Zynerba Pharmaceuticals Reports Third Quarter 2016 Financial Results and Operational Highlights

November 14, 2016

DEVON, Pa., Nov. 14, 2016 (GLOBE NEWSWIRE) -- Zynerba Pharmaceuticals, Inc. (NASDAQ:ZYNE), a clinical-stage specialty pharmaceutical company dedicated to the development of innovative transdermal synthetic cannabinoid treatments, today reported financial results for the third quarter ended September 30, 2016 and provided an overview of recent operational highlights.

“The third quarter was marked by significant advancement of our lead development candidate, ZYN002 CBD gel,” said Armando Anido, Chairman and CEO. “We initiated randomization and dosing, and are continuing to enroll patients into the STAR 1 refractory epilepsy clinical trial. We also initiated the STOP trial, which will evaluate ZYN002 CBD gel in patients with knee pain associated with osteoarthritis. We look forward to initiating a third Phase 2 clinical trial of ZYN002 CBD gel in patients with Fragile X Syndrome by year-end. We expect to report top line results of all three Phase 2 clinical trials in the first half of 2017.”

Highlights from the Third Quarter 2016 & Recent Developments
Began Dosing of First Patients in STAR 1 Clinical Trial for the Treatment of Adult Epilepsy

- In August, Zynerba began dosing patients in STAR 1 (**S**ynthetic **T**ransdermal C**a**nnabidiol for the T**r**eatment of Epilepsy), a randomized, multi-center, multi-dose Phase 2 clinical trial that will evaluate 97.5 mg or 195 mg of CBD in ZYN002 4.2% gel or placebo every 12 hours in approximately 180 adult refractory epilepsy patients with focal seizures. The primary endpoint will assess the median percentage change in seizure frequency over the 12-week treatment period versus baseline. Safety and tolerability will also be assessed.

Initiated STAR 2 Open-Label Extension for the Treatment of Adult Epilepsy

- In November, Zynerba initiated an open-label clinical trial in adult epilepsy patients with refractory focal seizures who complete the STAR 1 study. Patients will receive treatment with ZYN002 for up to 52-weeks. The open-label clinical trial is designed to support long-term safety and tolerability of ZYN002 CBD gel.

Launched Phase 2 STOP Clinical Trial for the Treatment of Osteoarthritis (OA)

- In September, Zynerba initiated the STOP (**S**ynthetic **T**ransdermal Cannabidi**o**l for the Treatment of Knee **P**ain due to Osteoarthritis) trial, a multi-center, placebo-controlled, Phase 2 clinical trial that will evaluate 125 mg or 250 mg of CBD in ZYN002 4.2% gel or placebo twice daily in approximately 300 patients with knee pain due to OA. The primary endpoint is the change from baseline in the weekly mean of the 24-hour average worst pain score.

Updated Progress with ZYN001 pro-drug of THC Patch

- In October, the Company announced that it is working with LTS Lohmann Therapie-Systeme AG, a market leader in transdermal therapeutic solutions, to optimize the formulation of ZYN001 into a state of the art drug-adhesive matrix transdermal patch. ZYN001 is a patent-protected pro-drug of THC being developed for the treatment of fibromyalgia and peripheral neuropathic pain.

Upcoming Events in the Fourth Quarter of 2016

- At the **American Society of Epilepsy** meeting to be held in Houston, TX, from December 2-6, Zynerba will present two posters highlighting safety and tolerability and cognitive and mood effects for ZYN002.
- Zynerba will host a **Clinical Research Day** on December 15th in New York City featuring distinguished experts who will discuss the role of cannabinoid-based treatments in epilepsy, osteoarthritis and Fragile X syndrome.

Upcoming Clinical Milestones
ZYN002 CBD Gel

- Zynerba plans to initiate a third Phase 2 clinical trial of ZYN002 in patients with Fragile X syndrome (FXS) by year-end 2016.
- Top line results of three Phase 2 clinical trials in refractory epilepsy, OA and FXS are expected in the first half of 2017.

ZYN001 pro-drug of THC Patch

- Zynerba expects to initiate Phase 1 clinical trials to evaluate the pharmacokinetic profile and tolerability of ZYN001 in healthy volunteers in the first half of 2017.

- Phase 2 clinical trials in the treatment of fibromyalgia and peripheral neuropathic pain are planned to begin in the second half of 2017.

Third Quarter 2016 Financial Results
As of September 30, 2016, cash and cash equivalents were $31.8 million, compared to $32.1 million as of June 30, 2016. In September 2016, the Company entered into an Open Market Sales Agreement with Jefferies LLC pursuant to which, as of November 11, 2016, the Company sold and issued 753,799 shares of its common stock in the open market at a weighted average selling price of $13.38 per share, for net proceeds of $9.5 million, $5.3 million of which were received and included in cash and cash equivalents as of September 30, 2016. The remaining $4.2 million of net proceeds was received after September 30, 2016 and will be included in the fourth quarter financial statements.

Research and development expenses for the third quarter of 2016 were $4.5 million, including non-cash stock-based compensation of $0.3 million. General and administrative expenses for the third quarter of 2016 were $1.5 million, including non-cash stock-based compensation expense of $0.5 million. Net loss for the third quarter of 2016 was $6.0 million with basic and diluted net loss per share of ($0.67).

