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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

█ Individually and
on behalf of all others similarly situated,

Plaintiff,

v.

AMPIO PHARMACEUTICALS, INC.,
MICHAEL MACALUSO, MARK D.
MCGREGOR, and GREGORY A.
GOULD,

Defendants.

Case No:

**CLASS ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

JURY TRIAL DEMANDED

Plaintiff █ (“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

1 Ampio Pharmaceuticals, Inc. (“Ampio” or the “Company”), analysts’ reports and
2 advisories about the Company, and information readily obtainable on the Internet.
3 Plaintiff believes that substantial evidentiary support will exist for the allegations set
4 forth herein after a reasonable opportunity for discovery.

5 **NATURE OF THE ACTION**

6 1. This is a federal securities class action on behalf of a class consisting of
7 all persons other than Defendants (defined below) who purchased or otherwise
8 acquired Ampio securities between January 13, 2014 and August 21, 2014, inclusive
9 (the “Class Period”), seeking to recover compensable damages caused by
10 Defendants’ violations of the federal securities laws (the “Class”).

11 2. Ampio is a biopharmaceutical company focused primarily on the
12 development of therapies to treat prevalent inflammatory conditions for which there
13 are limited treatment options. Ampio’s two lead product candidates in development
14 are Ampion for osteoarthritis of the knee and Optina for diabetic macular edema.

15 3. Throughout the Class Period, Defendants made materially false and
16 misleading statements regarding the Company’s business, operations, and prospects.
17 Specifically, Defendants made false and/or misleading statements and/or failed to
18 disclose that: (1) the clinical research organization conducting the STEP Study lacked
19 independence; (2) the trial drug supply for the STEP Study was shipped to clinical
20 sites at lower temperatures than permitted by the drug specifications; and (3) as a
21 result of the foregoing, the Company’s public statements were materially false and
22 misleading at all relevant times.

23 **JURISDICTION AND VENUE**

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

27 5. This Court has jurisdiction over the subject matter of this action under
28 28 U.S.C. §1331 and §27 of the Exchange Act.

1 15. The Class Period begins on January 13, 2014, the Company issued a
2 press release announcing that the 500 patient Phase III pivotal trial of Ampion (the
3 “STEP Study”) for the treatment for osteoarthritis of-the-knee (“OAK”) has received
4 IRB approval and FDA IND clearance and that patients enrollment and treatments
5 have commenced.

6 16. On February 14, 2014, the Company filed a Form 10-K for the fiscal
7 year ended December 31, 2013 (the “2013 10-K”) with the SEC, which was signed
8 by Defendants Macaluso and McGregor. The 2013 10-K states in part:

9 In January 2014, Ampio entered into an agreement with a clinical
10 research organization to conduct its 500 patient Phase III pivotal trial of
11 Ampion for the treatment of osteoarthritis of the knee. The contract fees
12 total \$4.7 million and extend over approximately ten months.

13 17. On February 18, 2014, the Company issued a press release announcing it
14 has completed enrollment and dosing of 500 patient in the pivotal trial of Ampion for
15 the treatment of OAK.

16 18. The statement referenced in ¶¶15-17 above were materially false and/or
17 misleading and/or failed to disclose that: (1) the clinical research organization
18 conducting the STEP Study lacked independence; and (2) the trial drug supply for the
19 STEP Study was shipped to clinical sites at lower temperatures than permitted by the
20 drug specifications.

21 19. On August 21, 2014, the Company issued a press release announcing a
22 delay in the data analysis of the STEP Study due to the discovery by the independent
23 Clinical Research Organization (CRO) that the study drug (both Ampion and the
24 placebo) were, during shipment to the clinical sites, exposed to lower temperatures
25 than permitted by the drug specifications. The press releases states in part:

26 Ampio reports that due to temperature deviations below product
27 specifications during shipments to the Ampion™ STEP Study clinical
28 sites, release of data will be delayed.

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ENGLEWOOD, CO., August 21,2014 /PRNewswire/ — Ampio Pharmaceuticals, Inc. (NYSE MKT: AMPE) today announced a delay in the data analysis of the STEP Study due to the discovery by the ***independent Clinical Research Organization (CRO)*** that the study drug (both Ampion™ and the placebo) were, during shipment to the clinical sites, exposed to lower temperatures than permitted by the drug specifications

Michael Macaluso, Ampio’s CEO, explained “Pivotal clinical trial drug specifications dictate precise temperature and handling conditions for all study drug product in order to assure that the conclusions about the safety and effectiveness of the tested drugs will be accurate and repeatable during routine clinical use. During the review of all documentation following the unblinding of the Study, our CRO determined that there were multiple instances where the in-package temperature monitor fell significantly below the 15o C minimum required.

