UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF NORTH CAROLINA

No. 1:16-cv-01356

SHERI PASQUAL, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. CEMPRA, INC., PRABHAVATHI FERNANDES, MARK W. HAHN and DAVID W. OLDACH, Defendants.	CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff, individually and on behalf of all others similarly situated, by plaintiff's undersigned attorneys, for plaintiff's complaint against defendants, alleges the following based upon personal knowledge as to plaintiff and plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through plaintiff's attorneys, which included, among other things, a review of U.S. Securities and Exchange Commission ("SEC") filings by Cempra, Inc. ("Cempra" or the "Company"), as well as media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION AND OVERVIEW

1. This is a securities fraud class action on behalf of all persons who purchased Cempra common stock between October 22, 2015 and November 1, 2016, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 ("1934 Act"). These claims are asserted against Cempra and certain of its officers who made materially false and misleading statements during the Class Period in press releases and filings with the SEC.

2. Cempra is a clinical-stage biopharmaceutical company that develops antibiotics for the treatment of infectious diseases. Cempra's lead product, solithromycin (CEM-101), is being developed in oral capsule, intravenous ("IV") and suspension formulations for the treatment of community-acquired bacterial pneumonia ("CABP"), as well as for the treatment of gonorrhea and for other indications.

3. Throughout the Class Period, defendants violated the federal securities laws by disseminating false and misleading statements to the investing public. Defendants' Class Period conduct had its intended effect, with Cempra's stock trading at artificially inflated prices during the Class Period, reaching a high of $32.81 per share on November 25, 2015.

4. On November 2, 2016, the U.S. Food and Drug Administration ("FDA") released a report analyzing Cempra's clinical development program for solithromycin to treat CABP, which highlighted a significant safety signal for hepatotoxicity and drug-induced liver injury.

5. As a result of this news, the price of Cempra stock dropped $11.35 per share to close at $7.30 per share on November 2, 2016, a one-day decline of nearly 61% on volume of 20.7 million shares.

6. As a result of defendants' false and misleading statements, Cempra common stock traded at artificially inflated prices during the Class Period. However, after the above revelations seeped into the market, the price of the Company's common stock dropped nearly 78% from its Class Period high, causing economic harm and damages to class members.

JURISDICTION AND VENUE

7. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the 1934 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.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the 1934 Act.

9. Venue is proper in this District pursuant to §27 of the 1934 Act and 28 U.S.C. §1391(b). Cempra maintains its headquarters in this District and many of the acts charged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

10. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

THE PARTIES

11. Plaintiff Sheri Pasqual, purchased Cempra common stock during the Class Period as set forth in the attached certification and were damaged thereby.

12. Defendant Cempra is headquartered in Chapel Hill, North Carolina. Cempra's common stock is traded under the ticker "CEMP" on the NASDAQ, an efficient market.

13. Defendant Prabhavathi Fernandes ("Fernandes") co-founded the Company. Defendant Fernandes is, and at all relevant times was, President, Chief Executive Officer ("CEO") and a director of Cempra.

14. Defendant Mark W. Hahn ("Hahn") is, and at all relevant times was, Chief Financial Officer ("CFO") of Cempra.

15. Defendant David W. Oldach ("Oldach") is, and at all relevant times was, Chief Medical Officer of Cempra.

16. The defendants referenced above in ¶¶13-15 are collectively referred to herein as the "Individual Defendants." The Individual Defendants made, or caused to be made, false statements that caused the price of Cempra common stock to be artificially inflated during the Class Period. The Individual Defendants and Cempra are referred to collectively as "Defendants."

17. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Cempra's quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. They were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false and misleading statements pleaded herein.

FRAUDULENT SCHEME AND COURSE OF BUSINESS

18. Defendants are liable for: (i) making false statements; or (ii) failing to disclose adverse facts known to them about Cempra. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Cempra common stock was a success, as it: (i) deceived the investing public regarding Cempra's prospects and business; (ii) artificially inflated the prices of Cempra common stock; and (iii) caused plaintiff and other members of the Class to purchase Cempra common stock at artificially inflated prices.

SCIENTER ALLEGATIONS

19. During the Class Period, Defendants had the motive and opportunity to commit the alleged fraud. Defendants also had actual knowledge of the misleading statements they made and/or acted in reckless disregard of the true information known to them at the time. In doing so, the Defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of Cempra common stock during the Class Period.

20. Following Defendants' false and misleading statements made between October 22, 2015 and November 19, 2015, the Company launched a follow-on offering of Cempra common stock to continue funding the Company's operations. This offering took place in January 2016. But for Defendants' deliberate decision to misstate and withhold the material fact that solithromycin was associated with increased liver toxicity and drug-induced liver injury, Cempra's Class Period stock price would have been substantially lower, and the Company would have been unable to obtain the funds it otherwise received in the January 2016 offering.

