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10 **IN THE UNITED STATES DISTRICT COURT**
11 **NORTHERN DISTRICT OF CALIFORNIA**

12 AI PHUONG CHI, derivatively on behalf of
13 ACELRX PHARMACEUTICALS, INC.,

14 Plaintiff,

15 v.

16 VINCENT J. ANGOTTI, RAFFI
17 ASADORIAN, ADRIAN ADAMS, RICHARD
18 AFABLE, MARK G. EDWARDS, STEPHEN J.
19 HOFFMAN, PAMELA P. PALMER,
20 HOWARD B. ROSEN and MARK WAN,

21 Defendants,

22 and

23 ACELRX PHARMACEUTICALS, INC.,

24 Nominal Defendant.

Case No.:

JURY TRIAL DEMANDED

25 **VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT**

INTRODUCTION

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Plaintiff Ai Phuong Chi (“Plaintiff”), by Plaintiff’s undersigned attorneys, derivatively and on behalf of Nominal Defendant AcelRx Pharmaceuticals, Inc. (“AcelRx” or the “Company”), files this Verified Shareholder Derivative Complaint against Individual Defendants Vincent J. Angotti, Raffi Asadorian, Adrian Adams, Richard Afable, Mark G. Edwards, Stephen J. Hoffman, Pamela P. Palmer, Howard B. Rosen, and Mark Wan, (collectively, the “Individual Defendants”) for violations of the Securities Exchange Act of 1934 (the “Exchange Act”), breaches of their fiduciary duties as directors and/or officers of AcelRx, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and for contribution under Sections 10(b) and 21D Exchange Act. As for Plaintiff’s complaint against the Individual Defendants, Plaintiff alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding AcelRx, legal filings, news reports, securities analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by AcelRx’s directors and officers between March 17, 2020 and February 12, 2021 (the “Relevant Period”).
2. AcelRx is a pharmaceutical company specializing in the development and commercialization of therapies for acute pain treatment. The Company’s lead product candidate is a sublingual opioid tablet called DSUVIA, a sufentanil-based treatment for moderate-to-severe acute pain.
3. The Company announced on November 2, 2018 that the United States Food and Drug Administration (“FDA”) had approved DSUVIA “for the management of acute pain in adults that is severe enough to require an opioid analgesic in certified medically supervised healthcare settings, such as hospitals, surgical centers, and emergency departments.”

1 4. Under the Federal Food, Drug and Cosmetic Act (“FD&C Act”), it is prohibited to
2 introduce or deliver for introduction into interstate commerce any drug that is misbranded.

3 5. In contravention of the FD&C Act, the Company developed and used a banner and a
4 tabletop display as promotional materials that were materially false or misleading and that misbranded
5 DSUVIA by, among other things, giving greater prominence to the benefits of DSUVIA while relegating
6 information regarding limitations of use and risks to significantly less prominent locations and employing
7 typographical and layout techniques less apt to achieve emphasis (the “Misbranding Violations”).

8 6. Throughout the Relevant Period, Individual Defendants made or caused AcelRx to make
9 false and/or materially misleading statements and failed to disclose, *inter alia*, that: (1) AcelRx failed to
10 implement and/or maintain sufficient disclosure controls and procedures regarding the marketing of
11 DSUVIA; (2) as a result, the Company engaged in the Misbranding Violations; and (3) the Company was
12 therefore subject to increased risk of regulatory investigations or enforcement actions. As a result, the
13 Company’s public statements were materially false and misleading at all relevant times.

14 7. The truth was revealed on February 16, 2021, when AcelRx disclosed that it had received
15 a warning letter from the FDA regarding promotional claims it had made about DSUVIA in a banner ad
16 and a tabletop display. In the letter, which the Company received on February 11, 2021, the FDA stated
17 as follows:

18 The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug
19 Administration (FDA) has reviewed an “SDS Banner Ad” (banner) (PM-US-DSV-0018)
20 and a tabletop display (PM-US-DSV-0049) (display) for DSUVIA (sufentanil) sublingual
21 tablet, CII (Dsuvia) submitted by AcelRx Pharmaceuticals, Inc. (AcelRx) under cover of
22 Form FDA 2253. The promotional communications, the banner and display, ***make false or
misleading claims and representations about the risks and efficacy of DSUVIA. Thus,
the banner and display misbrand Dsuvia within the meaning of the Federal Food, Drug
and Cosmetic Act (FD&C Act) and make its distribution violative.***

23 (Emphasis added.)

24 8. The warning letter “request[ed] that AcelRx cease any violations of the FD&C Act,” and
25 it instructed the Company to submit a response to the warning letter within fifteen days of having received
26 the warning letter, “listing all other promotional communications . . . for Dsuvia that contain
27 representations like those described above, and explaining any plan for discontinuing use of such
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1 communications, or for ceasing distribution of Dsuvia.”

2 9. Following the disclosure of the warning letter, AcclRx’s stock price fell \$0.21 per share,
3 or 8.37%, from its closing price on February 12, 2021 to close at \$2.30 per share on February 16, 2021.

4 10. During the Relevant, the Individual Defendants breached their fiduciary duties by
5 personally engaging in and/or causing the Company to engage in the Misbranding Violations.

6 11. Also during the Relevant Period, the Individual Defendants breached their fiduciary duties
7 by personally making and/or causing the Company to make to the investing public a series of materially
8 false and misleading statements regarding the Company’s business, operations, and prospects.
9 Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make
10 false and misleading statements that failed to disclose, *inter alia*, that: (1) AcclRx failed to implement
11 and/or maintain sufficient disclosure controls and procedures regarding the marketing of DSUVIA; (2) as
12 a result, the Company engaged in the Misbranding Violations; and (3) the Company was therefore subject
13 to increased risk of regulatory investigations or enforcement actions. As a result, the Company’s public
14 statements were materially false and misleading at all relevant times.

15 12. The Individual Defendants also breached their fiduciary duties by failing to correct and/or
16 causing the Company to fail to correct these false and misleading statements and omissions of material
17 fact.

18 13. Additionally, in breach of their fiduciary duties, the Individual Defendants caused the
19 Company to fail to maintain adequate internal controls.

20 14. In light of the Individual Defendants’ misconduct—which has subjected the Company, its
21 Chief Executive Officer (“CEO”), and its Chief Financial Officer (“CFO”) to a federal securities fraud
22 class action lawsuit pending in the United States District Court for the Northern District of California (the
23 “Securities Class Action”), the need to undertake intake internal investigations, the need to implement
24 adequate internal controls, losses from the waste of corporate assets, and losses due to the unjust
25 enrichment of Individual Defendants who were improperly overcompensated by the Company, and/or
26 who benefitted from the wrongdoing alleged herein—the Company will have to expend many millions of
27 dollars.
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