

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

8 KEVIN KHEDER, Individually and on Behalf
9 of All Others Similarly Situated,

10 Plaintiff,

11 vs.

12 ARADIGM CORPORATION, IGOR
13 GONDA and NANCY E. PECOTA,

14 Defendants

Case No.

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

JURY TRIAL DEMANDED

15
16 Plaintiff Kevin Kheder (“Plaintiff”), individually and on behalf of all other persons similarly
17 situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants (defined
18 below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts,
19 and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by
20 and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’
21 public documents, conference calls and announcements made by Defendants, United States Securities
22 and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding
23 Aradigm Corporation (“Aradigm” or the “Company”), analysts’ reports and advisories about the
24 Company, and information readily obtainable on the Internet. Plaintiff believes that substantial
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1 evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for
2 discovery.

3 **NATURE OF THE ACTION**

4 1. This is a federal securities class action on behalf of a class consisting of all persons other
5 than Defendants who purchased or otherwise acquired common shares of Aradigm between July 27,
6 2017 and January 8, 2018, both dates inclusive (the “Class Period”). Plaintiff seeks to recover
7 compensable damages caused by Defendants’ violations of the federal securities laws and to pursue
8 remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”)
9 and Rule 10b-5 promulgated thereunder.
10

11 2. Aradigm Corporation develops novel pulmonary drug delivery systems. The Company's
12 systems are designed to enhance the delivery and effectiveness of a number of existing and
13 development stage drugs and reduce the need for injectable drug therapy.
14

15 3. Founded in 1991, the Company is headquartered in Hayward, California, and its
16 securities trade on the NASDAQ Capital Market (“NASDAQ”) under the ticker symbol “ARDM.”
17

18 4. Among other lead product candidates, the Company’s portfolio includes Linhaliq (ARD-
19 3150), a proprietary formulation of the antibiotic ciprofloxacin that is delivered by inhalation for the
20 management of infections associated with severe respiratory diseases.

21 5. On July 27, 2017, Aradigm submitted a New Drug Application (“NDA”) to the U.S.
22 Food and Drug Administration (“FDA”) for U.S. marketing approval for Linhaliq for the treatment of
23 non-cystic fibrosis bronchiectasis (“NCFB”) patients with chronic lung infections.
24

25 6. Throughout the Class Period, Defendants made materially false and misleading
26 statements regarding the Company’s business, operational and compliance policies. Specifically,
27 Defendants made false and/or misleading statements and/or failed to disclose that: (i) the methodology
28 underlying Aradigm’s Linhaliq Phase III clinical trials was not well tailored to yield consistent efficacy

1 findings or to provide data sufficient to account for discordant efficacy findings; (ii) the endpoint of the
2 Phase III trials—namely, delaying the time to first exacerbation on study therapy compared to placebo
3 over approximately one year of observation—was unlikely to demonstrate a clinically meaningful
4 benefit with respect to a patient population that would likely be taking the drug for a longer duration;
5 (iii) accordingly, these studies were unlikely to support FDA approval of the Linhaliq NDA; and (iv) as
6 a result, Aradigm’s public statements were materially false and misleading at all relevant times.

7
8 7. On January 9, 2018, the FDA announced that it would discuss Aradigm's Linhaliq
9 NDA at the Antimicrobial Drugs Advisory Committee meeting scheduled for January 11, 2018. In the
10 briefing document for the meeting, the FDA stated, in part:

11 The Agency recommended that two adequate and well-controlled clinical trials be
12 conducted to support the NCFB indication because (1) this was a new treatment
13 indication and route of administration for ciprofloxacin; (2) there were too many
14 uncertainties with regard to duration of treatment, frequency of administration and
15 endpoints to allow for reliance on a single Phase 3 trial; (3) studies of inhaled
16 antibacterial drugs (tobramycin, gentamicin, aztreonam, and colistin) for the
17 prevention of NCFB exacerbations have yielded mixed results and none are
18 approved for this indication (4) there were no relevant animal models; (5) given
19 the proposed chronicity of administration, there was a need for adequate
20 assessment of safety in a reasonably large number of patients; and (6) the conduct
21 of two independent trials would be important in providing replicative evidence
22 supporting an overall demonstration of efficacy and safety.

23 ***

24 In ORBIT-3, for the primary endpoint of time to first PE, the overall hazard ratio
25 (Cipro/placebo) in the unweighted, stratified model including prior PEs and sex
26 was 0.99 yielding a 95% CI (0.71, 1.38) suggesting no difference between arms.
27 Additionally, secondary analyses including frequency of PEs by Week 48, change
28 in QoL-B, and FEV1 failed to demonstrate any effect of Cipro over placebo.

29 In ORBIT-4, a treatment effect was observed in time to first PE with a hazard ratio
30 of 0.71, 95% CI (0.52 to 0.97). Additionally, the mean number of PEs at Week 48
31 (secondary endpoint) was 0.98 and 1.47 in the Cipro and placebo arms,
32 respectively with an incidence rate ratio of 0.631 suggesting a 36.9% reduction
33 with a 95% CI ranging from 17.9% to 51.5%. Similar results were seen when
34 considering severe PEs and PEs. These findings suggest an overall decrease in the
35 48-week frequency of PEs. No differences were observed between treatment arms
36 on FEV1 or the change in QoL-B endpoints.

37 ***Reasons for the discordance in efficacy findings between trials cannot be***
38 ***explained based on the information collected in the two trials.*** However, neither
trial collected information on patient history of disease prior to screening, on the

1 underlying etiology of bronchiectasis, or number of affected lobes, which are all
2 factors that might have aided in better understanding if differences in baseline
3 disease severity existed between trial populations. Given the changes post-data
4 base lock and unblinding, the potential for bias in the findings cannot be excluded.
5 Regarding the design of the Phase 3 trials, and based on current understanding of
6 the disease under study, we note that time to first exacerbation has limitations
7 since it is *unclear that delaying the time to first exacerbation on study therapy*
8 *compared to placebo over approximately one year of observation, translates into*
9 *a clinically meaningful benefit for a patient population that would most likely be*
10 *on this therapy for long durations*. The frequency of PEs endpoint captures all
11 PEs during the trial; however, modeling of this endpoint does not fully capture the
12 at-risk intervals for each patient as it does not account for duration of exacerbation.
13 Additionally, we note the trial to trial heterogeneity in efficacy which cannot be
14 explained, and the magnitude of the treatment effect, which even if statistically
15 significant is small.

16 Finally, the duration of the Phase 3 trials may not have been long enough to
17 adequately assess whether Cipro DI reduces the frequency of exacerbations to a
18 clinically meaningful extent and whether such an effect would be durable beyond
19 approximately one year. Tied to the question of whether the trials were of adequate
20 duration to assess efficacy, *there is also uncertainty as to whether a longer*
21 *duration of exposure to Cipro DI, as would be expected in clinical practice*
22 *(likely lifelong after starting therapy), would result in additional safety issues*
23 *and bacterial resistance leading to erosion of efficacy over time*.

24 (Emphasis added.)

25 8. On this news, Aradigm's share price fell \$2.28, or 38.12%, to close at \$3.70 per share on
26 January 9, 2018.

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

29 JURISDICTION AND VENUE

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

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

1 12. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C.
2 §78aa) and 28 U.S.C. §1391(b). Aradigm's principal executive offices are located within this Judicial
3 District.

4 13. In connection with the acts, conduct and other wrongs alleged in this Complaint,
5 Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,
6 including but not limited to, the United States mail, interstate telephone communications and the
7 facilities of the national securities exchange.
8

9 **PARTIES**

10 14. Plaintiff, as set forth in the accompanying Certification, purchased Aradigm securities at
11 artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged
12 corrective disclosure.
13

14 15. Defendant Aradigm is incorporated in California, with principal executive offices
15 located at 3929 Point Eden Way, Hayward, California 94545. Aradigm's common stock trades on the
16 NASDAQ under the ticker symbol "ARDM."

17 16. Defendant Igor Gonda ("Gonda") has served at all relevant times as the Company's
18 Chief Executive Officer ("CEO"), President and Director.
19

20 17. Defendant Nancy E. Pecota ("Pecota") has served at all relevant times as the Company's
21 Chief Financial Officer ("CFO"), Vice President of Finance and Corporate Secretary.

