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 30, 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 March 30, 2023, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three and twelve months ended December 31, 2022 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 4.02. Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

In connection with the Company's year-end financial statement close and preparation of its Annual Report on Form 10-K for the year ended December 31, 2022, an error in the earnings per share calculations was identified in the interim financial statements (the "Prior Period Financial Statements") for the three and six months ended June 30, 2022 and nine months ended September 30, 2022 (the "Interim Periods"). The error in the earnings per share calculation was due to the Company not properly applying the two-class method of calculating earnings per share with respect to, or disclose that, the warrants issued in November 2021 are participating securities. The financial statements for the year ended December 31, 2021 and the three months ended March 31, 2022, did not require the application of the two-class method of calculating earnings per share, and therefore were not impacted by the issuance of the warrants in November 2021.

The error has no impact on the Company's cash balance, liquidity, revenues, operating expenses, or total net income. Further, there is no impact to the Company's balance sheet accounts or cash flows.

On March 30, 2023, the Company's management and the Audit Committee of the Company determined that the Company's Prior Period Financial Statements for the Interim Periods, should no longer be relied upon because of the error in the earnings per share calculations. The Company's management and the Audit Committee concluded that it is appropriate to restate the Prior Period Financial Statements for the Interim Periods noted above. The correction of this error will be reflected in the Company's financial statements to be filed on Form 10-K for the year ended December 31, 2022.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	**Description**
99.1	Press Release dated March 30, 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: March 30, 2023

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

Exhibit 99.1

AcelRx Pharmaceuticals Reports Full Year and Fourth Quarter 2022 Financial Results and Provides Corporate Update

Divestment of DSUVIA® to Alora Pharmaceuticals expected to close the week of April 3, 2023

AcelRx advancing its proprietary Niyad™ nafamastat program with FDA Breakthrough designation in line with a strategic focus on late-stage assets

Near-term corporate milestones expected by the end of Q2 2023 include Niyad Emergency Use Authorization submission and the filing of a New Drug Application for Fedsyra™, the first of two pre-filled syringe product candidates

$20.8 million in cash and short-term investments as of December 31, 2022

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

HAYWARD, Calif., March 30, 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 full year and fourth quarter 2022 financial results and provided a corporate update.

“We are pleased to have signed an agreement to divest DSUVIA to Alora Pharmaceuticals, a well-resourced commercial partner, to expand the reach of this innovative product,” stated Vince Angotti, Chief Executive Officer of AcelRx. “Alora has extensive experience commercializing products in hospitals, expertise in the manufacturing and sales of controlled substances and a team of over 200 salespersons. In addition, we believe the opportunity to receive a 75% royalty on net sales to the Department of Defense, the single largest customer of DSUVIA, will drive long-term value for our shareholders. With this transaction, we have continued to reduce costs while leveraging our clinical development and regulatory expertise to achieve the near-term milestones related to our late-stage development pipeline.”

Mr. Angotti continued, “We believe that the accelerated stability testing of Niyad, our lead nafamostat product candidate, has produced data to support a planned Emergency Use Authorization submission in the second quarter and to support initiation of the single registrational trial in the second half of 2023. Our recent market research continues to confirm the urgent medical need for an alternative anticoagulant for use in continuous renal replacement therapy, or CRRT. From this data, we believe the opportunity for Niyad is approximately 60% of the CRRT market. In addition, we are prepared to submit an NDA for Fedsyra, our ephedrine pre-filled syringe (PFS) product candidate, by the end of next quarter. Both the Niyad and Fedsyra regulatory submissions will bring us closer to delivering important advancements for the healthcare system and increased value for our shareholders.”

2022 Fourth Quarter and Recent Corporate Highlights

- In March 2023, AcelRx announced 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, DSUVIA’s single largest customer, and up to $116.5 million in sales-based milestones. Closing of the transaction is expected the week of April 3rd, and 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. Importantly, the divestment enables AcelRx to focus its operations and capital on its late stage, high-value asset programs, with specific prioritization of its lead nafamostat program, Niyad, as an anticoagulant for the extracorporeal circuit with peak sales potential of $200 million.

- Accelerated stability testing of Niyad at elevated temperatures has produced data for our near-term EUA submission and initiation of the single registrational clinical trial expected to start in the second half of 2023.

- In December 2022, AcelRx sponsored a quantitative market research study of current CRRT practices among 150 U.S. physicians which demonstrated an urgent need for alternative anticoagulants other than citrate and heparin. Due to side effects of citrate and heparin, 29% of patients receive no anticoagulant during CRRT, which is below the international standard of care. When no anticoagulant is used, over 80% of the physicians reported blood clotting the dialysis filter, which can lead to the patient requiring transfusions and increased filter changes. Despite physicians reporting significant side effects with the use of citrate, it is used in 28% of CRRT patients. The Company believes the market opportunity for Niyad includes patients that are receiving no anticoagulant as well as those that are receiving citrate, totaling 57% of CRRT patients. The Company plans to submit the study data for publication in the second quarter of 2023.

