Zynerba Pharmaceuticals Reports Second Quarter 2016 Financial Results and Organizational Changes

August 11, 2016

Jim Fickenscher will assume role as Chief Financial Officer, VP, Corporate Development

Dr. Nancy Tich appointed VP, Clinical, in a newly created position

DEVON, Pa., Aug. 11, 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 second quarter ended June 30, 2016 and changes to the Company's executive management team.

Zynerba announced that Jim Fickenscher will replace Richard Baron as Chief Financial Officer, Vice President, Corporate Development, effective September 13, 2016. Mr. Fickenscher joins Zynerba with 28 years of experience in the pharmaceutical industry. Most recently, he was Senior Vice President, Chief Financial Officer at Antares Pharma, a commercial pharmaceutical company focused on self-administered parenteral products. He has also held roles as CFO at Auxilium Pharmaceuticals and Aventis Behring LLC, a wholly owned subsidiary of Aventis, predecessor to Sanofi S.A, as well as business development and strategic planning positions. Mr. Baron will remain with the Company through the transition into September.

Zynerba also announced the appointment of Nancy Tich, MS, Ph.D, as Vice President, Clinical, a newly created position. Dr. Tich joins Zynerba with more than 26 years of clinical project management experience. Most recently, Dr. Tich served as Senior Director, Project Management, at Covance. She has also held senior clinical roles at Omnicare, Elan Pharmaceuticals and Abbott Laboratories.

"During the quarter, Zynerba achieved several clinical milestones and strengthened the organization. We achieved a significant milestone with our lead development compound, ZYN002, including initiation of a Phase 2 clinical study in epilepsy patients. We are also pleased to welcome two new additions to our executive management team. Jim Fickenscher, who will join us on September 13, is a seasoned executive in the pharmaceutical industry who has been the CFO for other biopharmaceutical companies, including Auxilium during my tenure as CEO. He brings a wealth of financial and corporate development experience and I look forward to working with him again and building Zynerba into a leading specialty pharmaceutical company," said Armando Anido, Chairman and CEO. "We also welcome Dr. Nancy Tich, who joined us in June, to our clinical team. She brings nearly three decades of experience to her role as Vice President, Clinical, and her knowledge will be invaluable as Zynerba advances its lead product candidate in the clinic."

Mr. Anido continued, "We deeply appreciate Rick Baron's numerous contributions, particularly his leadership through our listing on the Nasdaq in August 2015. On behalf of the entire company, we thank Rick for his financial expertise and friendship. We wish him much success as he pursues new personal and professional endeavors."

Clinical Highlights from the Second Quarter 2016
Initiated Phase 2 STAR 1 (**S**ynthetic **T**ransdermal C**a**nnabidiol for the T**r**eatment of Epilepsy) **clinical trial for ZYN002 CBD gel in refractory epilepsy:** Zynerba initiated the baseline phase of the STAR 1clinical study in refractory epilepsy patients with focal seizures in June. The Company announced in August that patients had begun randomization and dosing. The STAR 1 trial expects to enroll up to 180 refractory epilepsy patients who will receive either 97.5 mg of ZYN002 4.2% CBD gel, 195 mg of ZYN002 4.2% CBD gel, or placebo gel twice daily. The primary endpoint will assess the median percentage change in seizure frequency over the 12-week treatment period. Safety and tolerability will also be evaluated. Top line results are expected to be reported in the first half of 2017.

Reported top line results from a 7-day Phase 1 Multiple Rising Dose trial for ZYN002 CBD gel: The 7-day Phase 1 trial included 24 healthy volunteers ranging from 25 to 53 years old and 12 epilepsy patients from 19 to 65 years old. These results confirmed that ZYN002 CBD gel was safe and well-tolerated at all dose levels ranging from 200 to 500 mg CBD daily in 1% and 2.5% ZYN002 formulations.

Reported top line results from a 14-day Phase 1 Multiple Rising Dose trial for ZYN002 CBD gel: In this trial, 42 healthy volunteers received a range of CBD doses from 395 mg to 504 mg daily in 2.5% and 4.2% ZYN002 formulations for 14 days. ZYN002 was safe and very well tolerated with minimal skin erythema. The 4.2% formulation demonstrated a comparable pharmacokinetic and tolerability profile to the 2.5% concentration and was easier to use due to its lower volume.

