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 8, 2016

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 January 8, 2016, AcelRx Pharmaceuticals, Inc. issued a press release entitled "AcelRx Completes Protocol Review with FDA and Plans to Initiate Phase 3 Open-Label Study (IAP312) for Zalviso™ in 1Q 2016," 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 January 8, 2016.

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 8, 2016

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release dated January 8, 2016.

Exhibit 99.1

FOR IMMEDIATE RELEASE

AcelRx Completes Protocol Review with FDA and Plans to Initiate Phase 3 Open-Label Study (IAP312) for Zalviso™ in 1Q 2016

REDWOOD CITY, Calif., January 8, 2016 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain, today reported that the Company has received comments from the Division of Anesthesia, Analgesia, and Addiction Products (Division) of the U.S. Food and Drug Administration (FDA) on the Company's proposed protocol for a Phase 3 clinical study (IAP312) designed to assess the overall performance of Zalviso™(sufentanil sublingual tablet system). In response to the comments, the protocol has been amended and AcelRx plans to initiate the study in the first quarter of 2016. The IAP312 study will include approximately 310 post-operative patients and collect information requested by the Division to supplement the three positive Phase 3 trials already completed. Zalviso is being developed for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

"Even though we've performed extensive bench and human factors testing to demonstrate the reliability and usability of Zalviso since our successful Phase 3 trials, we acknowledge the Division's desire to see additional Zalviso use by patients in a clinical setting," commented Howie Rosen, interim chief executive officer of AcelRx. "We are pleased that we have a path forward in the U.S. that should lead to resubmission of the NDA."

The planned open-label Phase 3 study will enroll adult postoperative patients who will self-administer 15 mcg sublingual sufentanil using Zalviso for 24-to-72 hours. Patients will self-administer study drug as often as once every 20 minutes to manage their moderate-to-severe acute pain. The study will measure the rate of device errors, including the failure to dispense medication as well as the incidence of misplaced or dropped tablets. Efficacy pain measurements and safety data will also be collected in the study.

The NDA resubmission will include, in addition to the results of bench testing and human factors studies conducted with the modified Zalviso design, the results from the IAP312 study. Prior Phase 3 trials include two Phase 3 placebo-controlled studies (IAP310 and IAP311) in which Zalviso demonstrated superiority over placebo in the management of moderate-to-severe acute post-operative pain, as measured by time-weighted SPID48, the primary endpoint. In IAP309, a Phase 3 active-controlled study, Zalviso was statistically significantly superior ($p=0.007$) in patient global assessment (PGA) of method of pain control in comparison to intravenous (IV) PCA morphine. The most common adverse events experienced by patients using Zalviso were nausea, pyrexia (fever) and vomiting.

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 in the first quarter of 2016, with a focus on enrolling patients greater than 40 years of age, allowing for administration of ARX-04 for up to 12 hours. 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 (IAP312), which AcelRx is planning to initiate in the first quarter of 2016, to support resubmission of the NDA.

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 Zalviso and ARX-04; timing for initiation and completion along with anticipated results of IAP312 for Zalviso; anticipated results and timing of the completion of the SAP302 and SAP303 studies for ARX-04; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the United States; 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 successfully design and complete the additional clinical study requested by the FDA to support resubmission of the Zalviso NDA; 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 ambulatory surgery study of ARX-04 (SAP301); its ability to complete Phase 3 clinical development of ARX-04; the success, cost and timing of all product development activities and clinical trials, including the SAP302 and SAP303 ARX-04 trials and the IAP312 Zalviso trial; 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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