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 15, 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.)

351 Galveston Drive
Redwood City, CA 94063
(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 15, 2021, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three and twelve months ended December 31, 2020 (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 March 15, 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: March 15, 2021

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

Exhibit 99.1

AcelRx Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results

Full year 2020 revenues of $5.4 million compared to $2.3 million in 2019

REDWOOD CITY, Calif., March 15, 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 fourth quarter and full year 2020 financial results.

“Last year we achieved many important milestones and objectives that set the foundation for the growth of DSUVIA® in 2021 and beyond, despite the global pandemic,” said Vince Angotti, Chief Executive Officer of AcelRx. “Like many other companies in our space, COVID has had an impact on the pace of approvals and adoption of DSUVIA as formulary review meetings and elective surgeries have been postponed. However, with vaccine rollouts and elective surgeries ramping up, we expect formulary approvals in the second half of 2021 to be back to the accelerating rate we saw before the pandemic. Importantly, we expect data from ongoing and upcoming studies this year to continue to demonstrate the unique characteristics of DSUVIA that benefit the patient and institutions alike.”

FY 2020 and Recent Highlights

- In March, AcelRx announced an agreement with Brigham and Women's Hospital for an investigator-initiated study of DSUVIA led by Richard D. Urman MD, MBA, Associate Professor of Anesthesia and co-director of the Center for Perioperative Research at Brigham and Women's Hospital and Harvard Medical School. This study is ongoing and is evaluating the perioperative use of DSUVIA in patients undergoing spine surgery compared to their standard intravenous (IV) opioid regimen.

- In April, DSUVIA achieved Milestone C approval from the Department of Defense (DoD), a decision that approves DSUVIA for use in all U.S. Army sets, kits and outfits (SKOs). Initial stocking orders have begun for U.S. Army SKOs and are expected to approximate $30 million over the next three years, dependent on troop deployment schedules.

- In July, AcelRx entered into a distribution agreement with Zimmer Biomet to market DSUVIA within the dental and oral surgery markets in the United States exclusively through Zimmer Biomet's Dental division. The formal launch is planned in 2021 and will expand once Zimmer Biomet receives necessary licenses. The estimated applicable market in dental surgeries is 7.5 million annual procedures.

- In August, AcelRx announced the publication of a study entitled, "Reduced Opioid Use and Reduced Time in the Postanesthesia Care Unit Following Preoperative Administration of Sublingual Sufentanil in an Ambulatory Surgery Setting," by Christian Tvetenstrand, MD and Michael Wolff, MD, in the *Journal of Clinical Anesthesia and Pain Management*. Highlights of the publication included a greater than 50% overall reduction in opioids administered perioperatively and a 34% reduction in postanesthesia care unit (PACU) time in the DSUVIA-treated patients compared to historical controls. See Cautionary Statements section below.

- In August, AcelRx announced an investigator-initiated study with Cleveland Clinic evaluating the effects of DSUVIA on post-operative recovery from orthopedic surgery. This double-blind study is ongoing and compares DSUVIA to IV fentanyl for patients undergoing knee arthroscopy.

- In September, AcelRx announced that the U.S. military's access to DSUVIA was expanded with the addition of DSUVIA to the DoD Joint Deployment Formulary.

- In September, the U.S. Army awarded AcelRx a contract for up to $3.6 million over four years for the purchase of DSUVIA to support a DoD study to aid the development of clinical practice guidelines.

- In December, AcelRx announced the publication of clinical data in an article in the *Journal of Universal Surgery* entitled, "A Medication Use Evaluation of Sufentanil Sublingual Tablet 30 mcg for the Perioperative Management of Surgical Pain," by lead author Koth Cassavaugh, PharmD, Director of Pharmacy, which reported that perioperative dosing of DSUVIA can provide more rapid PACU recovery times compared to standard IV opioid administration. In addition, patients in the control group received 66% higher mean dosing of intraoperative IV opioids compared to patients receiving DSUVIA and postoperative opioid use for the DSUVIA group was less than half of the control IV opioid group, with orthopedic surgery patients having the largest decrease (69%). See Cautionary Statements section below.

- In January and February 2021, AcelRx issued approximately $36.3 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.

- Through February 2021, AcelRx has achieved 387 formulary approvals.

Financial Information

- As previously announced, the cash, cash equivalents and short-term investments balance was $42.9 million as of December 31, 2020, and net revenues for the fourth quarter 2020 were $0.7 million, and for the full year 2020 were $5.4 million.

- Combined R&D and SG&A expenses for the fourth quarter of 2020 totaled $8.7 million, a significant reduction compared to $13.8 million for the fourth quarter of 2019. Excluding stock-based compensation expense, these amounts were $7.6 million for the fourth quarter of 2020 compared to $12.6 million for the fourth quarter of 2019. R&D and SG&A expenses for the year ended December 31, 2020 totaled $40.3 million compared $49.7 million for the year ended December 31, 2019. Excluding stock-based compensation expense, these figures were $36.0 million for the year ended December 31, 2020, compared to $44.9 million for the year ended December 31, 2019. The decrease in combined R&D and SG&A expenses in the fourth quarter and year ended 2020 was primarily due to reductions in personnel-related costs, including travel expense, and DSUVIA-related commercialization expenses.

- Net loss for the fourth quarter of 2020 was $8.9 million, or $0.10 per basic and diluted share, compared to $14.4 million, or $0.18 per basic and diluted share, for the fourth quarter of 2019. Net loss for the year ended December 31, 2020 was $40.4 million, or $0.47 per basic and diluted share, compared to $53.2 million, or $0.67 per basic and diluted share, for the year ended December 31, 2019.

