Zynerba Pharmaceuticals Reports First Quarter 2016 Financial Results and Operational Highlights

May 12, 2016

DEVON, Pa., May 12, 2016 (GLOBE NEWSWIRE) -- Zynerba Pharmaceuticals, Inc. (NASDAQ:ZYNE), a specialty pharmaceutical company dedicated to the development of innovative transdermal synthetic cannabinoid treatments, today reported financial results for the quarter ended March 31, 2016, and provided an overview of recent operational highlights.

"We continue to make rapid progress in our ZYN002 cannabidiol (CBD) gel clinical development program with positive initial results reported in a Phase 1 single rising dose trial, the initiation of a second Phase 1 trial in healthy volunteers and patients with epilepsy, and a grant of orphan drug designation from the US Food and Drug Administration for the treatment of Fragile X syndrome," said Armando Anido, Chairman and CEO of Zynerba Pharmaceuticals.

"Further, important *in vitro* data were published in *Cannabis and Cannabinoid Research* demonstrating that orally administered CBD is converted into psychoactive cannabinoids when exposed to gastric fluid. Zynerba's transdermal delivery of CBD bypasses the acidic environment of the stomach and thus, avoids the potential for formation of psychoactive cannabinoids. These data support the Company's strategy of pursuing a transdermal delivery and we are on pace to initiate Phase 2 clinical trials in three indications in the second half of this year."

Highlights from the First Quarter 2016 and Recent Developments

Reported Positive Initial Results from a Phase 1 Single Rising Dose Trial and Initiated a Phase 1 Multiple Rising Dose Trial of ZYN002 CBD Gel: In January 2016, Zynerba reported positive initial safety results from its Phase 1 single rising dose clinical trial of its ZYN002 CBD gel. Initial results demonstrated that ZYN002 was safe and well tolerated at all four dose levels. The Company also announced the initiation of a Phase 1 multiple rising dose trial to evaluate the pharmacokinetic (PK) profile and tolerability of ZYN002 in 24 healthy volunteers, followed by 12 patients with epilepsy.

ZYN002 Granted Orphan Drug Designation for Fragile X Syndrome: In February 2016, the U.S. Food and Drug Administration granted orphan-drug designation to ZYN002 CBD gel, for the treatment of Fragile X syndrome (FXS). FXS is a genetic condition that causes intellectual disability, anxiety disorders, behavioral and learning challenges and various physical characteristics. In mouse knockout models for FXS, symptoms are improved when endocannabinoid levels are increased. There is also anecdotal evidence that high levels of CBD oil from plants have proven effective at improving socialization and language skills in children.

Data Published Demonstrating the Degradation of Orally Administered Cannabidiol to Psychoactive Cannabinoids when Exposed to Simulated Gastric Fluid: In April 2016, the Company announced publication online in *Cannabis and Cannabinoid Research* of *in vitro* data demonstrating that the acidic pH conditions provided in simulated gastric fluid converts CBD into psychoactive components Δ^9–THC, Δ^8–THC and other psychoactive cannabinoids. These data suggest that the oral route of administration may increase the potential for psychoactive adverse effects due to the conversion of CBD to THC following oral dosing of CBD- medications. Zynerba's transdermal formulation of CBD, ZYN002, is an alternative delivery method that bypasses the acidic environment of the stomach and avoids the potential for formation of psychoactive cannabinoids.

Anticipated 2016 Milestones

ZYN002, synthetic CBD formulated as a permeation-enhanced gel for transdermal delivery

- By the end of the first half of 2016, Zynerba expects to report final results from its ongoing Phase 1 single rising dose clinical trial, including results from 12 patients with epilepsy.
- By the end of the first half of 2016, Zynerba expects to report results from its second ongoing Phase 1 multiple rising dose clinical trial.
- Pending the results of the Phase 1 trials, Zynerba plans to initiate Phase 2 trials in refractory epilepsy, osteoarthritis (OA), and FXS in the second half of 2016.

ZYN001, pro-drug of THC that enables transdermal delivery via patch

- In the second half of 2016 Zynerba expects to initiate Phase 1 studies to evaluate the PK profile and tolerability of ZYN001 in healthy volunteers and patients with fibromyalgia.

First Quarter 2016 Financial Results

As of March 31, 2016, cash and cash equivalents were $36.8 million, compared to $41.5 million as of December 31, 2015.

Research and development expenses for the first quarter of 2016 were $2.6 million, including stock-based compensation of $0.3 million. General and administrative expenses for the first quarter of 2016 were $1.7 million, including stock-based compensation expense of $0.5 million. Net loss for the first quarter of 2016 was $4.3 million with basic and diluted net loss per share of $0.49. Adjusted EBITDA for the period, which excludes stock-based compensation and foreign currency loss, was $(3.5) million, or $0.39 per basic and diluted net loss per share.

