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 22, 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 September 22, 2015, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release entitled "AcelRx Pharmaceuticals Reports that the European Commission has Granted Marketing Authorization for Zalviso™ for Treatment of Acute Moderate-to-Severe Post-Operative Pain in Adult Patients," 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 22, 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: September 22, 2015

ACELRX PHARMACEUTICALS, INC.

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

Exhibit 99.1

AcelRx Pharmaceuticals Reports that the European Commission has Granted Marketing Authorization for Zalviso™ for Treatment of Acute Moderate-to-Severe Post-Operative Pain in Adult Patients

Approval triggers $15 million milestone payment to AcelRx from Grunenthal

REDWOOD CITY, Calif., Sept. 22, 2015 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX) (AcelRx) announced today that the European Commission (EC) has approved Zalviso™ (15 micrograms sufentanil sublingual tablets) for the management of acute moderate-to-severe post-operative pain in adult patients. The marketing authorization is granted for the 28 EU member states as well as for the European Economic Area (EEA) countries, Norway, Iceland and Liechtenstein. Zalviso is a system combining a drug and a device designed to deliver a sublingual tablet formulation of sufentanil 15 mcg via a proprietary, pre-programmed, non-invasive, patient-controlled analgesia (PCA) device. Grunenthal Group, AcelRx's licensee in Europe and Australia, expects the product to be available to Western European patients in the first half of 2016.

"This is a significant event for AcelRx. Not only is this the Company's first marketing approval, but it represents the successful development and commercialization of a product that we believe will provide a new way for physicians and their patients to treat acute moderate-to-severe post-operative pain using an innovative delivery method," stated Howie Rosen, interim chief executive officer of AcelRx Pharmaceuticals. "Our partner Grunenthal will be working with the member states of the EU and EEA to ensure that Zalviso is made available to those patients who would benefit from an effective and reliable solution for their moderate-to-severe post-surgical pain."

Zalviso is designed to offer sustained (for up to 72 hours) and reliable pain relief for acute moderate-to-severe post-operative pain. In a Phase 3 clinical trial in patients who had undergone major joint replacement or open abdominal surgery, a higher percentage of study participants who self-administered Zalviso over a 48-hour period rated the method of pain control "good" or "excellent" compared to those using intravenous (IV) morphine PCA ($p=0.007$). Moreover, patients surveyed in this study rated their overall ease of care ($p<0.001$) and overall satisfaction ($p=0.004$) with Zalviso as higher than with IV morphine PCA. Zalviso was also rated by nurses to provide higher treatment satisfaction ($p<0.001$) and overall ease of care ($p=0.017$) compared with IV morphine PCA. Adverse events reported in the study were generally mild or moderate in nature and similar in both placebo and treatment groups, however fewer patients using Zalviso™ experienced oxygen desaturation episodes < 95% ($p=0.028$).

Dott. Alberto Grua, chief commercial officer Europe, Australia, North America & Global Product Supply (CCO EU, AUS, NA & GPS) from Grunenthal, adds, "We are delighted to bring a new, innovative way to manage post-operative pain to European healthcare professionals and patients. By combining the benefits of patient-controlled analgesia with those of a non-invasive route of administration, Zalviso offers a unique solution to address unmet needs of adult patients suffering from acute moderate-to-severe post-operative pain."

On an annual basis, there are 19 million surgical procedures with associated acute moderate-to-severe post-operative pain in the European Union. A recent German survey in patients after surgery has shown that 55% of all patients are not satisfied with their treatment for post-operative pain1. Even more so, 30% mention that their pain management has been inadequately effective [1 Maier C et al. Dtsch Arztebl Int. 2010; 107; 607-614].

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 drug-related 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. Under the terms of the collaboration, Grunenthal is responsible for maintaining the regulatory approval for the drug product and all commercial activities for Zalviso, in the Grunenthal territory. AcelRx will be responsible for maintaining device regulatory approval in the Grunenthal territory, as well as manufacturing and supply of Zalviso to Grunenthal for commercial sales and clinical trials.

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. In the US, the Company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg) for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso (sufentanil sublingual tablet system) for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

ARX-04 delivers 30 mcg sufentanil sublingual, a high therapeutic index opioid, through a disposable, pre-filled, single-dose applicator (SDA). AcelRx has reported positive results from the pivotal Phase 3 SAP301 ambulatory surgery study, and will be advancing ARX-04 into a study in emergency room patients in 2015. Zalviso delivers 15 mcg sufentanil sublingual tablets through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. Zalviso is approved in the EU as well as Norway, Iceland and Liechtenstein and is in late-stage development in the U.S. In response to the New Drug Application (NDA) AcelRx submitted to the U.S. Food and Drug Administration (FDA) seeking approval for Zalviso, the Company received a Complete Response Letter (CRL) on July 25, 2014. The FDA has requested an additional clinical study prior to the resubmission of the Zalviso NDA.

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 timing of any commercial launch of Zalviso; commercial success of Zalviso in the market place, the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates, including Zalviso and ARX-04, the process and timing of anticipated future development of AcelRx's product candidates, including Zalviso and ARX-04, and any regulatory approval of AcelRx product candidates in the US.

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: therapeutic and commercial potential for AcelRx Pharmaceuticals' product candidates, including Zalviso and ARX-04; ability to complete Phase 3 development for ARX-04, file an NDA and to receive regulatory approval for ARX-04; the success, cost and timing of all product development activities and clinical trials, including the Phase 3 ARX-04 trial. 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.