

**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 13, 2020

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

**Delaware**  
(State of Incorporation)

**001-35068**  
(Commission File No.)

**41-2193603**  
(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 13, 2020, AcelRx Pharmaceuticals, Inc. (the “Company”) issued a press release announcing a business update, expected total revenues of \$2.3 million for 2019 and \$66.1 million in cash, cash equivalents and short-term investments as of December 31, 2019 (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, 2019 and these estimates for total revenues and cash, cash equivalents and short-term investments are 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 provided 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, 2019 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 our 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	<a href="#">Press Release dated January 13, 2020</a>

**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 13, 2020

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



## **AcelRx Announces Year-End 2019 Metrics and Provides Corporate Updates**

*Exceeds 2019 metrics with 166 REMS-certified facilities and 148 formulary approvals through December 31, greater than the year-end goals of 125 for each*

*Announces year-end 2020 REMS-certified facilities and formulary approvals goals of 465*

*\$66.1 million of cash and short-term investments at December 31, 2019*

REDWOOD CITY, Calif., January 13, 2020 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in healthcare institutions, today provided an update on its business and DSUVIA® launch metrics.

“Exceeding our 2019 formulary approvals and number of REMS-certified facilities targets after only two full quarters with our 40-person sales team demonstrates DSUVIA’s early acceptance by healthcare facilities,” said Vince Angotti, Chief Executive Officer of AcelRx. “We begin 2020 with a solid foundation of REMS-certified healthcare facilities, and will now increase our focus on DSUVIA’s adoption and orders from this installed base while continuing our expansion to an expected 465 REMS-certified facilities and 465 formulary approvals by the end of 2020. This increased focus on adoption is expected to accelerate revenue growth in 2020,” continued Angotti.

### **Business Updates and Highlights**

- 166 healthcare facilities are REMS-certified and able to purchase DSUVIA and 148 formulary approvals have been achieved through December 31, 2019, exceeding year-end goals of 125 for each metric.
  - Preliminary unaudited FY 2019 total revenues of \$2.3 million.
  - Cash, cash equivalents and short-term investments of \$66.1 million as of December 31, 2019.
  - Year-end 2020 goals of 465 REMS-certified facilities and 465 formulary approvals.
-

- Department of Defense Milestone C meeting for DSUVIA is expected in the second quarter of 2020; the Company expects the military to begin procuring DSUVIA following successful completion of this meeting.
- Commencement of investigator-initiated studies of DSUVIA in post-operative pain management and Enhanced Recovery protocols at prominent university hospitals is anticipated beginning in the first half of 2020.
- The Company is hosting investor meetings in San Francisco this week during the JP Morgan Healthcare Conference.

The information above related to the Company's expected operating results for the year ended and as of December 31, 2019, 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, 2019.

#### **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.

For more information, please visit [www.DSUVIA.com](http://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. 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 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.ancelrx.com](http://www.ancelrx.com).

### **Forward-Looking Statements**

*This press release contains forward-looking statements, including, but not limited to, statements related to revenues, cash, cash equivalents and short-term investments the Company expects to report for fiscal year 2019, the number of REMS-certified facilities and formulary approvals expected by the end of 2020, the timing of the Department of Defense Milestone C meeting and procurement of DSUVIA by the military, expected commencement of investigator-initiated studies and anticipated acceleration of revenue growth. 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 challenges in achieving market adoption of DSUVIA, REMS-certified facilities and formulary approvals, or acceleration of revenue growth in a timely manner, or at all. In addition, such risks and uncertainties may include, but are not limited to, those described in the Company’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 the Company’s most recent annual, quarterly or current report as filed or furnished with the SEC. The Company’s SEC reports are available at [www.ancelrx.com](http://www.ancelrx.com) under the “Investors” tab. Except to the extent required by law, the Company 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.*

#### **Media Contacts:**

**Theresa Dolge**, Evoke  
215-928-2748  
[theresa.dolge@evokegroup.com](mailto:theresa.dolge@evokegroup.com)

**Jessica Ross**, Evoke  
215-928-2346  
[jessica.ross@evokegroup.com](mailto:jessica.ross@evokegroup.com)

#### **Investor Contacts:**

**Raffi Asadorian**, CFO, AcelRx  
[investors@ancelrx.com](mailto:investors@ancelrx.com)

**Brian Korb**, Solebury Trout  
646-378-2923  
[investors@ancelrx.com](mailto:investors@ancelrx.com)

###