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): February 11, 2021

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35068**	**41-2193603**
(State of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

351 Galveston Drive
Redwood City, CA 94063
(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

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 "Letter") relating to a banner advertisement the Company submitted to the OPDP on December 6, 2019 (the "Banner Ad"), and a tabletop display the Company submitted on February 28, 2020, and resubmitted to the OPDP at its request on September 23, 2020 (the "Tabletop Display," and together with the Banner Ad, the "Promotional Material"). The Company submitted the materials to the OPDP pursuant to the FDA requirement that sponsors submit all promotional materials to the FDA at the time of their initial dissemination or publication. The FDA's concerns identified in the Letter include its view that the Promotional Material makes misleading claims and representations about the risks and efficacy of DSUVIA® because the Promotional Material does not reveal facts that are material in light of the representations made. The Company believes it can easily address these concerns without a material impact to the Company given the nature of the Promotional Materials and because the Company has not used the Banner Ad since late 2019, nor used the table drape that is part of the Tabletop Display since November 2019; however, the Company plans to review its marketing materials to identify any potential revisions in light of the Letter. The Company intends to respond to the FDA within the timeframe requested in the Letter and seek guidance and clarification from the FDA on the concerns raised in the Letter. The Letter does not restrict the Company's ability to manufacture or sell DSUVIA. The Company cannot give any assurances, however, that the FDA will be satisfied with its response to the Letter or that such response will resolve the issues identified in the Letter.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to the Company's intent to respond to the Letter in the timeframe required by the FDA and the Company's belief that the concerns set forth in the Letter can be resolved without a material impact to the Company or its financial statements. These and any other forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," or the negative of these words or other comparable terminology. The discussion of strategy, plans or intentions may also include forward-looking statements. 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 Securities and Exchange Commission (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.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	**Description**
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 16, 2021

ACELRX PHARMACEUTICALS, INC.
By: /s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer