**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF NORTH CAROLINA**
**DURHAM DIVISION**

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| [redacted] Individually and On Behalf of All Others Similarly Situated,<br><br>Plaintiff,<br><br>v.<br><br>CEMPRA, INC., PRABHAVATHI B. FERNANDES, and MARK W. HAHN,<br><br>Defendants. | **No. 1:16-cv-1303**<br><br>**CLASS ACTION**<br><br>**COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS**<br><br>**DEMAND FOR JURY TRIAL** |

## CLASS ACTION COMPLAINT

Plaintiff [redacted] ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Cempra, Inc., ("Cempra" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants (defined below) who purchased or otherwise acquired Cempra securities between May 1, 2016 and November 1, 2016, both dates inclusive (the "Class Period"), seeking to recover compensable damages caused by defendants' violations of the Securities Exchange Act of 1934 (the "Exchange Act") (the "Class").

## BACKGROUND

2. Cempra, a clinical-stage pharmaceutical company, focuses on developing antibiotics to meet medical needs in the treatment of bacterial infectious diseases in North America. One of its lead product candidates is solithromycin (CEM-101), which is in Phase III clinical trials for the treatment of community acquired bacterial pneumonia, as well as for uncomplicated bacterial urethritis.

3. Cempra, Inc. was formerly known as Cempra Holdings, LLC and changed its name to Cempra, Inc. in February 2012. Cempra was founded in 2005 and is headquartered in Chapel Hill, North Carolina. The Company's shares trades on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "CEMP."

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Cempra's lead product candidate solithromycin posed significant safety risks for hepatotoxicity; and (ii) as a result of the foregoing, Cempra' public statements were materially false and misleading at all relevant times.

5. On November 2, 2016, the United States Food and Drug Administration ("FDA") posted on its website a briefing document addressing solithromycin. The FDA reported that "[a]

significant safety signal for hepatotoxicity was observed in the solithromycin development program," and there was concern for "the high rate of infusion site-related reactions."

6. On this news, Cempra stock fell $11.35, or 60.86%, to close at $7.30 on November 2, 2016.

7. On November 4, 2016, Cempra issued a press release announcing that NASDAQ has halted trading of the Company's common stock. Cempra also announced that the FDA Antimicrobial Drugs Advisory Committee ("AMDAC") would meet that day to discuss the safety and efficacy of solithromycin to treat community-acquired bacterial pneumonia.

8. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

## JURISDICTION AND VENUE

9. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

11. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant is headquartered in this Judicial District and a significant portion of the Defendants' actions took place within this Judicial District.

12. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

## PARTIES

13. Plaintiff, as set forth in the attached Certification, acquired Cempra securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

14. Defendant Cempra is a Delaware corporation with its principal executive offices located at 6320 Quadrangle Drive, Suite 360, Chapel Hill, North Carolina 27517. Cempra's stock trades on the NASDAQ under the ticker symbol "CEMP."

15. Defendant Prabhavathi B. Fernandes ("Fernandes") has served at all relevant times as the Company's Chief Executive Officer ("CEO"), President, and Director.

16. Defendant Mark W. Hahn ("Hahn") has served at all relevant times as the Company's Chief Financial Officer ("CFO") and Executive Vice President.

17. The defendants referenced above in ¶¶ 15-16 are sometimes referred to herein as the "Individual Defendants."

## SUBSTANTIVE ALLEGATIONS

### Background

18. Cempra, a clinical-stage pharmaceutical company, focuses on developing antibiotics to meet medical needs in the treatment of bacterial infectious diseases in North America. One of the Company's lead product candidates is solithromycin (CEM-101), which is in Phase III clinical trials for the treatment of community acquired bacterial pneumonia, as well as for uncomplicated bacterial urethritis.

### The Alleged False and Misleading Statements

19. The Class Period begins on May 1, 2016, when Cempra issued a press release announcing the completion of its rolling submission of the Company's New Drug Application ("NDA") for solithromycin to the FDA (the "NDA Press Release").

