February 28, 2017

Cempra Provides Corporate Update and Reports Fourth Quarter and Full Year 2016 Financial Results

—Management to host webcast and conference call today at 8:45 a.m. ET—

CHAPEL HILL, N.C., Feb. 28, 2017 (GLOBE NEWSWIRE) -- Cempra, Inc. (Nasdaq:CEMP), a clinical-stage pharmaceutical company focused on developing antibiotics to meet critical medical needs in the treatment of bacterial infectious diseases, today reported financial results for the quarter ended December 31, 2016 and provided an update on recent corporate developments. The company will host a webcast and conference call today at 8:45 a.m. ET.

"We have made substantial progress in recent weeks to clarify our existing clinical programs, including positive phase 3 results with fusidic acid, further define the next steps to advance solithromycin, and take significant cost-reduction actions to preserve our sizable cash resources as we evaluate the best investments, including potential external opportunities, to deliver value to patients and shareholders," said David Zaccardelli, Pharm.D., acting chief executive officer of Cempra.

Fourth Quarter 2016 and Recent Corporate Highlights

Solithromycin--Regulatory

- On November 4, 2016, the U.S. Food and Drug Administration (FDA) Antimicrobial Drugs Advisory Committee (AMDAC) voted (7-6) that efficacy results of Cempra's solithromycin outweigh the risks for the treatment of community-acquired bacterial pneumonia (CABP). Members of AMDAC voted unanimously (13-0) that there was substantial evidence of the efficacy of solithromycin for CABP. The committee also voted (12-1) that the risk of hepatotoxicity with solithromycin had not been adequately characterized and discussed a variety of potential approaches to further characterize the existing liver safety information on solithromycin.
- On December 29, 2016, Cempra announced the company had received a complete response letter (CRL) from FDA relating to the company's new drug applications (NDAs) for oral and intravenous solithromycin for the treatment of CABP in adults. The CRL stated that the FDA could not approve the NDAs in their present form and noted that additional clinical safety information and the satisfactory resolution of manufacturing facility inspection deficiencies were required before the NDAs may be approved.
- Last week, the company met with the FDA to discuss the issues identified in the CRL.
- At the meeting, the FDA reiterated their request for additional clinical safety data prior to approval. Based on input from the FDA at the meeting, Cempra is developing a protocol which will propose including fewer than 9,000 patients at the time we respond to the CRL, and will propose to deliver data from defined cohorts as the study progresses. The company plans to discuss the protocol with the FDA to determine if it could support an initial approval in a limited group of patients with an urgent unmet need, while the company continues to accumulate a larger post-approval safety database to support a potential label expansion into the broader CABP population. If the company and FDA agree on a protocol, Cempra plans to seek non-dilutive funding to support the execution of the study.
- Cempra is preparing responses to the Day 120 questions the company has received from the European Medicines Agency (EMA) related to the marketing authorization application (MAA) the company submitted in June 2016 seeking approval of solithromycin for adults with community-acquired pneumonia. The EMA has suggested a post-approval clinical safety study (PASS) in the EU and we believe the EMA may request additional data prior to approval. We are currently assessing the path forward with the EMA that we believe would be most likely to achieve a positive benefit/risk assessment from them.

Solithromycin--Clinical

Gonorrhea

- Cempra has analyzed the data from the initial patient cohort of 262 patients in SOLITAIRE-U, a phase 3 study evaluating a single 1000 mg dose of oral solithromycin for treatment of uncomplicated genitourinary gonorrhea (GC), with or without concomitant chlamydia infection, compared with intramuscular ceftriaxone (500 mg) plus oral azithromycin (CTX/AZI) (1000 mg). While solithromycin demonstrated high success rates of 80.5 percent in the microbiological intent to treat (mITT) population (defined as achievement of a negative urethral or cervical swab culture at day seven to eight among those patients who had culture confirmation of GC infection at baseline) and 91.3 percent in the microbiologically evaluable (ME) population (comprised of those patients with a positive baseline culture who returned for their follow-up evaluation), and showed a 100 percent success rate for females in the ME

population, solithromycin did not demonstrate non-inferiority (NI) to standard of care treatment given the pre-specified 10 percent NI margin in the mITT population. The success rates for CTX/AZI in the mITT and ME populations were 84.5 percent and 100 percent, respectively.