BACKGROUND

21. Cempra is a clinical-stage pharmaceutical company. The Company is focused on developing differentiated antibiotics for the acute care and community settings to meet medical

needs in the treatment of bacterial infectious diseases, particularly respiratory tract infections and chronic staphylococcal infections. The Company's lead product, solithromycin, is being developed in oral capsule, IV and suspension formulations for the treatment of CABP, as well as for the treatment of gonorrhea and for other indications. Solithromycin has therapeutic potential and the spectrum of activity to target pathogenic bacteria.

22. Prior to and throughout the Class Period, Defendants touted solithromycin as safer than the drug known as Ketek. In 2004, the FDA approved Ketek as an anti-microbial agent that purportedly circumvented antibiotic resistance. Between 2004 and 2007, however, Ketek was linked to dozens of cases of severe liver injury that sparked two Congressional investigations into the FDA's approval of the compound.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

23. On October 22, 2015, Cempra conducted its third quarter 2015 earnings conference call. Defendants Fernandes, Hahn and Oldach participated in the conference call. During defendant Fernandes's opening remarks she stated:

> Now let's discuss liver safety. Cath studies are conducted in patients with serious disease and underlying comorbidity, meaning they have other bad illnesses. Transient and reversible [alanine transaminase ("ALT")] elevation, which is a liver enzyme increase, is a class-effective macrolide and this is also seen with almost all antibiotic classes, including agents commonly used for CABP, such as augmentin, Rocephin, and the respiratory fluoroquinolones like Avelox and Levaquin.
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> * * *
>
> As one would expect, in both Phase 3 trials, these we saw some Grade 3 ALT elevation, and to a much lesser extent some Grade 4 ALT elevations. ***In almost all cases of ALT elevations among solithromycin recipients, these elevations occurred early, peaked on day four – remember, it is day one through seven – and their levels were typically declining by day seven, despite continued study drug dosing. These ALT increases were asymptomatic and resolved post treatment***.
>
> ***No solithromycin recipient met Hy's Law criteria, defined as simultaneous ALT and bilirubin elevation – another liver factor – following dosing. There was no evidence of drug hypersensitivity reaction. For instance, one involving a combination of rash, fever, and ALT elevation, and other symptoms***.
>
> Let me remind you that in August, the FDA granted fast-track designation for solithromycin intravenous and capsule for the treatment of CABP. The FDA has also

designated solithromycin IV and capsule for the treatment of CABP and solithromycin capsule for the treatment of gonorrhea as qualified infections disease products of QIDP.

24. On November 19, 2015, the Company participated in the Jefferies Global Healthcare Conference. Defendant Fernandes spoke at the conference. During defendant Fernandes's opening remarks she stated:

> Now when we announced some of the effects of the drug, we did mention liver enzyme increases. ALT increases. And you can see that with the intravenous, we had slightly more ALTs than in the oral, which is listed in the bottom, the Grade 3 and the Grade 4.
>
> Now ALTs go up if you had a very good lunch like Jefferies provided this afternoon, I wish I had measured everyone's ALTs because you would've seen ALTs go up in a lot of people. ALTs go up if the liver is a little taxed and is trying to digest and put things out there. And ALTs did go up because we give very high doses of drugs. In antibiotics you always get ALTs go up [sic] in many, many patients because you give high doses of antibiotics either intravenously or orally. And these ALTs go up.
>
> With macrolides especially, which are metabolized and excreted by the liver, you will see ALTs go up. And I've seen – I have given you numbers from the 6% with the intravenous azithromycin, which does not have significant blood levels, even with azithromycin, you see up to 6% go up. Now the patients they studied were not sick as our patients because azithromycin is used in minor infections.
>
> * * *
>
> ***Now the most important things, none of them had any symptoms. They were all reversible, and there was no bilirubin increase in any of these patients. And that is a key point. If you are on this drug, if you don't measure ALTs, you won't even know because there's no symptoms at all, in these patients, and they are all reversible***.
>
> Now we have actually put out data of the reversibility. People said, how fast does this reverse? So we have actually posted this data as an 8-K, and if you look at the purple stars on this, we look at the blood levels of ALTs and [aspartate transaminase ("ASTs")] on day one, day four, day seven, and then day 13. And you will see that while on study drugs, the patient is on study drug until day seven, even while on study drug, you can see the ALTs coming down. The liver gets used to it and no longer is it putting out the ALT enzymes.
>
> You can see the same thing with ASTs. This is the reversible ALT and AST increases with no issues, no[] upper quadrant pain, no bilirubin increase and all reversible.

