammaitoni, A., Galer, B. S., Lagae, L. and Ceulemans, B. (2016). Eur J Neurol. doi:10.1111/ene.13195
- Presented further data at the 12th European Congress on Epileptology related to understanding the burden Dravet syndrome causes for the patient and their family, and also on identifying clinically relevant outcome measures to assess the quality of life impact on Dravet syndrome patients and their caregivers.
- Multiple abstracts accepted for presentation at the upcoming American Epilepsy Society Annual Meeting (December 2-6, 2016) highlighting new clinical and pre-clinical findings, including an interim analysis of an on-going investigator initiated open-label Phase 2 trial in Lennox Gastaut syndrome.
- Completed the nine-months ended September 30, 2016, with $109.9 million in cash and cash equivalents. Zogenix expects its cash runway to extend through 2017.

“During the third quarter, we continued to accelerate the clinical development of our lead product, ZX008 for Dravet syndrome,” said Stephen J. Farr, Ph.D., President and CEO. “We are continuing to enroll patients in both Phase 3 trials and intend to report top-line data in the second quarter of 2017. We look forward to having a significant presence, including the presentation of multiple posters and hosting a Scientific Exhibit Room, at the upcoming American Epilepsy Society Meeting in December.”

Third Quarter 2016 Financial Results Compared to Third Quarter 2015 Financial Results

As a result of the sale of the Zohydro ER business in April 2015, all Zohydro ER revenue and expenses have been excluded from continuing operations for all periods herein and reported as discontinued operations.

- Total revenue for the third quarter of 2016 was $6.6 million, consisting almost entirely of contract manufacturing revenue. This compared with total revenue of $9.1 million in the same quarter last year, which included $8.9 million of contract manufacturing revenue. The decrease in contract manufacturing revenue in the third quarter of 2016 was due primarily to a decrease in deliveries to Endo International Plc under the supply agreement between the two companies.
- Third quarter 2016 research and development expenses totaled $10.1 million, up from $7.9 million in the third quarter a year ago, as the Company progressed its two Phase 3 clinical trials for ZX008, continuing enrollment in Study 1501 and Study 1502.
- Third quarter 2016 selling, general and administrative expenses totaled $6.5 million, compared with $5.7 million in the third quarter a year ago.
- Net loss from continuing operations for the third quarter of 2016 was $16.6 million, compared with $13.0 million in the third quarter a year ago.
- Net loss from discontinued operations was $0.4 million for the third quarter of 2016, compared with net loss of $1.6 million in the third quarter a year ago.
- Total net loss for the third quarter of 2016 was $17.0 million, or $0.69 per share, compared with net loss of $14.6 million, or $0.65 per share, for the third quarter a year ago.

Nine-Months Ended September 30, 2016 Financial Results Compared to Nine-Months Ended September 30, 2015 Financial Results

- Total revenue for the nine-months ended September 30, 2016 was $17.9 million, consisting almost entirely of contract manufacturing revenue. This compared with total revenue of $21.1 million in the same period last year, which included $19.0 million of contract manufacturing revenue and $2.1 million of service and other product revenue.

- Research and development expenses for the nine months ended September 30, 2016 totaled $28.4 million, up from $19.3 million in the year ago period, as the Company enrolled patients into two Phase 3 clinical trials for ZX008.

- Selling, general and administrative expense for the nine months ended September 30, 2016 totaled $19.5 million, flat as compared to the same period a year ago.

- Net loss from continuing operations was $45.1 million for the nine months ended September 30, 2016, compared with $29.8 million in the same period a year ago.

- Net loss from discontinued operations was $1.1 million for the nine months ended September 30, 2016, compared to net income of $64.8 million in the same period a year ago, which included the net gain on the sale of the Zohydro ER business.

- Total net loss for the nine months ended September 30, 2016 was $46.2 million, or $1.87 per basic share and fully diluted, compared with net income of $35.0 million, or $1.72 per share, for the same period a year ago, which included the net gain on the sale of the Zohydro ER business.

- Cash and cash equivalents at September 30, 2016 totaled $109.9 million, as compared to $155.3 million at December 31, 2015.

2016 Financial Guidance

Zogenix is updating its financial guidance for the full year 2016.

