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): May 10, 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.)

25821 Industrial Boulevard, 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 2.02 Results of Operations and Financial Condition

On May 10, 2023, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 2023 and providing a corporate update (the "Release"). A copy of the Release is furnished herewith as Exhibit 99.1.

The information contained in this Item 2.02 and in Exhibit 99.1 shall be deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02 and in Exhibit 99.1 shall not be incorporated by reference into any filing under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	**Description**
99.1	Press Release dated May 10, 2023
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: May 10, 2023

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

Exhibit 99.1

AcelRx Pharmaceuticals Reports First Quarter 2023 Financial Results and Provides Corporate Update

Request for Emergency Use Authorization of Niyad™ submitted to the FDA in April

Divestment of DSUVIA® to Alora Pharmaceuticals closed April 3, 2023

$13.4 million in cash as of March 31, 2023

Webcast and conference call to be held today at 4:30 p.m. EDT

HAYWARD, Calif., May 10, 2023 -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today reported its first quarter 2023 financial results and provided a corporate update.

“We have embarked on a new AcelRx chapter by closing the DSUVIA transaction and submitting the request for an Emergency Use Authorization for Niyad,” stated Vince Angotti, Chief Executive Officer of AcelRx. “We’re very excited about the prospects for Niyad following interactions with key opinion leaders during our latest advisory board meeting. Feedback from this meeting, combined with data from our recently completed 150-physician market research study highlight the urgent need for an alternative anticoagulant for in-hospital dialysis and support our submission of a request for an EUA. Our focus is now on initiating the FDA-informed single registrational study for Niyad, expected in the second half of this year. We have agreed upon terms for the supply of the active pharmaceutical ingredient and, through our contract manufacturer, have already made finished product that has met all stability specifications to date,” continued Angotti.

2023 First Quarter and Recent Corporate Highlights

- On April 27, 2023, AcelRx submitted a request for an EUA for Niyad and responded to previous questions outlined by the FDA in a prior EUA submission made by Lowell Therapeutics. AcelRx's submission included information on nafamostat mesylate, the API in Niyad, and the finished drug product, including stability testing data and a process validation protocol, amongst other items requested by the FDA.

- On April 3, 2023, AcelRx announced the closing of the divestment of its FDA-approved drug, DSUVIA to Alora Pharmaceuticals (Alora). The agreement allows AcelRx to participate in the long-term value expected to be created by Alora as they expand the commercialization of DSUVIA. The agreement provides AcelRx with a 15% royalty on commercial sales of DSUVIA, a 75% royalty on sales of DSUVIA to the Department of Defense (DoD), DSUVIA's single largest customer, and up to $116.5 million in sales-based milestones. AcelRx will provide, and be reimbursed for, transition services during a period of up to 6 months post-closing. In exchange for the 75% royalty on net sales to the DoD, AcelRx will lead the relationship to ensure continued engagement and expected expansion of sales to the DoD.

First Quarter 2023 Financial Information

- The cash and cash equivalents balance was $13.4 million as of March 31, 2023.

- Combined R&D and SG&A expenses for the first quarter of 2023 totaled $5.3 million compared to $4.9 million for the first quarter of 2022. Excluding non-cash stock-based compensation expense, these amounts were $4.8 million for the first quarter of 2023, compared to $4.3 million for the first quarter of 2022. The increase in combined R&D and SG&A expenses in the first quarter of 2023 was primarily due to legal costs related to the divestment of DSUVIA and Niyad-related research and development costs.

- The divestment of DSUVIA represents a discontinued operation; accordingly, all historical operating results for the business are reflected within discontinued operations. For the three months ended March 31, 2023, we recognized an impairment on net assets held for sale of $7.0 million and a loss from discontinued operations of $1.2 million. For the three months ended March 31, 2022, we recognized a loss from discontinued operations of $4.1 million.

- Net loss attributable to common shareholders for the first quarter of 2023 was $8.2 million, or $0.75 per basic and diluted share, compared to a net loss of $8.7 million, or $1.19 per basic and diluted share, for the first quarter of 2022.

Webcast Information and Conference Call Information
As previously announced, AcelRx management will host a live webcast and conference call at 4:30 p.m. Eastern Daylight Time/1:30 p.m. Pacific Daylight Time on May 10, 2023 to discuss the financial results and provide an update on the Company's business.

The webcast can be accessed here or by visiting the "Investors" section of the Company's website at www.acelrx.com and clicking on the webcast link within the News & Events/Upcoming Events section. The webcast will include a slide presentation and a replay will be available on the AcelRx website for 90 days following the event.

Investors who wish to participate in the conference call may do so by dialing 1-866-361-2335 for domestic callers, 1-855-669-9657 for Canadian callers, 1-412-902-4204 (toll applies) for international callers. The conference ID is 10177890.

