Zynerba Pharmaceuticals Reports Third Quarter 2015 Financial Results and Operational Highlights

November 11, 2015

Successful IPO, Initiation of Phase 1 for ZYN002 CBD Gel and Leadership Team Build-Out

DEVON, Pa., Nov. 11, 2015 (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 September 30, 2015, and provided recent operational highlights.

"Following our successful initial public offering in August, we are well-positioned to advance the development of our pipeline of first-in-class transdermal cannabinoid treatments," said Armando Anido, Chairman and CEO of Zynerba Pharmaceuticals. "We are rapidly progressing clinical development of these novel transdermal synthetic cannabinoid candidates, with the initiation of a Phase 1 trial for ZYN002 CBD gel in October and expected results in the first half of 2016. With a strong board in place, successful recruitment of additional key leadership and initiation of clinical development for ZYN002, we expect a productive year ahead as we work to take the company and its pipeline to the next stage."

Third Quarter 2015 and Recent Highlights

Successful IPO: Zynerba closed its initial public offering of 3,450,000 shares of common stock at a public offering price of $14.00 per share, before underwriting discounts, on August 10, 2015. This included the exercise in full by the underwriters of their option to purchase up to 450,000 additional shares of common stock at the public offering price, resulting in gross proceeds of $48.3 million. All of the shares in the offering were sold by Zynerba.

Phase 1 Clinical Trial Initiation for ZYN002 CBD Gel: Zynerba initiated a Phase 1 clinical trial for its ZYN002 cannabidiol (CBD) gel on October 20, 2015. The "Single Rising Dose Study in Normal Subjects and Patients with Epilepsy" study evaluates the pharmacokinetic profile and tolerability of ZYN002 in 32 healthy volunteers and in 12 patients with epilepsy. Results are expected in the first half of 2016.

New Vice President, Manufacturing: Zynerba appointed Brian Boyd as Vice President, Manufacturing, on September 14, 2015. Mr. Boyd is a senior pharmaceutical manufacturing executive with more than 30 years of experience driving superior manufacturing process outcomes in the biotechnology and pharmaceutical industries. Most recently, he was Vice President, Process Development for Auxilium Pharmaceuticals and also held senior CMC and manufacturing roles with PolyMedix, Discovery Labs, Aviron/MedImmune Vaccines and US Bioscience/MedImmune. He earned a BS in Chemistry from Denison University.

Six New Board of Directors Members: Zynerba appointed six new members to its board of directors on August 6, 2015, joining Chairman of the Board and CEO Armando Anido. The appointees offer extensive scientific, regulatory, commercial and financial experience and successful track records in development- and commercial-stage pharmaceutical companies. The new board members include Warren D. Cooper, MB, BS, BSc, MPFM, former CEO, Prism Pharmaceuticals; William J. Federici, MBA, CPA, Vice President and Chief Financial Officer of West Pharmaceutical Services; Thomas L. Harrison, LH.D, Chairman Emeritus of Diversified Agency Services, a division of Omnicom Group; Daniel L. Kisner, MD, former venture partner, Aberdare Ventures; Kenneth I. Moch, President, Euclidean Life Sciences Advisors; and Cynthia Rask, MD, board certified in clinical neurophysiology and former Acting Director, Office of Cellular, Tissue and Gene Therapies, US Food and Drug Administration.

Pipeline Update

ZYN002

ZYN002 is the first and only synthetic CBD formulated as a permeation-enhanced gel for transdermal delivery, and is patent-protected through 2030. ZYN002 is being developed as a clear, odorless gel with once- or twice-daily dosing. Zynerba plans to evaluate ZYN002 in patients with refractory epilepsy, Fragile X Syndrome (FXS) and osteoarthritis (OA). A Phase 1 clinical trial for ZYN002 CBD gel was initiated on October 20, 2015 and will evaluate the pharmacokinetic profile (PK) and tolerability of ZYN002 in 32 healthy volunteers and in 12 patients with refractory epilepsy. Results are expected in the first half of 2016.

Subsequent to the single rising dose clinical trial, Zynerba intends to conduct a Phase 1 multiple rising dose clinical trial to examine the tolerability, PK and pharmacodynamics (PD), of multiple doses of ZYN002 in healthy human subjects and in patients with refractory epilepsy. Two randomized, double-blind, placebo-controlled Phase 2a clinical trials comparing the efficacy and safety of ZYN002 to placebo, each in refractory epilepsy and OA are planned for initiation in the second half of 2016. Zynerba intends to initiate in the second half of 2016, an open label Phase 2a clinical trial in FXS to evaluate efficacy and safety.

ZYN001

ZYN001 is a pro-drug of THC that enables transdermal delivery via a patch and is patent-protected through 2031. A pro-drug is a drug administered in an inactive or less active form and designed to enable more effective delivery, which is then converted into an active form through a normal metabolic process. The Company intends to study ZYN001 in patients with fibromyalgia and peripheral neuropathic pain.