Reported final results from a Phase 1 Single Rising Dose trial: These results confirmed initial findings that ZYN002 CBD gel was safe and well tolerated in healthy volunteers and patients with epilepsy across a wide range of doses.

Anticipated 2016 Clinical Milestones
ZYN002, synthetic CBD formulated as a permeation-enhanced gel for transdermal delivery

- Zynerba plans to initiate additional Phase 2 trials in osteoarthritis (OA) and Fragile X syndrome (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.

Second Quarter 2016 Financial Results
As of June 30, 2016, cash and cash equivalents were $32.1 million, compared to $36.8 million as of March 31, 2016.

Research and development expenses for the second quarter of 2016 were $4.8 million, including stock-based compensation of $0.4 million. General and administrative expenses for the second quarter of 2016 were $1.5 million, including stock-based compensation expense of $0.4 million. Net loss for the second quarter of 2016 was $6.2 million with basic and diluted net loss per share of $0.70.

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 top line results for the five indications being evaluated for ZYN002 and ZYN001.

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 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 STAR 1 Phase 2 clinical study of ZYN002 CBD gel in refractory epilepsy patients with focal seizures. Phase 2 studies in osteoarthritis and Fragile X syndrome (FXS) are 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 study for ZYN001 is planned to begin in the second half of 2016. 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.”

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		Six months ended	
	June 30, 2016	**June 30, 2015**	**June 30, 2016**	**June 30, 2015**
Revenue	$ -	$ 15,390	$ 7,250	$ 30,218
Operating expenses:				
Research and development	4,807,177	1,010,989	7,376,167	1,864,693
General and administrative	1,476,357	631,474	3,156,487	1,285,247
Total operating expenses	6,283,534	1,642,463	10,532,654	3,149,940
Loss from operations	(6,283,534)	(1,627,073)	(10,525,404)	(3,119,722)
Other income (expense):				

Interest income	18,118	697	30,496	1,377
Foreign exchange loss	(20,250)	-	(43,398)	
Total other income (expense)	(2,132)	697	(12,902)	1,377
Loss before income taxes	(6,285,666)	(1,626,376)	(10,538,306)	(3,118,345)
Income tax benefit	(56,277)	-	(27,543)	-
Net loss	$ (6,229,389)	$ (1,626,376)	$ (10,510,763)	$ (3,118,345)
Net loss per share - basic and diluted	$ (0.70)	$ (1.12)	$ (1.19)	$ (2.15)
Basic and diluted weighted average shares outstanding	8,860,592	1,449,865	8,842,271	1,449,865

ZYNERBA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 32,133,048	$ 41,513,060
Incentive and tax receivables	1,692,315	356,718
Prepaid expenses and other current assets	1,768,994	1,545,917
Total current assets	35,594,357	43,415,695
Property and equipment, net	209,287	227,646
Other assets	200	200
Total assets	$ 35,803,844	$ 43,643,541
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,681,122	$ 823,401
Accrued expenses	1,517,048	2,272,991
Deferred grant revenue	833,975	841,225
Total current liabilities	5,032,145	3,937,617
Stockholders' equity:		
Common stock	9,200	9,200
Additional paid-in capital	63,853,317	62,276,779
Accumulated deficit	(33,090,818)	(22,580,055)
Total stockholders' equity	30,771,699	39,705,924
Total liabilities and stockholders' equity	$ 35,803,844	$ 43,643,541

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

	Three months ended		Six months ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
GAAP Net loss	$ (6,229,389)	$ (1,626,376)	$ (10,510,763)	$ (3,118,345)
Add back:				
Depreciation	13,892	3,095	27,450	4,542
Interest income	(18,118)	(697)	(30,496)	(1,377)
Income tax benefit	(56,277)	-	(27,543)	-
EBITDA	(6,289,892)	(1,623,978)	(10,541,352)	(3,115,180)

Add back:				
Stock-based compensation	812,739	-	1,576,538	-
Foreign exchange loss	20,250	-	43,398	-
Adjusted EBITDA	$ (5,456,903)	$ (1,623,978)	$ (8,921,416)	$ (3,115,180)

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