

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION**

S _____, Individually and on Behalf
of All Others Similarly Situated,

Plaintiff,

v.

ARDELYX INC., MIKE RAAB, and JUSTIN
RENZ,

Defendants.

Case No. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

1 Plaintiff _____ (“Plaintiff”) makes the following allegations, individually and on
2 behalf of all other similarly situated, by and through Plaintiff’s counsel, upon information and
3 belief, except as to those allegations concerning Plaintiff, which are alleged upon personal
4 knowledge. Plaintiff’s information and belief is based upon, *inter alia*, counsel’s investigation,
5 which included, among other things, review and analysis of: (i) regulatory filings made by Ardelyx
6 Inc. (“Ardelyx” or the “Company”) with the SEC; (ii) press releases and media reports issued by
7 and disseminated by the Company; and (iii) analyst reports, media reports, and other publicly
8 disclosed reports and information about the Company. Plaintiff believes that substantial
9 evidentiary support will exist for the allegations set forth herein, after a reasonable opportunity for
10 discovery.

11 **SUMMARY OF THE ACTION**

12 1. Plaintiff brings this federal securities class action under §§10(b) and 20(a) of the
13 Securities Exchange Act of 1934 (the “Exchange Act”) and SEC Rule 10b-5 promulgated
14 thereunder, 17 C.F.R. §240.10b-5, on behalf of a class consisting of all persons and entities, other
15 than Defendants and their affiliates, who purchased Ardelyx securities between August 6, 2020
16 and July 19, 2021, inclusive (the “Class Period”), and who were damaged thereby (the “Class”).

17 2. Ardelyx is a specialized biopharmaceutical company focused on developing first-
18 in-class medicine to improve treatment for people with cardiorenal disease. This includes patients
19 with chronic kidney disease (“CKD”) on dialysis suffering from elevated serum phosphorus, or
20 hyperphosphatemia; and CKD patients and/or heart failure patients with elevated serum potassium,
21 or hyperkalemia.

22 3. In June 2020, Defendants submitted a New Drug Application (“NDA”) to the U.S.
23 Food and Drug Administration (“FDA”) for Ardelyx’s lead product candidate, tenapanor, a
24 supposedly first-in-class medicine for the control of serum phosphorus in adult patients with CKD
25 on dialysis. According to Ardelyx, tenapanor has “a unique mechanism of action and acts locally
26 in the gut to inhibit the sodium hydrogen exchanger 3, or NHE3,” resulting in the “tightening of
27 the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the
28

1 primary pathway of phosphate absorption.” If approved, tenapanor “would be the first therapy for
2 phosphate management that blocks phosphorus absorption at the primary pathway of uptake[.]”
3 and “could greatly improve patient adherence and compliance with one single pill dosed twice
4 daily in contrast to current therapies where typically multiple pills are taken before every meal.”
5 Thus, tenapanor (and its promise) was widely touted by Defendants and, accordingly, extremely
6 important to the valuation (and future success) of Ardelyx securities.

7 4. The FDA accepted Ardelyx’s NDA in September 2020 and set a Prescription Drug
8 User Fee Act (“PDUFA”) date of April 29, 2021.

9 5. The Company repeatedly lauded this development, highlighting the FDA’s
10 acceptance and review of the NDA, supported by so-called “successful” Phase 3 studies, in each
11 subsequently filed quarterly report and in the Company’s 2020 Annual Report (defined below).
12 Even when the FDA requested that the Company provide additional information related to
13 Ardelyx’s clinical data, which caused the PDUFA date to slip by three months, Defendants
14 continued to hype Ardelyx’s “positive” clinical trial results, which, according to them, showed
15 “improvements” over current treatments, supported tenapanor’s “clinical safety and efficacy,” and
16 reinforced its “potential” as a “transformative” treatment. At no point did Defendants state (much
17 less suggest) that there may be fatal issues with the drug, its clinical trial data, or both. Rather,
18 Defendants simply claimed that the FDA’s request was merely because they needed help to “better
19 understand the clinical data in light of tenapanor’s novel mechanism of action as compared to
20 approved therapies.”

