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): August 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 August 10, 2023, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three months ended June 30, 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 August 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: August 10, 2023

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

Exhibit 99.1

AcelRx Reports Second Quarter 2023 Financial Results and Provides Corporate Update

Capital raise closed in July, led by new healthcare investors; provides access to up to $26.3 million in capital, with $10 million immediately available

AcelRx awaits response to Emergency Use Authorization (EUA) of Niyad™ submitted to the FDA in April; registrational study set to initiate in Q4 2023

Proforma $17.4 million in cash as of June 30, 2023, including gross proceeds from financing closed in July 2023

Senior debt with Oxford fully repaid in Q2 2023

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

SAN MATEO, Calif., August 10, 2023 /PRNewswire/ -- 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 second quarter 2023 financial results and provided a corporate update.

“We are pleased that the transformation of AcelRx through the divestment of DSUVIA in April and the pivot to our late-stage product portfolio has attracted a new group of healthcare investors to support achieving our key milestones,” said Vince Angotti, Chief Executive Officer of AcelRx. “We are on track to begin our registrational study for Niyad later this year with an expected data readout mid-2024. Niyad’s Breakthrough Designation has facilitated our interactions with the FDA, and we expect this continued support for our planned PMA submission in the second half of 2024. In addition, a potential earlier milestone for Niyad is the receipt of an Emergency Use Authorization, which was submitted to the FDA in April. We remain highly focused on achieving these milestones to advance the transformation of AcelRx and give us the opportunity to provide essential products for medically supervised settings,” continued Angotti.

2023 Second Quarter and Recent Corporate Highlights

- In July, AcelRx announced a private placement of common stock, pre-funded warrants and common warrants for aggregate gross proceeds to the Company of $10 million, before deducting the placement agent’s fees and other offering expenses payable by the Company, with an additional potential $16.3 million upon the exercise of common warrants, which include an acceleration feature should the company achieve certain performance milestones. This financing provides access to up to $26.3 million of gross proceeds upon the exercise of milestone-affected warrants. The private placement was priced "at-the-market" under the rules and regulations of The Nasdaq Stock Market LLC. The private placement was led by new investors including Nantahala Capital Management and closed on July 21, 2023.

- In April, 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.

- In April, 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.

- In the second quarter, AcelRx received six-month stability data from our initial development batch of Niyad, with all criteria being met, which should allow for two-years dating at room temperature.

Second Quarter 2023 Financial Information

- The cash and cash equivalents balance was $7.4 million as of June 30, 2023. The senior debt with Oxford was fully repaid in the second quarter.

- Revenues of $0.3 million for the second quarter primarily represents the royalty revenue earned on the sales of DSUVIA by Alora, principally driven by sales to the Department of Defense. Revenues in the prior period are included within the net loss from discontinued operations line item of the Statement of Operations.

- Combined R&D and SG&A expenses for the second quarter of 2023 totaled $4.2 million compared to $5.1 million for the second quarter of 2022. Excluding non-cash stock-based compensation expense, these amounts were $3.8 million for the second quarter of 2023, compared to $4.3 million for the second quarter of 2022. The decrease in combined R&D and SG&A expenses in the second quarter of 2023 was primarily due to a reduction in headcount partially offset by an increase in 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 June 30, 2023, the Company recognized net income from discontinued operations of $0.1 million. For the three months ended June 30, 2022, the Company recognized a net loss from discontinued operations of $3.7 million.

- Net loss attributable to common shareholders for the second quarter of 2023 was $4.4 million, or $0.40 per basic and diluted share, compared to a net income of $63.2 million, or $8.58 per basic and diluted share, for the second quarter of 2022.

Webcast Information

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 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.

Conference Call Information

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, or 1-412-902-4204 (toll applies) for international callers. The conference ID is 10181172.

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 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.

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. 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.

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 June 30		Six Months Ended June 30	
	2023	2022	2023	2022
Statement of Comprehensive Income (Loss) Data				
Royalty revenue	$ 253	$ -	$ 253	$ -
Operating costs and expenses:				
Research and development (1)	1,552	1,094	2,599	1,930
Selling, general and administrative (1)	2,670	3,960	6,951	8,060
Impairment of property and equipment	-	4,901	-	4,901
Total operating costs and expenses	4,222	9,955	9,550	14,891
Loss from operations	(3,969)	(9,955)	(9,297)	(14,891)
Other income (expense):				
Interest expense	(15)	(293)	(134)	(683)
Interest income and other income (expense), net	(441)	51	5,070	89
Non-cash interest income on liability related to sale of future royalties	-	463	-	1,136
Gain on extinguishment of liability related to sale of future royalties	-	84,052	-	84,052
Total other income (expense)	(456)	84,273	4,936	84,594
Net income (loss) before income taxes	(4,425)	74,318	(4,361)	69,703
Provision for income taxes	(3)	(3)	(3)	(3)
Net income (loss) from continuing operations	(4,428)	74,315	(4,364)	69,700
Net income (loss) from discontinued operations	57	(3,652)	(8,159)	(7,711)
Net income (loss)	(4,371)	70,663	(12,523)	61,989
Income allocated to participating securities	-	(7,511)	-	(6,619)
Net income (loss) attributable to Common Shareholders, basic	$ (4,371)	$ 63,152	$ (12,523)	$ 55,370
Net income (loss) attributable to Common Shareholders, diluted	$ (4,371)	$ 63,155	$ (12,523)	$ 55,371
Net income (loss) per share attributable to stockholders:				
Basic earnings (loss) per share				
Income (loss) from continuing operations	$ (0.41)	$ 9.08	$ (0.40)	$ 8.62
Income (loss) from discontinued operations	$ 0.01	$ (0.50)	$ (0.75)	$ (1.06)
Net income (loss)	$ (0.40)	$ 8.58	$ (1.15)	$ 7.56
Diluted earnings (loss) per share				
Income (loss) from continuing operations	$ (0.41)	$ 9.08	$ (0.40)	$ 8.62
Income (loss) from discontinued operations	$ 0.01	$ (0.50)	$ (0.75)	$ (1.06)
Net income (loss)	$ (0.40)	$ 8.58	$ (1.15)	$ 7.56
Shares used in computing net income (loss) per share of common stock, basic	10,924	7,357	10,909	7,319
Shares used in computing net income (loss) per share of common stock, diluted	10,924	7,360	10,909	7,321
(1) Includes the following non-cash stock-based compensation expense:				
Research and development	$ 80	$ 153	$ 173	$ 327
Selling, general and administrative	391	562	848	1,026
Discontinued operations	-	38	19	183
Total	$ 471	$ 753	$ 1,040	$ 1,536

Selected Balance Sheet Data
(in thousands)

	June 30, 2023 (Unaudited)	December 31, 2022[1]
Cash, cash equivalents, restricted cash and investments	$ 7,410	$ 20,770
Total assets	17,725	47,487
Total liabilities	7,306	25,673
Total stockholders' equity	10,419	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 June 30		Six Months Ended June 30	
	2023	2022	2023	2022
Operating expenses (GAAP):				
Research and development	$ 1,552	$ 1,094	$ 2,599	$ 1,930
General and administrative	2,670	3,960	6,951	8,060
Total operating expenses	4,222	5,054	9,550	9,990
Less stock-based compensation expense	471	715	1,021	1,353
Operating expenses (non-GAAP)	$ 3,751	$ 4,339	$ 8,529	$ 8,637