About Nafamostat
Nafamostat is a broad spectrum, synthetic serine protease inhibitor with anticoagulant, anti-inflammatory and potential anti-viral activities. Niyad™ is a lyophilized formulation of nafamostat and is currently being studied under an investigational device exemption, or IDE, as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation Status from the FDA. A request for an Emergency Use Authorization has been submitted to the FDA for Niyad. LTX-608 is a proprietary nafamostat formulation for direct IV infusion that will be investigated and developed as a potential anti-viral for the treatment of COVID, acute respiratory distress syndrome (ARDS), disseminated intravascular coagulation (DIC) and acute pancreatitis.

About AcelRx Pharmaceuticals, Inc.
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. AcelRx's lead product candidate, Niyad is a lyophilized formulation of nafamostat and is currently being studied under an investigational device exemption, or IDE, as an anticoagulant for the extracorporeal circuit, and has received Breakthrough Device Designation Status from the FDA. AcelRx is also developing two pre-filled syringes in-licensed from its partner Aguettant: Fedsyra™, a pre-filled ephedrine syringe, with an expected NDA filing in the first half of 2023, and PFS-02, a pre-filled phenylephrine syringe with an expected NDA filing in 2024. This release is intended for investors only. For additional information about AcelRx, please visit www.acelrx.com.

Forward-looking statements
This press release contains forward-looking statements based upon AcelRx's current expectations. 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 "potential," "believe," "expect," "expects," "expected," "anticipate," "may," "will," "enable," "should," "seek," "approximately," "intends," "intended," "plans," "planned," "planning," "estimates," "benefits," or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans or intentions may also include forward-looking statements, which are predictions, projections and other statements about future events that are based on current expectations and assumptions. 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, including: (i) risks relating to AcelRx's product development activities and ongoing commercial business operations; (ii) risks related to the ability of AcelRx and its business partners to implement development plans, launch plans, forecasts and other business expectations; (iii) risks related to unexpected variations in market growth and demand for AcelRx's commercial and developmental products and technologies; (iv) risks related to AcelRx's liquidity and our ability to maintain capital resources sufficient to conduct the required clinical studies; (v) AcelRx's ability to retaining its listing on the Nasdaq exchange; and (vi) risks relating to AcelRx's ability to obtain regulatory approvals for our developmental product candidates. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described under the caption "Risk Factors" and elsewhere in AcelRx'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) and any subsequent public filings. 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. To the degree financial information is included in this press release, it is in summary form only and must be considered in the context of the full details provided in AcelRx's most recent annual, quarterly or current report as filed or furnished with the SEC. AcelRx's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, AcelRx undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect new information, events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

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Selected Financial Data
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31	
	2023	**2022**
Statement of Comprehensive Income (Loss) Data		
Operating costs and expenses:		
Research and development (1)	$ 1,047	$ 836
Selling, general and administrative (1)	4,281	4,100
Total operating costs and expenses	5,328	4,936
Loss from operations	(5,328)	(4,936)
Other income (expense):		
Interest expense	(119)	(390)
Interest income and other income (expense), net	5,511	38
Non-cash interest income on liability related to sale of future royalties	-	673
Total other income (expense)	5,392	321
Net income (loss) from continuing operations	$ 64	$ (4,615)
Net loss from discontinued operations	(8,216)	(4,059)
Net loss	$ (8,152)	$ (8,674)
Net income (loss) per share attributable to stockholders:		
Basic and diluted, continuing operations	$ -	$ (0.63)
Basic and diluted, discontinued operations	$ (0.75)	$ (0.56)
Basic and diluted loss per share	$ (0.75)	$ (1.19)
Shares used in computing net loss per common share, basic and diluted	10,894	7,281
(1) Includes the following non-cash stock-based compensation expense:		
Research and development	$ 93	$ 174
Selling, general and administrative	457	464
Discontinued operations	19	145
Total	$ 569	$ 783

Selected Balance Sheet Data
(in thousands)

	March 31, 2023	December 31, 2022[1]
	(Unaudited)	
Cash, cash equivalents, restricted cash and investments	$ 13,353	$ 20,770
Total assets	26,292	47,487
Total liabilities	12,050	25,673
Total stockholders' equity	14,242	21,814

[1] Derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Reconciliation of Non-GAAP Financial Measures
(Operating expenses less stock-based compensation expense)

	Three Months Ended March 31	
	2023	2022
Operating expenses (GAAP):		
Research and development	$ 1,047	$ 836
General and administrative	4,281	4,100
Total operating expenses	5,328	4,936
Less stock-based compensation expense	550	638
Operating expenses (non-GAAP)	$ 4,778	$ 4,298