A Phase 1 clinical trial for ZYN001 is planned to initiate in mid-2016 and will evaluate the PK profile and tolerability of ZYN001. Subsequent to the single rising dose clinical trial, the Company expects to conduct a Phase 1 multiple rising dose clinical trial to examine the tolerability, PK and PD of ZYN001 in healthy human subjects and in patients with fibromyalgia. A Phase 2a randomized, double-blind, placebo-controlled clinical trial comparing the efficacy and safety of ZYN001 with placebo in fibromyalgia and peripheral neuropathic pain is planned for the first half of 2017.

Third Quarter 2015 Financial Results

As of September 30, 2015, Zynerba had cash and cash equivalents of $44.8 million. Research and development expenses for the three month period ended September 30, 2015 were $2.3 million, including stock-based compensation of approximately $0.3 million. General and administrative expenses for the three month period ending September 30, 2015 were $1.9 million, including stock-based compensation of approximately $0.5 million and a transaction related expense for the initial public offering of $0.5 million. Net loss for the period was $4.0 million with net loss per share of $0.66 per basic and diluted weighted average shares outstanding. Non-GAAP net loss for the period, which excludes stock-based compensation and a transaction related expense, was $2.7 million, or $0.44 per basic and diluted weighted average shares outstanding. As of September 30, 2015, the Company had 6,045,211 basic and diluted weighted average shares outstanding.

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, Fragile X syndrome 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 are 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 non-GAAP net loss (defined as net loss before stock-based compensation and transaction related expense) 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 Non-GAAP Net Loss."

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 under the heading "Risk Factors" in the registration statement on Form S-1 (commission file number 333-205355), which was declared effective by the Securities and Exchange Commission on August 4, 2015. 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, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Revenues	$ 199,407	$ 525,471	$ 229,625	$ 735,855
Operating expenses:				
Research and development	2,271,968	932,838	4,136,659	1,585,711
General and administrative	1,922,755	2,107,520	3,208,003	3,413,560
Total operating expenses	4,194,723	3,040,358	7,344,662	4,999,271
Loss from operations	(3,995,316)	(2,514,887)	(7,115,037)	(4,263,416)
Other income (expense):				
Interest income (expense), net	1,572	(359)	2,948	(1,844)
Net loss	(3,993,744)	(2,515,246)	(7,112,089)	(4,265,260)

Accretion of redeemable convertible preferred stock	-	-	-	(87,954)
Net loss applicable to common stockholders	$ (3,993,744)	$ (2,515,246)	$ (7,112,089)	$ (4,353,214)
Net loss per share - basic and diluted	$ (0.66)	$ (2.17)	$ (2.37)	$ (6.19)
Basic and diluted weighted average shares outstanding	6,045,211	1,160,812	2,998,480	703,321

ZYNERBA PHARMACEUTICALS, INC.
Consolidated Balance Sheets
(unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 44,806,731	$ 9,330,681
Deferred offering costs	-	1,080,199
Prepaid expenses and other current assets	2,059,169	1,183,949
Total current assets	46,865,900	11,594,829
Property and equipment, net	229,012	19,642
Other assets	200	2,200
Total assets	$ 47,095,112	$ 11,616,671
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable	$ 615,530	$ 313,937
Accrued expenses	1,207,698	1,711,473
Deferred grant revenue	890,500	1,120,125
Total current liabilities	2,713,728	3,145,535
Commitments and contingencies		
Convertible Preferred Stock:		
Series 1 convertible preferred stock, $0.001 par value	-	16,522,811
Stockholders' equity (deficit):		
Common stock, $0.001 par value	9,200	2,030
Additional paid-in capital	61,512,978	1,975,000
Accumulated deficit	(17,140,794)	(10,028,705)
Total stockholders' equity (deficit)	44,381,384	(8,051,675)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 47,095,112	$ 11,616,671

ZYNERBA PHARMACEUTICALS, INC.
Reconciliation of Non-GAAP Net Loss
(unaudited)

	Three months ended		Nine months ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
GAAP Net loss	$ (3,993,744)	$ (2,515,246)	$ (7,112,089)	$ (4,353,214)
Add back:				
Stock-based compensation	836,824	-	836,824	-
Transaction related expense	500,000	-	500,000	-

Non-GAAP net loss	$ (2,656,920)	$ (2,515,246)	$ (5,775,265)	$ (4,353,214)
GAAP Net loss per share	$ (0.66)	$ (2.17)	$ (2.37)	$ (6.19)
Add back:				
Stock-based compensation	0.14	-	0.28	-
Transaction related expense	0.08	-	0.17	-
Non-GAAP net loss per share	$ (0.44)	$ (2.17)	$ (1.93)	$ (6.19)
Shares used in computation of GAAP and non-GAAP net loss per share - basic and diluted	6,045,211	1,160,812	2,998,480	703,321

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