21 6. Defendants’ rosy narrative, however, came to a screeching halt after the market
22 closed on July 19, 2021. At that time, Ardelyx announced that it had received a letter from the
23 FDA, dated July 13, 2021, that said the administration had found deficiencies that precluded
24 discussion around the would-be labeling and post-marketing requirements for tenapanor.
25 Critically, the FDA said it *detected issues with both the size and clinical relevance* of the drug’s
26 treatment effect.

1 Defendants knew that the adverse facts specified herein had not been disclosed to and were being
2 concealed from the public and that the positive representations being made were false and
3 misleading. The Individual Defendants are liable for the false statements pleaded herein.

4 **SUBSTANTIVE ALLEGATIONS**

5 22. Ardelyx is a biotechnology company focused on the development of therapies for
6 cardiorenal disorder. Though Ardelyx’s lead product candidate, tenapanor, has been approved by
7 the FDA as a treatment for irritable bowel syndrome associated constipation, the Company has not
8 commercialized it in the United States nor generated any revenue from its sale. Rather, Ardelyx
9 has focused on advancing another indication for the drug, namely for helping to control serum
10 phosphorus in adult CKD patients on dialysis.

11 23. In fact, Ardelyx presented tenapanor to the FDA as a new treatment to manage
12 hyperphosphatemia in CKD patients undergoing dialysis treatment based on a Phase 3 program
13 for the control of serum phosphorus in CKD patients on dialysis. In December 2019, the Company
14 reported (purportedly) statistically significant topline efficacy results from its second monotherapy
15 Phase 3 clinical trial, the PHREEDOM trial, which had followed a “successful” monotherapy
16 Phase 3 clinical trial completed in 2017 that (again, purportedly) achieved statistical significance
17 for the primary endpoint.¹

18 24. Consequently, obtaining regulatory approvals for tenapanor for the control of
19 serum phosphorus in adult CKD patients on dialysis was critical.

20 **MATERIALLY FALSE AND MISLEADING STATEMENTS**

21 25. The Class Period begins on August 6, 2020, when Ardelyx issued a press release
22 announcing that it submitted an NDA to the FDA for the review of tenapanor as a first-in-class
23 therapy to control serum phosphorus in adult patients with CKD on dialysis. According to the
24

25 ¹ PHREEDOM was a one-year study with a 26-week *open-label* treatment period and a 12-
26 week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week
27 *open-label* safety extension period. An active safety control group, for safety analysis only,
28 received sevelamer, *open-label*, for the entire 52-week study period. Patients completing the
PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had
the option to participate in NORMALIZE, an ongoing *open-label* 18-month extension study.

1 press release, the filing was supported by three *successful* Phase 3 studies demonstrating
2 tenapanor’s ability to *reduce* phosphate levels. In addition, the release noted that “additional
3 *positive data* from the ongoing NORMALIZE Phase 4 study” showed a “58% *improvement* over
4 current standard of care.” [Emphasis added.]

5 26. Also on August 6, 2020, Ardelyx filed with the SEC its quarterly report on Form
6 10-Q for the period ending June 30, 2020 (the “2Q20 10-Q”), further touting the apparent benefits
7 of tenapanor, stating in relevant part:

8 In June 2020, we announced *positive* results from a planned interim data analysis
9 from our ongoing NORMALIZE Phase 4 study evaluating tenapanor, as
10 monotherapy or in combination with sevelamer, to achieve serum phosphorus
11 levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The
12 NORMALIZE extension study allowed patients from our PHREEDOM study to
13 continue therapy with tenapanor and enabled those patients in the PHREEDOM
14 safety control arm receiving sevelamer carbonate to transition to tenapanor. *The*
15 *data from the planned interim analysis demonstrated that the foundational use*
16 *of tenapanor as monotherapy or in combination with sevelamer carbonate*
17 *produces a significant phosphorus-lowering effect* with a mean serum
18 phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27
19 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the
20 time of this analysis. Of the 171 patients in this interim analysis who completed up
21 to 9 months of treatment in this extension study, up to 47.4% achieved a normal
22 serum phosphorus level, and of those, the majority were on tenapanor alone or
23 tenapanor with low dose sevelamer of ≤ 3 sevelamer tablets per day. These data
24 represent a 58% *improvement* in the rate of patients who achieve a normal serum
25 phosphorus level, as compared to current treatment practice data as reported in the
26 April 2020 Dialysis Outcomes Practice Patterns Study (“DOPPS”) Practice
27 Monitor.