22 18. The Defendants referenced above in ¶¶ 16-17 are sometimes referred to- herein as the
23 "Individual Defendants."
24

25 19. The Individual Defendants possessed the power and authority to control the contents of
26 Aradigm's SEC filings, press releases, and other market communications. The Individual Defendants
27 were provided with copies of the Company's SEC filings and press releases alleged herein to be
28 misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their

1 issuance or to cause them to be corrected. Because of their positions with the Company, and their
2 access to material information available to them but not to the public, the Individual Defendants knew
3 that the adverse facts specified herein had not been disclosed to and were being concealed from the
4 public, and that the positive representations being made were then materially false and misleading. The
5 Individual Defendants are liable for the false statements and omissions pleaded herein.

6 **SUBSTANTIVE ALLEGATIONS**

7 **Background**

8
9 20. Aradigm Corporation develops novel pulmonary drug delivery systems. The Company's
10 systems are designed to enhance the delivery and effectiveness of a number of existing and
11 development stage drugs and reduce the need for injectable drug therapy. Among other lead product
12 candidates, the Company's portfolio includes Linhaliq (ARD-3150), a proprietary formulation of the
13 antibiotic ciprofloxacin that is delivered by inhalation for the management of infections associated with
14 severe respiratory diseases.
15

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

17 21. The Class Period begins on July 27, 2017, when Aradigm issued a press release entitled
18 "Aradigm Submits New Drug Application (NDA) to FDA for U.S. Marketing Approval of Linhaliq in
19 Non-Cystic Fibrosis Bronchiectasis," announcing the submission of an NDA for U.S. marketing
20 approval for Linhaliq for the treatment of NCFB patients with chronic lung infections. In the press
21 release, the Company stated in relevant part:
22

23 **Aradigm Corporation (NASDAQ: ARDM)** (the "Company") today announced it
24 has submitted its New Drug Application (NDA) to the U.S. Food and Drug
25 Administration (FDA) for Linhaliq™ for the treatment of non-cystic fibrosis
26 bronchiectasis (NCFBE) patients with chronic lung infections with *Pseudomonas*
aeruginosa (*P. aeruginosa*).

27 Pursuant to the Food and Drug Administration Modernization Act of 1997
28 (FDAMA) Sec. 115(a) and FDA guidance, *Providing Clinical Evidence of*
Effectiveness for Human Drug and Biological Products (May 1998), Aradigm is
submitting the Linhaliq NDA based on the positive Phase 3 pivotal clinical trial

1 ARD-3150-1202 (ORBIT-4) and confirmatory evidence from Phase 3 study ARD-
2 3150-1201 (ORBIT-3) and Phase 2b study ARD-3150-0902 (ORBIT-2), together
3 with other supporting evidence from proprietary preclinical and clinical studies, as
4 well as referencing other information about ciprofloxacin from publicly available
5 sources.

6 ***

7 The Phase 3 clinical program for Linhaliq in NCFBE consisted of two worldwide,
8 double-blind, placebo-controlled pivotal trials (ORBIT-3 and ORBIT-4) that were
9 identical in design except for a pharmacokinetics sub-study that was conducted in
10 one of the trials. Each trial enrolled NCFBE patients (278 in ORBIT-3 and 304 in
11 ORBIT-4) into a 48-week double-blind period consisting of 6 cycles of 28 days on
12 treatment with Linhaliq or placebo plus 28 days off treatment, followed by a 28
13 day open label extension in which all participants received Linhaliq (total
14 treatment duration, including the double-blind period, of approximately one year).
15 The superiority of Linhaliq vs. placebo during the double-blind period was
16 evaluated in terms of the primary endpoint - time to first PE, while key secondary
17 endpoints included the reduction in the number of PEs and the number of severe
18 PEs, and improvements in quality of life measures. Lung function was monitored
19 as a safety indicator.

20 Aradigm discussed the results of the Phase 3 studies at meetings with FDA in
21 December 2016 and March 2017. Based on these discussions, the statistical
22 analysis of the results was changed from the pre-specified plan to stratification
23 based on sex and the frequency of pulmonary exacerbations in the prior year, as
24 the stratum for current smokers contained a small number of subjects.

25 Top-line results for the two Phase 3 studies using the new stratification are
26 described below:

27 In ORBIT-4 the median time to first PE was 230 days in the Linhaliq treatment
28 group as compared to 158 days in the placebo group. This increase of 72 days in
the median time to first PE was statistically significant ($p=0.0323$) using stratified
unweighted log-rank analysis. For the first secondary efficacy endpoint, there was
a 37% reduction in the frequency of PEs over the 48-week treatment period in the
Linhaliq treatment group as compared to the placebo group. This result was
statistically significant ($p=0.0006$). In the analysis of the second secondary
endpoint, a statistically significant 60% reduction in the frequency of severe PEs in
the Linhaliq group compared with placebo was found ($p=0.0031$).

