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 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 8.01. Other Events.

On July 24, 2015, AcelRx Pharmaceuticals, Inc., or AcelRx, issued a press release titled "AcelRx Announces Positive CHMP Opinion for Zalviso in the Management of Acute Moderate-to-Severe Post-Operative Pain in Adult Patients." A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated July 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.

Date: July 24, 2015

ACELRX PHARMACEUTICALS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated July 24, 2015.

Exhibit 99.1

AcelRx Announces Positive CHMP Opinion for Zalviso in the Management of Acute Moderate-to-Severe Post-Operative Pain in Adult Patients

REDWOOD CITY, Calif. – DATE – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), has adopted a positive opinion for Zalviso™ (sufentanil sublingual tablet system). The opinion, while not binding, recommends marketing authorization for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. Zalviso is an investigational drug-device combination product designed to deliver a sublingual formulation of sufentanil 15 mcg via a proprietary pre-programmed, non-invasive, patient-controlled device. Grunenthal Group, AcelRx's licensee in Europe, submitted the Marketing Authorization Application (MAA) under the centralized procedure in July of 2014.

"We believe that Zalviso represents a significant advancement in the management of acute pain, including the moderate-to-severe acute pain experienced by patients recovering from surgery. With this positive opinion from CHMP, Grunenthal and AcelRx are one step closer to bringing a non-invasive, self-dosing, pain management system to the estimated 15.7 million Europeans who undergo surgeries associated with moderate-to-severe post-operative pain every year," stated Howie Rosen interim chief executive officer of AcelRx Pharmaceuticals. "We appreciate the collaborative approach of the CHMP and look forward to continued collaboration with EMA to complete the regulatory process."

The positive opinion by the CHMP will next be reviewed by the European Commission for central marketing authorization in the European Union (EU), which has the authority to approve medicines for the 28 member countries of the EU which will also be valid in Norway, Iceland and Liechtenstein. If approved, Grunenthal expects to launch Zalviso beginning in the first half of 2016. In addition, AcelRx would be eligible to receive a $15 million milestone payment from Grunenthal upon approval.

AcelRx had previously received CE Mark approval of the Zalviso device and ISO certification of its quality management system issued by the British Standards Institution, or BSI, a Notified Body. Under the terms of the collaboration, Grunenthal is responsible for all commercial activities for Zalviso, including obtaining and maintaining pharmaceutical product regulatory approval in the Grunenthal territory. AcelRx will be responsible for maintaining device regulatory approval in the Grunenthal territory and manufacturing and supply of Zalviso to Grunenthal for commercial sales and clinical trials.

About Zalviso™

Zalviso is an innovative pre-programmed, non-invasive, handheld system that allows hospital patients with acute moderate-to-severe post-operative pain to self-dose with sufentanil sublingual tablets, 15 mcg, to manage their pain. The system is designed to help address certain problems associated with post-operative analgesia, such as the side effects and delayed analgesic effect of morphine, the invasive intravenous (IV) route of delivery of current systems for patient-controlled analgesia (PCA) and the complexity of infusion pumps used for IV PCA delivery. Grunenthal holds the rights for Zalviso in Europe and Australia while AcelRx retains all rights in North America, Asia, Latin America and Middle East/Africa.

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. AcelRx's product candidate, Zalviso, is designed for 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 submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for Zalviso in the treatment of moderate-to-severe acute pain in adult patients in the hospital setting and on July 25, 2014, received a Complete Response Letter (CRL) from the FDA. In March 2015, AcelRx received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies AcelRx had completed in response to the issues identified in the CRL, an additional clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. AcelRx submitted a formal meeting request to the FDA and this request was denied. AcelRx is currently evaluating its next steps to seek a pathway forward towards gaining approval of Zalviso in the U.S., including potential additional clinical studies, additional Human Factors studies, or the formal dispute resolution process provided for by the FDA. In March 2015, AcelRx initiated SAP301, a pivotal Phase 3 study for ARX-04 (sufentanil sublingual tablet, 30 mcg), a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting. AcelRx expects top-line data from this study in the fourth quarter of 2015. 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 process and timing of anticipated future development of AcelRx's product candidates, including Zalviso and ARX-04; statements related to the therapeutic and commercial potential of Zalviso; the size of the European market; potential approval and timing of commercial launch of Zalviso in Europe; potential milestone payments under the Grunenthal agreement; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the U.S., including potential additional clinical studies, additional Human Factors studies, additional data analyses, or the dispute resolution processes provided for by the FDA; and the anticipated timing of the Phase 3 ARX-04, SAP-301 trial's top line results.

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: any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso, in the United States and Europe, and ARX-04; inability to successfully manufacture Zalviso to meet the requirements of Grunenthal and potential delays in the timing of the European launch; the market potential for its product candidates, including Zalviso, in the United States and Europe, and ARX-04; its ability to obtain sufficient financing to receive regulatory approval for and commercialize Zalviso in the United States, and complete Phase 3 clinical development of ARX-04; AcelRx Pharmaceuticals' ability to finalize the pathway towards timely resubmission of the Zalviso NDA to the FDA, including its ability to use the dispute resolution process provided for by the FDA; potential additional clinical trials, Human Factors studies, and/or additional data analyses necessary in order to resubmit the Zalviso NDA; the ability to maintain compliance with contractual compliance matters and requirements; 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 5, 2015. 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.