Financial Outlook

Based on current operating plans, the Company expects that its existing cash and cash equivalents will fund its research and development programs

and operations through 2017, which will include Phase 2 data readout for the five indications of ZYN002 and ZYN001.

About Zynerba Pharmaceuticals, Inc.
Zynerba Pharmaceuticals (NASDAQ:ZYNE) is a 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 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 and is being studied in refractory epilepsy, FXS and osteoarthritis. Zynerba is also developing ZYN001, which utilizes a synthetically manufactured pro-drug of THC in a transdermal patch to deliver THC through the skin and into the bloodstream. ZYN001 will be studied in fibromyalgia and peripheral neuropathic pain. Learn more at www.zynerba.com and follow the Company on Twitter at @ZynerbaPharma.

Non-GAAP Financial Measures
The non-GAAP financial information contained herein is a supplement to the corresponding financial measures prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). Non-GAAP measures should be considered in addition to, but not as a substitute for, reported GAAP results. Further, non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared.

Management uses adjusted EBITDA (defined as earnings before interest, income taxes, depreciation, amortization, stock-based compensation and foreign currency loss) in its evaluation of the Company's core results of operations and trends between fiscal periods and believes that these measures are important components of its internal performance measurement process. Management believes that this non-GAAP financial information reflects an additional way of viewing aspects of our business that, when viewed with our GAAP results, provide a more complete understanding of factors and trends affecting our business. Please see the section of this press release titled "Reconciliation of Adjusted EBITDA and Adjusted EBITDA Per Share."

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	
	March 31, 2016	**March 31, 2015**
Revenues	$ 7,250	$ 14,828
Operating expenses:		
Research and development	2,568,989	853,704
General and administrative	1,680,130	653,773
Total operating expenses	4,249,119	1,507,477
Loss from operations	(4,241,869)	(1,492,649)
Other income (expense):		
Interest income	12,377	680
Foreign currency loss	(23,148)	-
Total other income (expense)	(10,771)	680
Loss before income taxes	(4,252,640)	(1,491,969)
Income tax expense	28,734	-
Net loss	$ (4,281,374)	$ (1,491,969)
Net loss per share - basic and diluted	$ (0.49)	$ (1.03)

Basic and diluted weighted average shares outstanding	8,823,951	1,449,865

ZYNERBA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 36,809,693	$ 41,513,060
Incentive receivable	356,718	356,718
Prepaid expenses and other current assets	1,359,890	1,545,917
Total current assets	38,526,301	43,415,695
Property and equipment, net	223,180	227,646
Other assets	352,980	200
Total assets	$ 39,102,461	$ 43,643,541
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable	$ 989,414	$ 823,401
Accrued expenses	1,090,724	2,272,991
Deferred grant revenue	833,974	841,225
Total current liabilities	2,914,112	3,937,617
Stockholders' equity (deficit):		
Common stock	9,200	9,200
Additional paid-in capital	63,040,578	62,276,779
Accumulated deficit	(26,861,429)	(22,580,055)
Total stockholders' equity (deficit)	36,188,349	39,705,924
Total liabilities and stockholders' equity (deficit)	$ 39,102,461	$ 43,643,541

ZYNERBA PHARMACEUTICALS, INC.
RECONCILIATION OF ADJUSTED EBITDA AND ADJUSTED EBITDA PER SHARE
(Unaudited)

	Three months ended	
	March 31, 2016	**March 31, 2015**
GAAP Net loss	$ (4,281,374)	$ (1,491,969)
Add back:		
Depreciation	13,558	1,447
Interest (income)	(12,377)	(680)
Income tax expense	28,734	-
EBITDA	(4,251,459)	(1,491,202)
Add back:		
Stock-based compensation	763,799	-
Foreign currency loss	23,148	-
Adjusted EBITDA	$ (3,464,512)	$ (1,491,202)
GAAP Net loss per share	$ (0.49)	$ (1.03)
Add back:		
Depreciation	0.00	0.00
Interest (income) expense	(0.00)	(0.00)

Income tax expense	0.01	-
EBITDA per share	(0.48)	(1.03)
Add back:		
Stock-based compensation	0.09	-
Foreign currency loss	0.00	-
Adjusted EBITDA per share	$ (0.39)	$ (1.03)
Shares used in computation of GAAP and adjusted EBITDA per share - basic and diluted	8,823,951	1,449,865

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