Financial Outlook

Management believes that the Company's available funds, including proceeds from the sale of common stock received through November 11, 2016, are sufficient to develop five Phase 3 ready programs and these resources are sufficient to fund operations and capital requirements into 2018.

About Zynerba Pharmaceuticals, Inc.
Zynerba Pharmaceuticals (NASDAQ:ZYNE) is a clinical-stage specialty pharmaceutical company focused on developing and commercializing proprietary next-generation synthetic cannabinoid therapeutics formulated for transdermal delivery. Zynerba is developing therapeutic candidates based on proprietary transdermal technologies that, if successfully developed, may allow sustained, consistent and controlled delivery of therapeutic levels of two cannabinoids: cannabidiol (CBD), a non-psychoactive cannabinoid, and tetrahydrocannabinol (THC). Transdermal delivery has the potential to reduce adverse effects associated with oral dosing. ZYN002, the Company's CBD gel, is the first and only synthetic CBD formulated as a patent protected permeation-enhanced gel. In June 2016, the company initiated the Phase 2 STAR 1 (Synthetic Transdermal Cannabidiol for the Treatment of Epilepsy) clinical trial of ZYN002 CBD gel in refractory epilepsy patients with focal seizures and has also launched the STAR 2 open-label extension trial which allows patients who complete STAR 1 to receive treatment with ZYN002 gel for up to 52 weeks. In August 2016, the Phase 2 STOP (Synthetic Transdermal Cannabidiol for the Treatment of Knee Pain due to Osteoarthritis) clinical trial in patients with knee pain due to OA was initiated. A Phase 2 clinical trial in Fragile X syndrome (FXS) is expected to initiate in the second half of 2016. Zynerba is also developing ZYN001, which utilizes a synthetically manufactured pro-drug of THC. A Phase 1 clinical trial for ZYN001 is planned to begin in the first half of 2017. Learn more at www.zynerba.com and follow the Company on Twitter at @ZynerbaPharma.

Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the Company's current expectations. For example, there can be no guarantee that the Company will obtain approval for ZYN002 or ZYN001 from the U.S. Food and Drug Administration (FDA) or foreign regulatory authorities; even if ZYN002 or ZYN001 are approved, the Company may not be able to obtain the label claims that it is seeking from the FDA. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: the success, cost and timing of the Company's product development activities, studies and clinical trials; the success of competing products that are or become available; the Company's ability to commercialize its product candidates; the size and growth potential of the markets for the Company's product candidates, and the Company's ability to service those markets; the Company's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of the Company's product candidates; and the Company's expectations regarding its ability to obtain and adequately maintain sufficient intellectual property protection for its product candidates. These and other risks are described in the Company's periodic reports, including the annual report on Form 10K, quarterly reports on Form 10Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission and available at www.sec.gov. Any forward-looking statements that the Company makes in this press release speak only as of the date of this press release. The Company assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

ZYNERBA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended		Nine months ended	
	September 30, 2016	**September 30, 2015**	**September 30, 2016**	**September 30, 2015**
Revenue	$ -	$ 199,407	$ 7,250	$ 229,625
Operating expenses:				
Research and development	4,504,097	2,271,968	11,880,264	4,136,659
General and administrative	1,493,461	1,922,755	4,649,948	3,208,003
Total operating expenses	5,997,558	4,194,723	16,530,212	7,344,662
Loss from operations	(5,997,558)	(3,995,316)	(16,522,962)	(7,115,037)
Other income (expense):				
Interest income	22,747	1,572	53,243	2,948

Foreign exchange loss	(6,270)	-	(49,668)	
Total other income (expense)	16,477	1,572	3,575	2,948
Loss before income taxes	(5,981,081)	(3,993,744)	(16,519,387)	(7,112,089)
Income tax benefit	-	-	(27,543)	-
Net loss	$ (5,981,081)	$ (3,993,744)	$ (16,491,844)	$ (7,112,089)
Net loss per share - basic and diluted	$ (0.67)	$ (0.66)	$ (1.86)	$ (2.37)
Basic and diluted weighted average shares outstanding	8,912,508	6,045,211	8,865,854	2,998,480
Non-cash stock-based compensation included above:				
Research and development	$ 292,385	$ 297,169	$ 916,036	$ 297,169
General and administrative	513,019	539,655	1,465,906	539,655
Total	$ 805,404	$ 836,824	$ 2,381,942	$ 836,824

ZYNERBA PHARAMCEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 31,780,773	$ 41,513,060
Incentive and tax receivables	2,281,205	356,718
Prepaid expenses and other current assets	1,464,564	1,545,917
Total current assets	35,526,542	43,415,695
Property and equipment, net	304,141	227,646
Other assets	463,600	200
Total assets	$ 36,294,283	$ 43,643,541
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,694,470	$ 823,401
Accrued expenses	2,882,060	2,272,991
Deferred grant revenue	370,575	841,225
Total current liabilities	4,947,105	3,937,617
Deferred grant revenue, long-term	463,400	—
Total liabilities	5,410,505	3,937,617
Stockholders' equity:		
Common stock	9,628	9,200
Additional paid-in capital	69,946,049	62,276,779
Accumulated deficit	(39,071,899)	(22,580,055)
Total stockholders' equity	30,883,778	39,705,924
Total liabilities and stockholders' equity	$ 36,294,283	$ 43,643,541

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