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Zosano Pharma Reports Fourth Quarter and Fiscal 2016 Financial Results and Business Update

FREMONT, Calif., March 01, 2017 (GLOBE NEWSWIRE) -- Zosano Pharma Corporation (NASDAQ:ZSAN), an emerging central nervous system company focused on providing symptom relief to patients using the Company's proprietary intracutaneous delivery system, today announced financial results for the fourth quarter and year ended December 31, 2016.

"The past year was an important period of progress for the Company as we initiated and in the fourth quarter completed ZOTRIP, our pivotal efficacy trial in migraine," commented Konstantinos Alataris, PhD, President and Chief Executive Officer of Zosano Pharma. "Subsequent to the fiscal year end, we announced positive results from the ZOTRIP trial, which not only advances our lead migraine program towards FDA approval but also further validates the effectiveness of our technology platform. If approved, M207 could be an important new therapeutic option for migraine patients."

The ZOTRIP trial was designed to be a registration-enabling, pivotal efficacy trial of M207 as an acute treatment for migraine. The study was a multicenter, double-blind, randomized, placebo-controlled, dose-ranging trial comparing three doses (1.0mg, 1.9mg and 3.8mg) of M207, a novel transdermal therapeutic, for a single migraine attack. A total of 589 subjects were enrolled at 36 sites across the United States. Dosing of ZOTRIP's first subject was announced in July of 2016. This past November, the Company announced the completion of ZOTRIP's enrollment.

Recent Highlights and Key Upcoming Milestones

- In January 2017, and in line with previously provided guidance, the Company announced the treatment of the last patient in ZOTRIP.
- In February 2017, the Company announced statistically significant results from the Phase 2/3 ZOTRIP trial, which demonstrated that the 3.8mg dose of M207 met both co-primary endpoints, achieving pain freedom and most bothersome symptom freedom at 2 hours. The 3.8mg dose achieved statistical significance in the secondary endpoints of pain freedom at 45 minutes and 1 hour, and showed durability of effect on pain freedom at 24 and 48 hours. Additionally, M207 was not associated with any Serious Adverse Events (SAEs).
- The FDA has indicated that a single, positive, pivotal efficacy study, in addition to a safety study of M207, will be sufficient to file for approval under a 505(b)(2) pathway. The Company plans to initiate the safety study in the second half of 2017.

About Migraine

Migraine is the leading cause of disability among neurological disorders in the United States according to the American Migraine Foundation. An estimated 30 million men, women and children in the United States suffer from migraine. Migraine can be extremely disabling and costly, accounting for more than an estimated $20 billion in direct (e.g., doctor visits, medications) and indirect (e.g., missed work, lost productivity) expenses each year in the United States.

About M207

M207 is our proprietary formulation of zolmitriptan coated onto our patented intracutaneous microneedle patch, which is then applied with our proprietary applicator to ensure uniform and consistent application. In a Phase 1 trial, M207 demonstrated markedly faster absorption kinetics compared to oral zolmitriptan. The Company presented these results at the 2016 annual meeting of the American Headache Society.

Financial Results for the Year Ended December 31, 2016

- Zosano reported a net loss for 2016 of $29.8 million, or $2.17 per share on a basic and diluted basis, compared with a net loss of $28.4 million, or $2.49 per share on a basic and diluted basis, for 2015. Our net loss for the fourth quarter of 2016 was $7.7 million, or $0.46 per share on a basic and diluted basis, compared with a net loss of $7.6 million, or $0.64 per share on a basic and diluted basis, for the same quarter in 2015.

- Total revenue for the year ended December 31, 2016, was zero, compared with $0.3 million in 2015. We had no revenue for the fourth quarters of 2016 and 2015.

- Research and development (R&D) expenses for the year 2016 were $20.5 million, compared with $20.4 million in 2015. The amounts were relatively flat year over year. Expenses in 2016 primarily consisted of M207 ZOTRIP trial, Phase 1 clinical trial and related preclinical toxicology studies, whereas expenses in 2015 consisted primarily of ZP-Glucagon Phase 2 clinical trial, and Phase 3 GMP manufacturing preparation for our Daily ZP-PTH product candidate conducted in connection with our now terminated collaboration with Lilly. R&D expenses for the fourth quarter of 2016 were $5.4 million, compared with $5.7 million for the same quarter in 2015.