Although our entire trial drug supply was housed, packaged, and shipped in early January by a specialized drug shipment vendor contractually obligated to maintain pre-determined temperature requirements under all conditions, our CRO discovered much of the drug product received at the clinical sites had been below the temperature requirement and may have been frozen for some period of time. The drug temperature specifications were set because Ampion™ may lose potency if it is exposed to temperatures approaching freezing. We have contacted the FDA who has agreed to analyze the STEP trial as supportive data for our BLA.”

Mr. Macaluso concluded, “Although we are frustrated by these shipping and receiving deviations of the Step Study protocols, the company is pursuing alternative solutions to meeting the requirements for filing a Biologic License Application (BLA) for Ampion™ on schedule. We are consulting with our regulatory advisors about substituting the data from our Multiple Injection (MI) Study that is currently underway. The compilation of data from the “SPRING” single injection study and the MI study may provide a more comprehensive and clinically meaningful analysis by the FDA reviewers. If the MI study confirms the 85+%

1 reduction in pain reported by the initial patients, it is unlikely that
2 physicians will choose to treat the severe chronic pain experienced by
3 Kellgren Lawrence Grades 3 and 4 OA patients with a single injection.
4 The “Indications for Use” and improved efficacy over placebo, provided
5 by multiple injections, should be of greatest interest to the FDA and the
6 physician community, who are trying to improve the quality of life of
7 their patients.”

8 (Emphasis added).

9 20. On this news, shares of Ampio fell \$1.80 per share or over 24% to close
10 at \$5.66 per share on August 21, 2014, damaging investors.

11 21. The statement referenced in ¶19 above were materially false and/or
12 misleading and/or failed to disclose that the clinical research organization conducting
13 the STEP Study lacked independence.

14 22. On August 22, 2014, the blog *Buyerstrike* issued a report on Ampio,
15 which asserts a number of red flags with the STEP Study, including that: (1) it was
16 conducted at only one site in Anaheim, California with only one doctor supervising it,
17 even though it enrolled 500 patients; (2) the clinical research organization that
18 conducted the trial—Dream Team Clinical Research—has little clinical trial
19 management experience; and (3) Dream Team Clinical Research lacks independence
20 as its office is located next door to Dr. Quang D. Vo, the principal investigator of the
21 trial and its door directs all visitors to Dr. Vo office in the event it is locked.

22 23. On this news, shares of Ampio fell \$0.82 per share or over 14% to close
23 at \$4.84 per share on August 22, 2014, further damaging investors.

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

27 **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

28 25. Plaintiff brings this action as a class action pursuant to Federal Rule of
Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who

1 purchased or otherwise acquired Ampio securities traded on the NYSE MKT during
2 the Class Period; and were damaged upon the revelation of the alleged corrective
3 disclosures. Excluded from the Class are Defendants herein, the officers and directors
4 of the Company, at all relevant times, members of their immediate families and their
5 legal representatives, heirs, successors or assigns and any entity in which Defendants
6 have or had a controlling interest.

7 26. The members of the Class are so numerous that joinder of all members is
8 impracticable. Throughout the Class Period, Ampio securities were actively traded on
9 the NYSE MKT. While the exact number of Class members is unknown to Plaintiff
10 at this time and can be ascertained only through appropriate discovery, Plaintiff
11 believes that there are hundreds or thousands of members in the proposed Class.
12 Record owners and other members of the Class may be identified from records
13 maintained by Ampio or its transfer agent and may be notified of the pendency of this
14 action by mail, using the form of notice similar to that customarily used in securities
15 class actions.

16 27. Plaintiff's claims are typical of the claims of the members of the Class as
17 all members of the Class are similarly affected by Defendants' wrongful conduct in
18 violation of federal law that is complained of herein.

19 28. Plaintiff will fairly and adequately protect the interests of the members
20 of the Class and has retained counsel competent and experienced in class and
21 securities litigation. Plaintiff has no interests antagonistic to or in conflict with those
22 of the Class.

23 29. Common questions of law and fact exist as to all members of the Class
24 and predominate over any questions solely affecting individual members of the Class.
25 Among the questions of law and fact common to the Class are:

- 26 • whether the federal securities laws were violated by Defendants' acts as
27 alleged herein;

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- 1 • whether statements made by Defendants to the investing public during
2 the Class Period misrepresented material facts about the business,
3 operations and management of Ampio;
- 4 • whether the Individual Defendants caused Ampio to issue false and
5 misleading financial statements during the Class Period;
- 6 • whether Defendants acted knowingly or recklessly in issuing false and
7 misleading financial statements;
- 8 • whether the prices of Ampio securities during the Class Period were
9 artificially inflated because of Defendants' conduct complained of
10 herein; and,
- 11 • whether the members of the Class have sustained damages and, if so,
12 what is the proper measure of damages.