28 * * *

29 Tenapanor, if approved, would be the first therapy for phosphate management that
30 blocks phosphorus absorption at the primary pathway of uptake. It is not a
31 phosphate binder. *Tenapanor is a novel, potent, small molecule, that has been*
32 *shown in the phase 3 studies to treat hyperphosphatemia* as monotherapy and as
33 a dual mechanism approach. Additionally, as such we believe tenapanor could
34 greatly improve patient adherence and compliance with one single pill dosed twice
35 daily in contrast to current therapies where typically multiple pills are taken before
36 every meal.

37 [Emphasis added].

38 27. On November 5, 2020, Ardelyx filed with the SEC on Form 10-Q its third quarter
2020 financial results, substantially repeating the same claims made in the Company’s 2Q20 10-
Q. Defendants also issued a press release that emphasized certain “business highlights,” including

1 that the FDA accepted the NDA submitted by Defendants for tenapanor to control serum
2 phosphorus in adult patients with CKD on dialysis. Defendants, again, claimed that the filing was
3 supported by three *successful* Phase 3 studies *demonstrating tenapanor’s ability to reduce*
4 phosphate levels, with Defendant Raab, specifically, touting “clinical data presented at ASN
5 Kidney Week 2020[, which] *support[s] the clinical safety and efficacy of tenapanor and*
6 *reinforce[s] its potential* to transform the treatment landscape for patients.” [Emphasis added.]

7 28. On March 8, 2021, Ardelyx filed with the SEC on Form 10-K its Fourth Quarter
8 and Full year 2020 Financial Results, which touted the Company’s ability to monetize tenapanor
9 upon FDA approval. For example, it stated:

10 **Tenapanor: A New Approach for The Control of Serum Phosphorus in CKD**
11 **Patients on Dialysis**

12 Our portfolio is led by the development of tenapanor, a first-in-class medicine for
13 the control of serum phosphorus in adult patients with CKD on dialysis. Tenapanor
14 for the control of serum phosphorus has a unique mechanism of action and acts
15 locally in the gut to inhibit the sodium hydrogen exchanger 3 (“NHE3”). This
16 results in the tightening of the epithelial cell junctions, thereby significantly
17 reducing paracellular uptake of phosphate, the primary pathway of phosphate
18 absorption. On September 15, 2020 we announced that the FDA accepted the filing
19 of our NDA for tenapanor for the control of serum phosphorus in adult patients
20 with CKD on dialysis. The acceptance of our NDA represents the next critical step
21 toward *bringing to market* a completely new approach to the management of
22 hyperphosphatemia. The FDA has set a PDUFA date of April 29, 2021. *We*
23 *continue to advance commercial preparations for the launch of tenapanor for*
24 *this indication*. The NDA is supported by three *successful* Phase 3 trials involving
25 over 1,000 patients that evaluated the use of tenapanor for the control of serum
26 phosphorus in CKD patients on dialysis, with two trials evaluating tenapanor as
27 monotherapy and one trial evaluating tenapanor as part of a dual mechanism
28 approach with phosphate binders.