- General and administrative (G&A) expenses for the year 2016 were $8.2 million, compared with $6.3 million in 2015. The increase in G&A was primarily attributable to additional costs for postemployment severance and benefits paid to our former Chief Executive Officer, an increase in stock based compensation expense, and an increase in personnel, consulting and insurance costs. G&A expenses were $2.0 million for the fourth quarter of 2016, compared with $1.5 million for the same quarter in 2015.

- As of December 31, 2016, we had cash and cash equivalents of $15.0 million, and debt of $12.5 million. As of February 15, 2017 we had 17.9 million common shares outstanding.

About Zosano Pharma

Zosano Pharma Corporation is an emerging CNS company focusing on providing rapid symptom relief to patients using known therapeutics and altering their delivery profile using the Company's proprietary intracutaneous delivery system. The Company's goal is to make intracutaneous drug delivery a standard of care for delivering drugs requiring fast onset of action. Zosano Pharma has developed its proprietary intracutaneous delivery system to administer proprietary formulations of existing drugs through the skin for the treatment of a variety of indications. The Company believes that its intracutaneous delivery system offers rapid and consistent drug delivery combined with ease of use. The Company is focused on developing products that deliver established molecules with known safety and efficacy profiles for markets where patients remain underserved by existing therapies. Zosano Pharma anticipates that many of its current and future development programs may enable the Company to utilize a regulatory pathway that would streamline clinical development and accelerate the path towards commercialization. Learn more at www.zosanopharma.com.

Forward-Looking Statements

This press release contains forward-looking statements regarding the timing of expected clinical development milestones, sufficiency of our capital resources and need for future funding and other future events and expectations. Readers are urged to consider statements that include the words "may," "will," "would," "could," "should," "might," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," "unaudited," "approximately" or the negative of those words or other comparable words to be uncertain and forward-looking. These statements are subject to risks and uncertainties that are difficult to predict and actual outcomes may differ materially. These include risks and uncertainties, without limitation, associated with the process of discovering, developing and commercializing products that are safe and effective for use as human therapeutics, risks inherent in the effort to build a business around such products and other risks and uncertainties described under the heading "Risk Factors" in the Company's most recent annual report on Form 10-K.. Although we believe that the expectations reflected in these forward-looking statements are reasonable, we cannot in any way guarantee that the future results, level of activity, performance or events and circumstances reflected in forward-looking statements will be achieved or occur. All forward-looking statements are based on information currently available to Zosano and Zosano assumes no obligation to update any such forward-looking statements.

ZOSANO PHARMA CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited; in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
	(unaudited)	(unaudited)		
Revenue:				
License fees	$ -	$ -	$ -	$ 170
Collaboration revenue	-	-	-	143
Total revenue	-	-	-	313
Operating expenses:				
Research and development	5,413	5,665	20,457	20,366
General and administrative	2,039	1,518	8,176	6,315
Total operating expenses	7,452	7,183	28,633	26,681

Loss from operations	(7,452)	(7,183)	(28,633)	(26,368)
Other income (expenses):				
Interest expense, net	(241)	(317)	(1,192)	(1,564)
Other expense, net	(56)	(146)	(7)	(97)
Warrant revaluation income	-	-	-	48
Loss on debt extinguishment	-	-	-	(446)
Net loss	$ (7,749)	$ (7,646)	$(29,832)	$(28,427)
Net loss per common share basic and diluted	$ (0.46)	$ (0.64)	$ (2.17)	$ (2.49)
Weighted-average shares used in computing net loss per common share basic and diluted	16,816	11,967	13,773	11,414

ZOSANO PHARMA CORPORATION AND SUBSIDIARIES
SELECTED CONSOLIDATED BALANCE SHEETS DATA
(in thousands)

	December 31, 2016	December 31, 2015
Cash, cash equivalents and marketable securities	$15,003	$ 36,933
Total current assets	15,276	37,271
Total assets	20,906	45,337
Secured promissory note	12,542	15,270
Total liabilities	16,421	18,835
Stockholders' equity	4,485	26,502

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