

# CEMPRA, INC.

## FORM 8-K (Current report filing)

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Address	6320 QUADRANGLE DRIVE SUITE 360 CHAPEL HILL, NC 27517-8149
Telephone	919-576-2306
CIK	0001461993
Symbol	CEMP
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934

**Date of Report (Date of earliest event reported): April 28, 2017**

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**CEMPRA, INC.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of incorporation)

**001-35405**  
(Commission File Number)

**45-4440364**  
(IRS Employer ID Number)

**6320 Quadrangle Drive, Suite 360, Chapel Hill, NC**  
(Address of principal executive offices)

**27517**  
(Zip Code)

**Registrant's telephone number, including area code (919) 313-6601**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02. Results of Operations and Financial Condition.**

On April 28, 2017, Cempira, Inc. issued a press release announcing its operating results for the first quarter ended March 31, 2017. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated April 28, 2017 to report first quarter 2017 results of operations.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**CEMPRA, INC.**

Date: April 28, 2017

/s/ Mark W. Hahn

Mark W. Hahn, Chief Financial Officer



**FOR IMMEDIATE RELEASE**

**CEMPRA REPORTS FIRST QUARTER 2017 FINANCIAL RESULTS AND PROVIDES  
CORPORATE UPDATE**

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

**CHAPEL HILL, N.C. – April 28, 2017** – 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 March 31, 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.

“With our sizable cash resources and the significant cost reduction actions we took in the first quarter, along with advancing the regulatory process for solithromycin and fusidic acid and the robust process we have underway to evaluate potential strategic business opportunities, we believe we are well-positioned to deliver value to patients and shareholders,” said David Zaccardelli, Pharm.D., acting chief executive officer of Cempra.

**First Quarter 2017 and Recent Corporate Highlights**

***Fusidic Acid***

- In February 2017, 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 in the intent to treat patient population.
- Based on the results of this study, Cempra plans to meet with the U.S. Food and Drug Administration (FDA) in the second quarter to discuss the next steps required to bring fusidic acid to patients in the United States.

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### **Solithromycin**

- Following a meeting with the FDA in February 2017, Cempra has recently submitted a protocol to the FDA which proposes including fewer than 9,000 patients at the time the company responds to the complete response letter it received in December 2016.
- The company plans to discuss the protocol with the FDA to determine if it could support an initial approval in patients with community-acquired bacterial pneumonia (CABP), while the company continues to accumulate a larger post-approval safety database. If the company and FDA agree on a protocol, Cempra plans to seek non-dilutive funding to support the execution of the study.
- In March 2017, Cempra announced the company had withdrawn its marketing authorization application seeking European Medicines Agency (EMA) approval of oral capsule and intravenous formulations of solithromycin for the treatment of community-acquired pneumonia in adults. This action enabled the company to conserve considerable financial resources, and to align its strategy to provide additional data to both the EMA and FDA to support potential approval.

### **Corporate Activities**

- In February 2017, the company initiated cost and personnel reductions, resulting in an approximately 67 percent reduction in the company's workforce and significant reductions in external spending related to commercial preparedness and non-essential activities. The principal objective of the reductions was to enable the company to conserve its financial resources as it evaluates the best path forward with its existing late stage clinical pipeline and potential business development opportunities.
- As a result of the restructuring, the company expects research and corporate expenses to trend significantly downward beginning in the second quarter of this year and expects 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 the company's product candidates. Future discussions with regulatory authorities and agreement on further clinical development requirements may lead to additional expense and the company would expect to provide more granular expense guidance at that time.
- In March 2017, the company announced it had retained Morgan Stanley & Co. LLC as financial advisor to the company and to lead a process to review strategic business options. The goal of this process is for Cempra 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.

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***Financial Results for the Three Months Ended March 31, 2017***

For the quarter ended March 31, 2017, Cempra reported a net loss of \$22.9 million, or \$0.44 per share. During the same period in 2016, Cempra reported a net loss of \$29.4 million, or \$0.61 per share.

Research and development (R&D) expense in the first quarter of 2017 was \$15.4 million, a decrease of 34.5 percent compared to the same quarter in 2016. The reduced R&D expense was primarily due to decreased regulatory expenses in the first quarter of 2017, compared to higher new drug application related expenses in the first quarter of 2016, and decreases in commercial preparation activities, partially offset by an increase in BARDA related expenses. General and administrative expense was \$8.8 million, an increase of 5.3 percent compared to the same quarter in 2016. Employee costs increased by \$1.1 million as the result of an increased headcount compared to the same period last year, before the reduction in workforce, offset by a decrease in professional services of \$0.7 million related to the delay of our planned commercial launch of solithromycin. In the first quarter of 2017, the company also recorded a one-time restructuring charge of \$3.6 million for severance and other expenses related to the cost and personnel reductions activities the company initiated in February 2017.

As of March 31, 2017, Cempra had cash and equivalents of \$202.8 million and 52.4 million shares outstanding.

**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 # 99531916. A live webcast of the call will be available online from the investor relations section of the company website at [www.cempra.com](http://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 # 99531916.

**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

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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](http://www.cempra.com).

*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 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 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; 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)	March 31, 2017	December 31, 2016
<b>Assets</b>		
Current assets		
Cash and equivalents	202,763	231,553
Receivables	6,339	6,162
Prepaid expenses	1,228	579
<b>Total current assets</b>	<u>210,330</u>	<u>238,294</u>
Furniture, fixtures and equipment, net	39	48
Deposits	129	173
<b>Total assets</b>	<u>210,498</u>	<u>238,515</u>
<b>Liabilities</b>		
Current liabilities		
Accounts payable	11,783	15,657
Accrued expenses	4,620	2,929
Accrued payroll and benefits	627	4,267
Current portion of long-term debt	6,667	6,667
<b>Total current liabilities</b>	<u>23,697</u>	<u>29,520</u>
Deferred revenue	16,987	16,987
Long-term debt	7,002	8,660
<b>Total liabilities</b>	<u>47,686</u>	<u>55,167</u>
Commitments and Contingencies		
<b>Shareholders' Equity (Deficit)</b>		
Common stock	52	52
Additional paid-in capital	622,631	620,279
Accumulated deficit	(459,871)	(436,983)
<b>Total shareholders' equity</b>	<u>162,812</u>	<u>183,348</u>
<b>Total liabilities and shareholders' equity</b>	<u>210,498</u>	<u>238,515</u>

## Condensed Consolidated Statement of Operations

(unaudited; in thousands, except loss per share data)

	Three Months Ended March 31,	
	2017	2016
Revenues	4,872	2,679
Operating Expenses		
R&D	15,410	23,529
G&A	8,765	8,324
Restructuring charge	3,553	—
<b>Total Operating Expenses</b>	<b>27,728</b>	<b>31,853</b>
<b>Loss from operations</b>	<b>(22,856)</b>	<b>(29,174)</b>
Other income (expense), net	(32)	(232)
<b>Net loss and comprehensive loss</b>	<b>(22,888)</b>	<b>(29,406)</b>
Net loss attributable to common shareholders	(22,888)	(29,406)
Basic and diluted net loss per share	(0.44)	(0.61)
Basic and diluted weighted average shares outstanding	52,404	47,853

### Contact:

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