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 30, 2013

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.)**

575 Chesapeake 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 30, 2013, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Zalviso™ (sufentanil sublingual microtablet system). 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 September 30, 2013.

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 30, 2013

ACELRX PHARMACEUTICALS, INC.

By: /s/ James H. Welch
James H. Welch
Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release dated September 30, 2013.

Exhibit 99.1

FOR IMMEDIATE RELEASE

AcelRx Pharmaceuticals Submits New Drug Application to the FDA for Zalviso™

Zalviso NDA submitted for the management of moderate-to-severe acute pain in adult patients in the hospital setting

REDWOOD CITY, Calif., September 30, 2013 – 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 it submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Zalviso ™ (sufentanil sublingual microtablet system). Zalviso is a patient-activated, non-invasive analgesic system, which delivers 15 mcg sufentanil per dose as needed for pain control, subject to a 20 minute lockout period between doses. The proposed indication for Zalviso is the management of moderate-to-severe acute pain in adult patients in the hospital setting. The NDA submission is based primarily on data from a Phase 3 registration program that included two double-blind randomized placebo-controlled clinical trials, one conducted in patients following major abdominal surgery, the other in patients following major joint replacement surgery. Additionally, a Phase 3 open-label active-comparator trial was conducted in patients following either major abdominal or orthopedic surgery, comparing Zalviso to the current standard of care, intravenous patient-controlled analgesia (IV PCA) with morphine. Zalviso successfully achieved the primary efficacy endpoints for each of these studies. Treatment-emergent adverse events were typical of opioid usage post-operatively, were generally mild-to-moderate in nature, and were similar in both active- and placebo-treatment groups for the majority of adverse events.

“The Zalviso NDA submission represents a major milestone for AcelRx as we seek FDA approval for our first product candidate based on our proprietary sublingual sufentanil formulation and our delivery system technology,” stated Richard King, president and CEO of AcelRx. “Based on the results of our clinical trials, we believe Zalviso has demonstrated an ability to achieve rapid onset of pain relief, thereby enabling patients to manage their moderate-to-severe acute pain effectively over 48 to 72 hours post-surgery. If approved by the FDA, Zalviso could provide hospitals and patients with an attractive alternative to the current standard of care, specifically IV PCA-delivered opioids.”

The NDA submission required payment to the FDA of a $1.95 million NDA filing fee in the third quarter of 2013, which will be included in the Company’s income statement as an additional research and development expense. FDA regulations allow for the waiver of the NDA filing fee if the Company is filing its first NDA and qualifies as a small business with less than 500 employees. The FDA requested the Small Business Administration (SBA) to determine if AcelRx was a small business, and the SBA recently ruled that AcelRx could not qualify as a small business.

Previously Reported Phase 3 Clinical Trial Results for Zalviso

The 505(b)(2) NDA submission for Zalviso is based on a comprehensive development program and includes data from AcelRx's three Phase 3 clinical trials. As previously reported, Zalviso met the FDA-agreed primary endpoints in the two double-blind, placebo-controlled Phase 3 registration studies conducted in patients who had undergone major open-abdominal surgery or orthopedic surgery that involved either knee or hip replacement procedures. In each of these trials, patients treated with Zalviso to manage their post-surgical pain reported a greater sum of the pain intensity difference to baseline over 48 hours (SPID-48) compared to placebo-treated patients ($p=0.001$ and $p<0.001$, respectively). Adverse events considered possibly or probably related to treatment were generally mild-to-moderate in nature and similar for the majority of adverse events between Zalviso- and placebo-treated patients, with the exception of itching, which was significantly greater ($p < 0.05$) in the Zalviso-treated group.

The third Phase 3 study, an open-label, active-comparator trial comparing Zalviso to IV PCA with morphine demonstrated that:

- Zalviso was non-inferior ($p<0.001$) to IV PCA morphine based on the primary endpoint of Patient Global Assessment of method of pain control comparison over the 48-hour trial period (PGA48) as determined by the combined percentage of patients with PGA ratings of "good" or "excellent".
- A secondary comparison of the primary endpoint demonstrated that Zalviso was statistically superior to IV PCA morphine for the PGA48 endpoint ($p=0.007$). Statistically superior and non-inferior PGA comparisons for Zalviso compared to IV PCA morphine were also seen at the 24-hour and 72-hour time points.
- Secondary endpoints of summed pain intensity, summed pain relief, and dropouts due to inadequate analgesia over the 48-hour study period were similar between treatment groups.

