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): October 12, 2017

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))

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 October 12, 2017, AcelRx Pharmaceuticals, Inc. (the "Company" or "AcelRx") issued a press release that disclosed that the Company's estimated cash balance as of September 30, 2017 was $67.9 million. The aforementioned financial information is included in the press release, as furnished in Exhibit 99.1 to this Current Report and is incorporated herein by reference.

Item 8.01 Other Events.

On October 12, 2017, the Company issued a press release entitled "AcelRx Pharmaceuticals Receives Complete Response Letter from the FDA for DSUVIA™ NDA," a copy of which is attached as Exhibit 99.1 to this Report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated October 12, 2017

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: October 12, 2017

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell
Jane Wright-Mitchell
Chief Legal Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated October 12, 2017

Exhibit 99.1

Press Release

AcelRx Pharmaceuticals Receives Complete Response Letter from the FDA for DSUVIA™ NDA

REDWOOD CITY, Calif., October 12, 2017 /PRNewswire/-- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX) (AcelRx), a specialty pharmaceutical company, today announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for DSUVIA™ (sufentanil sublingual tablet), 30 mcg.

The CRL states that the FDA determined it cannot approve the NDA in its present form and provides recommendations needed for resubmission. The two primary recommendations within the CRL are: first, while the safety database was suitable in number of patients, the collection of additional data was requested on at least 50 patients to assess the safety of DSUVIA dosed at the maximum amount described in the proposed labelling; second, to ensure proper administration of the tablet with the single-dose applicator, the FDA recommended certain changes to the Directions for Use to address use-related errors, including dropped tablets, to be validated through a human factors study.

"We believe the recommendations stated in the CRL are manageable and plan to fully cooperate with the FDA. We remain focused on the NDA resubmission and our mission to provide physicians and patients with precise and efficient non-invasive pain management options for moderate-to-severe acute pain within medically supervised settings," said Vincent J. Angotti, chief executive officer, AcelRx.

AcelRx will request a meeting with the FDA to discuss the topics covered in the CRL, and confirm plans to move towards resubmission of the DSUVIA NDA. AcelRx ended the third quarter with an estimated $67.9 million in cash and we will provide further financial updates on our third quarter earnings call.

Conference Call
AcelRx's management will host a conference call on Thursday, October 12, 2017, at 9:00AM ET to discuss the Complete Response Letter. The dial-in number for the conference call is 1-866-361-2335 for domestic participants and 1-412-902-4204 for international participants. A live webcast of the conference call can also be accessed through the "Investors" tab on the AcelRx Pharmaceuticals website, and a replay will be available online after the call.

About DSUVIA™ (sufentanil sublingual tablet), 30 mcg
DSUVIA™ (sufentanil sublingual tablet, SST, 30 microgram), known as ARX-04 outside the United States, is designed to reduce moderate-to-severe acute pain and dosing errors associated with IV administration via its non-invasive single-dose applicator (SDA) in medically supervised settings. Sufentanil is an opioid analgesic currently marketed for intravenous (IV) and epidural anesthesia and analgesia. However, its use has been limited due to its short duration of action when delivered intravenously. The sufentanil pharmacokinetic profile when delivered sublingually potentially avoids the high peak plasma levels and short duration of action observed with IV administration. In the EU, the European Medicines Agency (EMA) has notified the company that the ARX-04 Marketing Authorization Application (MAA) is under scientific review.

About AcelRx Pharmaceuticals, Inc.
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain. AcelRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles.

The company is simultaneously developing ZALVISO® (sufentanil sublingual tablet system, SST system, 15 microgram) as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe pain in medically supervised settings. The company recently completed a Phase 3 clinical trial, IAP312, which included input from the FDA on the study protocol. This study was designed to evaluate the effectiveness of changes made to the functionality and usability of the ZALVISO device, to evaluate the incidence of inadvertent dosing, and to take into account comments from the FDA on the study protocol. AcelRx intends to resubmit the NDA for ZALVISO to the FDA by the end of the year. AcelRx has successfully received EU Marketing Approval for ZALVISO® in the EU. Grunenthal Group holds the rights for ZALVISO® in Europe, where a commercialization across multiple countries is underway. In June 2017, ZALVISO® was selected for a Red Dot Award in the category of Product Design – Life Sciences and Medicine.

For additional information about AcelRx's clinical programs, please visit www.acelrx.com.

Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to the process and timing of anticipated future development of AcelRx's product candidates, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, and ZALVISO® (sufentanil sublingual tablet system), including U.S. Food and Drug Administration, or FDA, review of the New Drug Application, or NDA, for DSUVIA; and evaluation of the CRL and AcelRx's plans for resubmission of the NDA for DSUVIA with the FDA. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitation, risks related to AcelRx Pharmaceuticals' DSUVIA and ARX-04 development programs, including the EMA review of the ARX-04 MAA, and the possibility that EMA may dispute or interpret differently clinical results obtained from the ARX-04 Phase 2 and 3 studies; the possibility that the FDA may dispute or interpret differently the results of the ZALVISO development program, including the results from the IAP312 clinical trial; the resubmission of the ZALVISO NDA to the FDA; any delays or inability to obtain and maintain regulatory approval of its product candidates, including DSUVIA in the United States, ARX-04 in Europe and ZALVISO in the United States; the uncertain clinical development process, including adverse events; the success, cost and timing of all development activities and clinical trials; the accuracy of AcelRx's estimates regarding expenses, capital requirements and the need for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on August 2, 2017. AcelRx undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

Investors
Brian Korb, The Trout Group LLC
646-378-2923
bkorb@troutgroup.com

or

Raffi Asadorian
Chief Financial Officer
AcelRx Pharmaceuticals
rasadorian@acelrx.com

Media
Stephanie Eisenstat, Medical Dynamics
646-599-8627
seisenstat@rxmedyn.com