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6 **UNITED STATES DISTRICT COURT**
7 **CENTRAL DISTRICT OF CALIFORNIA**

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9 _____, Individually and on Behalf of
10 All Others Similarly Situated,

11 Plaintiff,

12 vs.

13
14 ARROWHEAD
15 PHARMACEUTICALS, INC.,
16 CHRISTOPHER R. ANZALONE, and
17 KENNETH A. MYSZKOWSKI,

18 Defendants

Case No. _____

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

JURY TRIAL DEMANDED

19 Plaintiff _____ (“Plaintiff”), individually and on behalf of all other
20 persons similarly situated, by his undersigned attorneys, for his complaint against the
21 Defendants named herein, alleges the following based upon personal knowledge as to
22 himself and his own acts, and information and belief as to all other matters, based upon,
23 *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which
24 included, among other things, a review of the Defendants’ public documents, conference
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1 calls and announcements made by Defendants, United States Securities and Exchange
2 Commission (“SEC”) filings, wire and press releases published by and regarding
3 Arrowhead Pharmaceuticals, Inc. (“Arrowhead” or the “Company”), analysts’ reports
4 and advisories about the Company, and information readily obtainable on the Internet.
5 Plaintiff believes that substantial evidentiary support will exist for the allegations set
6 forth herein after a reasonable opportunity for discovery.
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9 NATURE OF THE ACTION

10 1. This is a federal securities class action on behalf of a class consisting of all
11 persons other than Defendants who purchased or otherwise acquired common shares of
12 Arrowhead between May 11, 2015 and November 8, 2016, both dates inclusive (the
13 “Class Period”). Plaintiff seeks to recover compensable damages caused by Defendants’
14 violations of the federal securities laws and to pursue remedies under Sections 10(b) and
15 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5
16 promulgated thereunder.
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20 2. Arrowhead, a biopharmaceutical company, develops novel drugs to treat
21 intractable diseases in the United States. Among the Company’s products under
22 development at all relevant times was ARC-520, an RNAi-based therapeutic in Phase IIb
23 clinical efficacy studies to treat chronic hepatitis B virus infection.
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26 3. The Company was formerly known as Arrowhead Research Corporation
27 and changed its name to Arrowhead Pharmaceuticals, Inc. in April 2016. Arrowhead was
28

1 incorporated in 1989 and is headquartered in Pasadena, California. Arrowhead's
2 common stock trades on the NASDAQ Global Select Market ("NASDAQ") under the
3 ticker symbol "ARWR."
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5 4. Throughout the Class Period, Defendants made materially false and
6 misleading statements regarding the Company's business, operational and compliance
7 policies. Specifically, Defendants made false and/or misleading statements and/or failed
8 to disclose that: (i) ARC-520 was fatal at certain doses; (ii) consequently, the U.S. Food
9 & Drug Administration ("FDA") was unlikely to approve ARC-520 as a hepatitis B
10 treatment; (iii) Arrowhead had overstated the approval prospects and commercial
11 viability of ARC-520; and (iv) as a result, Arrowhead's public statements were
12 materially false and misleading at all relevant times.
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16 5. On November 8, 2016, post-market, Arrowhead issued a press release
17 announcing that the FDA would be placing a clinical hold on the Company's Heparc-
18 2004 clinical study of ARC-520, likely due to deaths at the highest dose of an ongoing
19 non-human primate toxicology study.
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21 6. On this news, Arrowhead's share price fell \$1.91, or 31.26%, to close at
22 \$4.20 on November 9, 2016.
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24 7. As a result of Defendants' wrongful acts and omissions, and the precipitous
25 decline in the market value of the Company's common shares, Plaintiff and other Class
26 members have suffered significant losses and damages.
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JURISDICTION AND VENUE

8. 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).

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

10. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as a significant portion of the Defendants' actions, and the subsequent damages, took place within this District.

11. 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

12. Plaintiff, as set forth in the accompanying Certification, purchased common shares of Arrowhead at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

13. Defendant Arrowhead Pharmaceuticals, Inc. is incorporated in Delaware, and the Company's principal executive offices are located at 225 South Lake Avenue,

1 Suite 1050, Pasadena, California 91101. Arrowhead’s common stock trades on the
2 NASDAQ under the ticker symbol “ARWR.”

3 14. Defendant Christopher R. Anzalone has served at all relevant times as the
4 Company’s Chief Executive Officer, President, and Director.
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6 15. Defendant Kenneth A. Myszkowski has served at all relevant times as the
7 Company’s Chief Financial Officer.
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9 16. The Defendants referenced above in ¶¶ 14-15 are sometimes referred to
10 herein as the “Individual Defendants.”
11

12 **SUBSTANTIVE ALLEGATIONS**

13 **Background**

14 17. Arrowhead, a biopharmaceutical company, develops novel drugs to treat
15 intractable diseases in the United States. Among the Company’s products under
16 development at all relevant times was ARC-520, an RNAi-based therapeutic in Phase IIb
17 clinical efficacy studies to treat chronic hepatitis B virus infection.
18

19 18. The Company was formerly known as Arrowhead Research Corporation
20 and changed its name to Arrowhead Pharmaceuticals, Inc. in April 2016. Arrowhead was
21 incorporated in 1989 and is headquartered in Pasadena, California.
22

23 **Materially False and Misleading Statements Issued During the Class Period**

24 19. The Class Period begins on May 11, 2015, when Arrowhead issued a press
25 release and filed a Current Report on Form 8-K with the SEC, announcing certain of the
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1 Company's financial and operating results for the fiscal quarter ended March 31, 2015
2 (the "Q2 2015 8-K"). For the quarter, Arrowhead reported a net loss of \$28.68 million,
3 or \$0.51 per diluted share, on revenue of \$0.04 million, compared to a net loss of \$13.94
4 million, or \$0.31 per diluted share, on revenue of \$0.04 million for the same period in
5 the prior year.
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8 20. In the Q2 2015 8-K, Arrowhead stated, in part:

9 **Fiscal 2015 Second Quarter and Recent Company Highlights**

10 * * *

- 11
12 • Gained clearance from the U.S. Food and Drug and
13 Administration to begin the Heparc-2004 multi-dose Phase
14 2b study of ARC-520

15 21. On May 11, 2015, Arrowhead also filed a Quarterly Report on Form 10-Q
16 with the SEC, reiterating the financial and operating results previously announced in the
17 Q2 2015 8-K and reporting in full the Company's financial and operating results for the
18 quarter ended March 31, 2015 (the "Q2 2015 10-Q").
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20 22. The Q2 2015 10-Q stated, in part:

21 ***Overview***

22 Arrowhead Research develops novel drugs to treat intractable diseases
23 by silencing the genes that cause them. Using the broadest portfolio of RNA
24 chemistries and efficient modes of delivery, Arrowhead therapies trigger the
25 RNA interference mechanism to induce rapid, deep and durable knockdown
26 of target genes. Arrowhead's most advanced drug candidate in clinical
27 development is ARC-520, which is designed to treat chronic hepatitis B
28 infection by inhibiting the production of all HBV gene products. The goal is
to reverse the immune suppression that prevents the body from controlling
the virus and clearing the disease. Arrowhead's second clinical candidate is

1 ARC-AAT, a treatment for a rare liver disease associated with a genetic
2 disorder that causes alpha-1 antitrypsin deficiency.

3 Arrowhead operates a lab facility in Madison, Wisconsin, where the
4 Company's research and development activities, including the development
5 of its RNAi therapeutics, are based. The Company's principal executive
6 offices are located in Pasadena, California.

7 During the first half of fiscal year 2015, the Company continued to
8 develop its lead clinical candidate, ARC-520, for the treatment of chronic
9 hepatitis B as well as its second clinical candidate, ARC-AAT, an RNAi
10 therapeutic designed to treat liver disease associated with Alpha-1
11 antitrypsin deficiency (AATD). *The Company continues its Phase 2a
12 studies in ARC-520, with no dose-limiting toxicities or serious adverse
13 events having been observed to date.* The Company submitted an
14 Investigational New Drug application to the U.S. Food and Drug
15 Administration in December 2014 for ARC-520 to initiate phase 2b multi-
16 dose studies to determine the depth of hepatitis B surface antigen (HBsAg)
17 reduction following ARC-520 injection. The Company received feedback
18 from the FDA, and based on that feedback the Company adjusted the
19 protocol in order to begin the trial. In April 2015, the application was
20 approved by the FDA. The Company also expects to file with Asian and
21 European agencies to begin additional phase 2b studies in fiscal year 2015.
22 Additionally, the Company has initiated dosing in a phase 1 clinical trial for
23 ARC-AAT following successful completion of the Clinical Trial
24 Notification (CTN) regulatory process in Australia.

19 (Emphasis added).

21 23. The Q2 2015 10-Q contained signed certifications pursuant to the Sarbanes-
22 Oxley Act of 2002 ("SOX") by the Individual Defendants, stating that the financial
23 information contained in the Q2 2015 10-Q was accurate and disclosed any material
24 changes to the Company's internal control over financial reporting.

26 24. On August 4, 2015, Arrowhead issued a press release and filed a Current
27 Report on Form 8-K with the SEC, announcing certain of the Company's financial and
28

1 operating results for the fiscal quarter ended June 30, 2015 (the “Q3 2015 8-K”). For the
2 quarter, Arrowhead reported a net loss of \$15.94 million, or \$0.27 per diluted share, on
3 revenue of \$0.12 million, compared to a net loss of \$11.63 million, or \$0.22 per diluted
4 share, on revenue of \$0.04 million for the same period in the prior year.
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6 25. In the Q3 2015 8-K, Arrowhead stated, in part:
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8 **Fiscal 2015 Third Quarter and Recent Company Highlights**

9 **ARC-520**

- 10 • Received regulatory permission to initiate three multiple-
11 dose Phase 2b studies in the United States (Heparc-2004)
12 and in Germany and Hong Kong (Heparc-2002 and 2003)
13
- 14 • Completed dosing of four cohorts in a single-dose Phase 2a
15 study (Heparc-2001) and expanded the study to include
16 three additional cohorts
- 17 • *Completed dosing in a non-clinical study in chronically*
18 *infected chimpanzees that spanned more than a year*
- 19 • *Highlights of the Phase 2a and chimpanzee studies to be*
20 *presented at an analyst day planned for September 24,*
21 *2015*

22 (Emphases added).

23 26. On August 4, 2015, Arrowhead also filed a Quarterly Report on Form 10-Q
24 with the SEC, reiterating the financial and operating results previously announced in the
25 Q3 2015 8-K and reporting in full the Company’s financial and operating results for the
26 quarter ended June 30, 2015 (the “Q3 2015 10-Q”).
27
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1 27. The Q3 2015 10-Q stated, in part:

2 **Overview**

3 Arrowhead Research develops novel drugs to treat intractable diseases
4 by silencing the genes that cause them. Using the broadest portfolio of RNA
5 chemistries and efficient modes of delivery, Arrowhead therapies trigger the
6 RNA interference mechanism to induce rapid, deep and durable knockdown
7 of target genes. Arrowhead's most advanced drug candidate in clinical
8 development is ARC-520, which is designed to treat chronic hepatitis B
9 infection by inhibiting the production of all HBV gene products. The goal is
10 to reverse the immune suppression that prevents the body from controlling
11 the virus and clearing the disease. Arrowhead's second clinical candidate is
12 ARC-AAT, a treatment for a rare liver disease associated with a genetic
13 disorder that causes alpha-1 antitrypsin deficiency.