13 30. A class action is superior to all other available methods for the fair and
14 efficient adjudication of this controversy since joinder of all members is
15 impracticable. Furthermore, as the damages suffered by individual Class members
16 may be relatively small, the expense and burden of individual litigation make it
17 impossible for members of the Class to individually redress the wrongs done to them.
18 There will be no difficulty in the management of this action as a class action.

19 31. Plaintiff will rely, in part, upon the presumption of reliance established
20 by the fraud-on-the-market doctrine in that:

- 21 • Defendants made public misrepresentations or failed to disclose material
22 facts during the Class Period;
- 23 • the omissions and misrepresentations were material;
- 24 • Ampio securities are traded in efficient markets;
- 25 • the Company's shares were liquid and traded with moderate to heavy
26 volume during the Class Period;
- 27 • the Company traded on the NYSE MKT, and was covered by multiple
28 analysts;

- 1 • the misrepresentations and omissions alleged would tend to induce a
2 reasonable investor to misjudge the value of the Company's securities;
3 and
- 4 • Plaintiff and members of the Class purchased and/or sold Ampio
5 securities between the time the Defendants failed to disclose or
6 misrepresented material facts and the time the true facts were disclosed,
7 without knowledge of the omitted or misrepresented facts.

8 32. Based upon the foregoing, Plaintiff and the members of the Class are
9 entitled to a presumption of reliance upon the integrity of the market.

10 33. Alternatively, Plaintiff and the members of the Class are entitled to the
11 presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of*
12 *the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants
13 omitted material information in their Class Period statements in violation of a duty to
14 disclose such information, as detailed above.

15 **COUNT I**

16 **Violation of Section 10(b) of The Exchange Act and Rule 10b-5** 17 **Against All Defendants**

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

20 35. This Count is asserted against Defendants and is based upon Section
21 10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated
22 thereunder by the SEC.

23 36. During the Class Period, Defendants engaged in a plan, scheme,
24 conspiracy and course of conduct, pursuant to which they knowingly or recklessly
25 engaged in acts, transactions, practices and courses of business which operated as a
26 fraud and deceit upon Plaintiff and the other members of the Class; made various
27 untrue statements of material facts and omitted to state material facts necessary in
28 order to make the statements made, in light of the circumstances under which they

1 were made, not misleading; and employed devices, schemes and artifices to defraud
2 in connection with the purchase and sale of securities. Such scheme was intended to,
3 and, throughout the Class Period, did: (i) deceive the investing public, including
4 Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and
5 maintain the market price of Ampio securities; and (iii) cause Plaintiff and other
6 members of the Class to purchase or otherwise acquire Ampio securities and options
7 at artificially inflated prices. In furtherance of this unlawful scheme, plan and course
8 of conduct, Defendants, and each of them, took the actions set forth herein.

9 37. Pursuant to the above plan, scheme, conspiracy and course of conduct,
10 each of the Defendants participated directly or indirectly in the preparation and/or
11 issuance of the quarterly and annual reports, SEC filings, press releases and other
12 statements and documents described above, including statements made to securities
13 analysts and the media that were designed to influence the market for Ampio
14 securities. Such reports, filings, releases and statements were materially false and
15 misleading in that they failed to disclose material adverse information and
16 misrepresented the truth about Ampio's finances and business prospects.

17 38. By virtue of their positions at Ampio, Defendants had actual knowledge
18 of the materially false and misleading statements and material omissions alleged
19 herein and intended thereby to deceive Plaintiff and the other members of the Class,
20 or, in the alternative, Defendants acted with reckless disregard for the truth in that
21 they failed or refused to ascertain and disclose such facts as would reveal the
22 materially false and misleading nature of the statements made, although such facts
23 were readily available to Defendants. Said acts and omissions of Defendants were
24 committed willfully or with reckless disregard for the truth. In addition, each
25 defendant knew or recklessly disregarded that material facts were being
26 misrepresented or omitted as described above.

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1 39. Defendants were personally motivated to make false statements and omit
2 material information necessary to make the statements not misleading in order to
3 personally benefit from the sale of Ampio securities from their personal portfolios.

4 40. Information showing that Defendants acted knowingly or with reckless
5 disregard for the truth is peculiarly within Defendants' knowledge and control. As the
6 senior managers and/or directors of Ampio, the Individual Defendants had knowledge
7 of the details of Ampio's internal affairs.

