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): November 15, 2012

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 November 15, 2012, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing top-line results in a phase 3 non-inferiority study of sublingual Sufentanil NanoTab® PCA System vs. IV PCA morphine for post-operative pain. 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 November 15, 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: November 15, 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 November 15, 2012.

Exhibit 99.1

FOR IMMEDIATE RELEASE

AcelRx Announces Primary Endpoint Met in Phase 3 Non-Inferiority Study of Sublingual Sufentanil NanoTab ® PCA System vs. IV PCA Morphine for Post-Operative Pain

-In this open-label study, the Sufentanil NanoTab PCA System also demonstrated statistical superiority to IV PCA morphine for primary endpoint of Patient Global Assessment of method of pain control

- Nurses and patients rated Sufentanil NanoTab PCA System higher for

Overall Satisfaction and Ease of Care compared to IV PCA morphine

- AcelRx to conduct conference call and webcast today, November 15, at

8:00 a.m. EST (5:00 a.m. PST) to discuss top-line results in detail

REDWOOD CITY, Calif., November 15, 2012 — 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 top-line data showing that the open-label Phase 3 study of its investigational sublingual (under the tongue) Sufentanil NanoTab PCA (patient-controlled analgesia) System met its primary endpoint of non-inferiority in patient global assessment (PGA) with method of pain control in comparison to intravenous (IV) PCA with morphine. Additional analyses also showed that in this study the NanoTab System was statistically significantly superior to IV morphine for the PGA measurement. In addition, using validated assessment tools, nurses managing patients in the study and the patients themselves reported that they had significantly greater Overall Satisfaction with the NanoTab System compared to IV PCA morphine and significantly greater Overall Ease of Care with the NanoTab System compared to IV PCA morphine.

“With these impressive top-line results from this head-to-head clinical trial, we have successfully completed an important step towards our New Drug Application (NDA) submission and, dependent on completing the remaining Phase 3 trials and obtaining FDA approval, eventual commercialization of the Sufentanil NanoTab PCA System,” commented Richard King, President and CEO, of AcelRx Pharmaceuticals, Inc. “Delivering patient-controlled analgesia in a non-invasive, pre-programmed system that provides powerful pain control while enhancing patient ease of care and satisfaction and nurse satisfaction compared to current invasive delivery systems will be a major advance for hospital care.”

Utilizing a randomized, open-label, parallel-group design, this Phase 3 study enrolled 359 adult patients at 26 U.S. sites and compared efficacy and safety of AcelRx’s investigational ARX-01 sublingual Sufentanil NanoTab PCA System (15 mcg/dose) to the commonly used IV PCA with morphine (1 mg/dose) for the treatment of acute post-operative pain immediately following major abdominal or orthopedic surgery. Patients were randomized 1:1 to treatment with the NanoTab System or IV PCA morphine and were treated for post-operative pain for a minimum of 48 hours and up to 72 hours.

Top-line results of the Phase 3 clinical trial demonstrate that the Sufentanil NanoTab PCA System was non-inferior ($p<0.001$) to IV PCA morphine for the primary endpoint of PGA over the 48-hour study period as determined by the combined percentage of patients with PGA ratings of “good” or “excellent” (78.5% vs. 66.1% respectively). The assessment of non-inferiority is based on a lower limit of -15% for the 95% confidence interval (CI) around the difference between these percentages. Because the 95% CI was +3.2% to +21.6% for the 48 hour PGA and therefore didn’t cross the zero difference line, a statistical analysis for superiority could be performed, which demonstrated that for this study, the NanoTab System was statistically superior to IV PCA morphine for the PGA endpoint ($p=0.009$). This statistically superior PGA was also seen at the 24 hour and 72 hour timepoints. Additionally, the percentage of patients rating the NanoTab System as “Excellent” was higher than those rating IV PCA morphine as excellent (42.9% vs. 30.6%, $p=0.016$). Similar percentages of NanoTab System-treated and IV PCA morphine-treated patients dropped out of the study prematurely due to lack of efficacy (7.3% vs. 8.3% respectively) or due to an adverse event (7.9% vs. 11.1% respectively).