14 Arrowhead operates a lab facility in Madison, Wisconsin, where the
15 Company's research and development activities, including the development
16 of its RNAi therapeutics, are based. The Company's principal executive
17 offices are located in Pasadena, California.

18 During fiscal year 2015, the Company has continued to develop its lead
19 clinical candidate, ARC-520, for the treatment of chronic hepatitis B as well
20 as its second clinical candidate, ARC-AAT, an RNAi therapeutic designed
21 to treat liver disease associated with Alpha-1 antitrypsin deficiency (AATD).
22 ***The Company continues its Phase 2a studies in ARC-520, with no dose-***
23 ***limiting toxicities or serious adverse events having been observed to date.***
24 The Company submitted an Investigational New Drug application to the
25 U.S. Food and Drug Administration in December 2014 for ARC-520 to
26 initiate phase 2b multi-dose studies to determine the depth of hepatitis B
27 surface antigen (HBsAg) reduction following ARC-520 injection. The
28 Company received feedback from the FDA, and based on that feedback the
Company adjusted the protocol in order to begin the trial. In April 2015,
the application was approved by the FDA. In June 2015, the Company
received regulatory clearance in Germany for two additional Phase 2b
multiple-dose studies of ARC-520 to be conducted in parallel, and also
expects to file with additional Asian and European agencies to begin
additional phase 2b studies.

In May 2015, the Company completed protocol-required dosing of
healthy volunteers in an on-going phase 1 study of ARC-AAT, and in July

1 2015, initiated dosing of patients in Part B of that same study. The study
2 recently received regulatory clearance in the United Kingdom and New
3 Zealand. In June 2015, ARC-AAT was granted orphan drug designation by
4 the FDA.

5 (Emphasis added).

6 28. The Q3 2015 10-Q contained signed certifications pursuant to SOX by the
7 Individual Defendants, stating that the financial information contained in the Q3 2015
8 10-Q was accurate and disclosed any material changes to the Company's internal control
9 over financial reporting.

10 29. On December 14, 2015, Arrowhead issued a press release and filed a
11 Current Report on Form 8-K with the SEC, announcing certain of the Company's
12 financial and operating results for the fiscal quarter and year ended September 30, 2015
13 (the "2015 8-K"). For the quarter, Arrowhead reported a net loss of \$24.98 million, or
14 \$0.41 per diluted share, on revenue of \$0.04 million, compared to a net loss of \$22.43
15 million, or \$0.40 per diluted share, on revenue of \$0.04 million for the same period in
16 the prior year. For 2015, Arrowhead reported a net loss of \$91.94 million, or \$1.60 per
17 diluted share, on revenue of \$0.38 million, compared to a net loss of \$58.63 million, or
18 \$1.25 per diluted share, on revenue of \$0.18 million for 2014.

19 30. The 2015 8-K stated, in part:

20 **Fiscal 2015 Fourth Quarter and Recent Company Highlights**

21 **ARC-520**

- 1 • Presented data at AASLD Liver Meeting 2014 showing
2 statistically significant reduction in HBsAg through day 43
3 after a single injection ($p < 0.05$) in human clinical trials
- 4 • Submitted an Investigational New Drug (IND) application to
5 the U.S. Food and Drug Administration and submitted
6 additional clinical trial authorization applications with
7 regulatory authorities in various jurisdictions in Europe, Asia,
8 and Australia/New Zealand for ARC-520
- 9 • Initiated dosing in Heparc-2004, a multiple-dose Phase 2b
10 clinical study of ARC-520 in the U.S.
- 11 • Initiated multiple-dose Heparc-2002 and Heparc-2003 Phase
12 2b studies of ARC-520 in Europe and Asia
- 13 • Hosted an analyst day to discuss top-line findings from the
14 Heparc-2001 Phase 2a clinical study of ARC-520 and
15 findings from a study of 9 chimpanzees that have been treated
16 monthly with ARC-520 for between 6 and 11 months. Key
17 messages included the following:
 - 18 • Arrowhead's proprietary DPC™ platform can
19 effectively and consistently knock down target genes in
20 humans
 - 21 • ARC-520 achieved significant HBV s-Antigen
22 (HBsAg) reductions in humans, particularly in
23 treatment naïve, HBeAg-positive patients
 - 24 • Arrowhead identified a large target HBV population for
25 ARC-520 and described a new paradigm for the HBV
26 lifecycle
 - 27 • ARC-520 induced deep HBsAg reduction in
28 chronically HBV infected chimpanzees
 - *ARC-520 was well tolerated, no serious or severe*

adverse events were reported in these studies

- Arrowhead expanded its HBV portfolio by nominating ARC-521, an additional clinical candidate that is complementary to ARC-520
- Presented data at the AASLD Liver Meeting 2015 including the following:
 - ***ARC-520 led to robust, sustained anti-viral effects in chimpanzees with chronic HBV***, and we also described an important new discovery that HBV DNA integrated into the host genome is likely an important source of HBV surface antigen (HBsAg) production
 - In a Phase 2a clinical study, ARC-520 effectively reduced HBV viral antigens derived from cccDNA. HBV surface antigen (HBsAg) was reduced substantially with a maximum reduction of 1.9 logs (99%) and a mean maximum reduction of 1.5 logs (96.8%) in treatment naïve e-antigen (HBeAg)-positive patients
 - Presented data at Hep DART 2015 showing that ARC-520 led to immune reactivation in 7 of 9 chimpanzees with chronic hepatitis B infection

(Emphases added).

