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 17, 2021

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 17, 2021, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 2021 (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 17, 2021
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 17, 2021

ACELRX PHARMACEUTICALS, INC.

By: /s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer

Exhibit 99.1

AcelRx Pharmaceuticals Reports First Quarter 2021 Financial Results

$67.3 million of cash and short-term investments at March 31, 2021

432 formulary approvals at April 30, 2021

The American Dental Association provided a CDT code establishing a pathway to reimbursement for DSUVIA®

HAYWARD, Calif., May 17, 2021 – 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 2021 financial results.

“We continue to make solid progress on the commercialization of DSUVIA despite the impact from the pandemic, which appears to be easing as the month of April was our highest commercial ordering month since the launch,” said Vince Angotti, Chief Executive Officer of AcelRx. “We remain committed to building the body of evidence for DSUVIA and its unique benefit to healthcare providers and their patients by supporting real-world use studies in a number of different settings. We look forward to expected data read-outs from investigator-initiated studies with several prestigious institutions.”

First Quarter and Recent Highlights

- In the first quarter of 2021, AcelRx issued approximately $36.4 million of stock through an underwritten public offering and under its At-the-Market sales agreement.
- In January 2021, AcelRx announced an investigator-initiated study with University Hospitals Cleveland Medical Center to evaluate the postoperative use of DSUVIA in a prospective cohort of patients undergoing cardiac surgery with cardiopulmonary bypass following a specialized enhanced recovery protocol.
- In February 2021, AcelRx announced an investigator-initiated study with Newport Plastic and Reconstructive Surgery Center analyzing data from the historical use of DSUVIA for various same-day plastic surgery procedures.
- In March 2021, AcelRx announced the publication of a pooled analysis of Phase 3 data on the use of DSUVIA for acute pain management in the postoperative and emergency department settings in the *Journal of Pain Research*, which reported high ratings for global assessment of the method of pain control and a well-tolerated safety profile for all demographic subgroups following the dosing of DSUVIA. See Cautionary Statements section below.

- In March 2021, AcelRx announced the appointment of Marina Bozilenko as an independent member of the company's Board of Directors. Ms. Bozilenko has over 30 years of investment banking and other healthcare industry experience, including raising more than $30 billion in capital and executing numerous M&A transactions.

- In April 2021, AcelRx announced an investigator-initiated study at Montefiore Medical Center evaluating the perioperative use of DSUVIA for same-day surgical procedures in patients on buprenorphine therapy for opioid-use disorder or for chronic pain management.

- In April 2021, the American Dental Association provided a CDT Code (Code on Dental Procedures and Nomenclature) establishing a pathway to reimbursement for DSUVIA for dental and oral surgeons.

- In May 2021, AcelRx announced an investigator-initiated study to be conducted at The CORE Institute Specialty Hospital in Phoenix, Arizona by the Musculoskeletal Orthopedic Research and Education (MORE) Foundation evaluating the perioperative use of DSUVIA for patients undergoing hip or knee replacement as a same-day surgical procedure.

- In May 2021, AcelRx announced a poster presentation at the 46th Annual American Society of Regional Anesthesia (ASRA) Meeting reviewing the results of a study on the intraoperative administration of DSUVIA (sufentanil sublingual tablet; SST) 30 mcg for the management of acute pain in an ambulatory surgery center.

- Through April 2021, AcelRx has achieved 432 formulary approvals.

- A response to the FDA Warning Letter has been provided and dialogue is ongoing to ensure a successful closeout. The Company believes it has successfully addressed the points raised. Once corrective actions are satisfactorily completed, AcelRx expects the FDA to issue a Close-Out Letter.

Financial Information

- Cash, cash equivalents and short-term investments balance of $67.3 million as of March 31, 2021;

- First quarter 2021 net revenues were $0.5 million;

- Combined R&D and SG&A expenses for the first quarter of 2021 totaled $8.6 million compared to $14.7 million for the first quarter of 2020. Excluding stock-based compensation expense, these amounts were $7.5 million for the first quarter of 2021 compared to $13.6 million for the first quarter of 2020. The decrease in combined R&D and SG&A expenses in the first quarter 2021 was primarily due to reductions in personnel-related costs, including travel expense, and DSUVIA-related commercialization expenses. For the first quarter of 2021, net loss was $9.0 million, or $0.08 per basic and diluted share, compared to $15.9 million, or $0.20 per basic and diluted share, for the first quarter of 2020.

