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 15, 2016

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 15, 2016, the Company issued a press release entitled "AcelRx Reports Positive Results for ARX-04 (sufentanil sublingual tablet, 30 mcg), Including in Elderly Patients and Patients with Organ Impairment, in Third Phase 3 Registration Trial, SAP303," 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 15, 2016.

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 15, 2016

ACELRX PHARMACEUTICALS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated September 15, 2016.

Exhibit 99.1

AcelRx Reports Positive Results for ARX-04 (sufentanil sublingual tablet, 30 mcg), Including in Elderly Patients and Patients with Organ Impairment, in Third Phase 3 Registration Trial, SAP303

- Majority of Patients Had No Adverse Event; Similar Across All Subgroups
- Pain Intensity Was Reduced by 27% at 1 Hour, 49% at 2 Hours, 57% at 12 Hours
- Phase 3 Program Now Complete; AcelRx Intends to Submit ARX-04 NDA This Year

REDWOOD CITY, California, September 15, 2016 – AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX) today announced that in an open-label Phase 3 trial (SAP303), investigational product candidate ARX-04 (sufentanil sublingual tablet 30 mcg) was well tolerated in the management of moderate-to-severe acute pain in post-operative study patients, including elderly patients and those with organ impairment. Regardless of age and organ function, approximately 2 in 3 patients had no adverse events during the study (63% of all patients, 63% of those aged ≥65 years, 62% of those with hepatic impairment, 70% of those with renal impairment). The most common adverse events were nausea and headache. On a global assessment of ARX-04 as a method of pain control, 90% of healthcare professionals and 87% of patients responded "good" or "excellent."

"Following short-stay in-hospital surgery, post-operative patients who do not require long-term analgesia still need safe and effective short-term pain management for efficient discharge," said Pamela Palmer, MD, PhD, co-founder and Chief Medical Officer of AcelRx Pharmaceuticals. "In the SAP303 trial, I was impressed that the majority of patients—including the majority of higher-risk patients—did not experience any adverse events."

SAP303 (NCT02662556) is a multicenter, single-arm, open-label Phase 3 trial that enrolled 140 patients aged ≥40 years who were expected to have moderate-to-severe acute pain after surgery. The primary objective of SAP303 was to study the safety of ARX-04 in the post-operative management of moderate-to-severe acute pain. Recruitment included patients aged ≥65 years and patients with comorbidities.

The mean age for all patients in SAP303 was 54.7 years, and 17% of patients were aged ≥65 years. More than 1 in 4 patients (29%) had some degree of baseline hepatic and/or renal impairment. Nearly 7 in 10 patients (69%) were American Society of Anesthesiologists Physical Status Classification II or III (mild or severe systemic disease). During the 12-hour study period, the mean total number of ARX-04 doses administered was 3.3, which was similar for patients with normal and impaired liver function and for patients with normal and impaired renal function. The mean inter-dosing interval was more than 3 hours (193 minutes).

Safety variables included the assessment of adverse events, vital signs (blood pressure, heart rate, and respiratory rate), and oxygen saturation. The primary efficacy variable was the time-weighted summed pain intensity difference over the 12-hour study period (SPID12), and secondary efficacy variables included pain intensity by evaluation time point.

Safety results showed that, overall, there were no differences in adverse events between patients with normal and impaired liver function or between patients with normal and impaired renal function. No clinically meaningful changes from baseline in vital signs or oxygen saturation were observed, and no opioid reversal agents were needed in the study.

The primary and secondary efficacy endpoints showed a reduction in pain intensity starting at 30 minutes after the first dose of ARX-04, followed by 27%, 49%, and 57% reductions in mean pain intensity from a baseline mean pain score of 6.2 at 1 hour, 2 hours, and 12 hours, respectively.

“Following surgery, and especially following short-stay in-hospital surgery, there is a significant unmet need for an efficacious opioid with good tolerability, particularly in higher-risk patients,” said Maurice Jové, MD, who is Medical Director of the Joint Solutions Center at DeKalb Medical and an orthopedic surgeon at Atlanta Knee and Sports Medicine in Decatur, Ga. “ARX-04, if approved, could be the treatment option to meet that need.”

Today’s announcement marks the completion of the ARX-04 Phase 3 clinical program, which comprises SAP303 and 2 earlier Phase 3 trials in patients with moderate-to-severe acute pain:

- SAP301, an ambulatory surgery study that reported positive results in 2015 at the American Society of Anesthesiologists annual meeting
- SAP302, an emergency room study that reported positive results in 2016 at the Military Health System Research Symposium (MHSRS)

With positive data from all 3 studies, AcelRx intends to submit a new drug application (NDA) for ARX-04 for the treatment of moderate-to-severe acute pain in medically supervised settings with the U.S. Food and Drug Administration (FDA) by the end of 2016.

Conference Call
AcelRx will conduct a conference call and webcast this morning, September 15, at 9:00 a.m. Eastern time (6:00 a.m. Pacific time) to discuss the trial results. To listen to the conference call, dial in approximately ten minutes before the scheduled call 877-407-9129 for domestic and Canadian callers, or 201-493-6753 for international callers. Those interested in listening to the conference call live via the Internet may do so by visiting the Investors section of the company's website at www.acelrx.com. A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investors section of the company's website at www.acelrx.com.

Clinical and Rehabilitative Medicine Research Program (CRMRP)
ARX-04 is funded in part by the Clinical and Rehabilitative Medicine Research Program (CRMRP) of the U.S. Army Medical Research and Materiel Command (USAMRMC) under contract No. W81XWH-15-C-0046. The CRMRP was established in 2008 to foster research and technology advances for regeneration, restoration, and rehabilitation of traumatic injuries.

In accordance with USAMRMC guidelines, in the conduct of clinical research, AcelRx has adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects).

About ARX-04
ARX-04 is a non-invasive investigational product candidate consisting of 30-mcg sufentanil tablets delivered sublingually by a healthcare professional using a disposable, pre-filled, single-dose applicator (SDA). Sufentanil is a synthetic opioid analgesic with a high therapeutic index and no known active metabolites.

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), designed for the treatment of moderate-to-severe acute pain in medically supervised settings; and Zalviso® (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting. Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, non-invasive, patient-controlled analgesia device. Zalviso is approved in the E.U. as well as Norway, Iceland, and Liechtenstein and is investigational and in late-stage development in the U.S. Grunenthal Group holds the rights for Zalviso in Europe and Australia, while AcelRx retains all other world-wide rights.

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, ARX-04 (sufentanil sublingual tablet, 30 mcg) and Zalviso® (sufentanil sublingual tablet system), including the ARX-04 clinical trial results; anticipated submission of the New Drug Application, or NDA, for ARX-04 to the U.S. Food and Drug Administration, or FDA; AcelRx's pathway forward towards gaining approval of Zalviso in the U.S.; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for ARX-04 and Zalviso. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitation, risks related to AcelRx Pharmaceuticals' ARX-04 development program, including anticipated submission of the ARX-04 NDA and the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 studies of ARX-04; AcelRx's ability to successfully execute the pathway towards a resubmission of the Zalviso NDA, including the successful initiation and completion of the IAP312 clinical study for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates including ARX-04 in the United States and Europe, and Zalviso in the United States; the uncertain clinical development process, including adverse events; the risk that planned clinical trials, including the IAP312 clinical study for Zalviso, may not begin on time, have an effective clinical design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on July 29, 2016. AcelRx 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.

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