

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 28, 2022

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State of incorporation)

001-35068

(Commission File No.)

41-2193603

(IRS Employer Identification No.)

25821 Industrial Blvd, Suite 400

Hayward, CA 94545

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (650) 216-3500

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	ACRX	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events

As previously disclosed, on February 11, 2021, AcelRx Pharmaceuticals, Inc. (the “Company”) received a warning letter from the Office of Prescription Drug Promotion (“OPDP”) of the U.S. Food and Drug Administration (the “FDA”) (the “Warning Letter”) relating to certain promotional materials used by the Company in 2019.

On March 28, 2022, the Company received a Warning Letter close-out letter (“close-out letter”) from the OPDP indicating that the FDA has concluded its evaluation of the Company’s corrective actions in response to the Warning Letter and that the Company has addressed the issues raised by the Warning Letter.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to risks related to our assumptions regarding whether the corrective actions taken have addressed all violations contained in the Warning Letter and additional or future actions by or requests from the FDA. These statements may be identified by the use of forward-looking terminology such as “remains,” “believes,” “expects,” “anticipates,” “may,” “will,” “should,” “seeks,” “approximately,” “intends,” “plans,” “estimates,” or the negative of these words or other comparable terminology. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements. In addition, such risks and uncertainties may include, but are not limited to, those described in the Company’s annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the SEC. You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. The Company’s SEC reports are available at www.acelrx.com under the “Investors” tab. Except to the extent required by law, the Company undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 31, 2022

ACELRX PHARMACEUTICALS, INC.

By: /s/ Raffi Asadorian

Raffi Asadorian

Chief Financial Officer