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 11, 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 August 11, 2022, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three and six months ended June 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 August 11, 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: August 11, 2022

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

Exhibit 99.1

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

Advanced Niyad™ supply chain development with a focus on obtaining an Emergency Use Authorization in 2023

$0.6 million net revenue in Q2 2022; fifth consecutive quarter of commercial (ex-DoD) sales volume growth for DSUVIA, with a 133% increase compared to Q2 2021; on track for EU launch of DZUVEO in the third quarter

Projected annual savings of $9 million beginning in June 2022 from realigned cost structure

$27.9 million in cash and short-term investments as of June 30, 2022

$84.1 million gain on extinguishment of debt due to termination of royalty monetization

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

HAYWARD, Calif., August 11, 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 second quarter 2022 financial results.

“Our commercial emphasis on procedural suites has resulted in a successful quarter of growth for DSUVIA, while also reducing our costs, allowing us to focus on our robust pipeline,” stated Vince Angotti, Chief Executive Officer of AcelRx. “DSUVIA continues to demonstrate solid sales growth in the procedural suite setting, with adoption beginning across national accounts. Our European partner, Aguettant, also is gearing up for the launch of DZUVEO. This said, we remain mindful of our operating costs and plan to continue reducing our cash burn. Importantly, we remain in discussions with potential partners with the commercial resources to amplify the expected growth for DSUVIA.”

Mr. Angotti continued, “We’re focused on a potential Emergency Use Authorization for our lead nafamostat candidate, Niyad™, in 2023 as we are making solid progress across the supply chain. Additionally, our pre-filled syringes remain on track for NDA submissions this year. We believe each of these product candidates will provide multiple value-creating catalysts in the near-term.”

Second Quarter and Recent Highlights

- In August, AcelRx announced:
    - An abstract, entitled, “Experience in Complex Outpatient Plastic Surgery Procedures Using Sufentanil Sublingual Tablets” was accepted for podium presentation at *Plastic Surgery: The Meeting* 2022, October 27-30 in Boston, MA.
    - An abstract, entitled, “The Impact of Sublingual Sufentanil on Postoperative Pain Control in Patients Undergoing Spine Surgery” (abstract # A4262) was accepted for e-Abstract presentation at the ANESTHESIOLOGY® 2022 annual meeting, being held October 21-25 in New Orleans, LA.
- In June 2022, AcelRx realigned its cost structure to reduce headcount by approximately 40%, generating expected annual savings of $9 million.
- In May 2022, AcelRx announced:
    - The publication of clinical data from an investigator-initiated trial in patients undergoing lengthy plastic surgery procedures performed under general anesthesia, where use of a single sufentanil sublingual tablet 30 mcg (SST; DSUVIA®) in conjunction with intravenous (IV) opioids was able to dramatically reduce postoperative opioid requirements compared to an equivalent dose of opioids administered only via the IV route.
    - The U.S. Food and Drug Administration (FDA) revised the DSUVIA Risk Evaluation and Mitigation Strategies (REMS) program to eliminate the 6-month healthcare setting audit requirement and reduce annual healthcare setting audits to a total of up to 400 sites that have received a shipment of DSUVIA in the past 6 months.
- In May 2022, a key opinion leader webinar highlighting the market for and benefits of Niyad and LTX-608 with two internationally renowned acute kidney injury experts, Stuart Goldstein, MD, from Cincinnati Children’s Hospital, and Lakhmir Chawla, MD, former Chief of the Division of Intensive Care Medicine at the Washington D.C. Veterans Affairs Medical Center. To listen to a replay of the event, click here or visit the Investors/News & Events section of the company website.
- Advanced progress on Niyad supply chain with contract manufacturing agreements in place with a focus on obtaining an Emergency Use Authorization next year.
- As of July 31, 2022, AcelRx has achieved 983 DSUVIA formulary approvals.

Financial Information

- The cash, cash equivalents and short-term investments balance was $27.9 million as of June 30, 2022.
- Second quarter 2022 net revenues were $0.6 million. Commercial unit sales growth, excluding fluctuating DoD revenues, increased 18% in the second quarter of 2022 from the first quarter of 2022 and 133% compared to the second quarter of 2021. Total DSUVIA units sold in the second quarter of 2022, including the fluctuating DoD volumes, were 10,600 compared to 10,530 units In the first quarter of 2022.

- Combined R&D and SG&A expenses for the second quarter of 2022 totaled $8.4 million compared to $9.4 million for the second quarter of 2021. Excluding non-cash depreciation and stock-based compensation expense, these amounts were $7.5 million for the second quarter of 2022, compared to $8.0 million for the second quarter of 2021. The decrease in combined R&D and SG&A expenses in the second quarter of 2022 was primarily due to reductions in facilities and DSUVIA related selling expenses and stock-based compensation expense.

- In the quarter ended June 30, 2022, the company entered into a Termination Agreement with SWK Funding, LLC to terminate the royalty monetization related to Zalviso in Europe which resulted in an $84.1 million gain recognized on extinguishment of the liability.

- Net income for the second quarter of 2021 was $70.7 million, or $0.48 per basic and diluted share, compared to a net loss of $9.9 million, or $0.08 per basic and diluted share, for the second quarter of 2021.

Webcast and Conference Call Information
As previously announced, AcelRx will host a live conference call and webcast Thursday, August 11th at 4:30 p.m. Eastern Daylight Time (1:30 p.m. Pacific Time) to discuss these financial results and provide other corporate updates.

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 10168540. The webcast will be accessible by visiting the Investors page of AcelRx's website at www.acelrx.com and clicking on the webcast link. The webcast will be accompanied by a slide presentation. A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investor page of AcelRx's website at www.acelrx.com.

About DSUVIA (sufentanil sublingual tablet), 30 mcg
DSUVIA®, known 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 was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with intravenous (IV) administration. DSUVIA 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, will market the drug in Europe.

This release is intended for investors only. 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-inflamatory 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, including, but not limited to, statements related to maintaining commercial sales performance of DSUVIA, our plans to focus DSUVIA commercialization efforts on select markets and certain potential national accounts, DSUVIA partnering discussions with potential commercial entities, the potential European launch of DZUVEO by Aguettant, our plans to pursue a potential Emergency Use Authorization for Niyad and establish a supply chain to support such efforts, our plans to reduce cash burn and potentially reduce operating costs, our plans to potentially file NDAs for our developmental pre-filled syringe products and the timing of such filings, expected effect and scope of cost savings arising from our restructuring efforts, and potential near-term value-creating catalysts arising under our development pipeline. 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 "believe," "expect," "expected," "anticipate," "may," "potential," "will," "should," "seek," "approximately," "intends," "plans," "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) the risk that the restructuring of the Company could adversely affect our ability to successfully market DSUVIA in existing and in new and untested markets; (ii) risks relating to our ability to obtain regulatory approvals for the pre-filled syringe product candidates in-licensed from Aguettant; (iii) risks relating to our ability to successfully commercialize the pre-filled syringe product candidates in-licensed from Aguettant should we obtain such regulatory approvals; (iv) risks relating to our ability to obtain regulatory approvals for the nafamostat product candidates acquired from Lowell; (v) risks relating to our ability to obtain an Emergency Use Authorization for Niyad; (vi) risks relating to our ability to successfully commercialize the nafamostat product candidates acquired from Lowell should we obtain regulatory approvals and/or authorizations; (vii) risks relating to AcelRx's product development activities diverting AcelRx management's attention from ongoing commercial business operations; (viii) risks related to the ability of AcelRx to implement its development plans, forecasts and other business expectations; and (ix) risks related to unexpected variations in market growth and demand for AcelRx's commercial and developmental products and technologies. 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	
	2022	2021	2022	2021
Statement of Comprehensive Loss Data				
Revenue:				
Product sales	$ 570	$ 392	$ 1,012	$ 843
Contract and other collaboration	-	51	-	111
Total revenue	570	443	1,012	954
Operating costs and expenses:				
Cost of goods sold (1)	876	1,040	1,660	2,080
Research and development (1)	1,544	724	2,859	1,693
Selling, general and administrative (1)	6,822	8,694	14,160	16,338
Impairment of property and equipment	4,901	-	4,901	-
Total operating costs and expenses	14,143	10,458	23,580	20,111
Loss from operations	(13,573)	(10,015)	(22,568)	(19,157)
Other income (expense):				
Interest expense	(327)	(614)	(717)	(1,286)
Interest income and other income (expense), net	51	(16)	89	60
Non-cash interest income on liability related to sale of future royalties	463	799	1,136	1,581
Gain on termination of liability related to sale of future royalties	84,052	-	84,052	-
Total other income (expense)	84,239	169	84,560	355
Provision for income taxes	(3)	(5)	(3)	(5)
Net income (loss)	$ 70,663	$ (9,851)	$ 61,989	$ (18,807)
Basic net income (loss) per common share	$ 0.48	$ (0.08)	$ 0.42	$ (0.16)
Shares used in computing basic net income (loss) per common share	147,139	119,120	146,386	116,204
Diluted net income (loss) per common share	$ 0.48	$ (0.08)	$ 0.42	$ (0.16)
Shares used in computing diluted net income (loss) per common share	147,209	119,120	146,420	116,204
(1) Includes the following non-cash depreciation and stock-based compensation expense:				
Cost of goods sold	$ 64	$ 70	$ 131	$ 148
Research and development	239	200	500	381
Selling, general and administrative	663	1,191	1,384	2,239
Total	$ 966	$ 1,461	$ 2,015	$ 2,768

	June 30, 2022	December 31, 2021
Selected Balance Sheet Data		
Cash, cash equivalents, restricted cash and investments	$ 27,923	$ 51,630
Total assets	56,133	77,893
Total liabilities	22,990	113,786
Total stockholders' equity (deficit)	33,143	(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 June 30		Six Months Ended June 30	
	2022	**2021**	**2022**	**2021**
Operating expenses (GAAP):				
Research and development	$ 1,544	$ 724	$ 2,859	$ 1,693
Selling, general and administrative	6,822	8,694	14,160	16,338
Impairment of property and equipment	4,901	-	4,901	-
Total operating expenses	13,267	9,418	21,920	18,031
Less impairment of property and equipment, depreciation and stock-based compensation expense	5,803	1,391	6,785	2,620
Operating expenses (non-GAAP)	$ 7,464	$ 8,027	$ 15,135	$ 15,411