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): January 14, 2021

ACELRX PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-35068**	**41-2193603**
(State of Incorporation)	(Commission File No.)	(I.R.S. 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 January 14, 2021, AcelRx Pharmaceuticals, Inc. (the "*Company*") issued a press release announcing key achievements including preliminary financial information and metrics for 2020 (the "*Release*"). A copy of the Release is furnished herewith as Exhibit 99.1.

The Company has not yet completed its year-end financial close process for the year ended December 31, 2020 and the preliminary financial information is based on preliminary estimates of the Company's financial results that it expects to report for the applicable periods. These estimates are subject to change upon completion of the Company's financial closing procedures. The Company's independent registered public accounting firm, OUM & Co. LLP, has not audited, reviewed or compiled these estimates and, accordingly, does not express an opinion on, or provide any other form of assurance with respect to, these preliminary estimates. These estimates are not a comprehensive statement of the Company's financial results for the year ended December 31, 2020 and its actual results may differ materially from these estimates as a result of the completion of the Company's financial closing procedures, final adjustments and other developments arising between now and the time that the Company's financial results for this period are finalized.

ITEM 8.01 Other Events

The information contained in Item 2.02 above and the Release are incorporated herein by reference.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated January 14, 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.

ACELRX PHARMACEUTICALS, INC.

Date: January 14, 2021

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

AcelRx Announces Year-End 2020 Metrics and Review of 2020 Achievements

REDWOOD CITY, Calif., January 14, 2021 – AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced preliminary unaudited financial results and other information in connection with its participation in investor presentations, meetings and events during the week of the 39th Annual J.P. Morgan Healthcare Conference. The Company will post its revised corporate presentation in the investor section of its website.

Key Highlights of 2020

- 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 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 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, once Zimmer Biomet receives necessary licenses. The estimated applicable market in dental surgeries is over 7 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* (Tvetenstrand and Wolff Study). 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 of 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 (the Cassavaugh Evaluation), 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.

- Achieved 348 formulary approvals through the close of 2020, a significant achievement in a year with COVID-related restrictions and delays.

- Preliminary unaudited FY 2020 revenues approximated $5.4 million.

- Preliminary December 31, 2020 cash, cash equivalents and short-term investments balance was $42.9 million.

"I'm pleased with our team's commercial execution during these challenging times," said Vince Angotti, AcelRx Chief Executive Officer. "We expect further real-world data to support the value proposition of DSUVIA as an alternative to IV opioids, and we continue to make solid progress on the four pillars of our revenue plan. I look forward to providing further updates during our year-end earnings call."

The information above related to the Company's expected operating results for the year ended and as of December 31, 2020, including revenue and cash, cash equivalents and short-term investments, is preliminary, has not been audited and is subject to change upon completion of the audit of the Company's financial statements as of and for the year ended December 31, 2020.

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 the Company 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.

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 Evaluation
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 revenues and cash, cash equivalents and short-term investments AcelRx expects to report for fiscal year 2020, the timing of the procurement of DSUVIA by the military, the timing of the formal launch by Zimmer Biomet, and expectations for further real-world data to support the value proposition of DSUVIA as an alternative to IV opioids. 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. 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. In addition, such risks and uncertainties 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. 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

###