Webcast and Conference Call Information

As previously announced, AcelRx will host a live webcast Monday, May 17, 2021 at 4:30 p.m. Eastern Time (1:30 p.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. The European Commission approved DZUVEO for marketing in Europe and AcelRx is currently in discussions with potential European marketing partners.

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 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. AcelRx 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 one product candidate, Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S., is being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings. DZUVEO and Zalviso are both approved products in Europe.

For additional information about AcelRx, please visit www.acelrx.com.

Non-GAAP Financial Measures
To supplement AcelRx's financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), AcelRx uses certain non-GAAP financial measures in this press release, in particular, excluding stock-based compensation expense from its operating expenses. AcelRx believes that these non-GAAP financial measures provide useful supplementary information to, and facilitate additional analysis by, investors and analysts. In particular, AcelRx believes that these non-GAAP financial measures, when considered together with AcelRx's financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare AcelRx's results from period to period and to its forward-looking guidance. In addition, these types of non-GAAP financial measures are regularly used by investors and analysts to model and track AcelRx's financial performance. AcelRx's management also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate AcelRx's business and to make operating decisions. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read in conjunction with AcelRx's consolidated financial statements prepared in accordance with GAAP. The non-GAAP financial measures in this press release and the accompanying tables have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

Cautionary Statements

Pooled Analysis. The global satisfaction analysis included a total of 283 patients who had completed the assessments as well as their healthcare professionals who had dosed DSUVIA in the clinical trials. Adverse events occurring in ≥ 2% of the patients were nausea (22.9%), headache (5.0%), dizziness (4.0%) and vomiting (3.1%). Importantly, the adverse events of decreased oxygen saturation and somnolence were low, occurring in 1.5% and 1.2% of the patients, respectively. Study limitations included a higher enrollment of younger compared to older patients, and opioid-tolerant patients were excluded. These Phase 3 studies were funded by AcelRx and the Clinical and Rehabilitative Medicine Research Program (CRMRP) of the US Army Medical Research and Materiel Command (USAMRMC). The lead author, David Leiman, MD, University of Texas at Houston Department of Surgery and HD Research, Houston TX, is a paid consultant of AcelRx.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the ongoing effects of the COVID-19 pandemic and its anticipated impacts on AcelRx's business, expectations for loosening of COVID-related restrictions, the expected continuation of investigator-initiated studies and the scope of the studies, the expected analysis and publication of clinical data, the belief that AcelRx has successfully addressed the points raised in the FDA Warning Letter, and the expectation that the FDA will issue a close-out letter once corrective actions are satisfactorily completed by AcelRx. 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 "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," 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. 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 the uncertainties inherent in the initiation, execution and completion of investigator-initiated studies. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described 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). 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 events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

Investor Contacts
Raffi Asadorian, CFO AcelRx
investors@acelrx.com

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Selected Financial Data
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31	
	2021	**2020**
Statement of Comprehensive Loss Data		
Revenue:		
Product sales	$ 451	$ 274
Contract and other collaboration	60	112
Total revenue	511	386
Operating costs and expenses:		
Cost of goods sold (1)	1,040	1,511
Research and development (1)	969	1,412
Selling, general and administrative (1)	7,644	13,311
Total operating costs and expenses	9,653	16,234
Loss from operations	(9,142)	(15,848)
Other income (expense):		
Interest expense	(672)	(855)
Interest income and other income (expense), net	76	(65)
Non-cash interest income on liability related to sale of future royalties	782	843
Total other income (expense)	186	(77)
Net loss	$ (8,956)	$ (15,925)
Basic and diluted net loss per common share	$ (0.08)	$ (0.20)
Shares used in computing basic and diluted net loss per common share	113,257	80,057

(1) Includes the following non-cash, stock-based compensation expense:

Cost of goods sold	$ 22	$ 46
Research and development	181	200
Selling, general and administrative	886	900
Total	$ 1,089	$ 1,146

	March 31, 2021	**December 31, 2020**
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 67,345	$ 42,886
Total assets	87,347	66,295
Total liabilities	114,659	122,045
Total stockholders' deficit	(27,312)	(55,750)

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

	Three Months Ended March 31	
	2021	**2020**
Operating expenses (GAAP):		
Research and development	$ 969	$ 1,412
Selling, general and administrative	7,644	13,311
Total operating expenses	8,613	14,723
Less associated stock-based compensation expense	1,067	1,100
Operating expenses (non-GAAP)	$ 7,546	$ 13,623