August 9, 2017

Cempra Provides Corporate Update and Reports Second Quarter 2017 Financial Results

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

CHAPEL HILL, N.C., Aug. 09, 2017 (GLOBE NEWSWIRE) -- Cempra, Inc. (Nasdaq:CEMP), a clinical-stage pharmaceutical company focused on developing differentiated anti-infectives for acute care and community settings to meet critical medical needs in the treatment of infectious diseases, today reported financial results for the quarter ended June 30, 2017 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 achieved significant progress with the FDA, reaching an agreement on a smaller, more focused and efficient approach to generating a first cohort of solithromycin safety data to support our response to the CRL," said David Zaccardelli, Pharm.D., acting chief executive officer of Cempra.

"We have also progressed our discussions with the FDA on fusidic acid and the agency has agreed that an additional Phase 3 study, similar in design to the successful Phase 3 study we reported earlier this year, would support potential approval of fusidic acid in ABSSSI. This clarity on both programs is very helpful to us as we progress our next steps," Zaccardelli added.

Second Quarter 2017 and Recent Corporate Highlights

Solithromycin

Community-acquired bacterial pneumonia (CABP)

- In the first quarter of 2017, we met with the U.S. Food and Drug Administration (FDA) to discuss the solithromycin complete response letter (CRL) and the FDA reiterated their request for additional clinical safety data prior to approval. Importantly, the FDA has stated that the Phase 3 trials provided evidence that oral and intravenous (IV) solithromycin are effective for the treatment of CABP. The FDA has not requested further efficacy data to support our response to the CRL.

- Based on input from the FDA, we proposed a protocol that would obtain safety data from an initial cohort of 6,000 CABP patients treated for five days with oral solithromycin, along with 1,200 CABP patients treated with the standard of care (5:1 randomization), at the time we respond to the CRL. We would subsequently provide follow-on data from an additional 3,000 CABP patients treated for five days with oral solithromycin.

- The FDA has communicated to us that this initial cohort of safety data with oral dosing, along with a satisfactory response to the manufacturing items raised in the CRL, would be acceptable to support a response to the CRL for the oral NDA and allow the FDA to evaluate the potential approval of oral solithromycin for CABP.

- Inclusion/exclusion criteria have been defined in the safety protocol and incorporate exclusion of patients taking selected concomitant medications which may be associated with higher liver enzyme levels, based on data from the Phase 3 SOLITAIRE-ORAL study.

- By eliminating the inclusion of IV formulation data in our initial response to the CRL, we expect to be able to conduct the safety study efficiently with the oral formulation and a dosing regimen that appeared to have a more favorable liver safety profile than IV dosing in our Phase 3 program. This approach also simplifies our response to manufacturing items in the CRL by focusing our response only on oral manufacturing. Additional safety data to support the potential approval of IV solithromycin would need to be provided under a separate study to be discussed with the FDA.

- We continue to advance our manufacturing activities for solithromycin at Uquifa and we believe that the time required to accumulate clinical safety data will be the rate-limiting step in our timeline to respond to the CRL.

- Based on the completed protocol for the proposed safety study, we are actively engaged with potential government and industry partners to identify non-dilutive funding to support the execution of the study.

Ophthalmic

- We have an ongoing ophthalmic development program for solithromycin and are completing preclinical work to support a potential IND filing in 2018.
- In the second quarter, we presented data at the annual meeting of the Association for Research in Vision and Ophthalmology highlighting topical ophthalmic formulations of solithromycin in preclinical models of activity, tolerability and pharmacokinetics in the eye.
- We are exploring the potential effects of solithromycin to treat ophthalmic bacterial infection as well as dry eye.

Fusidic Acid

- Based on the results we announced in the first quarter of 2017 from a successful Phase 3 study of fusidic acid in patients with acute bacterial skin and skin structure infections (ABSSSI), we met with the FDA in the second quarter to discuss the next steps required to bring fusidic acid to patients in the United States.
- The FDA has agreed that a second Phase 3 study with a similar design to the first successfully completed Phase 3 study could support potential approval of fusidic acid in patients with ABSSSI. Additionally, a thorough QT and drug interaction studies would be required for an NDA submission.
- We are also exploring the potential use of fusidic acid for the long-term oral treatment of refractory bone and joint infections, including prosthetic joint infections, caused by staphylococci, including *S. aureus* and MRSA. Currently, there is no optimal oral, chronic antibiotic for treating these infections. Enrollment in this 30 patient exploratory, open-label study completed in the second quarter. The primary endpoint of the study is clinical success six months after the start of treatment.

Evaluation of Strategic Business Opportunities

As we have announced in a separate press release today, Cempra and Melinta Therapeutics have entered into a definitive agreement under which Melinta will merge with Cempra.