Zalviso had a significantly faster reduction in pain intensity compared to IV PCA morphine in the first 4 hours of treatment. Fewer patients experienced oxygen desaturation events below 95% in the Zalviso-treated group compared to the IV PCA morphine-treated patients ($p=0.028$). In addition, both nurses and patients rated Zalviso significantly higher for Overall Satisfaction and Ease of Care compared to IV PCA with morphine. Overall, adverse events in the comparison trial were similar and most were mild-to-moderate in nature in both treatment groups.

About Zalviso

Zalviso is an investigational pre-programmed, non-invasive, handheld system that allows hospital patients with moderate-to-severe acute pain to self-dose with sublingual sufentanil microtablets to manage their pain. Zalviso is designed to address the limitations of IV PCA by offering:

- *A high therapeutic index opioid* - Zalviso uses the high therapeutic index opioid sufentanil. It offers hospitalized adult patients with moderate-to-severe acute pain the potential for effective patient-controlled analgesia with a low incidence of drug-related side effects.
- *A non-invasive route of delivery* - The sublingual route of delivery used by Zalviso provides rapid onset of analgesia, and also eliminates the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections in IV PCA treated patients. In addition, because Zalviso patients do not require direct connection to an IV PCA infusion pump through IV tubing, Zalviso allows for ease of patient mobility.
- *A simple, pre-programmed PCA solution* - Zalviso is a pre-programmed PCA system designed to eliminate the risk of infusion pump programming errors.

About Moderate-to-Severe Acute Pain

Moderate-to-severe acute pain management in the hospital remains a challenge for healthcare providers

with up to 75% of patients reporting inadequate pain relief following surgery. Inadequate treatment of moderate-to-severe pain can lead to decreased mobility, which increases the risks for serious medical complications, including deep vein thrombosis and partial lung collapse, potentially resulting in extended hospital stays. Approximately 12 million surgical procedures per year result in moderate-to-severe pain in the U.S., with an additional 7.4 million hospital inpatients in the U.S. annually experiencing moderate-to-severe acute pain from other, non-post surgical, medical conditions. Currently, patients experiencing moderate-to-severe acute pain in the hospital may have IV PCA treatment, typically utilizing morphine or hydromorphone. However, there are deficiencies associated with the current use of IV PCA that can negatively impact patient safety, well-being and recovery. These include drug-related side effects associated with morphine or hydromorphone, complications associated with IV delivery and medication delivery errors typically associated with misprogramming of the complex IV PCA pumps.

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 and breakthrough pain. AcelRx's lead product candidate, Zalviso™, is designed to solve the problems associated with post-operative intravenous patient-controlled analgesia which has been shown to cause harm to patients following surgery because of the side effects of morphine, the invasive IV route of delivery and the complexity of infusion pumps. AcelRx has announced positive results from each of the three Phase 3 clinical trials for Zalviso and has submitted an NDA to the FDA seeking its approval. AcelRx has also announced positive top-line results for a Phase 2 trial for ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from the U.S. Army Medical Research and Materiel Command. 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 therapeutic benefits of Zalviso, the process and timing of anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, the commercial potential of Zalviso and the anticipated timing and therapeutic and commercial potential of AcelRx Pharmaceuticals' other product candidates. 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: the fact that FDA may not accept for filing Zalviso NDA; ability to obtain regulatory approval for Zalviso, including whether the results of the Phase 3 clinical trials for Zalviso are sufficient to obtain marketing approval for Zalviso, which depends on the ability of AcelRx to demonstrate to the satisfaction of the FDA the safety and efficacy of Zalviso based upon its findings of the Phase 3 trials; any delays or inability to obtain and maintain regulatory approval of its product candidates in the United States and Europe; its ability to attract funding from partners or collaborators with development, regulatory and commercialization expertise; its ability to obtain sufficient financing to complete registration of its product candidates in the United States and Europe; the market potential for its product candidates; resolution of the determination of AcelRx Pharmaceutical's status as a small business by SBA; the accuracy of AcelRx Pharmaceuticals' estimates regarding expenses, capital requirements and needs for financing; 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 August 12, 2013. 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.

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