ACELRX PHARMACEUTICALS INC
Form 8-K
September 08, 2015
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 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 7.01. Regulation FD Disclosure.

AcelRx Pharmaceuticals, Inc. (the "Company") recently held a meeting with the U.S. Food and Drug Administration (the "FDA"). The purpose of the meeting was to discuss the timeline and activities necessary to resubmit the Zalviso New Drug Application ("NDA").

During the meeting the FDA reiterated the request to complete a clinical study prior to the resubmission of the Zalviso NDA. The Company continues to believe that the results of the bench testing and the Human Factors studies adequately demonstrate the modifications made to the Zalviso System address the items raised in the CRL and that additional clinical studies are not needed. The Company will await formal minutes of the meeting and seek additional input from the FDA before deciding next steps.

The information contained in this Item 7.01 to this Current Report shall be deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01 to this Current Report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Forward-Looking Statements

The information in this Current Report contains forward-looking statements, including, but not limited to, statements related to the process and timing of anticipated future development of Zalviso, including AcelRx's belief that an additional clinical study should not be required to demonstrate the safety and efficacy of the Zalviso System and that the results of the bench testing and the human factors studies adequately demonstrate that the modifications made to the Zalviso System address the items raised in the CRL.

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 resubmit the Zalviso NDA to the FDA; potential additional clinical trials, and/or additional data analyses necessary in order to resubmit the Zalviso NDA; AcelRx's 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; its ability to obtain sufficient

financing to receive regulatory approval for and commercialize Zalviso; the success, cost and timing of all product development activities and clinical trials; 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 4, 2015. AcelRx Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements as a result of new information, future events or changes in its expectations.

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 8, 2015	ACELRX PHARMACEUTICALS, INC.	
	By:	/s/ Jane Wright-Mitchell Jane Wright-Mitchell Chief Legal Officer