31. On December 14, 2015, Arrowhead also filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the 2015 8-K and reporting in full the Company's financial and operating results for the quarter and year ended September 30, 2015 (the "2015 10-K").

32. In the 2015 10-K, Arrowhead stated, in part:

Recent Events

1 Arrowhead made significant progress on product and platform development
2 during fiscal year 2015 with an expanding pipeline of RNAi therapeutics
3 based on the Dynamic Polyconjugate (DPC™) delivery system. The
4 following are highlights of this progress:

- 5 • Hosted an analyst day to discuss top-line findings from
6 the Heparc-2001 Phase 2a clinical study of ARC-520 and
7 findings from a study of 9 chimpanzees that have been
8 treated monthly with ARC-520 for between 6 and 11
9 months. Key messages included the following:
 - 10 • Arrowhead's proprietary DPC™ platform
11 can effectively and consistently knock
12 down target genes in humans
 - 13 • ARC-520 achieves significant HBV s-
14 Antigen (HBsAg) reductions in humans,
15 particularly in treatment naïve, HBeAg-
16 positive patients
 - 17 • Arrowhead identifies a large target HBV
18 population for ARC-520 and describes a
19 new paradigm for the HBV lifecycle
 - 20 • ARC-520 induces deep HBsAg reduction
21 in chronically HBV infected chimps
 - 22 • *ARC-520 has been well tolerated*
 - 23 • Arrowhead expands its HBV portfolio by
24 nominating an additional clinical
25 candidate that is complementary to ARC-
26 520

27 (Emphases added).

28 33. The 2015 10-K contained signed certifications pursuant to SOX by the
Individual Defendants, stating that the financial information contained in the 2015 10-K

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

3 34. On February 9, 2016, Arrowhead issued a press release and filed a Current
4 Report on Form 8-K with the SEC, announcing certain of the Company's financial and
5 operating results for the quarter ended December 31, 2015 (the "Q1 2016 8-K"). For the
6 quarter, Arrowhead reported a net loss of \$19.26 million, or \$0.32 per diluted share, on
7 revenue of \$0.04 million, compared to a net loss of \$22.58 million, or \$0.41 per diluted
8 share, on revenue of \$0.17 million for the same period in the prior year.
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11 35. In the Q1 2016 8-K, Arrowhead stated, in part:

12
13 **About ARC-520**

14
15 Arrowhead's RNAi-based candidate ARC-520 is being investigated in the
16 treatment of chronic HBV infection. The small interfering RNAs (siRNAs)
17 in ARC-520 intervene at the mRNA level, upstream of the reverse
18 transcription process where current standard of care nucleotide and
19 nucleoside analogues act. Arrowhead is investigating ARC-520 specifically
20 to determine if it can be used to achieve a functional cure, which is an
21 immune clearant state characterized by hepatitis B s-antigen negative serum
22 with or without seroconversion. Approximately 350-400 million people
23 worldwide are chronically infected with the hepatitis B virus, which can lead
24 to cirrhosis of the liver and is responsible for 80% of primary liver cancers
25 globally. Arrowhead is currently conducting Phase 2b multiple dose and
26 combination studies in chronic HBV patients. *In clinical studies to date, the
27 most common reported adverse events in all subjects completing treatment
28 were upper respiratory infection and headache.*

(Emphases added).

36. On February 9, 2016, Arrowhead also filed a Quarterly Report on Form
10-Q with the SEC, reiterating the financial and operating results previously announced

1 in the Q1 2016 8-K and reporting in full the Company's financial and operating results
2 for the quarter ended December 31, 2015 (the "Q1 2016 10-Q").

3
4 37. The Q1 2016 10-Q stated, in part:

5 ***Overview***

6 During the first quarter of fiscal year 2016, the Company continued to
7 develop its lead clinical candidate, ARC-520, for the treatment of chronic
8 hepatitis B as well as its second clinical candidate, ARC-AAT, an RNAi
9 therapeutic designed to treat liver disease associated with Alpha-1
10 antitrypsin deficiency (AATD). ***The Company continued its Phase 2
11 studies in ARC-520, with no dose-limiting toxicities or serious adverse
12 events having been observed to date.*** In connection with its Phase 2a study,
13 the Company reported data showing that ARC-520 effectively reduced HBV
14 viral antigens derived from cccDNA. The data showed that HBV surface
15 antigen (HBsAg) was reduced substantially with a maximum reduction of
16 1.9 logs (99%) and a mean maximum reduction of 1.5 logs (96.8%) in
17 treatment naïve e-antigen (HBeAg)-positive patients. ***The Company also
18 discussed data from an ARC-520 chimpanzee study showing that in
19 chronically HBV-infected chimpanzees treated with ARC-520 in
20 combination with nucleoside analogs, 7 of 9 (78%) exhibited signs of
21 immune reactivation, which is likely a necessary step for achieving a
22 functional cure of chronic HBV.*** The Company believes these data strongly
23 support advancement of ARC-520 into Phase 2b and future clinical studies.
24 In January 2016, the Company announced that it had dosed the first patient
25 in its Phase 2b combination study for ARC-520 and is continuing to enroll
26 patients at multiple centers in Australia and New Zealand. The Company
27 submitted an Investigational New Drug application to the FDA which was
28 approved in April 2015 and the Company also received regulatory clearance
in Germany for two additional Phase 2b multiple-dose studies of ARC-520
to be conducted in parallel. The Company expects to file with additional
Asian and European agencies to begin additional Phase 2b studies.

(Emphases added).

38. The Q1 2016 10-Q contained signed certifications pursuant to SOX by the
Individual Defendants, stating that the financial information contained in the Q1 2016

1 10-Q was accurate and disclosed any material changes to the Company's internal control
2 over financial reporting.

3 39. On May 10, 2016, Arrowhead issued a press release and filed a Current
4 Report on Form 8-K with the SEC, announcing certain of the Company's financial and
5 operating results for the quarter ended March 31, 2016 (the "Q2 2016 8-K"). For the
6 quarter, Arrowhead reported a net loss of \$20.82 million, or \$0.35 per diluted share, on
7 revenue of \$0.04 million, compared to a net loss of \$28.68 million, or \$0.51 per diluted
8 share, on revenue of \$0.04 million for the same period in the prior year.
9
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11 40. In the Q2 2016 8-K, Arrowhead stated, in part:

12
13 **Fiscal 2016 Second Quarter and Recent Company Highlights**

14 * * *

15 **ARC-520**

- 16
17 • Began dosing patients in three Phase 2b studies: the
18 MONARCH study, 2007 long-term extension, and 2001
19 open-label extension
- 20 • Presented promising ARC-520 hepatitis B data at The
21 International Liver Congress™ 2016, including the
22 following key findings:
 - 23 • ARC-520 and entecavir produced rapid HBV
24 DNA suppression with all hepatitis B e-
25 antigen (HBeAg) positive, treatment naïve
26 patients achieving serum HBV DNA
27 reductions of up to 5.5 log (99.9997%), and
28 all HBeAg negative, treatment naïve patients
achieving reductions that put them below the
limit of quantitation

- 1 • ARC-520 effectively inhibited HBV
2 cccDNA-derived mRNA with observed viral
3 protein reduction in HBV patients of up to
4 2.0 log (99%) after a single dose
- 5 • ARC-520 had a long duration of effect after a
6 single dose with HBsAg still reduced by 83%
7 after 2 months and 75% after 3 months,
8 which is the final time point of the study
- 9 • Based on HBsAg epitope profile analysis,
10 poster authors and Arrowhead collaborators
11 had previously identified a predictive
12 hepatitis B surface-antigen (HBsAg)
13 Clearance Profile associated with HBsAg
14 clearance in antiviral therapy cohorts
- 15 • There was a significant association between
16 the development of an HBsAg Clearance
17 Profile and ARC-520 therapy in HBV patients
- 18 • Complexed HBsAg antibodies (anti-HBs)
19 were developed and detected in HBV patients
20 treated with ARC-520, which may represent a
21 recovery of the immune system response
- 22 • After monthly administration of 6-11 doses of
23 ARC-520 in chimpanzees chronically infected
24 with HBV, the ARC-520 target site sequences
25 remained virtually unchanged, indicating that
26 no drug resistance developed during the
27 treatment period

28 (Emphases added).

41. On May 10, 2016, Arrowhead also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the

1 Q2 2016 8-K and reporting in full the Company's financial and operating results for the
2 quarter ended March 31, 2016 (the "Q2 2016 10-Q").

3 42. The Q2 2016 10-Q stated, in part:

4
5 **Overview**

6 Arrowhead Pharmaceuticals, Inc. develops novel drugs to treat
7 intractable diseases by silencing the genes that cause them. Using a broad
8 portfolio of RNA chemistries and efficient modes of delivery, Arrowhead
9 therapies trigger the RNA interference mechanism to induce rapid, deep and
10 durable knockdown of target genes. RNA interference (RNAi) is a
11 mechanism present in living cells that inhibits the expression of a specific
12 gene, thereby affecting the production of a specific protein. Arrowhead's
13 RNAi-based therapeutics leverage this natural pathway of gene silencing.
14 The company's pipeline includes ARC-520 and ARC-521 for chronic
15 hepatitis B virus, ARC-AAT for liver disease associated with alpha-1
16 antitrypsin deficiency, ARC-F12 for hereditary angioedema and
17 thromboembolic disorders, ARC-LPA for cardiovascular disease, and ARC-
18 HIF2 for renal cell carcinoma

19 In April 2016, the Company changed its name from Arrowhead
20 Research Corporation to Arrowhead Pharmaceuticals, Inc., which reflects
21 the Company's transition to and focus on advancing products through
22 clinical development to bring innovative new medicines to patients.

23 Arrowhead operates lab facilities in Madison and Middleton,
24 Wisconsin, where the Company's research and development activities,
25 including the development of RNAi therapeutics, are based. The Company's
26 principal executive offices are located in Pasadena, California.

27 During the first half of fiscal year 2016, the Company continued to
28 develop its lead clinical candidate, ARC-520, for the treatment of chronic
hepatitis B as well as its second clinical candidate, ARC-AAT, an RNAi
therapeutic designed to treat liver disease associated with Alpha-1
antitrypsin deficiency (AATD). ***The Company continued its Phase 2
studies in ARC-520, with no dose-limiting toxicities or serious adverse
events having been observed to date.*** In connection with its Phase 2a study,
the Company reported data showing that ARC-520 effectively reduced HBV
viral antigens derived from cccDNA. The data showed that HBV surface

1 antigen (HBsAg) was reduced substantially with a maximum reduction of
2 1.9 logs (99%) and a mean maximum reduction of 1.5 logs (96.8%) in
3 treatment naïve e-antigen (HBeAg)-positive patients. *The Company also*
4 *discussed data from an ARC-520 chimpanzee study showing that in*
5 *chronically HBV-infected chimpanzees treated with ARC-520 in*
6 *combination with nucleoside analogs, 7 of 9 (78%) exhibited signs of*
7 *immune reactivation, which is likely a necessary step for achieving a*
8 *functional cure of chronic HBV. The Company believes these data*
9 *strongly support advancement of ARC-520 into Phase 2 and later-stage*
10 *clinical studies.* In January 2016, the Company announced that it had dosed
11 the first patient in its Phase 2 combination study for ARC-520 and is
12 continuing to enroll patients at multiple centers in Australia and New
13 Zealand. The Company submitted an Investigational New Drug application
14 to the FDA which was approved in April 2015 and the Company also
15 received regulatory clearance in Germany for two additional Phase 2
16 multiple-dose studies of ARC-520 to be conducted in parallel. The
17 Company has also received regulatory clearance in South Korea and Hong
18 Kong. The sites are actively recruiting and treating patients.

