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): September 22, 2023

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.)

1850 Gateway Drive, Suite 175
San Mateo, CA 94404
(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 Information

As previously disclosed on April 27, 2023, AcelRx Pharmaceuticals, Inc. (the "Company") submitted a request to the U.S. Food and Drug Administration ("FDA") pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act ("FDCA") for Emergency Use Authorization ("EUA") for Niyad™ (lyophilized vial containing nafamostat for injection), for use as a regional anticoagulant in patients receiving Continuous Renal Replacement Therapy (“CRRT”) who cannot tolerate heparin or are at a higher risk of bleeding. On September 22, 2023, the FDA notified the Company that due to the volume of EUA requests the FDA has received, the FDA has determined that review of the Niyad EUA is not a priority and has therefore declined to issue an EUA for Niyad at this time pursuant to the FDA’s current prioritization of EUA requests. In the notice letter, the FDA encouraged the Company to continue to assess clinical development of the Niyad device. The Company plans to initiate a registrational study of Niyad later this year and anticipates submitting a Pre-Market Application (“PMA”) for Niyad to the FDA in 2024.

This Current Report on Form 8-K contains "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements related to the timing of its registrational study of Niyad and the Company’s belief that the results of the study should support a PMA submission to the FDA for Niyad and the timing of such submission. The words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. While the Company believes its plans, intentions and expectations reflected in those forward-looking statements are reasonable, these plans, intentions or expectations may not be achieved. The Company's actual results, performance or achievements could differ materially from those contemplated, expressed or implied by the forward-looking statements. For information about the factors that could cause such differences, please refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2022, including the information discussed under the captions "Item 1 Business," "Item 1A. Risk Factors" and "Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as the Company's various other filings with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The Company assumes no obligation to update any forward-looking statement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	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: September 22, 2023

ACELRX PHARMACEUTICALS, INC.

By: /s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer