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): December 13, 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 December 13, 2016, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it had submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for ARX-04 (sufentanil sublingual tablet, 30 mcg). A copy of the press release 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 December 13, 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: December 13, 2016

ACELRX PHARMACEUTICALS, INC.

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release dated December 13, 2016.

Exhibit 99.1

AcelRx Pharmaceuticals Submits New Drug Application for ARX-04 for the Treatment of Moderate-To-Severe Acute Pain

REDWOOD CITY, Calif., December 13, 2016 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain, announced that it has submitted a New Drug Application (NDA) under section 505(b)(2) with the U.S. Food and Drug Administration (FDA) for ARX-04 (sufentanil sublingual tablet, 30 mcg) for the treatment of patients experiencing moderate-to-severe acute pain in a medically supervised setting.

The NDA contains results of the entire ARX-04 clinical program, including data from four clinical trials in which ARX-04 was assessed as a treatment for moderate-to-severe acute pain in postoperative and emergency department patients. In each of these clinical studies, patients treated with ARX-04 demonstrated improvements in pain intensity as early as 15-to-30 minutes after the start of dosing. Adverse events reported in the studies were typical of opioid therapy, with the most common being nausea, headache, vomiting and dizziness. For more details on these trials, please visit the ARX-04 webpage on the AcelRx website.

“During my career before AcelRx, I saw first-hand the challenges of treating pain with IV opioids; and through our market research, it’s clear that my experiences were not isolated,” explained Dr. Pamela Palmer, co-founder and chief medical officer at AcelRx. “Even today, needs exist for non-invasive, cost-effective pain management in the emergency room, ambulatory surgical center, pre-hospital care, battlefield, and other diverse medical settings. We believe that ARX-04, with its sublingual delivery, could offer physicians and nurses a valuable treatment option in the treatment of moderate-to-severe acute pain. ”

Howie Rosen, AcelRx’s chief executive officer, added, “The submission of the ARX-04 NDA is a significant corporate milestone for AcelRx. We are in the process of completing our commercialization plans so that we will be ready for an initial pilot launch in 2017, should ARX-04 be approved by the FDA. We also are using the NDA to prepare a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) with a target submission date in the first half of 2017 and are continuing to talk with potential European partners for ARX-04.”

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 505(b)(2) Designation

Under the FDA's 505(b)(2) regulatory pathway, FDA may consider data not developed by the applicant when reviewing an NDA. It also allows the potential for fewer pivotal Phase 3 studies and/or the enrollment of a smaller number of patients than is typical. These allowances may reduce the length and cost of a drug's regulatory path. In addition, the drug, once approved by the FDA, is eligible for three years of market exclusivity.

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 moderate-to-severe acute pain. An NDA for ARX-04 (sufentanil sublingual tablet, 30mcg) with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, was recently submitted to the FDA for review.

The Company's other late stage product, Zalviso® (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting, is currently enrolling patients in a Phase 3 clinical trial, IAP312. Zalviso delivers 15 mcg sufentanil sublingually 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 investigational and in late-stage development in the U.S. Grunenthal Group holds the rights for Zalviso in Europe, where a commercial launch has begun, 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 U.S. Food and Drug Administration, or FDA, review of the New Drug Application, or NDA, for ARX-04; the ARX-04 clinical trial results; 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 and market size 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; the uncertain clinical development process; the success, cost and timing of all development activities and clinical trials; actual market size for AcelRx products; 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 November 2, 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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