20. The NDA Press Release stated, in part:

> Based on the Qualified Infectious Disease Product (QIDP) designation by the FDA of solithromycin, Cempra has Priority Review and has been granted Fast Track for both the oral capsule and intravenous formulations for the treatment of CABP, which could result in an FDA decision on solithromycin's NDA within eight months, or by the end of 2016, based on the Prescription Drug User Fee Act (PDUFA) performance goals.
>
> "Completion of the rolling submission of our first NDAs during Cempra's ten year anniversary year represents a major milestone for the company and a significant step toward our goal of developing antibiotics to meet the critical medical needs of patients in the treatment of bacterial infectious diseases," stated Prabhavathi Fernandes, Ph.D., president and chief executive officer of Cempra. "We believe the intravenous and capsule formulations will provide dosing flexibility that could lead to fewer hospital admissions, earlier discharge if admitted, and increased treatment of CABP on an outpatient basis. We are confident we have a strong data package for solithromycin."
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> "The management of CABP remains a challenge to healthcare professionals and I firmly believe that solithromycin has the potential to be a significant part of the treatment of this life threatening illness, given its published clinical efficacy and potential for multiple formulations," stated Thomas M. File, M.D., principal investigator for solithromycin clinical trials, Northeast Ohio Medical University. "Solithromycin's potency, spectrum of activity and tolerability could help to offset the rising problem of bacterial resistance, and it is gratifying to note that patients could be closer to benefiting from this potential new treatment."

21. On May 2, 2016, Cempra issued a press release and filed a Form 8-K with the SEC announcing the Company's financial and operating results for the quarter ended March 31, 2016 (the "Q1 2016 8-K"). For the quarter, the Company reported a net loss of $29.41 million, or $0.61 per diluted share, on revenue of $2.68 million, compared to a net loss of $17.42 million, or $0.41 per diluted share, on revenue of $13.96 million for the same period in the prior year.

22. The Q1 2016 8-K stated, in part:

> "I am truly delighted that Cempra is able to mark the tenth anniversary of its founding with our submission to the FDA of two NDAs for solithromycin in community-acquired bacterial pneumonia," said Prabhavathi Fernandes, Ph.D., president and chief executive officer of Cempra. "As a new chemical entity, we expect that solithromycin will be subject to an advisory committee review, however given the compelling data package that we have assembled, we look

> forward to working with the agency during the review process to bring this important new macrolide antibiotic to patients with CABP and the physicians who treat them. Our development programs for solithromycin for pediatric patients and urogenital gonorrhea, as well our development program for Taksta, are continuing to move forward."

23. On May 2, 2016, Cempra also filed a quarterly report on Form 10-Q with the SEC reiterating the financial and operating results previously announced in the Q1 2016 8-K (the "Q1 2016 10-Q").

24. The Q1 2016 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, stating that the financial information contained in the Q1 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

25. On August 1, 2016, Cempra issued a press release and filed a Form 8-K with the SEC announcing the Company's financial and operating results for the quarter ended June 30, 2016 (the "Q2 2016 8-K"). For the quarter, the Company reported a net loss of $24.81 million, or $0.51 per diluted share, on revenue of $3.42 million, compared to a net loss of $24.97 million, or $0.57 per diluted share, on revenue of $5.05 million for the same period in the prior year.

26. The Q2 2016 8-K stated, in part:

> "Cempra continues to advance its programs successfully and I am excited by the progress we are making with both our clinical development programs and our commercial initiatives as we prepare for the launch of Solithera, subject to approval, early next year," said Prabhavathi Fernandes, Ph.D., president and chief executive officer of Cempra. "We remain confident in the data underpinning our NDA and MAA submissions and look forward to working with the regulators to bring the product to the patients who need treatment. In addition, we believe we have the people, strategy and financing in place to see us through our key milestones near-term including the initial commercialization of Solithera in the U.S."

27. On August 1, 2016, Cempra also filed a quarterly report on Form 10-Q with the SEC reiterating the financial and operating results previously announced in the Q2 2016 8-K (the "Q2 2016 10-Q").

28. The Q2 2016 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q2 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

29. On October 27, 2016, Cempra issued a press release and filed a Form 8-K with the SEC announcing the Company's financial and operating results for the quarter ended September 30, 2016 (the "Q3 2016 8-K"). For the quarter, the Company reported a net loss of $32.31million, or $0.62 per diluted share, on revenue of $3.97 million, compared to a net loss of $27.57 million, or $0.63 per diluted share, on revenue of $2.5 million for the same period in the prior year.

30. The Q3 2016 stated, in part:

> "Cempra continued an exceptional 2016 with further progress in the third quarter, including FDA acceptance of our NDAs for intravenous and oral capsule formulations of solithromycin, the submission of our solithromycin MAA in Europe, publication of our IV to oral Phase 3 solithromycin study in a prestigious journal, and the announcement of exciting interim results from our Phase 2 NASH study," said Prabhavathi Fernandes, Ph.D., president and chief executive officer of Cempra.

31. On October 27, 2016, Cempra also filed a quarterly report on Form 10-Q with the SEC reiterating the financial and operating results previously announced in the Q3 2016 8-K (the "Q3 2016 10-Q").

32. The Q3 2016 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q3 2016 10-Q was

accurate and disclosed any material changes to the Company's internal control over financial reporting.

