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 16, 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 May 16, 2022, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 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 9.01 Financial Statements and Exhibits

Exhibit No.	**Description**
99.1	Press Release dated May 16, 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: May 16, 2022

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

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

Realigning cost structure from a focus on commercialization to a focus on development to advance late-stage pipeline; expected to result in annual savings of $9 million

Completed acquisition of Lowell Therapeutics and nafamostat franchise, including Niyad™ with Breakthrough Device Designation

Continued DSUVIA sales momentum with fourth consecutive quarter of sales volume growth, including 64% commercial (ex-DoD) growth in Q1 2022 compared to Q4 2021

$39.3 million of cash and short-term investments at March 31, 2022

Webcast and Conference Call to be held today at 8:30 am EDT

HAYWARD, Calif., May 16, 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 first quarter 2022 financial results.

“DSUVIA continues to demonstrate solid sales growth and potential even with our limited commercial resources,” stated Vince Angotti, Chief Executive Officer of AcelRx. “We remain steadfast in our belief in DSUVIA’s value and its benefits to patients and healthcare providers with its unique pharmacokinetic characteristics, which are supported by favorable feedback received from physicians administering DSUVIA and numerous published studies. We believe that the uptake of this product will be maximized through a larger commercial infrastructure and, as such, we are in active discussions with potential partners that can execute a more robust commercial plan to support DSUVIA sales expansion, while further reducing AcelRx’s operating costs.”

Mr. Angotti continued, “Accordingly, we are aligning our cost structure to concentrate on our recently expanded development pipeline, which now includes our nafamostat portfolio and our pre-filled syringes. We believe these product candidates will provide multiple value-creating catalysts in the near-term, with two planned NDA submissions for the pre-filled syringes in 2022 and a potential emergency use authorization for Niyad in 2023. The reorganization of our corporate structure will drive shareholder value by extending our cash runway allowing us to continue progressing these development programs, remain focused on procedural suite sales and pursue further upside with a partner for DSUVIA.”

First Quarter and Recent Highlights

- In May 2022, AcelRx reorganized to reduce headcount by approximately 40%, generating projected initial annual savings of $9 million.

- AcelRx announced the closing of its acquisition of Lowell Therapeutics, Inc. (Lowell) in January 2022 in a transaction for consideration of approximately $32.5 million plus net cash acquired and certain other adjustments, and which includes up to approximately $26.0 million of contingent consideration payable in cash or stock at AcelRx's option, upon the achievement of certain regulatory and sales-based milestones. Niyad™ (nafamostat) is the lead product, with a targeted indication of anticoagulation of the extracorporeal circuit, and which has received Breakthrough Device Designation from the FDA, as well as an ICD-10 procedural code from CMS which allows for reimbursement. Annual peak sales potential for Niyad is expected to exceed $200 million.

- In May 2022, AcelRx hosted 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. https://www.acelrx.com/events/event-details/key-opinion-leader-kol-webinar-discuss-niyadtm-lyophilized-form-nafamostat

- As of March 31, 2022, AcelRx has achieved 855 DSUVIA formulary approvals. As of April 30, 2022, AcelRx has achieved 893 formulary approvals for DSUVIA.

- In the first quarter of 2022, AcelRx announced three publications, including: (1) a comparative data study between two different dialysis circuit anticoagulants in pediatric patients undergoing continuous renal replacement therapy (CRRT); (2) a study evaluating the use of a sufentanil sublingual tablet (SST) 30 mcg for management of pain of radiofrequency microneedling of the face or abdomen; and (3) a study evaluating real-world data in patients undergoing awake plastic surgery showing a rapid recovery time and minimal side effects with the use of SST for pain management.

- In March 2022, AcelRx received a close-out letter from the U.S. Food and Drug Administration (FDA) confirming that it had concluded its evaluation of the Company's corrective actions in response to the Warning Letter and that the Company had addressed the issues raised by the FDA Warning Letter dated February 11, 2021 regarding certain DSUVIA promotional materials.

Financial Information

- The cash, cash equivalents and short-term investments balance was $39.3 million as of March 31, 2022.

- First quarter 2022 net revenues were $0.4 million. DSUVIA units sold in the first quarter of 2022 were 10,530, compared to 8,960 units in the fourth quarter of 2021, reflecting unit sales growth of 18% from the prior quarter. Excluding fluctuating DoD revenues, unit sales growth was 64% in the first quarter of 2022 from the fourth quarter of 2021.

- Combined R&D and SG&A expenses for the first quarter of 2022 totaled $8.7 million compared to $8.6 million for the first quarter of 2021. Excluding non-cash depreciation and stock-based compensation expense, these amounts were $7.7 million for the first quarter of 2022, compared to $7.4 million for the first quarter of 2021. The increase in combined R&D and SG&A expenses in the first quarter of 2022 was primarily due to increased DSUVIA manufacturing-related costs, partially offset by reductions in personnel-related expenses.

- Net loss for the first quarter of 2021 was $8.7 million, or $0.06 per basic and diluted share, compared to $9.0 million, or $0.08 per basic and diluted share, for the first quarter of 2021.

Webcast and Conference Call Information
As previously announced, AcelRx will host a live webcast Monday, May 16th at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) to discuss these financial results and provide other corporate updates. The webcast is 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. Investors who wish to participate in the conference call may do so by dialing (866) 361-2335 for domestic callers, (855) 669-9657 for Canadian callers or (412) 902-4204 for international callers. 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 and Zalviso are both approved products 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 the expected effect and scope of cost savings arising from our restructuring efforts, the potential extension of our cash runway, the expected benefits arising from potential partnerships with DSUVIA, the expected benefits arising from our recent acquisition of Lowell, potential near-term value-creating catalysts arising under our development pipeline, the expected market opportunity for our new product candidates in-licensed from Aguettant and/or acquired through the Lowell acquisition, our plans to file NDAs and other regulatory submissions for our new product candidates and the timing of such filings. 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," "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; (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 March 31	
	2022	**2021**
Statement of Comprehensive Loss Data		
Revenue:		
Product sales	$ 442	$ 451
Contract and other collaboration	-	60
Total revenue	442	511
Operating costs and expenses:		
Cost of goods sold (1)	784	1,040
Research and development (1)	1,315	969
Selling, general and administrative (1)	7,338	7,644
Total operating costs and expenses	9,437	9,653
Loss from operations	(8,995)	(9,142)
Other income (expense):		
Interest expense	(390)	(672)
Interest income and other income (expense), net	38	76
Non-cash interest income on liability related to sale of future royalties	673	782
Total other income (expense)	321	186
Net loss	$ (8,674)	$ (8,956)
Basic and diluted net loss per common share	$ (0.06)	$ (0.08)
Shares used in computing basic and diluted net loss per common share	145,624	113,257
(1) Includes the following non-cash depreciation and stock-based compensation expense:		
Cost of goods sold	$ 67	$ 77
Research and development	260	180
Selling, general and administrative	721	1,049
Total	$ 1,048	$ 1,306

	March 31, 2022	**December 31, 2021**
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 39,349	$ 51,630
Total assets	71,971	77,893
Total liabilities	110,244	113,786
Total stockholders' deficit	(38,273)	(35,893)

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

	Three Months Ended March 31	
	2022	**2021**
Operating expenses (GAAP):		
Research and development	$ 1,315	$ 969
Selling, general and administrative	7,338	7,644
Total operating expenses	8,653	8,613
Less depreciation and stock-based compensation expense	981	1,229
Operating expenses (non-GAAP)	$ 7,672	$ 7,384