

**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): April 11, 2012

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State of
incorporation)

001-35068

(Commission
File No.)

41-2193603

(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

**575 Chesapeake Drive
Redwood City, CA 94063**

(Former Name or Former Address, if Changed Since Last Report)

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 April 11, 2012, AcelRx Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its receipt from the U.S. Patent and Trademark Office of two Notices of Allowance for the patent applications entitled “Small-Volume Oral Transmucosal Dosage Forms” and “Bioadhesive Drug Formulations for Oral Transmucosal Delivery.” A copy of the press release is attached as Exhibit 99.1 to this report.

On April 12, 2012, the Company issued a press release announcing the initiation of the second of three planned Phase 3 studies that will form the basis of a planned New Drug Application (NDA) for the Sufentanil NanoTab® PCA System, ARX-01. A copy of the press release 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 April 11, 2012.
99.2		Press Release dated April 12, 2012.

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: April 12, 2012

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 April 11, 2012.
99.2	Press Release dated April 12, 2012.



FOR IMMEDIATE RELEASE

AcelRx Pharmaceuticals Receives Two Notices of Allowance for Small-Volume Oral Transmucosal Dosage Forms

First US allowances could provide for intellectual property protection for AcelRx pipeline of NanoTab® pain products until at least 2029.

REDWOOD CITY, April 11, 2012 – AcelRx Pharmaceuticals, Inc. (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 issued AcelRx two Notices of Allowance for the patent applications entitled “Small-Volume Oral Transmucosal Dosage Forms” and “Bioadhesive Drug Formulations for Oral Transmucosal Delivery.” The patents to be issued from these applications describe a method of treating pain by adhering a small-volume solid tablet containing sufentanil to the oral mucosa, as well as compositions and dosage forms broadly covering NanoTab formulations. The patents to be issued can be kept in force for sufentanil NanoTab based products through at least February of 2029.

A related European patent, EP2114383B1, was previously issued by the European Patent Office (EPO) in June 2010 and AcelRx is also prosecuting similar claims internationally through the Patent Cooperation Treaty (PCT).

“These are important additions to our patent portfolio and strengthen our ability to protect our proprietary technology as we advance clinical development of the ARX-01 sublingual sufentanil PCA system for management of moderate to severe acute pain in the hospital setting,” said Richard King, AcelRx’s President and CEO. Mr. King added, “We are focused on continued expansion of our patent portfolio as we further investigate the safety and efficacy profile of our sublingual sufentanil NanoTabs.”

These allowances issued by the USPTO are in relation to sublingual sufentanil NanoTabs. AcelRx exclusively owns the underlying patent applications, which when issued will individually and collectively provide domestic protection for each of the Company’s four development programs. The 11/650,174 patent application covers AcelRx’s proprietary NanoTab technology for delivering sufentanil with claims to a method for treating pain by adhering a small volume (3-15 mcL) substantially homogenous solid tablet containing the active ingredient sufentanil to the oral mucosa of a subject while generating a minimal saliva response and delivering the majority of the drug through the transmucosal route resulting in consistent pharmacokinetics. The 11/825,251 patent application contains broad claims to sufentanil-containing bioadhesive tablets up to 50 microliters in volume which generate a minimal saliva response and deliver the majority of the active ingredient through the transmucosal route.

AcelRx also holds a related European patent EP2114383, which covers small-volume NanoTab® dosage forms for transmucosal administration containing the opioid sufentanil. The European patent covers elements of AcelRx’s dispensing technology and also provides patent protection of specific pharmacokinetic parameters derived from sublingual administration using the NanoTab technology. AcelRx currently has more than 50 pending worldwide patent applications and continues to file additional new patent applications to further strengthen its market exclusivity.

About AcelRx Pharmaceuticals, Inc.

Based in Redwood City, CA, AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX) 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 providing mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician's office. A fourth product candidate, ARX-04, is a sufentanil product for the treatment of moderate-to-severe acute pain that is expected to enter Phase 2 clinical development in the second quarter of 2012 under a grant from the USAMRMC.

Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to AcelRx Pharmaceuticals' patent portfolio, including the likely issuance and useful life of the pending US patent for a method of treating pain by administering a small-volume solid tablet containing sufentanil by adhering to the oral mucosa, the continued expansion of its patent protection, market exclusivity, its ability to protect its proprietary technology, the scope of patent protection when issued, and planned or anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the timing of the top-line data from its clinical trials, the timing of submission of an NDA with the FDA, 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' patent prosecution strategy and product development activities and clinical trials; 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 and reports, including its Annual Report on Form 10-K for the year ended December 31, 2011. 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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FOR IMMEDIATE RELEASE

AcelRx Announces Initiation of Second Phase 3 Clinical Trial for ARX-01, the Sufentanil NanoTab® PCA System, for the Treatment of Acute Post-Operative Pain

First Subject Dosed in Open-Label, Active-Comparator Trial

REDWOOD CITY, Calif., April 12, 2012—AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain, today reported dosing of the first patient in the second of three planned Phase 3 studies that will form the basis of a planned New Drug Application (NDA) for the Sufentanil NanoTab® PCA System, ARX-01. Utilizing a multicenter, randomized, open-label, parallel-group design, the study will compare the efficacy and safety of the Sufentanil NanoTab PCA System to the standard of care, IV PCA with morphine, in the treatment of acute post-operative pain immediately after major abdominal or orthopedic surgery. The primary objective of the study is to demonstrate non-inferiority of ARX-01 to IV PCA with morphine as determined by patient global satisfaction with the method of pain relief. Approximately 400 adult patients, randomized 1:1 to treatment with ARX-01 or IV PCA with morphine, will be treated for post-operative pain for a minimum of 48 hours after randomization. The study will be conducted at approximately 32 academic and community hospitals in the United States with top-line data expected in second half of 2012.

In March 2012, AcelRx initiated its first Phase 3 clinical study for ARX-01, a randomized, double-blind, placebo-controlled efficacy and safety study comparing ARX-01 to placebo for post-operative pain control following major open abdominal surgery. Data from this study is expected in second half of 2012. A third Phase 3 clinical study for ARX-01, expected to start in the third quarter of 2012, will be a randomized, double-blind, placebo-controlled efficacy and safety study comparing ARX-01 to placebo in treating post-operative pain following major joint replacement surgery.

“We are extremely pleased to have our second ARX-01 Phase 3 clinical trial underway. This study is expected to meet several objectives. Firstly, in addition to the two placebo-controlled studies, data from this active-comparator study will complete our ARX-01 safety database enabling review for marketing approval by regulatory agencies in the US and Europe. Secondly, positive results from this study demonstrating that pre-programmed, non-invasive delivery of Sufentanil NanoTabs provide non-inferior pain relief compared to IV PCA with morphine could support commercial adoption. Finally, secondary endpoint data from this study including comparison of average dosing intervals, sedation scores, system-related events and ease of care questionnaires, could support the pharmacoeconomic advantage of ARX-01, which we believe will help support adoption of the product in the US, and enable pricing of the product in Europe,” said Richard King, AcelRx’s Chief Executive Officer. Mr. King added, “This year is an exciting time for AcelRx, with the delivery of top-line data from all three ARX-01 Phase 3 clinical trials expected by late 2012 or early 2013.”

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 (US, 5 main EU countries and Japan), resulting in \$5.1 billion of acute pain treatment product sales in 2008. Current standard of care for managing post-operative pain is IV PCA, typically utilizing morphine or hydromorphone. However, there are many 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 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 IV PCA 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. Published data on IV PCA side-effect profiles suggests that somnolence (~50% of patients) and oxygen desaturation (~10% of patients) is unacceptably high. In our Phase 2 clinical studies, patients dosing up to 12 hours with Sufentanil NanoTabs (15 mcg) exhibited a low incidence of somnolence (3%) and oxygen desaturation (1%).
- **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.

Based in Redwood City, CA, AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX) 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 providing mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician's office. A fourth product candidate, ARX-04, is a sufentanil product for the treatment of moderate-to-severe acute pain that is expected to enter Phase 2 clinical development in the second quarter of 2012 under a grant from the US Army Medical Research and Material Command.

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 AcclRx Pharmaceuticals' product candidates, including the initiation of the third and final Phase 3 clinical study for ARX-01, the timing of the top-line data from all three clinical trials, the timing of submission of an NDA with the FDA, the therapeutic potential of AcclRx Pharmaceuticals' product candidates and the pace of adoption and commercialization of ARX-01 in US and Europe. These forward-looking statements are based on AcclRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcclRx 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 AcclRx 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, including ARX-01; 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 AcclRx Pharmaceuticals' estimates regarding expenses, capital requirements and needs for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcclRx Pharmaceuticals' US Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-K for the year ended December 31, 2011. AcclRx 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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