In ORBIT-3 the median time to first PE was 214 days in the Linhaliq treatment
group as compared to 136 days in the placebo group. This increase of 78 days in
the median time to first PE was similar to ORBIT-4 but was not statistically
significant ($p=0.9743$). For the first secondary efficacy endpoint, there was a 15%
reduction in the frequency of PEs over the 48-week treatment period in the
Linhaliq treatment group as compared to the placebo group but it was not
statistically significant ($p=0.2565$). In the analysis of the second secondary
endpoint, a statistically non-significant 20% reduction in the frequency of severe
PEs in the Linhaliq group compared with placebo was found ($p=0.4827$).

1 22. On August 11, 2017, Aradigm filed a Quarterly Report on Form 10-Q with the SEC,
2 announcing the Company's financial and operating results for the quarter ended June 30, 2017 (the "Q2
3 2017 10-Q"). For the quarter, Aradigm reported net income of \$1.04 million, or \$0.07 per diluted
4 share, on revenue of \$7.68 million, compared to a net loss of \$8.73 million, or \$0.59 per diluted share,
5 on revenue of \$10,000 for the same period in the prior year.

6 23. In the Q2 2017 10-Q, the Company stated in part:

7
8 In December 2016, we announced top-line results for the Phase 3 studies for
9 Linhaliq in NCFBE, which consisted of the two worldwide, double-blind, placebo-
10 controlled pivotal trials, ORBIT-3 and ORBIT-4, that were identical in design
11 except for a pharmacokinetics sub-study that was conducted in one of the trials.
12 We held pre-NDA meetings with the FDA in December 2016 and March 2017 to
13 discuss our Phase 3 studies.

14 In July 2017, we submitted a New Drug Application, or NDA, to the FDA for
15 Linhaliq for the treatment of NCFBE patients with chronic lung infections with *P.*
16 *aeruginosa*. Pursuant to the Food and Drug Administration Modernization Act of
17 1997 (FDAMA) Sec. 115(a) and FDA guidance, *Providing Clinical Evidence of*
18 *Effectiveness for Human Drug and Biological Products* (May 1998), we submitted
19 the Linhaliq NDA based on the positive pivotal clinical trial ARD-3150-1202
20 (ORBIT-4) and confirmatory evidence from Phase 3 study ARD-3150-1201
21 (ORBIT-3) and Phase 2b study ARD-3150-0902 (ORBIT-2), together with other
22 supporting evidence from proprietary preclinical and clinical studies, as well as
23 referencing other information about ciprofloxacin from publicly available sources.

24 ***

25 We have focused primarily on the development of our leading product candidate
26 Linhaliq for the treatment of NCFBE. In July 2017, we submitted the NDA for
27 Linhaliq to the FDA based on the positive results from the ORBIT-4 study in the
28 Phase 3 clinical program for Linhaliq and confirmatory evidence from the ORBIT-
29 2 and ORBIT-3 studies. The FDA may choose to not accept our NDA for filing.
30 For example, the FDA may conclude that our ORBIT-3 and ORBIT-4 studies in
31 the Phase 3 clinical program for Linhaliq in NCFBE did not meet a finding of
32 superiority based on the pre-specified endpoints. While ***we believe that our Phase***
33 ***3 studies for Linhaliq support the filing of our NDA***, we cannot assure you that
34 the FDA will agree with our conclusions.

35 (Emphasis added.)

36 24. The Q2 2017 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of
37 2002 ("SOX") by the Individual Defendants, stating that the financial information contained in the Q2
38

1 2017 10-Q was accurate and disclosed any material changes to the Company's internal control over
2 financial reporting.