33. The statements referenced in ¶¶ 19-32 were materially false and misleading because defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Cempra's lead product candidate solithromycin posed significant safety risks for hepatotoxicity; and (ii) as a result of the foregoing, Cempra' public statements were materially false and misleading at all relevant times.

**The Truth Emerges**

34. On November 2, 2016, the FDA posted on its website a preliminary review of solithromycin. The FDA reported that "[a] significant safety signal for hepatotoxicity was observed in the solithromycin development program," and there was concern for "the high rate of infusion site-related reactions."

35. On this news, Cempra stock fell $11.35, or 60.86%, to close at $7.30 on November 2, 2016.

**Post-Class Period Disclosures**

36. On November 4, 2016, Cempra issued a press release announcing that NASDAQ has halted trading of the Company's common stock. Cempra also announced that the FDA's AMDAC scheduled a meeting to begin at 8:30 a.m. ET and to end at 5:00 p.m. ET on November 4, 2016 to discuss the safety and efficacy of solithromycin to treat community-acquired bacterial pneumonia.

37. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

## PLAINTIFF'S CLASS ACTION ALLEGATIONS

38. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of the Class (as defined *supra* at ¶ 1). Excluded from the Class are defendants and their family members, directors and officers of Cempra and their families and affiliates.

39. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Cempra has millions of shares of stock outstanding, owned by hundreds or thousands of persons.

40. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions that may affect individual Class members include:

(a) Whether the Exchange Act was violated by defendants;

(b) Whether defendants omitted and/or misrepresented material facts;

(c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether the price of Cempra common stock was artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

41. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

42. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

43. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

**NO SAFE HARBOR**

44. Cempra's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") were ineffective to shield those statements from liability.

45. The defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Cempra who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:**
**FRAUD ON THE MARKET**

46. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts;

(b) The omissions and misrepresentations were material;

(c) The Company's stock traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and

(e) Plaintiff and other members of the Class purchased Cempra common stock between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

47. At all relevant times, the market for Cempra's common stock was efficient for the following reasons, among others:

(a) As a regulated issuer, Cempra filed periodic public reports with the SEC; and

(b) Cempra regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services

48. As a result of the foregoing, the market for Cempra's securities promptly digested current information regarding Cempra from all publicly available sources and reflected such information in Cempra's stock price. Under these circumstances, all purchasers of Cempra's

securities at relevant times suffered similar injury through their purchases of Cempra's securities at artificially inflated prices, and a presumption of reliance applies.

**COUNT I**
**Violation of Section 10(b) of The Exchange Act**
**and Rule 10b-5 Promulgated Thereunder Against All Defendants**

49. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

50. Defendants carried out a plan, scheme and course of conduct which was intended to and did: (1) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (2) cause Plaintiff and other members of the Class to purchase Cempra's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, each of the Defendants took the actions set forth herein.

51. Defendants: (1) employed devices, schemes, and artifices to defraud; (2) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (3) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Cempra securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

52. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business and future prospects of Cempra as specified herein.

53. These Defendants employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Cempra's value and performance and continued substantial growth, which included the making of, or participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Cempra and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of Cempra securities.

54. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (1) the Individual Defendants were high-level executives, directors, and/or agents at the Company at all relevant times and members of the Company's management team or had control thereof; (2) each of these Defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's business prospects and operations; (3) each of these Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's operations and business projects at all relevant times; and (4) each of these Defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

55. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to

ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing the Company's flawed manufacturing processes, thereby artificially inflating price of its securities. As demonstrated by Defendants' omissions and misstatements of the Company's business strategy, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

56. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Cempra securities was artificially inflated. In ignorance of the fact that market prices of Cempra's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants, Plaintiff and the other members of the Class acquired Cempra securities at artificially high prices and were or will be damaged thereby.

57. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the Company's flawed manufacturing processes, which was not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Cempra securities,

or, if they had acquired such securities, they would not have done so at the artificially inflated prices that they paid.

58. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

59. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities.

60. This action was filed within two years of discovery of the fraud and within five years of each plaintiff's purchases of securities giving rise to the cause of action.

**COUNT II**
**Violation of Section 20(a) of the Exchange Act Against the Individual Defendants**

61. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

62. The Individual Defendants acted as controlling persons of Cempra within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, agency, ownership and contractual rights, and participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to have been misleading prior to and/or shortly

after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

63. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

64. As set forth above, Cempra and the Individual Defendants each violated Section 10(b), and Rule 10b-5 promulgated thereunder, by their acts and omissions as alleged in this Complaint.

65. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities.

66. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff's purchases of securities giving rise to the cause of action.

**WHEREFORE**, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

**DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated: November 4, 2016