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): November 14, 2022

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 November 14, 2022, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended September 30, 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 9.01 Financial Statements and Exhibits

Exhibit No.	**Description**
99.1	Press Release dated November 14, 2022
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: November 14, 2022

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

AcelRx Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Corporate Update

Initial Niyad development batch successfully produced; preparations on track for an Emergency Use Authorization submission

DSUVIA sales of $0.5M in the third quarter, a 217% increase over prior year

$20.9 million in cash and short-term investments as of September 30, 2022

Webcast and Conference Call to be held today at 4:30 p.m. EDT

HAYWARD, Calif., November 14, 2022 – 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 third quarter 2022 financial results.

“We have continued to reduce costs and advance the portfolio as planned. We have progressed our lead nafamostat product candidate, Niyad™ to prepare for a potential Emergency Use Authorization in the first half of 2023 and initiated early commercial planning to ensure we’re prepared for a potential launch next year,” stated Vince Angotti, Chief Executive Officer of AcelRx. “Additionally, we expect to submit our ephedrine pre-filled syringe NDA by the end of this year, with the second pre-filled syringe product submission planned for the first half of next year to ensure we have multiple potential commercial products available by the end of 2023.”

Mr. Angotti continued, “Related to DSUVIA®, our commercial focus in the third quarter remained on procedural suites, demonstrating continued year-over-year growth despite the significant reduction in the size of our commercial organization. We expect to finalize an agreement for DSUVIA by the end of the year with a strategic partner that can more fully maximize the DSUVIA opportunity with additional resources. Our European partner, Aguettant, recently launched DZUVEO® in Europe, further extending the commercial footprint of our novel sufentanil sublingual tablet.”

Third Quarter and Recent Highlights

- The initial development batch of Niyad was successfully produced earlier this month in preparation for the potential Emergency Use Authorization in the first half of 2023.

- 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 expected to begin in the first half of 2023.

- In October, the Company announced the podium presentation of a study of DSUVIA in a large cohort of patients undergoing plastic surgery procedures entitled, "Experience in Complex Outpatient Plastic Surgery Procedures Using Sufentanil Sublingual Tablets". The study, conducted in 324 plastic surgery cases, was presented on October 28th by Jeffrey DeWeese, M.D., FACS, at *Plastic Surgery The Meeting 2022*, held October 27-30, in Boston, MA. The study found many positive benefits of using DSUVIA, including the ability to perform complex, extensive cosmetic procedures without general anesthesia, allowing for a rapid discharge time.

- In October, the Company announced two abstracts 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 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.

Financial Information

- The cash, cash equivalents and short-term investments balance was $20.9 million as of September 30, 2022.

- Third quarter 2022 DSUVIA net sales were $0.5 million, a 217% increase over 2021; year-to-date September 30, 2022 DSUVIA net sales were $1.5 million, representing a 51% increase over the same period in 2021. Total DSUVIA units sold in the third quarter of 2022 were 1,032 compared to 371 units in 2021. Total net revenues in the third quarter 2022 of $0.5 million declined $1.4 million compared to the same period in 2021 due to the recognition of $1.7 million in revenues in the third quarter of 2021 attributed to an upfront payment received related to our DZUVEO European licensing agreement.

- Combined R&D and SG&A expenses for the third quarter of 2022 totaled $6.6 million compared to $10.1 million for the third quarter of 2021. Excluding non-cash depreciation and stock-based compensation expense, these amounts were $5.7 million for the third quarter of 2022, compared to $8.6 million for the third quarter of 2021. The decrease in combined R&D and SG&A expenses in the third quarter of 2022 was primarily due to overall cost reductions principally focused on DSUVIA-related commercial expenses.

- Net loss attributable to common shareholders for the third quarter of 2022 was $6.9 million, or $0.94 per basic and diluted share, compared to a net loss of $8.4 million, or $1.40 per basic and diluted share, for the third quarter of 2021.

Webcast 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 November 14, 2022 to discuss the financial results and provide an update on the Company's business. The webcast can be accessed 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, or 1-412-902-4204 for international callers. The conference ID is 10172773.

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 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 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; Niyad™, a regional anticoagulant for the extracorporeal circuit; and LTX-608, for the potential treatment of COVID-19, disseminated intravascular coagulation, acute respiratory distress syndrome and acute pancreatitis. DZUVEO is an approved product in Europe.

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 September 30		Nine Months Ended September 30	
	2022	2021	2022	2021
Statement of Comprehensive Income (Loss) Data				
Revenue:				
Product sales	$ 507	$ 160	$ 1,519	$ 1,003
Contract and other collaboration	-	1,702	-	1,813
Total revenue	507	1,862	1,519	2,816
Operating costs and expenses:				
Cost of goods sold (1)	569	439	2,229	2,519
Research and development (1)	1,308	1,416	4,167	3,109
Selling, general and administrative (1)	5,262	8,640	19,422	24,978
Impairment of property and equipment	-	-	4,901	-
Total operating costs and expenses	7,139	10,495	30,719	30,606
Loss from operations	(6,632)	(8,633)	(29,200)	(27,790)
Other income (expense):				
Interest expense	(247)	(538)	(964)	(1,824)
Interest income and other income (expense), net	140	32	229	92
Non-cash interest income on liability related to sale of future royalties	-	764	1,136	2,345
Gain on termination of liability related to sale of future royalties	-	-	84,052	-
Total other income (expense)	(107)	258	84,453	613
Provision for income taxes	(11)	-	(14)	(5)
Net income (loss)	$ (6,750)	$ (8,375)	$ 55,239	$ (27,182)
Deemed dividend related to Series A Redeemable Convertible Preferred Stock	(186)	-	(186)	-
Income allocated to participating securities	-	-	(129)	-
Net income (loss) attributable to Common Shareholders	$ (6,936)	$ (8,375)	$ 54,924	$ (27,182)
Basic net income (loss) per common share	$ (0.94)	$ (1.40)	$ 7.48	$ (4.64)
Shares used in computing basic net income (loss) per common share	7,377	5,961	7,339	5,861
Diluted net income (loss) per common share	$ (0.94)	$ (1.40)	$ 7.46	$ (4.64)
Shares used in computing diluted net income (loss) per common share	7,377	5,961	7,367	5,861
(1) Includes the following non-cash depreciation and stock-based compensation expense:				
Cost of goods sold	$ 58	$ 73	$ 189	$ 221
Research and development	225	389	725	770
Selling, general and administrative	629	1,048	2,013	3,287
Total	$ 912	$ 1,510	$ 2,927	$ 4,278

	September 30, 2022	December 31, 2021
Selected Balance Sheet Data		
Cash, cash equivalents, restricted cash and investments	$ 20,926	$ 51,630
Total assets	48,310	77,893
Total liabilities	20,769	113,786
Total stockholders' equity (deficit)	27,226	(35,893)

Reconciliation of Non-GAAP Financial Measures
(Operating Expenses less impairment of property and equipment, depreciation and stock-based compensation expense)

	Three Months Ended September 30		Six Months Ended September 30	
	2022	**2021**	**2022**	**2021**
Operating expenses (GAAP):				
Research and development	$ 1,308	$ 1,416	$ 4,167	$ 3,109
Selling, general and administrative	5,262	8,640	19,422	24,978
Impairment of property and equipment	-	-	4,901	-
Total operating expenses	6,570	10,056	28,490	28,087
Less impairment of property and equipment, depreciation and stock-based compensation expense	854	1,437	7,639	4,057
Operating expenses (non-GAAP)	$ 5,716	$ 8,619	$ 20,851	$ 24,030