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 9, 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 9, 2015, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release entitled "AcelRx Pharmaceuticals' ARX-04 Meets all Endpoints in Pivotal Phase 3 Study for Moderate-to-Severe Acute Pain," 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 9, 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 9, 2015

ACELRX PHARMACEUTICALS, INC.

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

Exhibit 99.1

AcelRx Pharmaceuticals' ARX-04 Meets all Endpoints in Pivotal Phase 3 Study for Moderate-to-Severe Acute Pain

Detailed SAP301 Results to be Presented at the American Society of Anesthesiologists Annual Meeting October 24-28, 2015 in San Diego, CA.

REDWOOD CITY, Calif. -- September 9, 2015 -- 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 ARX-04 (sufentanil sublingual tablet, 30 mcg) met primary and secondary endpoints in a multi-center, double-blind, placebo-controlled Phase 3 trial (SAP301) designed to study the short-term treatment of patients with moderate-to-severe acute pain following ambulatory abdominal surgery. Results demonstrated that patients receiving ARX-04, administered via a disposable, pre-filled, single-dose applicator (SDA), experienced significantly greater pain reduction compared to placebo, as measured by the time-weighted summed pain intensity difference over the first 12 hours of treatment (SPID-12) ($p<0.001$). Adverse events reported in the study were typical of opioid therapy and were similar for patients treated with ARX-04 and placebo, the most common of which were nausea, headache and vomiting.

"These results bring AcelRx one step closer to commercializing a sublingual sufentanil product that we believe will have a meaningful impact by providing a non-invasive treatment of moderate-to-severe acute pain in several medically supervised settings," said Dr. Pamela Palmer, founder and chief medical officer of AcelRx Pharmaceuticals. "We look forward to working with the FDA and the Department of Defense to complete the development of ARX-04 and bring this novel and much needed product to market."

The Phase 3 SAP301 trial enrolled adult patients undergoing outpatient abdominal surgery procedures at four clinical sites in the United States. Following surgery, 163 patients were randomized to receive either ARX-04 or placebo in a 2:1 active to placebo ratio. ARX-04 or placebo was administered by site staff as requested by the patient, but no more than once per hour. The intent-to-treat (ITT) population in this study averaged 40.9 years of age with an average Body Mass Index of 27.5, and had a higher percent of females to males (68%:32%). Eighty-nine percent of patients entering the study completed the 24-hour study period.

The primary endpoint of the study was the difference in the SPID-12 score of patients receiving ARX-04 compared to those receiving placebo. SPID-12 scores were +25.8 for ARX-04-treated patients and +13.1 for placebo-treated patients; the difference between the two groups being highly statistically significant ($p<0.001$). Notably, the difference in pain intensity from baseline was superior for ARX-04 over placebo at the earliest time point measured (15 minutes; $p=0.002$). Secondary efficacy endpoints, which will be presented in detail at the upcoming American Society of Anesthesiologists Annual Meeting, were also superior for ARX-04 compared to placebo.

There were two serious adverse events (SAEs) reported during the study period, both of which were in the placebo group and resulted in early termination of the affected patients. No patient in the ARX-04 group dropped out of the study prior to 24 hours due to an adverse event. A lower percent of patients treated with ARX-04 dropped out of the study prior to 24 hours due to lack of efficacy compared to the placebo group (3.7% and 18.5%, respectively; $p=0.002$).

“In addition to the ambulatory surgery setting studied in this trial, we believe ARX-04 has broad application in emergency room and military settings, where patients often do not have immediate access to IV pain medications,” added Howie Rosen, interim chief executive officer of AcelRx. “To that end, we expect to initiate a study this year in emergency room patients. Beyond the ER, we are researching other medically supervised settings in which ARX-04’s non-invasive, rapid-acting profile would benefit patients.”

About ARX-04
ARX-04 is an investigational product candidate consisting of sufentanil sublingual tablets, 30 mcg, delivered via a disposable, pre-filled, single-dose applicator (SDA). AcelRx is developing ARX-04 for the management of moderate-to-severe acute pain in a variety of medically supervised settings, including in the emergency room, for outpatient or ambulatory surgery, for non-surgical patients experiencing pain in the hospital, or for post-operative patients, following short-stay surgery, who do not require more long-term patient-controlled analgesia (PCA). Based on its market research, the Company estimates there are more than 51 million injury-related emergency department visits annually that on average receive 2 doses of opioids for moderate to severe pain in the United States. ARX-04 is funded in part by the US Army Medical Research and Materiel Command (USAMRMC).

About Acute Pain
In situations of trauma or injury, it is advantageous to have a non-invasive method of treating acute pain. In the battlefield, in the emergency room and in ambulatory care environments, patients often do not have immediate intravenous, or IV, access available. Intramuscular injections are the current standard of care on the battlefield, but they are invasive, painful, and present an increased risk of infection to both patient and healthcare professional. In addition, in cases of severe trauma where the patient is often in hypovolemic shock and muscles are not well perfused, pain medication given by intramuscular injection may not readily reach the blood stream to provide pain relief, rendering this route of delivery suboptimal. Oral pills and liquids generally have erratic onset of analgesia. Moreover, IV dosing results in high peak plasma levels, thereby limiting the opioid dose and requiring frequent redosing intervals to titrate to satisfactory analgesia. Additional treatment options are needed which can safely and effectively treat acute pain, in both civilian and military settings.

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. 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 tablets) 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 through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. 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. Results of bench testing and two Human Factors studies were provided to the FDA to address matters raised in the Letter. During subsequent communications with the FDA, including a Type C meeting that was held in September 2015, the FDA reiterated the request to complete a 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.

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