3 25. On November 3, 2017, Aradigm filed a Quarterly Report on Form 10-Q with the SEC,
4 announcing the Company's financial and operating results for the quarter ended September 30, 2017
5 (the "Q3 2017 10-Q"). For the quarter, Aradigm reported a net loss of \$3.89 million, or \$0.26 per
6 diluted share, on revenue of \$2.73 million, compared to a net loss of \$8.19 million, or \$0.55 per diluted
7 share, on revenue of \$50,000 for the same period in the prior year.
8

9 26. In the Q3 2017 10-Q, the Company stated, in part:

10 In July 2017, we submitted a New Drug Application, or NDA, to the FDA for
11 Linhaliq for the treatment of NCFBE patients with chronic lung infections with *P.*
12 *aeruginosa*. Pursuant to the Food and Drug Administration Modernization Act of
13 1997 (FDAMA) Sec. 115(a) and FDA guidance, Providing Clinical Evidence of
14 Effectiveness for Human Drug and Biological Products (May 1998), we submitted
15 the Linhaliq NDA based on the positive pivotal clinical trial ARD-3150-
16 1202 (ORBIT-4) and confirmatory evidence from Phase 3 study ARD-3150-
17 1201 (ORBIT-3) and Phase 2b study ARD-3150-0902 (ORBIT-2), together with
18 other supporting evidence from proprietary preclinical and clinical studies, as well
19 as referencing other information about ciprofloxacin from publicly available
20 sources.

21 ***

22 We have focused primarily on the development of our leading product candidate
23 Linhaliq for the treatment of NCFBE. In July 2017, we submitted the NDA for
24 Linhaliq to the FDA based on the positive results from the ORBIT-4 study in the
25 Phase 3 clinical program for Linhaliq and confirmatory evidence from the ORBIT-
26 2 and ORBIT-3 studies. While the FDA accepted our NDA submission for filing,
27 the FDA retains complete discretion in deciding whether or not to approve the
28 NDA. Additionally, the FDA has indicated that it plans to convene an Advisory
Committee of independent experts, including clinicians and other scientific
experts, to review, evaluate and provide recommendations as to whether the NDA
should be approved and under what conditions.

29 27. The Q3 2017 10-Q contained signed certifications pursuant to SOX by the Individual
30 Defendants, stating that the financial information contained in the Q3 2017 10-Q was accurate and
31 disclosed any material changes to the Company's internal control over financial reporting.

32 28. The statements referenced in ¶¶ 21-27 above were materially false and/or misleading
33 because they misrepresented and/or failed to disclose the following adverse facts pertaining to the
34

1 Company's business, operational and financial results, which were known to Defendants or recklessly
2 disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to
3 disclose that: (i) the methodology underlying Aradigm's Linhaliq Phase III clinical trials was not well
4 tailored to yield consistent efficacy findings or to provide data sufficient to account for discordant
5 efficacy findings; (ii) the endpoint of the Phase III trials—namely, delaying the time to first
6 exacerbation on study therapy compared to placebo over approximately one year of observation—was
7 unlikely to demonstrate a clinically meaningful benefit with respect to a patient population that would
8 likely be taking the drug for a longer duration; (iii) accordingly, these studies were unlikely to support
9 FDA approval of the Linhaliq NDA; and (iv) as a result, Aradigm's public statements were materially
10 false and misleading at all relevant times.
11

12 **The Truth Begins to Emerge**

13
14 29. On January 9, 2018, the FDA announced that it would discuss Aradigm's Linhaliq
15 NDA at the Antimicrobial Drugs Advisory Committee meeting scheduled for January 11, 2018. In the
16 briefing document for the meeting, the FDA stated, in part:

17 The Agency recommended that two adequate and well-controlled clinical trials be
18 conducted to support the NCFB indication because (1) this was a new treatment
19 indication and route of administration for ciprofloxacin; (2) there were too many
20 uncertainties with regard to duration of treatment, frequency of administration and
21 endpoints to allow for reliance on a single Phase 3 trial; (3) studies of inhaled
22 antibacterial drugs (tobramycin, gentamicin, aztreonam, and colistin) for the
23 prevention of NCFB exacerbations have yielded mixed results and none are
24 approved for this indication (4) there were no relevant animal models; (5) given
25 the proposed chronicity of administration, there was a need for adequate
26 assessment of safety in a reasonably large number of patients; and (6) the conduct
27 of two independent trials would be important in providing replicative evidence
28 supporting an overall demonstration of efficacy and safety.

25 In ORBIT-3, for the primary endpoint of time to first PE, the overall hazard ratio
26 (Cipro/placebo) in the unweighted, stratified model including prior PEs and sex
27 was 0.99 yielding a 95% CI (0.71, 1.38) suggesting no difference between arms.
28 Additionally, secondary analyses including frequency of PEs by Week 48, change
in QoL-B, and FEV1 failed to demonstrate any effect of Cipro over placebo.

