ACELRX PHARMACEUTICALS INC
Form 8-K
February 24, 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): February 24, 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" or "AcelRx") will participate in various meetings with securities analysts and investors and will utilize a presentation handout during those meetings. The presentation handout has been updated to include confirmation of completion of the Zalviso system bench test evaluating the rate of optical system and total system errors. This test was designed to respond to issues identified in the Complete Response Letter (CRL) issued by the U.S. Food and Drug Administration, (FDA) relating to Zalviso in July 2014. Results from the Zalviso system bench test will be submitted to the FDA as part of the resubmission of the Zalviso New Drug Application, or NDA. The bench testing included 700 Zalviso systems. The actual error rate observed during the bench testing was lower than the target error rate discussed with the FDA and included in the bench test protocol submitted to and reviewed by the FDA. While the testing met the pre-specified endpoint, the results of the bench testing are subject to FDA test review. We have also received feedback from the FDA on the protocols submitted for the proposed Human Factor (HF) studies to review modifications to the Instructions For Use and system training screens to address misplaced tablets. The FDA had no additional comments on the HF protocols submitted in November 2014, and stated that "the proposed protocols are acceptable." The presentation handout confirms completion of the first of these HF studies, in healthy volunteers, which demonstrated that patients were able to follow and implement the revised instructions. The presentation handout also confirms completion of the second HF study in post-operative patients. We are waiting for the results from the second HF study. The results of both HF studies are subject to FDA review.

The presentation handout, together with a slide setting forth certain cautionary language intended to qualify the forward-looking statements included in the presentation handout, are furnished as Exhibit 99.1 to this Current Report and are incorporated herein by reference. The presentation handout will also be made available in the "Investor Relations" section of AcelRx Pharmaceuticals, Inc.'s website, located at www.acelrx.com.

The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 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 and in the accompanying Exhibit 99.1 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.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

**Exhibit Description**

**Number**

99.1 Slide presentation entitled, “AcelRx Pharmaceuticals, Inc. February 24, 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.

| | | |
|---|---|---|
| | ACELRX | |
| Date: February 24, 2015 | PHARMACEUTICALS, INC. | |
| | | /s/ |
| | By: | Timothy E. Morris |
| | | Timothy E. Morris |
| | | Chief Financial Officer |

**INDEX TO EXHIBITS**

| Exhibit Number | Description |
|---|---|
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