- Given the limited number of females and adolescents in SOLITAIRE-U, the National Institute of Allergy and Infectious Disease (NIAID) agreed to fund an expansion of the trial to enroll up to 76 women and adolescents (age 15-17) under a cooperative research and development agreement. Enrollment of this trial expansion has been much slower than anticipated.
- We believe that the small number of solithromycin treatment failures observed in SOLITAIRE-U could be reduced in an approval-enabling study with an adjustment to the dosing regimen, as we believe the treatment failures were most likely related to the duration of study drug exposure at the site of infection. We plan to discuss our next steps with the GC program with NIAID and the FDA, as resistance to existing therapies for GC has created an urgent unmet medical need. In SOLITAIRE-U, no GC isolates demonstrated solithromycin resistance at baseline, and there was no emergence of solithromycin resistance in the isolates obtained at follow-up cultures.

Nonalcoholic steatohepatitis (NASH)

- In September 2016, Cempra announced interim results from an exploratory trial showing anti-NASH effects in the first six NASH patients dosed with solithromycin. Based on the safety profile and activity seen in the first six patients, Cempra continued this study to obtain data from up to 15 NASH patients. In the first quarter of 2017, four additional patients had completed treatment and undergone end-of-treatment liver biopsies, and the company has evaluated the data from the cohort of 10 patients.
- While data from the initial six patients were promising, the overall efficacy from patients receiving a reduced dose of 200 mg three times a week (after a 200 mg loading dose), including the second cohort of four patients, is unclear. Therefore, Cempra has elected to suspend the NASH development program for solithromycin at this time.

COPD

- Based on safety data from several of the initial patients dosed in an exploratory study evaluating the effect of long term systemic solithromycin administration on airway inflammation in chronic obstructive pulmonary disease (COPD), Cempra has closed the study.

Solithromycin--Pre-clinical

Ophthalmic

- We have an ongoing ophthalmic development program for solithromycin and are completing preclinical work to support a potential IND. Many of the pathogens that cause CABP are the same as, or similar to, the pathogens that cause eye infections and we are developing an ophthalmic formulation of solithromycin as a potential treatment for bacterial conjunctivitis and other ophthalmic conditions. We plan to request a pre-IND meeting with the FDA during 2017 to discuss moving our ophthalmic program forward into clinical trials. We believe there is minimal spending required over the next 12 months to potentially advance our ophthalmic program.

Fusidic Acid

On February 24, Cempra announced positive topline results from a phase 3 study of oral fusidic acid in patients with acute bacterial skin and skin structure infections (ABSSSI). Fusidic acid was well tolerated in the study and achieved the primary endpoint, demonstrating non-inferiority (NI) (10% NI margin) of oral fusidic acid compared to oral linezolid for early clinical response (ECR) in the intent to treat (ITT) patient population. Based on the results of this study, Cempra plans to meet with the FDA to discuss the next steps required to bring fusidic acid to patients in the United States.

Corporate Restructuring Action

As a consequence of the CRL we received, and subsequent discussions with the FDA, resulting in a delay of the potential approval of solithromycin, we recently initiated companywide cost and personnel reductions. These actions have resulted in an approximately 67 percent reduction in our workforce, from 136 to 45 employees, and significant reductions in external spending related to commercial preparedness and non-essential activities. The principal objective of the reductions is to enable us to conserve our financial resources as we evaluate the best path forward with our existing pipeline and potential business development opportunities.

Business Development Activities

As Cempra progresses its internal programs, the company also is actively engaged in a process to evaluate and assess external late-stage assets and other potential strategic business opportunities to determine the best use of its significant

cash resources and clinical programs to deliver value to patients and shareholders through internal and/or potential external opportunities.

Financial Results for the Three Months Ended December 31, 2016

For the quarter ended December 31, 2016, Cempra reported a net loss of $31.4 million, or $0.60 per share. During the same period in 2015, Cempra reported a net loss of $21.2 million, or $0.48 per share.