1 In ORBIT-4, a treatment effect was observed in time to first PE with a hazard ratio
2 of 0.71, 95% CI (0.52 to 0.97). Additionally, the mean number of PEs at Week 48
3 (secondary endpoint) was 0.98 and 1.47 in the Cipro and placebo arms,
4 respectively with an incidence rate ratio of 0.631 suggesting a 36.9% reduction
5 with a 95% CI ranging from 17.9% to 51.5%. Similar results were seen when
6 considering severe PEs and PEs. These findings suggest an overall decrease in the
7 48-week frequency of PEs. No differences were observed between treatment arms
8 on FEV1 or the change in QoL-B endpoints.

9 ***Reasons for the discordance in efficacy findings between trials cannot be***
10 ***explained based on the information collected in the two trials.*** However, neither
11 trial collected information on patient history of disease prior to screening, on the
12 underlying etiology of bronchiectasis, or number of affected lobes, which are all
13 factors that might have aided in better understanding if differences in baseline
14 disease severity existed between trial populations. Given the changes post-data
15 base lock and unblinding, the potential for bias in the findings cannot be excluded.
16 Regarding the design of the Phase 3 trials, and based on current understanding of
17 the disease under study, we note that time to first exacerbation has limitations
18 since it is ***unclear that delaying the time to first exacerbation on study therapy***
19 ***compared to placebo over approximately one year of observation, translates into***
20 ***a clinically meaningful benefit for a patient population that would most likely be***
21 ***on this therapy for long durations.*** The frequency of PEs endpoint captures all
22 PEs during the trial; however, modeling of this endpoint does not fully capture the
23 at-risk intervals for each patient as it does not account for duration of exacerbation.
24 Additionally, we note the trial to trial heterogeneity in efficacy which cannot be
25 explained, and the magnitude of the treatment effect, which even if statistically
26 significant is small.

27 Finally, the duration of the Phase 3 trials may not have been long enough to
28 adequately assess whether Cipro DI reduces the frequency of exacerbations to a
clinically meaningful extent and whether such an effect would be durable beyond
approximately one year. Tied to the question of whether the trials were of adequate
duration to assess efficacy, ***there is also uncertainty as to whether a longer***
duration of exposure to Cipro DI, as would be expected in clinical practice
(likely lifelong after starting therapy), would result in additional safety issues
and bacterial resistance leading to erosion of efficacy over time.

(Emphasis added.)

30. On this news, Aradigm's share price fell \$2.28 or 38.12%, to close at \$3.70 per share on
January 9, 2018.

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

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

18 34. Plaintiff’s claims are typical of the claims of the members of the Class as all members of
19 the Class are similarly affected by Defendants’ wrongful conduct in violation of federal law that is
20 complained of herein.
21

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

25 36. Common questions of law and fact exist as to all members of the Class and predominate
26 over any questions solely affecting individual members of the Class. Among the questions of law and
27 fact common to the Class are:
28

1 whether the federal securities laws were violated by Defendants' acts as alleged
herein;

2 whether statements made by Defendants to the investing public during the Class
3 Period misrepresented material facts about the financial condition, business,
4 operations, and management of Aradigm;

5 whether Defendants caused Aradigm to issue false and misleading financial
6 statements during the Class Period;

7 whether Defendants acted knowingly or recklessly in issuing false and
8 misleading financial statements;

9 whether the prices of Aradigm securities during the Class Period were artificially
10 inflated because of Defendants' conduct complained of herein; and

11 whether the members of the Class have sustained damages and, if so, what is the
proper measure of damages.

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

17
18 38. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-
19 the-market doctrine in that:

20 Defendants made public misrepresentations or failed to disclose material facts
21 during the Class Period;

22 the omissions and misrepresentations were material;

23 Aradigm common shares are traded in efficient markets;

24 the Company's shares were liquid and traded with moderate to heavy volume
25 during the Class Period;

26 the Company traded on the NASDAQ, and was covered by multiple analysts;
27
28

1 the misrepresentations and omissions alleged would tend to induce a reasonable
2 investor to misjudge the value of the Company's common shares; and

3 Plaintiff and members of the Class purchased and/or sold Aradigm common
4 shares between the time the Defendants failed to disclose or misrepresented
5 material facts and the time the true facts were disclosed, without knowledge of
6 the omitted or misrepresented facts.