19 (Emphases added).

20 43. The Q2 2016 10-Q contained signed certifications pursuant to SOX by the
21 Individual Defendants, stating that the financial information contained in the Q3 2016
22 10-Q was accurate and disclosed any material changes to the Company's internal control
23 over financial reporting.

24 44. On August 9, 2016, Arrowhead issued a press release and filed a Current
25 Report on Form 8-K with the SEC, announcing certain of the Company's financial and
26 operating results for the quarter ended June 30, 2016 (the "Q3 2016 8-K"). For the
27 quarter, Arrowhead reported a net loss of \$19.42 million, or \$0.32 per diluted share, on
28 revenue of \$0.04 million, compared to a net loss of \$15.94 million, or \$0.27 per diluted
share, on revenue of \$0.12 million for the same period in the prior year.

1 45. In the Q3 2016 8-K, Arrowhead stated, in part:

2 **Fiscal 2016 Third Quarter and Recent Company Highlights**

3 * * *

4 **ARC-520**

- 5
- 6 • Presented promising ARC-520 hepatitis B data at The International Liver Congress™ 2016

7

 - 8 • Expanded the MONARCH study to include additional sites, investigators, and cohorts, including patients with HBV and hepatitis Delta virus co-infection

9

10 (Emphases added).

11

12 46. On August 9, 2016, Arrowhead also filed a Quarterly Report on Form 10-Q

13 with the SEC, reiterating the financial and operating results previously announced in the

14 Q3 2016 8-K and reporting in full the Company’s financial and operating results for the

15 quarter ended June 30, 2016 (the “Q3 2016 10-Q”).

16

17 47. The Q3 2016 10-Q stated, in part:

18

19 ***Overview***

20 Arrowhead Pharmaceuticals, Inc. develops novel drugs to treat

21 intractable diseases by silencing the genes that cause them. Using a broad

22 portfolio of RNA chemistries and efficient modes of delivery, Arrowhead

23 therapies trigger the RNA interference mechanism to induce rapid, deep and

24 durable knockdown of target genes. RNA interference (RNAi) is a

25 mechanism present in living cells that inhibits the expression of a specific

26 gene, thereby affecting the production of a specific protein. Arrowhead’s

27 RNAi-based therapeutics leverage this natural pathway of gene silencing.

28 The company’s pipeline includes ARC-520 and ARC-521 for chronic hepatitis B virus, ARC-AAT for liver disease associated with alpha-1 antitrypsin deficiency, ARC-F12 for hereditary angioedema and

1 thromboembolic disorders, ARC-LPA for cardiovascular disease, and ARC-
2 HIF2 for renal cell carcinoma

3 In April 2016, the Company changed its name from Arrowhead
4 Research Corporation to Arrowhead Pharmaceuticals, Inc., to reflect the
5 Company's focus on advancing products through clinical development to
6 bring innovative new medicines to patients.

7 Arrowhead operates lab facilities in Madison and Middleton,
8 Wisconsin, where the Company's research and development activities,
9 including the development of RNAi therapeutics, are based. The Company's
10 principal executive offices are located in Pasadena, California.

11 During the first nine months of fiscal year 2016, the Company
12 continued to develop its lead clinical candidate, ARC-520, for the treatment
13 of chronic hepatitis B as well as its second clinical candidate, ARC-AAT, an
14 RNAi therapeutic designed to treat liver disease associated with Alpha-1
15 antitrypsin deficiency (AATD). *The Company continued its Phase 2
16 studies in ARC-520, which continues to be generally well tolerated.* In
17 connection with its Phase 2a study, the Company reported data showing that
18 ARC-520 effectively reduced HBV viral antigens derived from cccDNA.
19 The data showed that HBV surface antigen (HBsAg) was reduced
20 substantially with a maximum reduction of 1.9 logs (99%) and a mean
21 maximum reduction of 1.5 logs (96.8%) in treatment naïve e-antigen
22 (HBeAg)-positive patients. *The Company also discussed data from an
23 ARC-520 chimpanzee study showing that in chronically HBV-infected
24 chimpanzees treated with ARC-520 in combination with nucleoside
25 analogs, 7 of 9 (78%) exhibited signs of immune reactivation, which is
26 likely a necessary step for achieving a functional cure of chronic HBV.
27 The Company believes these data strongly support advancement of ARC-
28 520 into Phase 2 and later-stage clinical studies.* In January 2016, the
Company announced that it had dosed the first patient in its Phase 2
combination study for ARC-520 and is continuing to enroll patients at
multiple centers in Australia and New Zealand. The Company also
continues to dose patients in multiple additional Phase 2 studies in Europe,
Asia and the US.

(Emphases added).

1 48. The Q3 2016 10-Q contained signed certifications pursuant to SOX by the
2 Individual Defendants, stating that the financial information contained in the Q3 2016
3 10-Q was accurate and disclosed any material changes to the Company's internal control
4 over financial reporting.

