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): September 26, 2014

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 September 26, 2014, 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 September 26, 2014.

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: September 26, 2014

ACELRX PHARMACEUTICALS, INC.

By: /s/ Timothy E. Morris
Timothy E. Morris
Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

AcelRx Pharmaceuticals Provides Regulatory Update on Zalviso™

REDWOOD CITY, Calif., September 26, 2014 /PRNewswire/ — AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain, today provided an update on the plans for the resubmission of the Company's New Drug Application (NDA) for Zalviso™ (sufentanil sublingual tablet system). The Company recently held a teleconference with representatives from the Food and Drug Administration (FDA) to review the Company's proposed response to the Zalviso Complete Response Letter (CRL) received on July 25, 2014. The Company had submitted a Briefing Document to the FDA ahead of the teleconference and received preliminary comments from the FDA on the Briefing Document. Based on the communications with the FDA, subject to the timing of the FDA review and comment on protocols to be submitted for the bench testing and Human Factors Study, the Company is targeting resubmission of the Zalviso NDA in the first quarter of 2015. However, depending on feedback from the FDA, the timing of the filing of the NDA could be later than the first quarter of 2015. The FDA also communicated that the planned resubmission will qualify as a Class 2 resubmission with a review period of six months.

During the teleconference with the FDA, the Company discussed the items included in the CRL, specifically: testing of the proposed mitigations to reduce the incidence of optical system errors, changes to the Instructions for Use (IFU) for the Zalviso System to address risk of inadvertent misplacement of tablets, and submission of additional data to support the shelf life of the product.

As a result of the communications, the Company confirmed that bench testing would be an acceptable approach to evaluate the reduction in optical system errors. The protocol for the bench testing will be submitted to the FDA for review and comment.

To address the risk of inadvertent misplacement of tablets, the Company proposed mitigations through the Zalviso System and IFU and to test these mitigations by way of a Human Factors Study. The protocol for the Human Factors Study will be submitted to the FDA for review and comment. The FDA stated that the adequacy of the Human Factors Study and the results of the study will be subject to final review and approval by the FDA.

Lastly, the Company proposed including additional stability data in the resubmission to support the proposed 24 month shelf life of the Zalviso System. The FDA has agreed with this approach subject to review of the data previously submitted and to be submitted.

“The discussion with the FDA was productive,” said Richard King, president and CEO of AcelRx. “Over the coming months we will prepare, submit and finalize with the FDA the protocols required to complete this work. Assuming timely review by the FDA on the protocols, we anticipate being able to complete the work with a target to refile the Zalviso NDA in the first quarter of 2015. However, depending on feedback from the FDA, the timing of the filing of the NDA could be later than the first quarter of 2015.”

The Company awaits receipt of the teleconference meeting minutes from the FDA to confirm the target timelines discussed above.

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 and breakthrough pain. AcelRx’s lead product candidate, Zalviso, is designed to improve the management of moderate-to-severe acute pain in adult patients in the hospital setting by utilizing a high therapeutic index opioid, through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. AcelRx has announced positive results from each of the three completed Phase 3 clinical trials for Zalviso, and has submitted an NDA to the FDA seeking approval for Zalviso in the treatment of moderate-to-severe acute pain in adult patients in the hospital setting and on July 25th, received a Complete Response Letter from the FDA. AcelRx plans to initiate a Phase 3 clinical trial for ARX-04, a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting, by the end of 2014. The Company has two additional pain treatment product candidates, ARX-02 and ARX-03, which have completed Phase 2 clinical development. 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 company’s Zalviso NDA and the Complete Response Letter (“CRL”), the recent meeting held with the FDA to discuss the CRL, our plans to address the issues raised in the CRL, our anticipated resubmission of the Zalviso NDA to the FDA, including the scope of the resubmission and the timing of the resubmission and FDA review time, planned initiation of the Phase 3 clinical trial for ARX-04, and the therapeutic and commercial potential of AcelRx Pharmaceuticals’ product candidates, including Zalviso. These forward-looking statements are based on AcelRx

Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' 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: AcelRx Pharmaceuticals' ability to receive regulatory approval for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso, in the United States and Europe; AcelRx's ability to build an effective commercial organization; its ability to obtain sufficient financing to commercialize Zalviso and proceed with clinical development of ARX-04; the success, cost and timing of all product development activities and clinical trials, including the planned Phase 3 ARX-04 trial; the market potential for its product candidates; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx Pharmaceuticals' U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on August 11, 2014. AcelRx Pharmaceuticals 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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