- In December 2022, AcelRx entered into an agreement with a life sciences-focused investment fund for the sale of shares of its common stock, pre-funded warrants and common warrants. Gross proceeds from the offering were approximately $7.5 million.

- In October, the Company announced the European Launch of DZUVEO by its partner, Aguettant across key European countries, with commercialization in Spain, Portugal and Italy commencing in the first half of 2023.

Recent Publications

- In March 2023, AcelRx announced the publication of a report arising from a series of rhinology procedures successfully performed using sufentanil sublingual tablet 30 mcg (SST; DSUVIA) in *Otolaryngology Case Reports*. The study was lead-authored by otolaryngologist Dr. Ashley Sikand and entitled "Evaluation of Sufentanil Sublingual Tablet 30 mcg for Perioperative Pain Management of In-Office Rhinology Procedures." The study demonstrated that DSUVIA can help manage acute pain during rhinology surgery in an office-based setting with a well-tolerated side-effect profile.

- In December, AcelRx announced a study published in the *Journal of Clinical Medicine* Special Issue "Advances in Postoperative Pain Management and Postoperative Chronic Pain". The study was lead-authored by orthopedic surgeon Dr. Andrea Angelini and entitled "Sublingual Sufentanil Tablet System for Postoperative Analgesia After Orthopedic Surgery: A Retrospective Study". The study was conducted by investigators at the University of Padova in Italy and retrospectively analyzed a total of 71 patients with respect to quality of postoperative pain management following total knee arthroplasty (TKA). Investigators analyzed data from 50 patients who received sufentanil sublingual tablets (SSTs) postoperatively versus a control group of 21 patients who were treated according to standard pain management protocol with continuous femoral nerve block. Adverse events were noted as being consistently lower in the group administered SSTs, and this was most notably observed to be the case with nausea (10% versus 30%), typically the most frequently reported adverse event with postoperative opioid administration.

- In October, an abstract, entitled, "Experience in Complex Outpatient Plastic Surgery Procedures Using Sufentanil Sublingual Tablets" was presented by Jeffrey DeWeese, M.D., FACS, at *Plastic Surgery The Meeting 2022*, held October 27-30, in Boston, MA. The study, conducted in 324 patients undergoing complex plastic surgery procedures, demonstrated the ability to perform such procedures using DSUVIA without general anesthesia, allowing for a rapid discharge time.

- Also in October, the Company announced two abstracts were presented at the *ANESTHESIOLOGY® Annual Meeting 2022*. The first presentation was of an investigator-initiated trial demonstrating the advantages of sufentanil sublingual tablet versus intravenous opioids for managing postoperative spine surgery pain and the second was a presentation by the Uniformed Services University of the Health Sciences on DSUVIA for battlefield pain management.

Fourth Quarter 2022 Financial Information

- The cash, cash equivalents and short-term investments balance was $20.8 million as of December 31, 2022.

- Fourth quarter 2022 DSUVIA net sales were $0.3 million. Full year DSUVIA net sales for 2022 were $1.8 million, representing a 76% increase over the same period in 2021.

- Combined R&D and SG&A expenses for the fourth quarter of 2022 totaled $7.3 million compared to $6.9 million for the fourth quarter of 2021. Excluding non-cash depreciation and stock-based compensation expense, these amounts were $6.6 million for the fourth quarter of 2022, compared to $5.6 million for the fourth quarter of 2021. The increase in combined R&D and SG&A expenses in the fourth quarter of 2022 was primarily due to allocated financing transaction related costs attributed to the accounting for the warrant issued in the December 2022 financing, partially offset by other net decreases in R&D and SG&A expenses compared to the fourth quarter of 2021.

- Net loss attributable to common shareholders for the fourth quarter of 2022 was $7.5 million, or $1.00 per basic and diluted share, compared to a net loss of $7.9 million, or $1.24 per basic and diluted share, for the fourth quarter of 2021.

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 March 30, 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 10175958.

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.

About Alora Pharmaceuticals, LLC
Alora Pharmaceuticals, LLC is the parent company of six specialty pharmaceutical and pharmaceutical manufacturing companies. Alora is headquartered in Alpharetta, GA. Alora is the parent company of the following organizations that comprise the Alora family of companies, Avion Pharmaceuticals, Acella Pharmaceuticals, Osmotica Pharmaceuticals, Sovereign Pharmaceuticals, Trigen Laboratories and Vertical Pharmaceuticals.

About DSUVIA (sufentanil sublingual tablet), 30 mcg
DSUVIA®, branded as DZUVEO® in Europe, is indicated for use in adults in certified medically supervised healthcare settings, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. DSUVIA/DZUVEO was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with intravenous (IV) administration. DSUVIA/DZUVEO is a single-strength solid dosage form administered sublingually via a single-dose applicator (SDA) by healthcare professionals. Sufentanil is an opioid analgesic previously only marketed for IV and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile, when delivered sublingually, avoids the high peak plasma levels and short duration of action observed with IV administration. DZUVEO has been approved by the European Medicines Agency and AcelRx's European commercialization partner, Aguettant, markets the drug in Europe.