5
6 49. The statements referenced in ¶¶ 19 – 48 above were materially false and/or
7 misleading because they misrepresented and/or failed to disclose the following adverse
8 facts pertaining to the Company's business, operational and financial results, which were
9 known to Defendants or recklessly disregarded by them. Specifically, Defendants made
10 false and/or misleading statements and/or failed to disclose that: (i) the Company's
11 ARC-520 was unsafe at certain doses and caused deaths in an ongoing primate
12 toxicology study; and (ii) as a result, Arrowhead's public statements were materially
13 false and misleading at all relevant times.
14
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16

17 **The Truth Emerges**

18
19 50. On November 8, 2016, post-market, the Company issued a press release on
20 Business Wire (the "Press Release") revealing that the U.S. Food & Drug Administration
21 ("FDA") will be placing a clinical hold on its Heparc-2004 clinical study of ARC-520,
22 likely due to deaths at the highest dose of an ongoing non-human primate toxicology
23 study.
24

25
26 51. The Press Release stated, in part:

27 *Arrowhead was notified today verbally by the United States Food & Drug*
28 *Administration (FDA) of its decision to place a clinical hold on Heparc-*

1 ***2004. The study is on hold while the company provides responses to***
2 ***questions arising from a nonclinical toxicology study in non-human***
3 ***primates using EX1, the company's liver-targeted, intravenously***
4 ***administered delivery vehicle.***

5 The FDA did not indicate the clinical hold was based on any human
6 findings. To date, EX1 has been administered over 800 times in more than
7 300 human study subjects and patients. Across this substantial clinical
8 experience, only ***3 serious adverse events (SAE) have been observed.*** Two
9 of these were fevers, treated with acetaminophen, after which the patients
10 continued on the study with no further complications. The other SAE was an
11 instance of hepatic carcinoma in a patient with chronic HBV and cirrhosis,
12 judged by the treating physician to be unrelated to the drug. A small
13 minority (6%) of infusions in ARC-520 studies have been associated with
14 infusion reactions, with 4 patients discontinuing ARC-520 treatment. In
15 addition, across the ARC-520, ARC-521, and ARC-AAT clinical programs,
16 laboratory values have not been deemed indicative of any drug-induced
17 organ toxicity.

18 Arrowhead has not yet received written notice of the clinical hold from the
19 FDA; however, based on verbal communications the clinical hold was
20 prompted by deaths at the highest dose of an ongoing non-human primate
21 toxicology study. This study involves higher doses of EX1 than those used
22 clinically in humans and higher than those used in the company's previous
23 animal toxicology studies. ***The cause of these animal deaths is unknown***
24 ***and under investigation.*** The EX1 delivery vehicle is used in the company's
25 ARC-520, ARC-521, and ARC-AAT programs.

26 (Emphases Added)

27 52. On this news, Arrowhead's share price fell \$1.91, or 31.26%, to close at
28 \$4.20 on November 9, 2016.

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

PLAINTIFF'S CLASS ACTION ALLEGATIONS

1
2 54. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil
3 Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or
4 otherwise acquired Arrowhead common shares traded on the NASDAQ during the Class
5 Period (the "Class"); and were damaged upon the revelation of the alleged corrective
6 disclosures. Excluded from the Class are Defendants herein, the officers and directors of
7 the Company, at all relevant times, members of their immediate families and their legal
8 representatives, heirs, successors or assigns and any entity in which Defendants have or
9 had a controlling interest.
10
11
12

13 55. The members of the Class are so numerous that joinder of all members is
14 impracticable. Throughout the Class Period, Arrowhead common shares were actively
15 traded on the NASDAQ. While the exact number of Class members is unknown to
16 Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff
17 believes that there are hundreds or thousands of members in the proposed Class. Record
18 owners and other members of the Class may be identified from records maintained by
19 Arrowhead or its transfer agent and may be notified of the pendency of this action by
20 mail, using the form of notice similar to that customarily used in securities class actions.
21
22
23

24 56. Plaintiff's claims are typical of the claims of the members of the Class as all
25 members of the Class are similarly affected by Defendants' wrongful conduct in
26 violation of federal law that is complained of herein.
27
28

1 57. Plaintiff will fairly and adequately protect the interests of the members of
2 the Class and has retained counsel competent and experienced in class and securities
3 litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.
4

5 58. Common questions of law and fact exist as to all members of the Class and
6 predominate over any questions solely affecting individual members of the Class.
7

8 Among the questions of law and fact common to the Class are:

- 9 • whether the federal securities laws were violated by Defendants' acts
10 as alleged herein;
- 11 • whether statements made by Defendants to the investing public
12 during the Class Period misrepresented material facts about the
13 financial condition, business, operations, and management of
14 Arrowhead;
- 15 • whether Defendants' public statements to the investing public during
16 the Class Period omitted material facts necessary to make the
17 statements made, in light of the circumstances under which they were
18 made, not misleading;
- 19 • whether the Individual Defendants caused Arrowhead to issue false
20 and misleading SEC filings and public statements during the Class
21 Period;
- 22 • whether Defendants acted knowingly or recklessly in issuing false
23 and misleading SEC filings and public statements during the Class
24 Period;
- 25 • whether the prices of Arrowhead common shares during the Class
26 Period were artificially inflated because of the Defendants' conduct
27 complained of herein; and
- 28 • whether the members of the Class have sustained damages and, if so,
what is the proper measure of damages.