- Research and development expenses are now expected to be $42-44 million compared to prior guidance of $54-$59 million, reflecting slower site initiation and ramp-up of ZX008 clinical studies than expected;
- Selling, general and administrative expenses are unchanged and expected to be $25-27 million; and
- Contract manufacturing revenue from the supply of Sumavel DosePro to Endo is expected at a low single-digit markup over cost of contract manufacturing.

Conference Call Details

Investors interested in participating in today's live call can dial 877-675-4749 from the U.S. and international callers can dial 719-325-4826 and use conference ID: 1385531. A telephone replay will be available approximately two hours after the call and will run through November 21, 2016, by dialing 844-512-2921 from the U.S., or 412-317-6671 from international locations, and entering Replay Pin Number: 1385531. The conference call will be broadcast live and will be available for replay for 60 days at: http://public.viavid.com/index.php?id=121629 and on the IR section of the company's website at: www.zogenix.com.

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 improve their daily functioning.

For more information, visit www.zogenix.com.

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 ZX008's potential as a treatment for seizures associated with Dravet syndrome; the enrollment of patients in the two on-going Phase 3 clinical trials for ZX008; the timing of top line results for the two on-going Phase 3 clinical trials; the timing of any NDA submission; the timing of the commencement of Cohort 2 of Study 1504; the presentation of data at the American Epilepsy Society Annual Meeting ; and revised 2016 financial guidance. 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, including potential delays in the commencement, enrollment and completion of clinical trials; the potential that earlier clinical trials and studies 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, as well as rules and regulations outside the United States, that apply to its product development activities; Fast Track designation may not result in an expedited regulatory review process; 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,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Contract manufacturing revenue	$ 6,345	$ 8,860	$ 17,537	$ 19,044
Service and other product revenue	225	260	327	2,057
Total revenue	6,570	9,120	17,864	21,101
Operating expense:				
Cost of contract manufacturing	6,391	7,780	16,256	17,506

Royalty expense	78	106	224	249
Research and development	10,076	7,919	28,447	19,310
Selling, general & administrative	6,538	5,696	19,506	19,547
Change in fair value of contingent consideration	200	(300)	2,800	(1,900)
Total operating expense	23,283	21,201	67,233	54,712
Loss from operations	(16,713)	(12,081)	(49,369)	(33,611)
Other income (expense):				
Interest expense, net	(567)	(718)	(1,788)	(2,259)
Change in fair value of warrant liabilities	(356)	(296)	5,148	(861)
Loss on short-term investments	-	(5,485)	-	(5,485)
Other (income) expense	25	103	2	(55)
Total other income (expense)	(898)	(6,396)	3,362	(8,660)
Net loss from continuing operations before income taxes	(17,611)	(18,477)	(46,007)	(42,271)
Income tax benefit	993	5,496	922	12,428
Net loss from continuing operations	(16,618)	(12,981)	(45,085)	(29,843)
Net income (loss) from discontinued operations, net of applicable tax	(379)	(1,635)	(1,130)	64,829
Net income (loss)	$ (16,997)	$ (14,616)	$ (46,215)	$ 34,986
Net income (loss) per share, basic and diluted	$ (0.69)	$ (0.65)	$ (1.87)	$ 1.72
Weighted average shares outstanding, basic and diluted	24,791	22,613	24,780	20,332

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

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 109,866	$ 155,349
Restricted cash	-	10,002
Trade accounts receivable, net	6,524	1,396
Inventory	9,412	12,030
Prepaid expenses and other current assets	9,467	5,518
Current assets of discontinued operations	6	208
Total current assets	135,275	184,503
Property and equipment, net	8,358	9,254
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	3,470	3,331
Total assets	$ 255,837	$ 305,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,107	$ 5,290
Accrued expenses	7,573	8,328
Common stock warrant liabilities	1,048	6,196
Long-term debt, current portion	-	6,321
Deferred revenue	1,194	945
Current liabilities of discontinued operations	1,203	2,906
Total current liabilities	14,125	29,986
Long-term debt, less current portion	21,845	15,899
Deferred revenue, less current portion	4,986	6,139
Contingent purchase consideration	53,800	51,000
Deferred income taxes	17,425	18,450
Other long-term liabilities	1,739	1,588
Stockholders' equity	141,917	182,760
Total liabilities and stockholders' equity	$ 255,837	$ 305,822

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Zogenix, Inc.