8 41. The Individual Defendants are liable both directly and indirectly for the
9 wrongs complained of herein. Because of their positions of control and authority, the
10 Individual Defendants were able to and did, directly or indirectly, control the content
11 of the statements of Ampio. As officers and/or directors of a publicly-held company,
12 the Individual Defendants had a duty to disseminate timely, accurate, and truthful
13 information with respect to Ampio's businesses, operations, future financial condition
14 and future prospects. As a result of the dissemination of the aforementioned false and
15 misleading reports, releases and public statements, the market price for Ampio's
16 securities was artificially inflated throughout the Class Period. In ignorance of the
17 adverse facts concerning Ampio's business and financial condition which were
18 concealed by Defendants, Plaintiff and the other members of the Class purchased or
19 otherwise acquired Ampio securities at artificially inflated prices and relied upon the
20 price of the securities, the integrity of the market for the securities and/or upon
21 statements disseminated by Defendants, and were damaged upon the revelation of the
22 alleged corrective disclosures.

23 42. During the Class Period, Ampio's securities were traded on an active and
24 efficient market. Plaintiff and the other members of the Class, relying on the
25 materially false and misleading statements described herein, which the Defendants
26 made, issued or caused to be disseminated, or relying upon the integrity of the
27 market, purchased or otherwise acquired shares of Ampio securities at prices
28 artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other

1 members of the Class known the truth, they would not have purchased or otherwise
2 acquired said securities, or would not have purchased or otherwise acquired them at
3 the inflated prices that were paid. At the time of the purchases and/or acquisitions by
4 Plaintiff and the Class, the true value of Ampio securities was substantially lower
5 than the prices paid by Plaintiff and the other members of the Class. The market price
6 of Ampio's securities declined sharply upon public disclosure of the facts alleged
7 herein to the injury of Plaintiff and Class members.

8 43. 56. By reason of the conduct alleged herein, Defendants knowingly or
9 recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and
10 Rule 10b-5 promulgated thereunder.

11 44. 57. As a direct and proximate result of Defendants' wrongful conduct,
12 Plaintiff and the other members of the Class suffered damages in connection with
13 their respective purchases, acquisitions and sales of the Company's securities during
14 the Class Period, upon the disclosure that the Company had been disseminating
15 misrepresented financial statements to the investing public.

16 **COUNT II**

17 **Violation of Section 20(a) of The Exchange Act** 18 **Against The Individual Defendants**

19 45. Plaintiff repeats and realleges each and every allegation contained in the
20 foregoing paragraphs as if fully set forth herein.

21 46. During the Class Period, the Individual Defendants participated in the
22 operation and management of Ampio, and conducted and participated, directly and
23 indirectly, in the conduct of Ampio's business affairs. Because of their senior
24 positions, they knew the adverse non-public information regarding Ampio's business
25 practices.

26 47. As officers and/or directors of a publicly owned company, the Individual
27 Defendants had a duty to disseminate accurate and truthful information with respect
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1 to Ampio's financial condition and results of operations, and to correct promptly any
2 public statements issued by Ampio which had become materially false or misleading.

3 48. Because of their positions of control and authority as senior officers, the
4 Individual Defendants were able to, and did, control the contents of the various
5 reports, press releases and public filings which Ampio disseminated in the
6 marketplace during the Class Period. Throughout the Class Period, the Individual
7 Defendants exercised their power and authority to cause Ampio to engage in the
8 wrongful acts complained of herein. The Individual Defendants therefore, were
9 "controlling persons" of Ampio within the meaning of Section 20(a) of the Exchange
10 Act. In this capacity, they participated in the unlawful conduct alleged which
11 artificially inflated the market price of Ampio securities.

12 49. Each of the Individual Defendants, therefore, acted as a controlling
13 person of Ampio. By reason of their senior management positions and/or being
14 directors of Ampio, each of the Individual Defendants had the power to direct the
15 actions of, and exercised the same to cause, Ampio to engage in the unlawful acts and
16 conduct complained of herein. Each of the Individual Defendants exercised control
17 over the general operations of Ampio and possessed the power to control the specific
18 activities which comprise the primary violations about which Plaintiff and the other
19 members of the Class complain.

20 50. By reason of the above conduct, the Individual Defendants are liable
21 pursuant to Section 20(a) of the Exchange Act for the violations committed by
22 Ampio.

23 **PRAYER FOR RELIEF**

24 WHEREFORE, Plaintiff demands judgment against Defendants as follows:

25 A. Determining that the instant action may be maintained as a class action
26 under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the
27 Class representative;

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1 B. Requiring Defendants to pay damages sustained by Plaintiff and the
2 Class by reason of the acts and transactions alleged herein;

3 C. Awarding Plaintiff and the other members of the Class prejudgment and
4 post- judgment interest, as well as their reasonable attorneys' fees, expert fees and
5 other costs; and

6 D. Awarding such other and further relief as this Court may deem just and
7 proper.

8 **DEMAND FOR TRIAL BY JURY**

9 51. Plaintiff hereby demands a trial by jury.

10 Dated: May 8, 2015

Respectfully submitted,

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