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): December 14, 2015

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))

Item 8.01. Other Events.

On December 14, 2015, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release entitled "AcelRx Pharmaceuticals Conducts Pre-NDA Meeting with U.S. Food and Drug Administration for ARX-04," 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 December 14, 2015.

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: December 14, 2015

ACELRX PHARMACEUTICALS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated December 14, 2015.

Exhibit 99.1

FOR IMMEDIATE RELEASE

AcelRx Pharmaceuticals Conducts Pre-NDA Meeting with U.S. Food and Drug Administration for ARX-04

- AcelRx Anticipates the Submission of the ARX-04 New Drug Application in the Second Half of 2016

- FDA Agrees to Include a Significant Number of Patients from the Zalviso Studies into the ARX-04 Safety Database

REDWOOD CITY, Calif., December 14, 2015 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies designed for the treatment of acute pain, today reported on the outcome of the ARX-04 (sufentanil sublingual tablet, 30 mcg) pre-NDA meeting held recently with the U.S. Food and Drug Administration (FDA). The Company intends to pursue an ARX-04 indication for moderate-to-severe pain in a medically supervised setting. To support this indication, based on feedback from the FDA, the Company will expand the clinical program by approximately 165 patients to include individuals from specific populations and settings. Enrollment in the ongoing SAP302 open-label study in the emergency room will be increased, and a new study known as SAP303 is expected to be initiated in the first quarter of 2016 in postoperative patients with moderate-to-severe pain. SAP303 will focus on enrolling patients greater than 40 years of age and will allow for administration of ARX-04 for up to 12 hours. With these modifications, assuming successful completion of the studies, AcelRx anticipates submitting the NDA for ARX-04 in the second half of 2016

The FDA has also agreed to include, as supporting safety information, data from 323 patients treated in the Zalviso™ (sufentanil sublingual tablet system) clinical studies who had administered two 15 mcg tablets 20-to-25 minutes apart. AcelRx had previously completed and analyzed pharmacokinetic and modeling data, which demonstrated the equivalency of one 30 mcg sublingual sufentanil to two 15 mcg sublingual sufentanil tablets taken 20-to-25 minutes apart.

“Our pre-NDA meeting with the FDA was productive and provided specific guidance for meeting the FDA’s requirements for submitting a New Drug Application for ARX-04,” stated Dr. Pamela Palmer, co-founder and chief medical officer of AcelRx. “Enrollment in the postoperative study (SAP303) is estimated to take three months, and is expected to yield results to help support the NDA submission and review. In addition, we are encouraged that the FDA has agreed to consider a portion of the Zalviso safety database when reviewing the ARX-04 NDA.”

About ARX-04
ARX-04 is a non-invasive investigational product candidate consisting of 30 mcg sufentanil tablets delivered as often as once an hour sublingually via a disposable, pre-filled, single-dose applicator (SDA). AcelRx is developing ARX-04 for the management of moderate-to-severe acute pain in a variety of medically supervised settings, including the emergency room, outpatient or ambulatory surgery, non-surgical patients experiencing pain in the hospital, and post-operative patients following short-stay surgery, who do not require more long-term patient-controlled analgesia (PCA). ARX-04 is funded in part by the U.S. Army Medical Research and Materiel Command (USAMRMC).

Based on its market research, the Company estimates there are more than 51 million injury-related emergency department visits annually that on average receive two doses of opioids for moderate-to-severe pain in the United States.

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 acute pain. The company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg) designed for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso™ designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting. ARX-04 delivers 30 mcg sufentanil, a high therapeutic index opioid, sublingually through a disposable, pre-filled, single-dose applicator. AcelRx has reported positive results from the pivotal Phase 3 SAP301 ambulatory surgery study, and has advanced ARX-04 into a study (SAP302) in emergency room patients. In addition, AcelRx intends to initiate SAP303, with a focus on enrolling patients greater than 40 years of age, allowing for administration of ARX-04 for up to 12 hours, in the first quarter of 2016. Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. In response to the New Drug Application (NDA) AcelRx submitted to the U.S. Food and Drug Administration (FDA) seeking approval for Zalviso, AcelRx received a Complete Response Letter (CRL) on July 25, 2014. The FDA has requested an additional clinical study and the Company is working with the FDA regarding the resubmission of the Zalviso NDA and initiation of a clinical study to support resubmission.

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, including the process and timing of anticipated future development of Zalviso and ARX-04; anticipated results and timing of the enrollment and completion of the SAP302 and SAP303 studies for ARX-04; estimated timing for filing the ARX-04 NDA; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the U.S.; and anticipated resubmission of the Zalviso NDA to the FDA, including the scope and timing of resubmission. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and uncertainties. AcelRx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso and ARX-04; its ability to timely resubmit the Zalviso NDA to the FDA and to receive regulatory approval for Zalviso; the fact that the FDA may dispute or interpret differently positive clinical results obtained to date from the pivotal Phase 3 SAP301 ambulatory surgery study of ARX-04 or for its SAP302 or SAP303 studies; its ability to complete Phase 3 clinical development of ARX-04; use of previously generated data for support of the ARX-04 NDA; the success, cost and timing of all product development activities and clinical trials, including the SAP302 and SAP303 ARX-04 trials; 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 November 3, 2015. 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.

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