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

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

13 **COUNT I**

14 **Violation of Section 10(b) of The Exchange Act and Rule 10b-5** 15 **Against All Defendants**

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

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

21 43. During the Class Period, Aradigm and the Individual Defendants, individually and in
22 concert, directly or indirectly, disseminated or approved the false statements specified above, which
23 they knew or deliberately disregarded were misleading in that they contained misrepresentations and
24 failed to disclose material facts necessary in order to make the statements made, in light of the
25 circumstances under which they were made, not misleading.
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1 44. Aradigm and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5
2 in that they:

3 employed devices, schemes and artifices to defraud;
4 made untrue statements of material facts or omitted to state material facts
5 necessary in order to make the statements made, in light of the circumstances
6 under which they were made, not misleading; or
7 engaged in acts, practices and a course of business that operated as a fraud or
8 deceit upon plaintiff and others similarly situated in connection with their
9 purchases of Aradigm common shares during the Class Period.

10 45. Aradigm and the Individual Defendants acted with scienter in that they knew that the
11 public documents and statements issued or disseminated in the name of Aradigm were materially false
12 and misleading; knew that such statements or documents would be issued or disseminated to the
13 investing public; and knowingly and substantially participated, or acquiesced in the issuance or
14 dissemination of such statements or documents as primary violations of the securities laws. These
15 Defendants by virtue of their receipt of information reflecting the true facts of Aradigm, their control
16 over, and/or receipt and/or modification of Aradigm allegedly materially misleading statements, and/or
17 their associations with the Company which made them privy to confidential proprietary information
18 concerning Aradigm, participated in the fraudulent scheme alleged herein.

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

25 47. As a result of the foregoing, the market price of Aradigm common shares was artificially
26 inflated during the Class Period. In ignorance of the falsity of Aradigm's and the Individual
27

1 Defendants' statements, Plaintiff and the other members of the Class relied on the statements described
2 above and/or the integrity of the market price of Aradigm common shares during the Class Period in
3 purchasing Aradigm common shares at prices that were artificially inflated as a result of Aradigm's and
4 the Individual Defendants' false and misleading statements.

5 48. Had Plaintiff and the other members of the Class been aware that the market price of
6 Aradigm common shares had been artificially and falsely inflated by Aradigm's and the Individual
7 Defendants' misleading statements and by the material adverse information which Aradigm's and the
8 Individual Defendants did not disclose, they would not have purchased Aradigm's common shares at
9 the artificially inflated prices that they did, or at all.

10 49. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the
11 Class have suffered damages in an amount to be established at trial.

12 50. By reason of the foregoing, Aradigm and the Individual Defendants have violated
13 Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and
14 the other members of the Class for substantial damages which they suffered in connection with their
15 purchase of Aradigm common shares during the Class Period.

16 **COUNT II**

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

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

20 52. During the Class Period, the Individual Defendants participated in the operation and
21 management of Aradigm, and conducted and participated, directly and indirectly, in the conduct of
22 Aradigm's business affairs. Because of their senior positions, they knew the adverse non-public
23 information regarding the Company's inadequate internal safeguards in data security protocols.

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

5 54. Because of their positions of control and authority as senior officers, the Individual
6 Defendants were able to, and did, control the contents of the various reports, press releases and public
7 filings which Aradigm disseminated in the marketplace during the Class Period. Throughout the Class
8 Period, the Individual Defendants exercised their power and authority to cause Aradigm to engage in
9 the wrongful acts complained of herein. The Individual Defendants therefore, were “controlling
10 persons” of Aradigm within the meaning of Section 20(a) of the Exchange Act. In this capacity, they
11 participated in the unlawful conduct alleged which artificially inflated the market price of Aradigm
12 common shares.
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15 55. By reason of the above conduct, the Individual Defendants are liable pursuant to Section
16 20(a) of the Exchange Act for the violations committed by Aradigm.

17 **PRAYER FOR RELIEF**

18 WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- 19 A. Determining that the instant action may be maintained as a class action under Rule 23 of
20 the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
21
22 B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of
23 the acts and transactions alleged herein;
24
25 C. Awarding Plaintiff and the other members of the Class prejudgment and post- judgment
26 interest, as well as their reasonable attorneys’ fees, expert fees and other costs; and
27 D. Awarding such other and further relief as this Court may deem just and proper.

28 **DEMAND FOR TRIAL BY JURY**

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Plaintiff hereby demands a trial by jury.

Dated: