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 8, 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 October 8, 2015, AcelRx Pharmaceuticals, Inc. issued a press release entitled "AcelRx Pharmaceuticals Provides Regulatory Update on Zalviso," 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 8, 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: October 8, 2015

ACELRX PHARMACEUTICALS, INC.

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release dated October 8, 2015.

Exhibit 99.1

FOR IMMEDIATE RELEASE

AcelRx Pharmaceuticals Provides Regulatory Update on Zalviso

REDWOOD CITY, Calif., October 8, 2015 – 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 provided a regulatory update on Zalviso™ (sufentanil sublingual tablet system) intended for the management of moderate-to-severe acute pain in adult patients in the hospital setting. The company has received formal minutes of the telephonic meeting held in early September 2015, with the Division of Anesthesia, Analgesia, and Addiction Products of the Food and Drug Administration (FDA). As reflected in the minutes, the Division restated at the meeting a request for clinical data to complement other data AcelRx has developed to assess the overall performance of the Zalviso device.

The company is planning to submit a protocol to the Division for a clinical study in post-operative patients designed to evaluate the effectiveness of changes made to enhance product performance. AcelRx expects to be ready to initiate the study in the first quarter of 2016, and likely will await comments on the protocol from the Division. The company will be prepared to work with the FDA to facilitate the timely study initiation.

“We have been preparing a clinical study to investigate the use of Zalviso in a more diverse post-surgical population than in our original Phase 3 studies,” stated Pamela P. Palmer, MD, PhD, chief medical officer of AcelRx, “so we are modifying the design of this study to include endpoints that we believe will address the Division’s concerns.”

“The teleconference and meeting minutes were constructive, because they further clarified the Division’s position,” stated Howie Rosen, interim chief executive officer of AcelRx. “Even as ARX-04 advances through clinical development, Zalviso remains an important product for AcelRx, especially given its recent approval in Europe. We look forward to moving Zalviso toward resubmission, review and ultimate approval.”

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) for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso™ (sufentanil sublingual tablet system) 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. Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. AcelRx submitted a New Drug Application (NDA) for Zalviso and received a Complete Response Letter (CRL) from the FDA on July 25, 2014. The FDA subsequently requested an additional clinical study to evaluate the effectiveness of product changes made in response to the CRL, and the Company is working with the FDA regarding the resubmission of the Zalviso 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 the process and timing of anticipated future development of Zalviso and ARX-04; anticipated results and timing of the completion of the SAP302 study for ARX-04; 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; 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 ARX-04 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 August 4, 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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