25. On January 7, 2016, Cempra filed its Prospectus with the SEC in connection with a public offering of common stock. Cempra sold a total of 4,166,667 shares of common stock in the offering at $24.00 per share. Defendants Fernandes and Hahn signed the Registration Statement associated with the offering of Cempra common stock. The Company's January 7, 2016 Prospectus stated:

> Ketek is a macrolide antibiotic that the FDA approved in 2004 for the treatment of multi-drug resistant pneumococci and other CABP bacteria. Soon after release, however, Ketek was found to cause reversible visual disturbances, exacerbate myasthenia gravis (a neurological disorder characterized by improper muscle regulation) and cause liver failure. These effects led the FDA to require the drug label for Ketek to include a strengthened warning section regarding specific drug-related adverse events and contributed to Ketek being withdrawn in 2007 for the treatment of all infections other than CABP. ***Through ongoing research, we have developed multiple ways to differentiate solithromycin from Ketek. Our research suggests these side effects may be caused by the pyridine moiety, which forms a part of the structure of Ketek. We have demonstrated that pyridine inhibits the action of nicotinic acid acetylcholine receptors that could result in the side effects caused by Ketek. Solithromycin and older generation macrolides, including azithromycin and clarithromycin, that have been widely marketed do not have a pyridine component***.

26. On January 13, 2016, the Company participated in the J.P. Morgan Healthcare Conference. Defendant Fernandes spoke at the conference. During defendant Fernandes's opening remarks she stated:

> We would also like to show you some of the ALT results. This is the liver enzyme results. Macrolides that are excreted by the liver and are known to cause liver enzyme increases. You see the label from azithromycin, which is over there, that you see ALT increases. This does not give you the idea that this is hepatic toxic. To have hepatic toxicity, you have to have bilirubin increases, which causes – which shows damage to the liver cells. ***So, ALT increases plus bilirubin equals what is called [Hy's Law] and that means liver toxicity. We did not have any case in those numbers which you see there, which had both ALTs as well as bilirubin, not one in those entire two studies***.
>
> ***So, we did not believe we have any side effects of liver toxicity in these particular patients***.
>
> ***I will also point out that they were asymptomatic, so there was nobody who would actually – know in real life during treatment that there was even any ALT increase. What is even more important is the gra[ph] at the very bottom. Even while on study drug, the ALT levels came down. So, if it was toxic, it would not come down, obviously it would stay up. So the liver learned to handle the drug, and***

then it came down. So we are very pleased with the safety of this as well as the efficacy.

27. On May 2, 2016, Cempra conducted its first quarter 2016 earnings conference call. Defendant Fernandes participated in the call. Defendant Fernandes engaged in the following question-and-answer session with a Leerink Partners securities analyst:

> PAUL MATTEIS [Leerink Partners – Analyst]: Okay. Thanks, Mark. That's helpful. And then maybe one more for Prabha.
>
> I'm wondering what you expect to be the key points of discussion at an advisory committee? I mean, the Phase 3 data, they're clearly positive. You met the FDA end points. So maybe can you speak to any sources of controversy that you expect if any, and to what degree prior experience with ketek may play into the discussion at an AdCom?
>
> FERNANDES: ***Thank you. So we have worked very hard, together with safety experts, people who have consulted in the past with other companies, with the FDA and so on, very aware of liver safety. We do believe that on the ketek issue, we are over that hurdle, because we have shown the mechanisms as to why ketek was toxic***.
>
> ***However, we do have ALT. So our job is to make a comparison to the older macrolides like [erythromycin], [azithromycin], clarithromycin. All of them do have ALT increases. We have that too. But you must remember that every one of them came down, some of them even – most of them even while on study drug. So we don't believe there is a big concern***.

28. On September 12, 2016, the Company participated in the Morgan Stanley Global Healthcare Conference. Defendant Hahn spoke at the conference. During the conference's question-and-answer session, defendant Hahn made the following statement concerning the safety profile of solithromycin: "***What we see is what you expect from a macrolide: you expect ALTs to go up in the early days, and come back down. Even in continued therapy, we saw ALT levels coming right back down***."

29. On September 30, 2016, the Company conducted a conference call for analysts and investors to discuss the interim results of an ongoing study of solithromycin in patients suffering from nonalcoholic steatohepatitis. Defendant Fernandes participated in the call. During the conference's question-and-answer session, defendant Fernandes made the following statement: "***I***

will remind you that in our CAB trial, which we presented to you, we have seen ALT increases even during the five to seven days of treatment which comes back."