29 59. A class action is superior to all other available methods for the fair and
30 efficient adjudication of this controversy since joinder of all members is impracticable.
31 Furthermore, as the damages suffered by individual Class members may be relatively
32

1 small, the expense and burden of individual litigation make it impossible for members of
2 the Class to individually redress the wrongs done to them. There will be no difficulty in
3 the management of this action as a class action.
4

5 60. Plaintiff will rely, in part, upon the presumption of reliance established by
6 the fraud-on-the-market doctrine in that:

- 7 • Defendants made public misrepresentations or failed to disclose
- 8 material facts during the Class Period;
- 9 • the omissions and misrepresentations were material;
- 10 • Arrowhead common shares are traded in efficient markets;
- 11 • the Company's shares were liquid and traded with moderate to heavy
- 12 volume during the Class Period;
- 13 • the Company traded on the NASDAQ, and was covered by multiple
- 14 analysts;
- 15 • the misrepresentations and omissions alleged would tend to induce a
- 16 reasonable investor to misjudge the value of the Company's common
- 17 shares; and
- 18 • Plaintiff and members of the Class purchased and/or sold Arrowhead
- 19 common shares between the time the Defendants failed to disclose or
- 20 misrepresented material facts and the time the true facts were
- 21 disclosed, without knowledge of the omitted or misrepresented facts.

22 61. Based upon the foregoing, Plaintiff and the members of the Class are
23 entitled to a presumption of reliance upon the integrity of the market.
24

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

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COUNT I

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

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

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

65. During the Class Period, Arrowhead and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately 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.

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

- employed devices, schemes and artifices to defraud;
- 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
- 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 Arrowhead common shares during the Class Period.

1 67. Arrowhead and the Individual Defendants acted with scienter in that they
2 knew that the public documents and statements issued or disseminated in the name of
3 Arrowhead were materially false and misleading; knew that such statements or
4 documents would be issued or disseminated to the investing public; and knowingly and
5 substantially participated, or acquiesced in the issuance or dissemination of such
6 statements or documents as primary violations of the securities laws. These Defendants
7 by virtue of their receipt of information reflecting the true facts of Arrowhead, their
8 control over, and/or receipt and/or modification of Arrowhead allegedly materially
9 misleading statements, and/or their associations with the Company which made them
10 privy to confidential proprietary information concerning Arrowhead, participated in the
11 fraudulent scheme alleged herein.
12

13 68. Individual Defendants, who are the senior officers and/or directors of the
14 Company, had actual knowledge of the material omissions and/or the falsity of the
15 material statements set forth above, and intended to deceive Plaintiff and the other
16 members of the Class, or, in the alternative, acted with reckless disregard for the truth
17 when they failed to ascertain and disclose the true facts in the statements made by them
18 or other Arrowhead personnel to members of the investing public, including Plaintiff and
19 the Class.
20

21 69. As a result of the foregoing, the market price of Arrowhead common shares
22 was artificially inflated during the Class Period. In ignorance of the falsity of
23
24
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1 Arrowhead's and the Individual Defendants' statements, Plaintiff and the other members
2 of the Class relied on the statements described above and/or the integrity of the market
3 price of Arrowhead common shares during the Class Period in purchasing Arrowhead
4 common shares at prices that were artificially inflated as a result of Arrowhead's and the
5 Individual Defendants' false and misleading statements.
6

7
8 70. Had Plaintiff and the other members of the Class been aware that the market
9 price of Arrowhead common shares had been artificially and falsely inflated by
10 Arrowhead's and the Individual Defendants' misleading statements and by the material
11 adverse information which Arrowhead's and the Individual Defendants did not disclose,
12 they would not have purchased Arrowhead's common shares at the artificially inflated
13 prices that they did, or at all.
14
15

16 71. As a result of the wrongful conduct alleged herein, Plaintiff and other
17 members of the Class have suffered damages in an amount to be established at trial.
18

19 72. By reason of the foregoing, Arrowhead and the Individual Defendants have
20 violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are
21 liable to the plaintiff and the other members of the Class for substantial damages which
22 they suffered in connection with their purchase of Arrowhead common shares during the
23 Class Period.
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COUNT II

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

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

74. During the Class Period, the Individual Defendants participated in the operation and management of Arrowhead, and conducted and participated, directly and indirectly, in the conduct of Arrowhead's business affairs. Because of their senior positions, they knew the adverse non-public information regarding Arrowhead's business practices.

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

76. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Arrowhead disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Arrowhead to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons"

1 of Arrowhead within the meaning of Section 20(a) of the Exchange Act. In this capacity,
2 they participated in the unlawful conduct alleged which artificially inflated the market
3 price of Arrowhead common shares.
4

5 77. Each of the Individual Defendants, therefore, acted as a controlling person
6 of Arrowhead. By reason of their senior management positions and/or being directors of
7 Arrowhead, each of the Individual Defendants had the power to direct the actions of, and
8 exercised the same to cause, Arrowhead to engage in the unlawful acts and conduct
9 complained of herein. Each of the Individual Defendants exercised control over the
10 general operations of Arrowhead and possessed the power to control the specific
11 activities which comprise the primary violations about which Plaintiff and the other
12 members of the Class complain.
13
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16 78. By reason of the above conduct, the Individual Defendants are liable
17 pursuant to Section 20(a) of the Exchange Act for the violations committed by
18 Arrowhead.
19

20 **PRAYER FOR RELIEF**

21 WHEREFORE, Plaintiff demands judgment against Defendants as follows:
22

23 A. Determining that the instant action may be maintained as a class action
24 under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the
25 Class representative;
26
27
28

1 B. Requiring Defendants to pay damages sustained by Plaintiff and the Class
2 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 other
5 costs; and
6

7 D. Awarding such other and further relief as this Court may deem just and
8 proper.
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10 **DEMAND FOR TRIAL BY JURY**

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12 Plaintiff hereby demands a trial by jury.
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