# 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) August 23, 2012**

# ACELRX PHARMACEUTICALS, INC.

**(Exact name of registrant as specified in 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 Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01. Other Events.**

On August 23, 2012, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release, a copy of which is attached as Exhibit 99.1 to this report.

On August 29, 2012, the Company issued a press release, a copy of which is attached as Exhibit 99.2 to this report.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated August 23, 2012. |
| 99.2 | Press Release dated August 29, 2012. |

**SIGNATURE**

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: August 31, 2012

**ACELRX PHARMACEUTICALS, INC.**

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

EXHIBIT INDEX

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press Release dated August 23, 2012. |
| 99.2 | Press Release dated August 29, 2012. |

**Exhibit 99.1**

**News Release**

## AcelRx Pharmaceuticals Initiates Third Phase 3 Clinical Trial for ARX-01, the Sufentanil NanoTab® PCA System, for the Treatment of Post-Operative Pain

### First orthopedic surgery patient dosed in randomized, double-blind, placebo-controlled trial

REDWOOD CITY, Calif., Aug. 23, 2012 /PRNewswire/ — 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 dosing of the first patient in the third of three planned Phase 3 studies for ARX-01, the Sufentanil NanoTab PCA System, its novel sublingual patient-controlled analgesia (PCA) system. This third ARX-01 Phase 3 study is a randomized, double-blind, placebo controlled efficacy and safety trial in adults following hip or knee replacement surgery.

“The start of our third Phase 3 clinical trial for ARX-01 is an important milestone for our lead Sufentanil NanoTab development program,” said Richard King, AcelRx’s president and CEO. “The results of all three Phase 3 registration studies are expected to form the basis of a New Drug Application for ARX-01, which we plan to submit to the FDA during the third quarter of 2013. The ARX-01 System is designed to provide an attractive post-operative pain treatment alternative compared to the current standard of care that utilizes intravenous pumps primarily delivering morphine.”

This third study is designed to enroll approximately 400 patients, randomized 3:1 to receive 15 mcg Sufentanil NanoTabs or placebo NanoTabs. Both treatments are being delivered via the ARX-01 system at a maximum dosing rate of one NanoTab every 20 minutes to control pain. Patients will be followed for a minimum of 48 hours and, as needed, up to 72 hours after randomization. The study will be conducted at approximately 45 academic and community hospitals in the U.S. The primary endpoint is the sum of the pain intensity difference to baseline, over the 48 hour study period, or SPID-48, which is the FDA standard for post-operative acute pain studies. Secondary endpoints include pain relief scores, patient global satisfaction ratings, and use of rescue medication. The ease of set up and operation of the ARX-01 system for nursing staff and patients, respectively, will also be measured through questionnaires. Topline results for the third Phase 3 clinical study are expected to be available during the first quarter of 2013.

In March 2012, AcelRx began its first Phase 3 clinical study for ARX-01, a randomized, double-blind, placebo-controlled efficacy and safety study for post-operative pain following major open abdominal surgery designed to enroll 150 patients. The primary endpoint for this study is SPID-48. In April 2012, the second Phase 3 clinical study for ARX-01 began. It is a randomized, multicenter, open-label, parallel group design that compares the efficacy and safety of the Sufentanil NanoTab PCA System to the standard of care, IV PCA with morphine, in the treatment of post-operative pain associated with major abdominal or orthopedic surgeries. The primary objective of the study, which is expected to enroll approximately 400 patients, is to compare ARX-01 to IV PCA with morphine in terms of patient global satisfaction with the method of pain relief. Patients in each of these two studies will be treated for a minimum of 48 hours after randomization and topline results for both clinical trials are expected during the fourth quarter of 2012.

### About Post-Operative Pain

Acute pain management in the hospital, in particular post-operative analgesia, remains a challenge for healthcare providers with up to 75% of patients reporting inadequate pain relief after surgery. Inadequate treatment of post-surgical pain can lead to decreased mobility, which increases the risks for medical complications, including deep vein thrombosis and partial lung collapse, potentially resulting in extended hospital stays. Over 23 million procedures per year result in moderate to severe post-operative pain in the major pharmaceutical markets (U.S., 5 main EU countries and Japan), resulting in $5.1 billion of acute pain treatment product sales in 2008.

**About ARX-01, the Sufentanil NanoTab PCA System**

ARX-01 is a pre-programmed, non-invasive, handheld system that allows post-operative patients to self-dose with sublingual Sufentanil NanoTabs to manage their post-operative pain. The ARX-01 System is designed to address the limitations of the current standard of care, IV PCA with morphine, by offering:

- **A high therapeutic index opioid:** Because ARX-01 uses the high therapeutic index opioid sufentanil, it offers post-operative pain patients 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 in ARX-01 provides rapid onset of analgesia, therefore eliminating the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections. In addition, because patients are not tethered to IV tubing and a pump for pain relief, ARX-01 allows for ease of patient mobility.
- **A simple, pre-programmed PCA solution**: ARX-01 is a pre-programmed PCA System designed to eliminate the risk of pump programming errors, which are a potential source of patient harm.