30. On November 2, 2016, the FDA released a report analyzing Cempra's Phase III studies of solithromycin to treat CABP, which highlighted a significant safety signal for hepatotoxicity and drug-induced liver injury. As a result of this news, the price of Cempra stock dropped $11.35 per share to close at $7.30 per share on November 2, 2016, a one-day decline of nearly 61% on volume of 20.7 million shares.

31. As a result of Defendants' false and misleading statements during the Class Period, Cempra common stock traded at artificially inflated prices.

32. Defendants' Class Period statements, set forth in ¶¶23-29, were false and misleading when made. Defendants misleadingly informed investors that solithromycin was not associated with liver toxicity and drug-induced liver injury. The true facts, which Defendants knew but failed to disclose during the Class Period, were that the Company's clinical development program had shown that solithromycin was, in fact, associated with liver toxicity and that numerous patients taking solithromycin had experienced drug-induced liver injury.

LOSS CAUSATION/ECONOMIC LOSS

33. During the Class Period, Defendants made false and misleading statements by misrepresenting the materiality of the interim clinical data and engaged in a scheme to deceive the market. Defendants' conduct artificially inflated the price of Cempra common stock and operated as a fraud or deceit on the Class. On November 2, 2016, when Defendants' prior misrepresentations were revealed to market participants, the price of Cempra common stock plummeted, as the prior artificial inflation came out of the price. As a result of their purchases of Cempra common stock

during the Class Period, plaintiff and members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

APPLICABILITY OF PRESUMPTION OF RELIANCE

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

35. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(a) The omissions and misrepresentations were material;

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

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

(d) 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.

36. At all relevant times, the market for Cempra stock was efficient for the following reasons, among others:

(a) Cempra stock met the requirements for listing, and was listed and actively traded on the NASDAQ, an efficient market;

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

(c) Cempra regularly communicated with public investors via established market communication mechanisms, including through the 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.

NO SAFE HARBOR

37. Many (if not all) of Defendants' false and misleading statements during the Class Period were not forward-looking statements ("FLS") and/or identified as such by Defendants, and thus did not fall within any "Safe Harbor."

38. Cempra's verbal "Safe Harbor" warnings accompanying its oral FLS issued during the Class Period were ineffective to shield those statements from liability.

39. 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. Further, 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.

CLASS ACTION ALLEGATIONS

40. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Cempra common stock during the Class Period (the "Class"). Excluded from the Class are Defendants and their immediate families, directors and officers of Cempra and their immediate families, and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

41. 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. During the Class Period, Cempra had more than 48 million shares of stock outstanding, owned by hundreds or thousands of persons.

42. 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 1934 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.

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

44. 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.

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

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

46. Plaintiff incorporates ¶¶1-45 by reference.

47. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

48. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Cempra common stock during the Class Period.

49. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Cempra common stock. Plaintiff and the Class would not have purchased Cempra common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

50. As a direct and proximate result of these Defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Cempra common stock during the Class Period.

COUNT II

For Violation of §20(a) of the 1934 Act Against All Defendants

51. Plaintiff incorporates ¶¶1-50 by reference.

52. During the Class Period, Defendants acted as controlling persons of Cempra within the meaning of §20(a) of the 1934 Act. By virtue of their positions and their power to control public statements about Cempra, the Individual Defendants had the power and ability to control the actions of Cempra and its employees. Cempra controlled the Individual Defendants and its other officers and employees. By reason of such conduct, Defendants are liable pursuant to §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for 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 plaintiff and the members of the Class damages and interest;

C. Awarding plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: November 22, 2016

s/ L. Bruce McDaniel

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CERTIFICATION OF PLAINTIFF PURSUANT TO THE FEDERAL SECURITIES LAWS

I, Sheri Pasqual, declare the following as to the claims asserted, or to be asserted, under the federal securities laws:

1. I have reviewed the complaint with my counsel and authorize its filing.

2. I did not acquire the securities that are the subject of this action at the direction of plaintiff's counsel or in order to participate in any private action or any other litigation under the federal securities laws.

3. I am willing to serve as a representative party on behalf of the class, including testifying at deposition or trial, if necessary.

4. I made the following transactions during the Class Period in the securities that are the subject of this action.

Acquisitions:

Date Acquired	Number of Shares Acquired	Acquisition Price Per Share
10/27/16	100	22.976

Sales:

Date Sold	Number of Shares Sold	Selling Price Per Share

5. I will not accept any payment for serving as a representative party beyond my pro-rata share of any recovery, except reasonable costs and expenses – such as lost wages and travel expenses – directly related to the class representation, as ordered or approved by the Court pursuant to law.

6. I have not sought to serve or served as a representative party for a class in an action under the federal securities laws within the past three years, except if detailed below:

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 19th day of November, 2016.

DocuSigned by:
Sheri Pasqual
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Sheri Pasqual