* * *

21 In December 2019, we reported *statistically significant* topline efficacy results
22 from our second monotherapy Phase 3 clinical trial, the PHREEDOM trial, which
23 evaluated tenapanor for the control of serum phosphorus in CKD patients on
24 dialysis. The PHREEDOM trial followed a *successful* monotherapy Phase 3
25 clinical trial completed in 2017, the BLOCK trial, which achieved *statistical*
26 *significance* for the primary endpoint. The only adverse event reported in these
27 Phase 3 trials in greater than 5% of patients was diarrhea, with an incidence rate of
28 52% in the PHREEDOM trial and 39% in the BLOCK trial, with most incidences
in each trial being mild to moderate in nature. PHREEDOM is a one-year study
with a 26-week *open-label* treatment period and a 12-week double-blind, placebo-
controlled randomized withdrawal period followed by a 14-week *open-label* safety
extension period. An active safety control group, for safety analysis only, received
sevelamer, open-label, for the entire 52-week study period. Patients completing the
PHREEDOM trial from both the tenapanor arm and the sevelamer active safety

1 control arm had the option to participate in NORMALIZE, an ongoing *open-label*
2 18-month extension study.

3 In June 2020, we announced *positive* results from a planned analysis from our
4 ongoing NORMALIZE extension study evaluating tenapanor, as monotherapy or
5 in combination with sevelamer, to achieve serum phosphorus levels in the normal
6 range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE
7 extension study allowed patients from our PHREEDOM study to continue therapy
8 with tenapanor and enabled those patients in the PHREEDOM safety control arm
receiving sevelamer carbonate to transition to tenapanor. The data from the planned
interim analysis demonstrated that the foundational use of tenapanor as
monotherapy or in combination with sevelamer carbonate produces a significant
phosphorus-lowering effect with a mean serum phosphorous reduction of 2.33
mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the
PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis.

9 [Emphasis added.]

10 29. Also on March 8, 2021, Ardelyx issued a press release within which Defendant
11 Raab stated: “[t]he stage is set for an exciting year for Ardelyx in 2021,” since “*we are well*
12 *positioned and well prepared to commercialize* tenapanor upon potential FDA approval of the
13 first and only phosphate absorption inhibitor for the control of serum phosphorus.” [Emphasis
14 added.]

15 30. Then, on April 29, 2021, Ardelyx issued a press release announcing the need to
16 provide additional analyses of its clinical data to the FDA in connection with the FDA’s ongoing
17 review of the Company’s NDA for tenapanor. According to the Company, the FDA requested this
18 information to help it “better understand the clinical data in light of tenapanor’s novel mechanism
19 of action as compared to approved therapies.” Since this information constituted a “major
20 amendment to the NDA,” the PDUFA date was extended three months to July 29, 2021.

21 31. Defendant Raab offered an optimistic take on the FDA’s request in a May 6, 2021
22 press release announcing the Company’s First Quarter 2021 Financial Results, stating in relevant
23 part:

24 We continue to prepare for the potential approval and launch of tenapanor
25 following the recent extension of our PDUFA date to July. *We remain confident*
26 *in the comprehensive data included in our New Drug Application* and believe
27 tenapanor represents an attractive alternative to currently available therapies to
28 control serum phosphorus in CKD patients on dialysis. To that end, we are
committed to working with the FDA through the completion of its review of our
NDA and *look forward to the possibility of making a significant impact* in the
lives of patients.

1 [Emphasis added.]

2 32. The statements identified above were materially false and misleading and failed to
3 disclose material facts about tenapanor and the likelihood that it would be approved by the FDA.
4 Defendants possessed, were in control over, and, as a result, knew (or had reason to know) that the
5 data submitted to support the NDA was insufficient in that it showed a lack of clinical relevance
6 of the drug’s treatment effect, making it foreseeably likely (if not certain) that the FDA would not
7 approve the drug.

8 **THE TRUTH EMERGES**

9 33. Defendants’ upbeat narrative came to a screeching halt after the markets closed on
10 July 19, 2021, when they announced that Ardelyx received a letter from the FDA *on July 13, 2021*,
11 stating that “the FDA *has identified deficiencies that preclude discussion of labeling and post-*
12 *marketing requirements/commitments.*” In particular, the FDA noted that “*a key issue is the size*
13 *of the treatment effect and its clinical relevance.*” [Emphasis added.]

14 34. On this news, the price of Ardelyx’s shares plunged from their July 19, 2021 closing
15 price of \$7.70 per share to a July 20, 2021 close of just \$2.01 each. This represents a one-day drop
16 of nearly 74%, or hundreds of millions of dollars in lost market capitalization.

