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): July 25, 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 July 25, 2014, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release entitled "AcelRx Pharmaceuticals Receives Complete Response Letter from FDA for New Drug Application for 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 July 25, 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: July 28, 2014

ACELRX PHARMACEUTICALS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated July 25, 2014.

Exhibit 99.1

AcelRx Pharmaceuticals Receives Complete Response Letter from FDA for New Drug Application for Zalviso™

REDWOOD CITY, Calif., July 25, 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 announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) for the Company's new drug application (NDA) for Zalviso™ (sufentanil sublingual tablet system). The Company is currently reviewing the FDA's comments and requests contained in the CRL and plans to discuss these requests with the FDA.

The CRL contains requests for additional information on the Zalviso System to ensure proper use of the device. The requests include provision of bench data demonstrating a reduction in the incidence of optical system errors which require premature drug cartridge change, changes to the Instructions for Use for the device, and additional data to support the shelf life of the product. We believe some of the requests have been addressed in amendments to the NDA that have been submitted prior to the receipt of the CRL but, as acknowledged by the FDA, have not been reviewed. There is no guarantee that the information previously provided to the FDA will be adequate to address the issues in the CRL. Additional bench testing will be required and human factors testing may be required to address certain items in the CRL. There were no requests to conduct additional human clinical studies.

"We believe we can satisfy all of FDA's requests in the CRL and resubmit the NDA by the end of 2014, although we will have more clarity on the process and timing after our conversation with FDA," said Richard King, president and CEO of AcelRx. "We are confident in the Zalviso development program and will work closely with the FDA to address the Agency's concerns as outlined in the CRL to ensure that healthcare professionals and patient communities will have access to Zalviso."

Conference Call

There will be a conference call and webcast with AcelRx management on Monday, July 28, 2014 at 8:30 a.m. Eastern time (5:30 a.m. Pacific time) to discuss the Zalviso CRL. The conference call will be available via phone and webcast. The dial in and webcast information is listed below:

Toll-Free US & Canada: 877-407-3109
International: 201-493-6798

Replay Information:

Conference ID #: 13587613
Replay Dial-In (Toll Free US & Canada): 877-660-6853
Replay Dial-In (International): 201-612-7415
Expiration Date: 8/4/14

Webcast URL: http://acelrx.equisolvewebcast.com/q2-2014

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"), 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 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 May 8, 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.

CONTACTS

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