Research and development (R&D) expense in the fourth quarter of 2016 was $21.0 million, an increase of five percent compared to the same quarter in 2015. The higher R&D expense was primarily due to costs related to pre-approval manufacturing of solithromycin and related scale-up activities at manufacturers, partially offset by a decrease in clinical trial expenses for solithromycin. General and administrative expense was $18.2 million, a 174 percent increase compared to the quarter ended December 31, 2015, driven primarily by pre-commercialization costs, increased headcount as the company was preparing for potential commercialization of solithromycin and severance related to the retirement of our former chief executive officer.

Financial Results for the Year Ended December 31, 2016

For the year ended December 31, 2016, Cempra reported a net loss of $118.0 million, or $2.34 per share, compared to a net loss of $91.1 million, or $2.09 per share, for the year ended December 31, 2015.

Research and development expense was $81.7 million, a decrease of 12 percent compared to the year ended December 31, 2015. The decrease was primarily due to the decrease of clinical trial expenses for solithromycin and the purchase of API in 2015 in anticipation of the launch of solithromycin. General and administrative expense was $53.5 million, a 134 percent increase compared to the year ended December 31, 2015, driven primarily by pre-commercialization costs, increased headcount as the company was preparing for the potential commercial launch of solithromycin.

As of December 31, 2016, Cempra had cash and equivalents of $231.6 million and 52.4 million shares outstanding.

Our corporate restructuring was implemented to enable us to conserve our financial resources. As a result of the restructuring, we expect our research and corporate expenses to trend significantly downward beginning in the second quarter of this year and we expect to reduce second half 2017 expenses by more than 70 percent compared to the second half of 2016. These operating expense assumptions do not contemplate the costs associated with a commercial launch of solithromycin or any additional clinical trials with any of our product candidates. Future discussions with regulatory authorities and agreement on further clinical development requirements may lead to additional expense and we would expect to provide more granular expense guidance at that time.

Conference Call and Webcast

Cempra management will host a webcast and conference call regarding this announcement at 8:45 a.m. ET today. The live call may be accessed by dialing 877-377-7553 for domestic callers and 253-237-1151 for international callers and using conference ID #71917020. A live webcast of the call will be available online from the investor relations section of the company website at www.cempra.com and will be archived there for 30 days. A telephone replay of the call will be available by dialing 855-859-2056 for domestic callers or 404-537-3406 for international callers and entering the conference ID # 71917020.

About Cempra, Inc.

Cempra, Inc. is a clinical-stage pharmaceutical company focused on developing differentiated anti-infectives for the acute care and community settings to meet critical medical needs in the treatment of infectious diseases. Cempra's two lead product candidates are currently in advanced clinical development. Solithromycin has been evaluated in two phase 3 clinical trials for community-acquired bacterial pneumonia (CABP). Cempra is currently seeking approval for both intravenous and oral capsule formulations from the U.S. Food and Drug Administration and the European Medicines Agency. Solithromycin is licensed to strategic commercial partner Toyama Chemical Co., Ltd., a subsidiary of FUJIFILM Holdings Corporation, for certain exclusive rights in Japan. Cempra is contracted with BARDA for the development of solithromycin for pediatric use and has commenced enrollment in a global Phase 2/3 trial to evaluate the safety and efficacy of solithromycin versus standard of care antibiotics in children and adolescents from two months to 17 years of age. Solithromycin is also in development for uncomplicated urogenital urethritis caused by *Neisseria gonorrhoeae* or chlamydia. Fusidic acid is Cempra's second product candidate, which has completed a phase 3 trial comparing fusidic acid to linezolid in patients with acute bacterial skin and skin structure infections (ABSSSI). Cempra also has an ongoing exploratory study of fusidic acid for chronic oral treatment of refractory infections in bones and joints. Both products seek to address the need for new treatments targeting drug-resistant bacterial infections in the hospital and in the community. Cempra is also studying solithromycin for ophthalmic conditions and has synthesized novel macrolides for non-antibiotic uses such as the treatment

of chronic inflammatory diseases, endocrine diseases and gastric motility disorders. Cempra was founded in 2006 and is headquartered in Chapel Hill, N.C. For additional information about Cempra please visit www.cempra.com.