17 **CLASS ACTION ALLEGATIONS**

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

20 36. Plaintiff brings this action as a class action, pursuant to Rules 23(a) and 23(b)(3) of
21 the Federal Rules of Civil Procedure, on behalf of the Class, consisting of all persons and entities
22 that purchased, or otherwise acquired, the common stock of Ardelyx during the Class Period.

23 37. Excluded from the Class are: (i) Defendants; (ii) present or former executive
24 officers of Ardelyx, members of the Board, and members of their immediate families (as defined
25 in 17 C.F.R. §229.404, Instructions (1)(a)(iii) and (1)(b)(ii)); (iii) any of the foregoing persons’
26 legal representatives, heirs, successors, or assigns; and (iv) any entities in which Defendants have
27 or had a controlling interest, or any affiliate of Ardelyx.

1 38. The members of the Class are so numerous that joinder of all members is
2 impracticable. Throughout the Class Period, the Company's common stock was actively traded
3 on the NASDAQ, a national securities exchange. While the exact number of Class members is
4 unknown to Plaintiff at this time, and can only be ascertained through appropriate discovery,
5 Plaintiff believes that there are hundreds or thousands of members in the Class. Millions of
6 Ardelyx shares were publicly traded during the Class Period on the NASDAQ. Record owners
7 and other members of the Class may be identified from records maintained by Ardelyx or its
8 transfer agent and may be notified of the pendency of this action by mail, using a form of notice
9 similar to that customarily used in securities class actions.

10 39. Plaintiff's claims are typical of the claims of Class members, who were all similarly
11 affected by Defendants' wrongful conduct in violation of the federal securities laws. Further,
12 Plaintiff will fairly and adequately protect the interests of Class members and have retained
13 counsel competent and experienced in class and securities litigation.

14 40. Common questions of law and fact exist as to all members of the Class and
15 predominate over any questions solely affecting individual members of the Class. Among the
16 questions of law and fact common to the members of the Class are:

- 17 (a) whether Defendants violated the Exchange Act;
- 18 (b) whether Defendants' statements to the investing public during the Class Period
19 omitted and/or misrepresented material facts;
- 20 (c) whether Defendants' statements to the investing public during the Class Period
21 omitted material facts necessary in order to make the statements made, in light
22 of the circumstances under which they were made, not misleading;
- 23 (d) whether Defendants knew or recklessly disregarded that their statements were
24 false and misleading;
- 25 (e) whether the price of Ardelyx's common stock was artificially inflated; and
- 26 (f) the extent of damage sustained by Class members and the appropriate measure
27 of damages.
- 28

1 maintain artificially high market prices for Ardelyx securities in violation of §10(b) of the
2 Exchange Act and Rule 10b-5 promulgated thereunder.

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

7 48. Defendants employed devices, schemes, and artifices to defraud while in
8 possession of material, adverse nonpublic information and engaged in acts, practices, and a course
9 of conduct, as alleged herein, in an effort to assure investors of Ardelyx's value and performance
10 and continued substantial growth, which included the making of, or participation in the making of,
11 false statements of material facts and omitting to state material facts necessary in order to make
12 the statements made about Ardelyx and its business operations and future prospects, in the light of
13 the circumstances under which they were made, not misleading, as set forth more particularly
14 herein, and engaged in transactions, practices, and a course of business that operated as a fraud
15 and deceit upon the purchasers of Ardelyx securities.

16 49. As described above, Defendants acted with scienter throughout the Class Period in
17 that they either had actual knowledge of the misrepresentations and omissions of material facts set
18 forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to
19 disclose such facts, even though such facts were available to them. Defendants' material
20 misrepresentations and/or omissions were done knowingly or recklessly and, for the purpose and
21 effect of concealing the Company's results and growth prospects, thereby artificially inflating the
22 price of its securities. As demonstrated by Defendants' omissions and misstatements of the
23 Company's business strategy, Defendants, if they did not have actual knowledge of the
24 misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by
25 deliberately refraining from taking those steps necessary to discover whether those statements
26 were false or misleading.

27
28