2021 Guidance

The Company’s 2021 year-end goals include obtaining 615 cumulative formulary approvals as we expect COVID restrictions on elective surgeries to be loosened in the second half of 2021. Quarterly combined R&D and SG&A expense is expected to be approximately $9-$10 million (and $8.0-$8.5 million excluding stock compensation and depreciation). Annual debt service is expected to approximate $10 million as we continue to pay down amounts outstanding under our senior debt facility. Annual capital expenditures are expected to range from $4-$5 million attributed mainly to the final installation of our new high-volume, automated packaging line at our contract manufacturer. We expect initial packaging batches to be produced at the end of this year, with commercial batches beginning after regulatory approvals are received in Q3 2022. With a path now clear to final installation of the automated packaging line, we also plan to close on an agreement to out-license DZUVEO for Europe later this year.

2021 financial guidance is based on the Company's current expectations and are forward-looking statements. Actual results could differ materially depending on market conditions and the factors set forth under Forward-Looking Statements below.

Webcast and Conference Call Information
As previously announced, AcelRx will host a live webcast Monday, March 15, 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 http://ir.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 http://ir.acelrx.com/.

About DSUVIA (sufentanil sublingual tablet), 30 mcg
DSUVIA®, known as DZUVEO™ in Europe, approved by the FDA in November 2018, 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 in June 2018 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. See the "Reconciliation of Non-GAAP Financial Measures" table below for a reconciliation of the non-GAAP operating expenses described above to their related GAAP measures.

Cautionary Statements

Tvetenstrand and Wolff Study. The study compared a prospective group of patients with preoperative dosing of a single sublingual DSUVIA tablet to a historical control group receiving standard intravenous (IV) opioid administration for same-day general surgery procedures. A total of 127 patients were evaluated in the study. Study limitations include that it was an open-label study, the retrospective nature of the control group, and the focus on only general surgery patients. AcelRx did not provide funding for the conduct of the Tvetenstrand and Wolff Study but did fund medical writing support. Dr. Tvetenstrand is a paid consultant of AcelRx.

Cassavaugh Study. The evaluation focused on 140 patients who were dosed with DSUVIA compared to 158 patients who had been dosed with traditional IV opioids during the same time period undergoing the same surgical procedures. Study limitations included that it was a single-center, retrospective study of DSUVIA dosing in a surgical patient population and both inpatient and outpatient surgery data was combined. The study did not control for whether patients were opiate naïve or opiate tolerant in the treatment groups, however, there is no reason for these patients to be present at a substantially higher frequency in either group. AcelRx did not provide funding for the conduct of the evaluation but did fund medical writing support. Dr. Cassavaugh 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 expected growth of DSUVIA, 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 timing and size of military orders, opportunities that may result from the Milestone C meeting, the timing of the expected formal launch by Zimmer Biomet under the distribution agreement, the market for DSUVIA in dental and oral surgeries, the number of formulary approvals expected by the end of 2021, expected R&D and SG&A expenses, debt service and capital expenditures, the production and timing of initial packaging and commercial batches, the timing of expected regulatory approvals, and the plan to close an agreement to out-license DZUVEO. 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 risk that the military and hospital systems delay, or fail to place, orders, that AcelRx may not experience the expected benefits from the Zimmer Biomet commercial opportunity and 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

Brian Korb, Solebury Trout
646-378-2923
Investors@acelrx.com

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

	Three Months Ended December 31		Twelve Months Ended December 31	
	2020	**2019**	**2020**	**2019**
Statement of Comprehensive Loss Data				
Revenue:				
Product sales	$ 657	$ 377	$ 2,521	$ 1,830
Contract and other collaboration	81	98	2,895	459
Total revenue	738	475	5,416	2,289
Operating costs and expenses:				
Cost of goods sold (1)	1,300	1,618	6,032	6,806
Research and development (1)	836	1,063	4,017	4,661
Selling, general and administrative (1)	7,846	12,786	36,330	45,027
Total operating costs and expenses	9,982	15,467	46,379	56,494
Loss from operations	(9,244)	(14,992)	(40,963)	(54,205)
Other income (expense):				
Interest expense	(754)	(831)	(3,305)	(2,535)
Interest income and other income (expense), net	272	438	583	2,166
Non-cash interest income (expense) on liability related to sale of future royalties	808	962	3,310	1,337
Total other income (expense)	326	569	588	968
Provision for income taxes	-	-	(4)	(3)
Net loss	$ (8,918)	$ (14,423)	$ (40,379)	$ (53,240)
Basic and diluted net loss per common share	$ (0.10)	$ (0.18)	$ (0.47)	$ (0.67)
Shares used in computing basic and diluted net loss per common share	92,290	79,573	85,257	79,184

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

Cost of goods sold	$ 25	$ 63	$ 123	$ 260
Research and development	192	221	764	920
Selling, general and administrative	867	994	3,537	3,877
Total	$ 1,084	$ 1,278	$ 4,424	$ 5,057

	December 31, 2020	**December 31, 2019**
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 42,886	$ 66,137
Total assets	66,295	91,356
Total liabilities	122,045	132,774
Total stockholders' (deficit) equity	(55,750)	(41,418)

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

	Three Months Ended December 31		Twelve Months Ended December 31	
	2020	**2019**	**2020**	**2019**
Operating expenses (GAAP):				
Research and development	$ 836	$ 1,063	$ 4,017	$ 4,661
Selling, general and administrative	7,846	12,786	36,330	45,027
Total operating expenses	8,682	13,849	40,347	49,688
Less associated stock-based compensation expense	1,059	1,215	4,301	4,797
Operating expenses (non-GAAP)	$ 7,623	$ 12,634	$ 36,046	$ 44,891