Please Note: *This press release contains forward-looking statements regarding future events. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: our ability to address the issues identified by the FDA in the complete response letter relating to our new drug applications for solithromycin for community acquired bacterial pneumonia; our ability to realize the cost savings of our recently initiated cost and personnel reductions; our ability to obtain FDA and foreign regulatory approval of solithromycin as a treatment for community acquired bacterial pneumonia; our ability to identify and enter into strategic business transactions; our ability to meaningfully reduce our research and corporate expenses; the impact of the recently announced changes in senior management and our ability to retain and hire necessary employees and to staff our operations appropriately; our anticipated capital expenditures and our estimates regarding our capital requirements, including the costs of addressing the complete response letter; our dependence on the success of solithromycin and fusidic acid; our and our strategic commercial partners' ability to obtain FDA and foreign regulatory approval of our product candidates; the costs, sources of funds, enrollment, timing, regulatory review and results of our studies and clinical trials and those of our strategic commercial partners; results of our and our strategic commercial partners' pre-clinical studies and clinical trials are not predictive of results from subsequent clinical trials for any possible therapy; our need to obtain additional funding and our ability to obtain future funding on acceptable terms; the unpredictability of the size of the markets for, and market acceptance of, any of our products, including solithromycin and fusidic acid; our ability to commercialize and launch, whether on our own or with a strategic partner, any product candidate that receives regulatory approval; our ability to produce and sell any approved products and the price we are able to realize for those products; the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties; our ability to compete in our industry; innovation by our competitors; and our ability to stay abreast of and comply with new or modified laws and regulations that currently apply or become applicable to our business. The reader is referred to the documents that we file from time to time with the Securities and Exchange Commission.*

CEMPRA, INC.

SELECTED FINANCIAL INFORMATION

Condensed Consolidated Balance Sheets (in thousands)	**December 31, 2016**	**December 31, 2015**
Assets		
Current assets		
Cash and equivalents	231,553	153,765
Receivables	6,162	7,639
Prepaid expenses	579	573
Total current assets	238,294	161,977
Furniture, fixtures and equipment, net	48	90
Deposits	173	73
Total assets	238,515	162,140
Liabilities		
Current liabilities		
Accounts payable	15,657	9,635
Accrued expenses	2,929	1,475
Accrued payroll and benefits	4,267	2,337
Current portion of long-term debt	6,667	4,444
Total current liabilities	29,520	17,891
Deferred revenue	16,987	11,326
Long-term debt	8,660	15,258
Total liabilities	55,167	44,475
Commitments and Contingencies		
Shareholders' Equity (Deficit)		
Common stock	52	44
Additional paid-in capital	620,279	436,643
Accumulated deficit	(436,983)	(319,022)
Total shareholders' equity	183,348	117,665
Total liabilities and shareholders' equity	238,515	162,140

Condensed Consolidated Statement of Operations
(unaudited; in thousands, except loss per share data) Three Months Ended December 31,

	2016	2015
Revenues	7,945	5,794
Operating Expenses		
R&D	21,043	20,018
G&A	18,205	6,641
Total Operating Expenses	39,248	26,659
Loss from operations	(31,303)	(20,865)
Other income (expense), net	(135)	(291)
Net loss and comprehensive loss	(31,438)	(21,156)
Net loss attributable to common shareholders	(31,438)	(21,156)
Basic and diluted net loss per share	(0.60)	(0.48)
Basic and diluted weighted avg shs	52,389	43,976

Condensed Consolidated Statement of Operations
(in thousands, except loss per share data) Twelve Months Ended December 31,

	2016	2015
Revenues	18,016	27,308
Operating Expenses		
R&D	81,686	93,353
G&A	53,538	22,871
Total Operating Expenses	135,224	116,224
Loss from operations	(117,208)	(88,916)
Other income (expense), net	(753)	(2,197)
Net loss and comprehensive loss	(117,961)	(91,113)
Net loss attributable to common shareholders	(117,961)	(91,113)
Basic and diluted net loss per share	(2.34)	(2.09)
Basic and diluted weighted avg shs	50,314	43,566

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