Financial Results for the Three Months Ended June 30, 2017

For the quarter ended June 30, 2017, Cempra reported a net loss of $12.3 million, or $0.23 per share. During the same period in 2016, Cempra reported a net loss of $24.8 million, or $0.51 per share.

Research and development (R&D) expense in the second quarter of 2017 was $8.5 million, a decrease of 46.7 percent compared to the same quarter in 2016. The lower R&D expense was primarily due to a reduced headcount as a result of the corporate restructuring we implemented in the first quarter of 2017, as well as the completion of all major clinical studies by the end of 2016. General and administrative expense was $4.7 million, a 61.1 percent decrease compared to the quarter ended June 30, 2016, driven primarily by reduced headcount as a result of the reduction in workforce, as well as the discontinuation of commercial launch preparation activities that were ongoing at the same time in 2016.

As of June 30, 2017, Cempra had cash and equivalents of $187.0 million and 52.5 million shares outstanding.

As a result of the corporate restructuring we implemented in the first quarter of 2017, our research and corporate expenses trended significantly downward in the second quarter of 2017 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 exclude the costs associated with any additional clinical trials with any of our product candidates.

Conference Call and Webcast

Management will host a webcast and conference call regarding this announcement and the proposed merger with Melinta 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 # 48439667. A live webcast of the call will be available online from the investor relations section of the company website at www.cempra.com. A replay of the conference call and an archived version of the webcast will be made available once a transcript has been filed with the SEC, and we expect the replay to remain available for 30 days. The telephone replay of the call, once available, can be accessed by dialing 855-859-2056 for domestic callers or 404-537-3406 for international callers and entering the conference ID # 48439667.

About Cempra, Inc.

Cempra, Inc. is a clinical-stage pharmaceutical company focused on developing differentiated anti-infectives for 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 CABP for both intravenous and oral capsule formulations from the U.S. Food and Drug Administration. 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 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 identify and enter into strategic business transactions, including for our planned additional trial for solithromycin in response to the complete response letter from the FDA; our ability to realize the cost savings of our recently initiated cost and personnel reductions and our ability to further meaningfully reduce our research and corporate expenses; the impact of the recent 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 ability to obtain FDA and foreign regulatory approval of solithromycin as a treatment for community acquired bacterial pneumonia; 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)	**June 30, 2017**	**December 31, 2016**
Assets		
Current assets		
Cash and equivalents	187,005	231,553
Receivables	2,413	6,162
Prepaid expenses	1,014	579
Total current assets	190,432	238,294
Furniture, fixtures and equipment, net	33	48
Deposits	83	173
Total assets	190,548	238,515
Liabilities		
Current liabilities		
Accounts payable	6,752	15,657
Accrued expenses	1,408	2,929
Accrued payroll and benefits	986	4,267

Current portion of long-term debt	6,667	6,667
Total current liabilities	15,813	29,520
Deferred revenue	16,987	16,987
Long-term debt	5,342	8,660
Total liabilities	38,142	55,167
Commitments and Contingencies		
Shareholders' Equity (Deficit)		
Common stock	53	52
Additional paid-in capital	624,491	620,279
Accumulated deficit	(472,138)	(436,983)
Total shareholders' equity	152,406	183,348
Total liabilities and shareholders' equity	190,548	238,515

Condensed Consolidated Statement of Operations (unaudited; in thousands, except loss per share data)	**Six Months Ended June 30,**	
	2017	**2016**
Revenues	5,732	6,099
Operating Expenses		
R&D	23,955	39,547
G&A	13,424	20,312
Restructuring charge	3,553	-
Total Operating Expenses	**40,932**	**59,859**
Loss from operations	**(35,200)**	**(53,760)**
Other income (expense), net	45	(451)
Net loss and comprehensive loss	**(35,155)**	**(54,211)**
Net loss attributable to common shareholders	(35,155)	(54,211)
Basic and diluted net loss per share	(0.67)	(1.12)
Basic and diluted weighted average shares	52,451	48,375

Condensed Consolidated Statement of Operations (unaudited; in thousands, except loss per share data)	**Three Months Ended June 30,**	
	2017	**2016**
Revenues	860	3,420
Operating Expenses		
R&D	8,545	16,018
G&A	4,659	11,988
Restructuring charge	-	-
Total Operating Expenses	13,204	28,006
Loss from operations	(12,344)	(24,586)
Other income (expense), net	77	(219)
Net loss and comprehensive loss	(12,267)	(24,805)
Net loss attributable to common shareholders	(12,267)	(24,805)
Basic and diluted net loss per share	(0.23)	(0.51)
Basic and diluted weighted average shares	52,498	48,898

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