Nurses setting up the different treatments for use and managing patients in the study reported that they had greater Overall Satisfaction (3.93 vs. 3.32 out of 5, $p<0.001$) and Overall Ease of Care (4.26 vs. 3.82, $p=0.018$) with the Sufentanil NanoTab PCA System compared to IV PCA morphine. Likewise, patients in the study reported that they had greater Overall Satisfaction (4.15 vs. 3.83 out of 5, $p=0.003$) and greater Overall Ease of Care (4.45 vs. 4.07, $p<0.001$) with the NanoTab System compared to IV PCA morphine.

“Our goal at AcelRx has always been to improve upon the management of post-operative pain using a simplified system that nurses don’t have to program,” commented Pamela Palmer MD, PhD, Chief Medical Officer and AcelRx co-founder. “The validated Patient Overall Ease of Care assessment is a multi-dimensional evaluation that includes confidence, comfort and ease of movement with the delivery device, along with dosing confidence, pain control and knowledge and understanding of product use. The higher score in this composite measure, which reflects higher scores in each of the subscales, along with the higher nursing Overall Satisfaction ratings, and combined with the excellent pain control demonstrated in the PGA rating validates our efforts for developing this product for hospitalized patients” added Dr. Palmer.

"It was impressive to observe the ease of set-up and use of the Sufentanil NanoTab PCA System by both nurses and patients compared to our typical IV PCA system," stated study investigator Dr. Harold Minkowitz in the Department of Anesthesiology at Memorial-Hermann Hospital in Houston, Texas. "Observing the rapid onset and significant level of pain relief obtained with this non-invasive route of opioid administration over a broad range of patients and types of surgery was remarkable."

In addition to this well-controlled supportive trial, two other Phase 3 clinical studies of the Sufentanil NanoTab PCA System are underway. In March 2012, AcelRx initiated a randomized, double-blind, placebo-controlled efficacy and safety study comparing the NanoTab System to placebo for post-operative pain control following major open abdominal surgery. In August 2012, AcelRx initiated a randomized, double-blind, placebo-controlled efficacy and safety study comparing the NanoTab System to placebo in treating post-operative pain following major joint replacement surgery. Data from both of these pivotal studies are expected in the first quarter of 2013. Additional information about the Phase 3 clinical trials with the NanoTab System can be found by visiting www.clinicaltrials.gov and using the identifiers, NCT01660763, NCT01539642 and NCT01539538.

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 following surgery. Inadequate treatment of post-surgical 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. More than 30 million surgical procedures per year result in moderate to severe pain in the US and EU, with an additional 27 million procedures in countries with moderate to high per capita healthcare expenditures. The US, 5 main EU countries and Japan represented $5.1 billion of acute pain treatment product sales in 2008. Currently patients experiencing post-operative 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 ARX-01, the Sufentanil NanoTab PCA System

ARX-01 is an investigational 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:** 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.

Conference Call

The conference call and webcast will be held today, Thursday, November 15, 2012 at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time) to discuss the Phase 3 top-line results. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (800) 860-2442 for domestic callers, (866) 605-3852 for Canadian callers, or (412) 858-4600 for international callers. Those interested in listening to the conference call live via the Internet may do so by visiting the Investor Relations 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 Investor Relations section of the company's website at www.acelrx.com

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 has initiated a Phase 2 study for a fourth product candidate, 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, or 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 process and timing of anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the release ARX-01 top-line clinical trial data, the release and anticipated timing of additional ARX-01 clinical trial data, the potential filing of an NDA for the ARX-01 and the timing thereof, therapeutic and commercial potential of ARX-01 and the anticipated timing and therapeutic and commercial potential of other 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 ability of AcelRx Pharmaceuticals to successfully complete the clinical trials for ARX-01, that fact that subsequent analyses of the full data set may lead

to different (including less favorable) interpretations of the results than the analyses conducted to date or may identify important implications of the study that are not reflected in these statements, or be subject to differing interpretations by the regulatory agencies; the success, cost and timing of all product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all; any delays or inability to obtain regulatory approval of its product candidates in the United States and Europe; 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 in the United States and Europe; 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 September 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.

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