For more information, including important safety information and black box warning for DSUVIA, please visit www.DSUVIA.com.

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 proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. The Company has one approved product in the U.S., DSUVIA® (sufentanil sublingual tablet, 30 mcg), known as DZUVEO® in Europe, indicated for the management of acute pain severe enough to require an opioid analgesic for adult patients in certified medically supervised healthcare settings, and several product candidates. The product candidates include: Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S. being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings; two pre-filled, ready-to-use syringes of ephedrine and phenylephrine licensed for the U.S. from Aguettant. AcelRx's lead nafamostat program is Niyad™, a regional anticoagulant for the extracorporeal circuit, and it is also developing LTX-608, for the potential treatment of COVID-19, disseminated intravascular coagulation, acute respiratory distress syndrome and acute pancreatitis. AcelRx plans to submit an Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for Niyad, which has Breakthrough device designation status, during the second quarter of 2023. AcelRx also is developing two pre-filled, ready-to-use syringes (PFS-01 and PFS-02) of ephedrine and phenylephrine, respectively, licensed for the U.S. from Aguettant. AcelRx plans to file an NDA on PFS-01 also by the end of the second quarter of 2023. 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; (v) AcelRx's ability to retaining its listing on the Nasdaq exchange; and (vi) risks relating to our 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 December 31		Twelve Months Ended December 31	
	2022	2021	2022	2021
Statement of Comprehensive Income (Loss) Data				
Revenue:				
Product sales	$ 252	$ 2	$ 1,771	$ 1,005
Contract and other collaboration	-	-	-	1,813
Total revenue	252	2	1,771	2,818
Operating costs and expenses:				
Cost of goods sold (1)	362	1,234	2,591	3,753
Research and development (1)	1,026	986	5,193	4,095
Selling, general and administrative (1)	6,250	5,957	25,672	30,935
Impairment of property and equipment	47	-	4,948	-
Total operating costs and expenses	7,685	8,177	38,404	38,783
Loss from operations	(7,433)	(8,175)	(36,633)	(35,965)
Other income (expense):				
Interest expense	(189)	(467)	(1,153)	(2,291)
Interest income and other income (expense), net	137	32	366	124
Non-cash interest income on liability related to sale of future royalties	-	693	1,136	3,038
Gain on termination of liability related to sale of future royalties	-	-	84,052	-
Total other income (expense)	(52)	258	84,401	871
Provision (benefit) for income taxes	(1)	-	13	5
Net income (loss)	$ (7,484)	$ (7,917)	$ 47,755	$ (35,099)
Deemed dividend related to Series A Redeemable Convertible Preferred Stock	-	-	(186)	-
Income allocated to participating securities	-	-	(5,240)	-
Net income (loss) attributable to Common Shareholders, basic	$ (7,484)	$ (7,917)	$ 42,329	$ (35,099)
Basic net income (loss) per common share	$ (1.00)	$ (1.24)	$ 5.73	$ (5.86)
Shares used in computing basic net income (loss) per common share	7,466	6,384	7,385	5,993
Net income (loss) attributable to Common Shareholders, diluted	$ (7,484)	$ (7,917)	$ 42,342	$ (35,099)
Diluted net income (loss) per common share	$ (1.00)	$ (1.24)	$ 5.72	$ (5.86)
Shares used in computing diluted net income (loss) per common share	7,466	6,384	7,407	5,993
(1) Includes the following non-cash depreciation and stock-based compensation expense:				
Cost of goods sold	$ 50	$ 73	$ 239	$ 294
Research and development	190	302	915	1,072
Selling, general and administrative	535	1,018	2,547	4,305
Total	$ 775	$ 1,393	$ 3,701	$ 5,671

	December 31, 2022	December 31, 2021
Selected Balance Sheet Data		
Cash, cash equivalents, restricted cash and investments	$ 20,770	$ 51,630
Total assets	47,487	77,893
Total liabilities	25,673	113,786
Total stockholders' equity (deficit)	21,814	(35,893)

Reconciliation of Non-GAAP Financial Measures
(Operating Expenses less associated depreciation and stock-based compensation expense)

	Three Months Ended December 31, 2022		Twelve Months Ended December 31, 2022	
	2022	**2021**	**2022**	**2021**
Operating expenses (GAAP):				
Research and development	$ 1,026	$ 986	$ 5,193	$ 4,095
Selling, general and administrative	6,250	5,957	25,672	30,935
Impairment of property and equipment	47	-	4,948	-
Total operating expenses	7,323	6,943	35,813	35,030
Less impairment of property and equipment, depreciation and stock-based compensation expense	772	1,320	8,410	5,377
Operating expenses (non-GAAP)	$ 6,551	$ 5,623	$ 27,403	$ 29,653