**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, the ARX-01 Sufentanil NanoTab PCA System, which is currently in Phase 3 clinical development, 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 inherent potential for programming and delivery errors associated with the complexity of infusion pumps. AcelRx has two additional product candidates which have completed Phase 2 clinical development: ARX-02 for the treatment of cancer breakthrough pain, and ARX-03 for mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician's office. AcelRx plans to initiate a Phase 2 study, pending protocol approval, for a fourth product candidate, ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from USAMRMC. 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 planned or anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the anticipated timing for clinical trials, progress towards initiation of the Phase 2 study for ARX-04, the timing of the top line data from all three Phase 3 clinical trials, the timing of submission of an NDA to the FDA and the therapeutic and commercial potential of AcelRx Pharmaceuticals' 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 success, cost and timing of AcelRx Pharmaceuticals' product development activities and clinical trials; the uncertain clinical development process, including the risk that planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; any delays or inability to obtain, regulatory approval of its product candidates; its ability to obtain adequate clinical supplies of the drug and device components of its product candidates; its ability to attract funding partners or collaborators with development, regulatory and commercialization expertise; its ability to obtain sufficient financing to complete development and registration of its product candidates in the United States and Europe; its ability to obtain and maintain regulatory approvals of its product candidates; the market potential for its product candidates; 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 for the three months ended June 30, 2012. 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.

SOURCE AcelRx Pharmaceuticals, Inc.

Jim Welch, Chief Financial Officer, +1-650-216-3511, jwelch@acelrx.com

**Exhibit 99.2**

**News Release**

## AcelRx Pharmaceuticals Receives Fourth and Fifth U.S. Patents for Small-Volume Oral Transmucosal Dosage Forms

### Two more U.S. patents expand intellectual property protection for AcelRx's pipeline of sufentanil NanoTab® pain products

REDWOOD CITY, Calif., Aug. 29, 2012 /PRNewswire/ — 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 the U.S. Patent and Trademark Office (USPTO) has recently issued AcelRx Patent Number 8,252,328 entitled "Bioadhesive Drug Formulations for Oral Transmucosal Delivery," and Patent Number 8,252,329 also entitled "Bioadhesive Drug Formulations for Oral Transmucosal Delivery." The '328 and '329 patents each make claims to a bioadhesive tablet for oral transmucosal administration of sufentanil. These newly issued patents will provide intellectual property protection for sufentanil NanoTab based products until at least January 5, 2027. AcelRx currently has more than 70 pending patent applications worldwide and continues to file additional new patent applications to further strengthen its market exclusivity.

"We have made significant progress this year in establishing our intellectual property portfolio, with five issued US patents now underpinning our novel NanoTab technology," said Richard King, AcelRx's President and CEO. "We look forward to building on this success through emphasis on the device aspects of our technology platforms as we seek multiple avenues of protection for our proprietary pipeline of product candidates."

The 8,252,328 patent is a composition of matter patent which provides protection in the United States for each of AcelRx's four development programs. The '328 patent covers AcelRx's proprietary NanoTab technology for delivering sufentanil with claims to a substantially homogenous bioadhesive tablet, comprising from about 2.5 to about 100 micrograms of sufentanil and a volume of from about 3 to about 15 microliters, which adheres throughout the period of drug delivery, generates a minimal saliva response and delivers a majority of the drug through the oral mucosa.

The 8,252,329 patent also covers the composition of sufentanil NanoTabs with claims to a bioadhesive tablet for sublingual administration to a subject, comprising from about 2.5 micrograms to about 100 micrograms of sufentanil, a volume of about 0.1 microliters to about 50 microliters, wherein the bioadhesive material is present at between 2% and 30% by weight, and the tablet generates a minimal saliva response and minimal swallowed drug and delivers at least 55% of the sufentanil through the oral transmucosal route. AcelRx exclusively owns both of these patents.

AcelRx also holds three other U.S. patents which claim both methods and compositions directed to sufentanil containing NanoTabs. Collectively these patents will provide intellectual property protection for sufentanil NanoTab based products in the United States through late 2030. European patent protection is provided by Patent Number EP2114383B1, which covers small-volume NanoTab dosage forms for transmucosal administration containing the opioid sufentanil. This European patent also covers elements of AcelRx's dispensing technology and provides patent protection of specific pharmacokinetic parameters derived from sublingual administration using the NanoTab technology.

**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, the ARX-01 Sufentanil NanoTab PCA System, which is currently in Phase 3 clinical development, 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 inherent potential for programming and delivery errors associated with the complexity of infusion pumps. AcelRx has two additional product candidates which have completed Phase 2 clinical development: ARX-02 for the treatment of cancer breakthrough pain, and ARX-03 for mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician's office. AcelRx plans to initiate a Phase 2 study, pending protocol approval, for a fourth product candidate, ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from USAMRMC. 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 AcelRx Pharmaceuticals' patent portfolio, including the useful life of its U.S. patents and the European patent, the continued expansion of its patent protection, market exclusivity, its ability to protect its proprietary technology, the scope of patent protection, and issued and planned or anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the execution of the Phase 3 clinical studies for ARX-01, the initiation of Phase 2 clinical trial for ARX-04, and the therapeutic potential of AcelRx Pharmaceuticals' 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 success, cost and timing of AcelRx Pharmaceuticals' product development activities and clinical trials; the success of its patent prosecution strategy; its ability to protect its proprietary technology, including the risks that pending patent applications may not result in issued patents; its ability to obtain sufficient financing to complete development and registration of its product candidates in the United States and Europe; its ability to obtain and maintain regulatory approvals of its product candidates; the market potential for its product candidates; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx Pharmaceuticals' U.S. Securities and Exchange Commission filings, including its Quarterly Report on Form 10-Q for the three months ended June 30, 2012. 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.

SOURCE AcelRx Pharmaceuticals, Inc.

Jim Welch, Chief Financial Officer, +1-650-216-3511, jwelch@acelrx.com